ODA E FARMACISTËVE TË KOSOVËS
CHAMBER OF PHARMACISTS OF KOSOVA | KOMORA FARMACEUTA KOSOVA

Për:	Znj. Afërdita Hoxha – UD. Udhëheqëse e departamentit ligjor të MSH-së
CC:	z. Bashkim Sadiku – Zyrtar përgjegjës për plotësim dhe ndryshim të Udhëzimit Administrativ nr. 11/15 për Qarkulluesit me pakicë për produkte dhe paisje medicinale z. Ardian Mehmetaj – UD Sekretar i pergjithshëm i MSH-së
NGA:	Arianit Jakupi - Kryetar i OFK-së
Lënda :	Propozim për plotësim ndryshimin e UA për qarkulluesit me pakicë të produkteve farmaceutike
Data:	21/10/2020

E nderuari znj.Hoxha,

Bazuar në kompetencat ligjore të të përcaktuara në Nenin 10, paragrafi 1.1 dhe 1.11 të Ligjit për Odat e Profesionistëve Shëndetësor (Nr.04/L-150), OFK detyrë kryesore ka përfaqësimin dhe mbrojtjen e interesave profesionale të anëtarëve të Odës në ushtrimin e profesionit, dhe përfaqësimi i interesave profesionale dhe sociale të profesionistëve shëndetësor dhe bashkëpunëtorëve tjerë shëndetësor.

Sic jeni në njohuri tani në process të plotësim ndryshimit është Udhëzimi Administrativ nr.11/2015 për qarkulluesit me pakicë të prodikteve dhe paisjeve medicinale i cili derivon nga Ligji për Produkte dhe Paisje Medicinale, të cilat paraqesin ndër aktet juridike fundamentale për farmacistët.

E nderuara znj. Hoxha, me që grupi punues ka mbajtur vetëm një takim, shfrytëzojmë rastin që emër të anëtarëve tanë të ju dorëzojmë komentet tona të dala si rezultat i anketave të zhvilluar me anëtarët tanë, disa prej të cilave shprehin mospajtim me propozimet e dërguara nga grupi punues, e disa janë plotësime të propozimeve të tyre si dhe disa propozime të reja që nuk janë përfshirë në draftin e grupit punues.

Propozimet tona do ti shprehim edhe në kuadër të konsultimeve publike.

Duke shpresuar se këto propozime do të bëhen pjese e UA për plotësim ndryshimin e UA 11/2015, ju urojmë punë të mbarë.

Të bashkangjitura propozimet e OFK-së.

Propozimi I-rë (propozim i ri – jo i përfshirë nga grupin punues)

Nënparagrafi 1.2 i paragrafit 1 të Nenit 3 të riformulohet si në vijim :

"**Bartësi i licencës profesionale për barnatore** – farmacisti i licencuar i cili paisjet me licencë profesionale për barnatore, për qarkullutesit me pakicë të produkteve dhe paisjeve medicinale "

Arsyetim

Ligji për leje dhe licenca në nenin 3, paragrafi , nënparagrafi 1.10 përcakton se "**Licencë profesionale** – lloj lejimi i dhënë njëpersoni fizik për tu angazhuar në një profesion me tu përcaktuar nga autoriteti kompetent se ky profesion paraqet rrezik të mesëm apo të lartë për shëndetin publik, sigurinë dhe mjedisin siç përcaktohet me ligj."

Për më tepër neni 14, paragrafi 1 me nënparagrafin 1.2 dhe paragrafin 3 i Ligjit për Produkte dhe Paisje medicinale si ligj organit me të cilin rregullohet veprimtaria e qarkulluesve me pakice të paisjeve dhe produkteve medicinale, njeh diskrecionin e aktit nënligjorë për caktimin e kushteve për ushtrimin e veprimtarisë së barnatoreve dhe kjo në asnjë mënyrë nuk nënkupton ndërhyrje në licenca të biznesit.

Formulimi i tillë do të ishte në përputhje të plotë me nenin 3, paragrafin 1.10 të Ligjit për leje dhe licenca i cili thekson se licencë profesionale i lëshohet personit fizik.

Ne këtë propozim e bazojmë edhe mbi licencat tjera profesionale që lëshohen nga Ministritë tjera. P.sh Ministria e Drejtësisë licencon noterët dhe të drejtën për ushtrimin e veprimtarisë njeh vetm personit fizik i cili ka të përfunduar provimin për noteri. Me rastin e licencimit caktohet personi fizik si bartës i asaj licence dhe caktohet adresa ku eshte selia e ushtrimit te veprimtarisë Për më tepër shih konkursin e Ministrisë së Drejtësisë të datës 23/07/2019 në të cilin kusht për ushtrim të profesionit të noterisë (zyrës noteriale) ka Certifikatën për dhënien e provimit të Noterisë, të lëshuar nga Ministri i Drejtësisë, dhe licencat e lëshuara nga Ministria e Drejtuesise të publikuar në web faqen e tyre. Po ashtu rastet e avokateve.

Ne dëshirojmë të sqarojmë se qështja e regjistrimit në Agjensionin e Bizneseve (Licenca e Bizneseve) është krejtësisht qështje tjetër ashtu sic është paraparë edhe në dispozitën e nenit 14, paragrafi 1, me nënparagrafin 1.1. dhe për më tepër është i rregulluar edhe me ligjin për shoqëritë tregtare dhe si e tillë qështja e regjistrimit të biznesit nuk është në fushëveprimin e AKPM-së dhe Ministrisë së Shëndetësisë. Këtë po e theksojmë meqë në grupin punues nuk arrihej të bëhej dallimi midis licencës profesionale dhe asaj të biznesit.

Cështja e pronësisë tashmë është e rregulluar në shumicën e shteteve të evropës .

Kjo cështje tashmë është sfiduar edhe në kuadër të Gjykaës së Drejtesisë së Bashkimit Evropian, e cila tashmë ka nxjerr vendime me të cilin është përcaktuar e drejta e pronësisa e farmacisë (barnatores) si e kufizuar vetëm për farmacistët.

Me vendimin e sajë të datës 19 Maj 2009 në rastin e njohur si *" Case C-531/06 and in Joined Cases C-171/07 and C-172/07, Commission v Italy & Apothekerkammer des Saarlandes and Others "* çështjen e pronësisë vetëm nga farmacisti e arsyeton se *" farmacisti me profesion, supozohet se operon me barnatoren jo me një objektiv thjesht ekonomik, por edhe nga pikëpamja profesionale. Interesi i tij privat i lidhur me krijimin e një fitimi zbutet nga edukimi i tij, nga përvoja e tij profesionale dhe nga përgjegjësia që i detyrohet, duke pasur parasysh që çdo shkelje e rregullave të ligjit ose sjellje profesionale minon jo vetëm vlerën e investimit të tij, por edhe ekzistencën e tij profesionale. Ndryshe nga farmacistët, jo-farmacistët nga përkufizimi nuk kanë trajnim, përvojë dhe përgjegjësi ekuivalente me ato të farmacistëve. Prandaj, ato nuk ofrojnë të njëjtat masa mbrojtëse si farmacistët. Prandaj, një shtet anëtar mund të marrë mendimin, në ushtrimin e gjykimit të tij, që funksionimi i një farmacie nga një jo-farmacist mund të paraqesë një rrezik për shëndetin publik, veçanërisht për besueshmërinë dhe cilësinë e furnizimit të produkteve medicinale me pakic "*

Për më tepër gjykata në këtë rast ka konstatuar se *"Kur ekziston pasiguri për ekzistencën ose shkallën e rreziqeve për shëndetin e njeriut, është e rëndësishme që një Shtet duhet të jetë në gjendje të marrë masa mbrojtëse pa pasur nevojë të presë derisa realiteti i atyre rreziqeve të bëhet plotësisht i dukshëm."*

Po ashtu gjykata tërheq vëmendjen për natyrën shumë të veçantë të produkteve medicinale, efektet terapeutike të të cilave dallojnë ato në mënyrë të konsiderueshme nga mallrat e tjera, për të cilat është konstatuar se barnatorja duhet të ketë pronar famracist.

Sipas gjykatës pronari jo-farmacist ka për qëllim parësor fitimin mbi shëndetin e individit dhe të popullatës

Prandaj mbi këto baza gjykata ka konstatuar se përckatimi i Gjermanisë dhe Italisë të cilat lejojnë në legjislacionin e tyre hapjen e barnatoreve vetëm nga farmacistët me profesion për shkak të specifikave të produkteve medicinale nuk paraqet shkelje të të drejtave dhe është në përputhje me rregullat e Bashkimit Evropian.

Për më tepër shih vendimin e gjykatës të bashkangjitur si Shtojca I në këtë shkresë.

Po ashtu edhe praktika e shteteve evropiane tregon se në legjislacionin e tyre, kjo e drejtë e pronësia e një farmacie në komunitet është e kufizuar në një farmacist (ose një grup farmacistësh)

Arsyeja kryesore është se konsiderohet se mundësohet një nivel i lartë gjykimi profesional duke zbutur rreziqet e pronësisë së korporatave, të cilat mund të japin direktivat për të favorizuar fitimin mbi shëndetin e individit dhe të popullatës.

Shtetet e ndryshme njohin të drejtën që një licencë e barnatores të jetë e transferueshme të një farmacist apo grup i farmacistëve me kusht që te personat që transferohet licenca ti kenë plotësuar kushtet për licencim pra edhe ata të jenë farmacist. Raste të tilla përshembull Gjermani dhe Spanja ku pronari i një barnatore duhet të jetë gjithmonë farmacist.

Rregull të tillë të transferit përmban edhe paragrafi 3 i Nenit 25 të Ligjit për leje dhe Licenca nr. 04/L-202.

Poloni qështjen e të drejtës së vetme të farmacistit për hapjen e barnatoreve e ka të rregulluar që nga viti 2017. Disa shtet të tjera si Austria, Hungaria dhe Letonia parashohin kufizimin që shumica e aksioneve të barnatoreve të jenë në pronësi të farmacistit.

Për të parë më shumë praktikën e vendeve evropiane të Rregullimit të qështjes së pronësisë së barnatores ju lutem referohuni në shtojcën II të bashkangjitur kësaj shkrese, i cili është një dokument nga Organizata Botërore e Shëndetësisë e cila përman kornizën rregullative dhe ligjore të rregullimit të qështjes së pronësisë . Për më tepër kjo rregullativ mund të gjendet edhe në linkun e bashkangjitur

https://apps.who.int/iris/bitstream/handle/10665/326394/9789289054249-eng.pdf?sequence=1&isAllowed=y

Prandaj, duke mos parë pengesë në legjislacionin aktual, vendimet e Gjykatës të Drejtësisë të Bashkimit Evropaine, këtë formulim e konsiderojmë si më adekuatin dhe në përputhje të plotë me legjislacionin në fuqi.

Propozimi 2 (mos pajtim me propozimin e grupit punues)

Ne propozojmë lartësia e përcaktuar në nënparagrafin 1, paragrafi 2 të nenit nenin 4, të mbetet ashtu siq është aktualisht 2.6 m

Arsyetim

OFK konsideron se cfardo shmangje nga lartësia e tillë do të shkaktonte kaos në barnatore gjatë rilicencimeve dhe do të ishte shmangie e praktikës së deritanishme si dhe standardeve ndërkombëtare

Propozimi 3 (mos pajtim me propozimin e grupit punues)

Nënparagrafi 2.2, i paragrafit 2 të nenit 4, të mbetet ashtu siq ka qenë ose të saktësohet lartësia 2.6m

Arsyetim

Të zbatohet standardi i njejtë si në nënparagrafin 1, paragrafi 2 të nenit nenin 4 të udhëzimit bazë.

Propozimi 4, (mos pajtim me propozimin e grupit punues)

Nënparagrafi 2.3 i paragrafi 2 të nenit 4 të mbetet si është aktualisht në udhëzimin bazë.

Arsyetim

Barnatoret aktuale përmbushin kriteret e përcaktuar, prandaj cfardo lëvizje nga këto kritere ne aspektin infrastrukturor do të shkaktone kaos në to dhe do të ishte i harmonizuar me nënparagrafin 1.

Propozimi 5 (plotësim dhe arsyetim i propozimit të grupit punues)

Pas paragrafit 5 të nenit 4 të udhëzimit administrativ bazë shtohet një paragrf i ri me numër rendor 6 dhe një nënparagrafi i ri si 6.1 si në vijim:

6. Qarkulluesi farmaceutikë me pakicë për produkte dhe pajisje medicinale duhet të këtë distancë minimale prej 300 m diametër nga subjekti tjetër i të njëjtës veprimtari.

6.1 Kriteri mbi distancën prej 300 m nuk zbatohet në rilicencim ndaj barnatoreve të cilat të drejtën e ushtrimit të veprimtarisë e kanë fituar para hyrjes në fuqi të kësaj dispozite "

Të shikohen mundësitë për vendosjen e kriterit demografik në bazë të numrit të banorëve, pas regjistrimit të saktë të popullësisë duke marrë për bazë shtetet Evropiane si në faqen 20 të Shtojcës II ose ne linkun

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Arsyetim

OFK e konsideron si të nevojëshme kriterin e distancës në mes barnatoreve të reja e cila si kriter duhet të vlejë vetëm ndaj barnatoreve të cilat licencohen për herë të parë dhe nuk duhet të vlejnë në procesin e rilicencimit. Një kriter të tillë do të ndikonte edhe në shpërndarjen proprcionale të barnatoreve nëpër lokalitete të ndryshme . Sa i përket kriterit 300 metra, është marrë një mesatare e bazuar edhe në shtojcën II të bashkangjitur të dokumentit të OBSH-së në faqen 21 në të cilën janë përshkruar distanca në disa shtet si Austria 500m, Kroacia 200 deri në 500 m, Italia 200 m , Polonia 500m, Sllovenia 400 etj

Për më shumë shih shtojcën II në faqën 21, ose në linkun
https://apps.who.int/iris/bitstream/handle/10665/326394/9789289054249-eng.pdf?sequence=1&isAllowed=y

Propozimi 6. (propozim i ri – jo i perfshire nga grupi punues)

Paragrafi 4 i Nenit 6 të riformulohet si në vijim *"Në rastet kur farmacisti nuk mund të jetë prezent në barnatore, bartësi i licencës profesionale të barnatores është i obliguar që ta angazhojë farmacistin zëvendësues me licencë valide, i cili autorizohet për kryerjen e detyrave të farmacistit* "

Arsyetim

Përmbajtja aktuale e udhëzimit bazë 11/15 lejon mundësi kolizioni të interpretimit pasi e njëjta qështje rregullohet në mënurë të ndryshme ne nenin 6 paragrafi 4 dhe nenin 3 paragrafi 1, me nënparagrafin 1.6. Njëra dispozitë këtë përgjegjësi e përcakton të farmacistit përgjegjës ndërsa tjetra përgjegjësi të bartësit të licencës profesionake.

Propozimi 7 (Propzim i ri - mos pajtim me propozimin e grupit punues)

Në nënparagrafin 5 të nenit 6, pas shprehjes "është e ndaluar" të shtohet shprehja "që në mungesë të prezencës së farmacistit:". Pjesa tjetër mbetet e njejtë.

Arsyetim

Ligji për Shëndetësi nr. 04/L-120 në paragrafin 2 të Nenit 26,, lejon dispenzimin e barnave nga ose në prezencë të farmacistit, prandaj formulimi i këtij nënparafi do të ishte në përputhje me këtë dispozitë të ligjit për shëndetësi.

Propozimi 8 (Propozim i ri)

Në nënparagrafin 6 të nenit 6, pas shprehjes "MSH" të shtohet "/OFK"

Arsyetim

Kompetencat mbi licencimin e profesionistëve shëndetësorë nga viti 2017 janë bartuar në kuadër të Odave të Profesionistëve Shëndetësor, prandaj në përputhje me këtë e konsiderojmë të domosdoshëm këtë plotësim.

Propozimi 9 (Propozim i ri)

Pas paragrafit 8 të nenit 6, të shtohet paragrafi i ri 9 me këtë përmbajtje *"Bartësi i licencës për barnatore me rastin e aplikimit për licencim deklaron ne AKPPM orarin e barnatores si dhe orarin farmacistit/tëve dhe personelit profesional sipas formularit për aplikim dhe konform ligjit të punës.*

Arsyetim

OFK e konsideron me rëndësi të veqantë deklarimin e farmacistëve përgjegjës dhe orarin e tyre për të cilën janë përgjegjës, sepse nga praktika e deritanishme disa raste të shkeljeve ligjore kanë ndodhur në barnatore në orare në të cilat sipas kontratave nuk ka farmacist përgjegjës. Përfshirja e këtij propzimi do të lehtsonte shumë punën e inspektoreve farmaceutike dhe organeve për shqiptimin e masave displinore të OFK-së.

Propozim 10 (Propozim i ri – plotësim i propozimit të grupit punues)

Paragrafi 1 i nenit 7 të mbetet ashtu siq është në udhëzimin bazë.

Paragrafi 2 i nenit 7 të udhëzimit administrative bazë plotësohet dhe ndryshohet si në vijim :

"Aplikuesi obligohet të plotësoj në sistemin online të AKPPM-së " Barnatari" aplikacionin duke bashkangjitur dokumentacionin përcjellës varësisht nga lloji i aplikimit të përcaktuar në mënyrë taksative në dispozitat e këtij udhëzimi dhe dispozitave tjera ligjore në fuqi. "

Arsyetim

OFK konsideron se publikimi dhe perckatimi i formularëve paraprakisht me dispozitat ligjore dhe publikimi i tyre do të ndikonte në rritjen e transparencës dhe do të shmangte cfardo

keqinformimi dhe keqinterpretimi si dhe do të shmangte mundësinë për interpretim të ndryshëm të aplikacioneve nëse ato nuk publikohen dhe përcaktohen paraprakisht

Propozimi 11 (Mos pajtim me propozimin e grupit punues)

Paragrafi 4 i nenit 7 të udhëzimit bazë të riformulohet si në vijim " AKPPM-ja është e obliguar që në afat prej 10 ditëve të punës nga dita e pranimit të aplikacionit t'i përgjigjet aplikuesit "

Arsyetim

OFK vlerësin se afati i propozuar nga grupi punues prej 15 ditëve të punës, është afat i gjatë i cili në praktikë ka kosto shtesë të mëdha për bartësit e licencës profesionale të barnatores e cila efektivisht nënkupton të paktën 20 ditë kalendarike për të cilat të njëjtit do të jenë të detyruar të paguajnë shpenzimet për objektet dhe shpenzimet tjera përcjellëse, prandaj ne vlerësojmë se afati 10 ditorë do të ishte i mjaftueshëm për realizimin e detyrave.

Propozimi 12 (mos pajtim me propozimin e grupit punues)

Paragrafi 5 i nenit 7 të mbetet ashtu siq është në udhëzim bazë.

Arsyetim

Lëshimi i vendimit dhe aryetimi i tij mbi shkaqet e refuzimit si dhe udhëzimi për përdorimin e mjetit juridik janë kërkesa esenciale që kërkohen për një akt administrativ të përcaktuar me Ligjin për Proceduren e Përgjithshme Administrative.

Propzimi 13 (pajtim me propozimin e grupit punues)

OFK përkrah propozimin e grupit punues për pagesë të njëherëshme të licencës për 5 vite nëse aprovohet UA për tarifat e shërbimeve të AKPPM-së (tarifa 500 Euro për 5 vite të Licencës)

Propozimi 14 (pajtim-plotësim i propozimit të grupit punues)

Plotësohet dhe ndryshohet paragrafi 1 i nenit 8 të udhëzimit administrativ bazë si në vijim : "Dokumentacioni i nevojshëm për t'iu bashkangjitur aplikacionit për licencim në sistemin online të AKPPM-së " Barnatari", i cili mund të shkarkohet edhe nga faqja e internetit është:"

Arsyetim

OFK konsideron se për një periudhë tranzitore duhet të shikohet mundësia që palët të kenë mundësi që aplikimet krahas Barnatarit të mund të bëhen edhe në prezencë fizike "Hard Copy"

Propozimi 15 (Propozim i ri)

Nënparagrafi 1.3 i paragrafi 1 të nenit 8 të riformulohet sipas kësaj përmbajtje . Licenca valide e punës e farmacistit përgjegjës e dhënë nga MSH/OFK

Arsyetim

Nga viti 2017 kompetencat mbi licencimin e profesionistëve shëndetësor janë bartur në kuadër të odave të profesionsitëve shëndetësor. Ne konsiderojmë të dosmosdoshme që pas gjdo dispozite ku kërkohet licencë të shtohet licencë valide për të shmangur cfardo kolizioni në interpretim

Propozimi 16 (Mospajtim me propozimin e grupit punues)

Nënparagrafi 1.5 i paragrafit të nenit 8 duhet të mbetet ashtu siq është tani "Kontrata e punës në mes të punëdhënësit dhe punëmarrësit"

Arsyetim

OFK konsideron se propozimi për noterizimin e kontratave është procedurë shtesë që ka kosto shtesë ekonomike dhe konsiderohet vetëm si burokraci e organeve. Prandaj qëndrojmë pranë asaj që kontratat të vlerësohen ashtu si deri më tani.

Propozimi 17 (Propozim i ri)

Pas propozimit për përfshirjen e nënparagrafit 1.8 shtohet një nënparaf i ri 1.9 me këtë përmbajtje " Përcaktimi i orarit të punës për farmacistin përgjegjës"

Arsyetim

OFK e konsideron me rëndësi të veqantë deklarimin e farmacistëve përgjegjës dhe orarin e tyre për të cilën janë përgjegjës, sepse nga praktika e deritanishme disa raste të shkeljeve ligjore kanë ndodhur në barnatore në orare në të cilat sipas kontratave nuk ka farmacist përgjegjës. Përfshirja e këtij propzimi do të lehtsonte shumë punën e inspektoreve farmaceutike dhe organeve për shqiptimin e masave displinore të OFK-së.

Propozimi 18 (plotësim i propozimit të grupit punues)

Pas paragrafit 2 të nenit 9 të udhëzimit administrativ bazë shtohet një paragraph i ri me numër rendor 3 dhe nënaragraf të ri 3.1 me tekstin si në vijim:

"Aplikimi për rilicencim në sistemin online të AKPPM-së (Barnatari) duhet të bëhet 30 ditë para skadimit të licencës së veprimtarisë, në të kundërtën aplikuesi duhet t'iu nënshtrohet :procedurave të licencimit sipas nenit 8 të udhëzimit administrativ.

3.1 AKPPM paralamëron në dy periudha kohore (60 ditë para skadimit dhe 45 ditë) bartësin e licencës dhe farmacistin përgjegjës për datën e skadimit të licencës profesionale të barnatores"

Arsyetim

OFK pajtohet me propozimin e grupit punues duke propozuar që ky propozim të plotësohet edhe me periudhën kohorë për të cilën AKPPM merr për detyrim paralajmërimin e bartësit të licencës dhe farmacistit përgjegjës për afatin e skadimit të licencës profesionale të barnatores

Propozimi 19 (Mos pajtim me propozimin e grupit punues)

OFK konsideron se propozimi i grupit punues "Pas nenit 9 të udhëzimit administrativ bazë shtohet një nen i ri me numër rendor 9A si në vijim:

Neni 9A

Vlerësimi për rilicencim

1. Procedura e vlerësimit për rilicencim aplikohet njëjt sikurse për licencim"

nuk duhet të përfshihet në këtë UA.

Arsyetim

OFK konsideron se ky propozim është propozim jo ligjorë për shkak se i njëjti cenon parimin e jo retroaktivitet të dispozitave ligjore, dhe cënon rëndë të drejtat e barnatoreve të cilat janë licencuar në përputhje me normat e përcaktuar në Udhëzimin 11/15.

Propozim i ri 20 (Propozim i ri – Gjobat)

Në nenin 16, pas paragrafit 5, shtohet paragrafi 6 me dy nënparagrafe si më poshtë

"1. Për recidivistët e shkeljeve të cilat në periudhen prej 2 viteve të operimit, përsërisin së paku 3 herë shkeljene e neneve 6 paragrafi 3 "barnatorja mund të funksionojë vetëm në prezencë të farmacistit" dhe shkeljet nga neni 12, paragrafi, 1, 2 dhe 3 , bartësi i licencës profesionale për barnatore I revokohet e drejta e ushtrimit të kësaj veprimtaria për 3 vite.

2. Për recidivistët e shkeljeve të cilat në periudhen prej 5 viteve të operimit, përsërisin së paku 4 herë shkeljene e neneve 6 paragrafi 3 "barnatorja mund të funksionojë vetëm në prezencë të farmacistit" dhe shkeljet nga neni 12, paragrafi, 1, 2 dhe 3 , bartësi i licencës profesionale për barnatore I revokohet e drejta e ushtrimit të kësaj veprimtaria për 5 vite."

Arsyetim

Duke parë që gjobat e shiptuara nga neni 16 I UA bazë deri më tani nuk po tregojnë rezultatë në luftimin e këtyre dukurive negative për sektorin farmaceutik, e konsiderojme si të domosdoshme që në përputhje me paragrafi 4 të Nenit 37 të LIGJI NR. 04/L -190 PËR PRODUKTE DHE PAJISJE MEDICINALE të shqiptohet ndalimi i ushtrimit të veprimtarisë profesionale të bartësit të licencës

SHTOJCA I

VENDIMI I GJYKATËS SË DREJTËSISË TË BASHKIMIT EVROPIAN

СЪД НА ЕВРОПЕЙСКИТЕ ОБЩНОСТИ
TRIBUNAL DE JUSTICIA DE LAS COMUNIDADES EUROPEAS
SOUDNÍ DVŮR EVROPSKÝCH SPOLEČENSTVÍ
DE EUROPÆISKE FÆLLESSKABERS DOMSTOL
GERICHTSHOF DER EUROPÄISCHEN GEMEINSCHAFTEN
EUROOPA ÜHENDUSTE KOHUS
ΔΙΚΑΣΤΗΡΙΟ ΤΩΝ ΕΥΡΩΠΑΪΚΩΝ ΚΟΙΝΟΤΗΤΩΝ
COURT OF JUSTICE OF THE EUROPEAN COMMUNITIES
COUR DE JUSTICE DES COMMUNAUTÉS EUROPÉENNES
CÚIRT BHREITHIÚNAIS NA gCÓMHPHOBAL EORPACH
CORTE DI GIUSTIZIA DELLE COMUNITÀ EUROPEE
EIROPAS KOPIENU TIESA
EUROPOS BENDRIJŲ TEISINGUMO TEISMAS
AZ EURÓPAI KÖZÖSSÉGEK BÍRÓSÁGA
IL-QORTI TAL-ĠUSTIZZJA TAL-KOMUNITAJIET EWROPEJ
HOF VAN JUSTITIE VAN DE EUROPESE GEMEENSCHAPPEN
TRYBUNAŁ SPRAWIEDLIWOŚCI WSPÓLNOT EUROPEJSKICH
TRIBUNAL DE JUSTIÇA DAS COMUNIDADES EUROPEIAS
CURTEA DE JUSTIȚIE A COMUNITĂȚILOR EUROPENE
SÚDNY DVOR EURÓPSKYCH SPOLOČENSTIEV
SODIŠČE EVROPSKIH SKUPNOSTI
EUROOPAN YHTEISÖJEN TUOMIOISTUIN
EUROPEISKA GEMENSKAPERNAS DOMSTOL

CVRIA
LUXEMBOURG

Press and Information

PRESS RELEASE No 44/09

19 May 2009

Judgments of the Court of Justice in Case C-531/06 and in Joined Cases C-171/07 and C-172/07

Commission v Italy
Apothekerkammer des Saarlandes and Others

OWNERSHIP AND OPERATION OF PHARMACIES CAN BE RESTRICTED TO PHARMACISTS ALONE

Italian and German legislation laying down such a rule is justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality

Today, the Court of Justice has brought to a close two sets of proceedings relating to the system of pharmacy ownership.

The cases relate, principally, to the issue whether Community law precludes provisions contained in Italian and German legislation which provide that only pharmacists may own and operate a pharmacy.

Joined Cases C-171/07 and C-172/07 (*Apothekerkammer des Saarlandes and Others*) arose from the authorisation granted by the competent ministry in Saarland to DocMorris, a Netherlands public limited company, entitling it to operate a branch pharmacy in Saarbrücken from 1 July 2006. The ministry's decision was challenged before the Administrative Court, Saarland, by several pharmacists and their professional associations, on the ground that it was not consistent with German legislation which restricts the right to own and operate a pharmacy exclusively to pharmacists.

The Administrative Court referred questions to the Court of Justice in order to ascertain whether the Treaty provisions on freedom of establishment must be interpreted as precluding such legislation.

In addition, in Case C-531/06 (*Commission* v *Italy*) the Commission applied to the Court for, amongst others, a declaration that, by allowing only pharmacists to own and operate private pharmacies, the Italian Republic has failed to fulfil its obligations under Community law.

In its judgments delivered today, the Court states that excluding the possibility for non-pharmacists to operate pharmacies or to acquire stakes in companies or firms operating pharmacies constitutes a restriction on the freedom of establishment and the free movement of capital

That restriction can nevertheless be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality.

Where there is uncertainty as to the existence or extent of risks to human health, it is important that a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. Furthermore, a Member State may take the measures that reduce, as far as possible, a public-health risk, including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public.

In this context, the Court draws attention to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods.

Those therapeutic effects have the consequence that, if medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered.

Overconsumption or incorrect use of medicinal products leads, moreover, to a waste of financial resources which is all the more damaging because the pharmaceutical sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied.

Given the power accorded to the Member States to determine the level of protection of public health, Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence.

It is undeniable that a pharmacist, like other persons, pursues the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence.

Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists.

A Member State may therefore take the view, in the exercise of its discretion, that the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level.

The Court also finds that it has not been established before it that a measure less restrictive than the exclusion of non-pharmacists would make it possible to ensure just as effectively the level of reliability and quality in the provision of medicinal products to the public that results from the application of that exclusion.

Having regard to the discretion which it is allowed, a Member State may take the view that there is a risk that less restrictive rules designed to ensure the professional independence of pharmacists, such as a system of controls and penalties, would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator could make it difficult for them to oppose instructions given by him.

The Court concludes that **the freedom of establishment and the free movement of capital do not preclude national legislation which prevents persons not having the status of pharmacist from owning and operating pharmacies**.

Since the Court finds that not only the exclusion of non-pharmacists from operation of a pharmacy can be justified, but also the prohibition preventing undertakings engaged in the distribution of pharmaceutical products from taking stakes in municipal pharmacies, it dismisses the action for failure to fulfil obligations brought by the Commission against Italy.

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SHTOJCA II

World Health Organization
REGIONAL OFFICE FOR Europe

The legal and regulatory framework for community pharmacies in the WHO European Region

World Health Organization

REGIONAL OFFICE FOR Europe

The legal and regulatory framework for community pharmacies in the WHO European Region

ABSTRACT

Community pharmacists are the health professionals most accessible to the public and are a cornerstone of primary health care. The role of community pharmacists is expanding globally. This report provides an overview of existing components and provisions of the legal and regulatory framework for community pharmacies and their activities in Europe. It presents the diverse approaches to community pharmacy licenses and to establishment of new pharmacies and their ownership. It also details the framework for community pharmacy operating requirements (including opening hours, workforce, premises and equipment, services provided and identification of a community pharmacy) and the types of activity undertaken. Provisions associated with possible alternative forms of dispensing medicines (over-the-counter medicines, prescription-only medicines, dispensing by medical doctors and online medicine sales) are also described. The report concludes with the possible key players involved in the legal and regulatory framework and outlines their missions and functions. Adoption of provisions from one country to another needs a full analysis of advantages and disadvantages and adoption into the local context and adjusted to the coherence of the national framework.

Keywords

COMMUNITY PHARMACY SERVICES – legislation and jurisprudence
PHARMACIES – legislation and jurisprudence
LICENSURE, PHARMACY
EUROPE
GOOD PHARMACY PRACTICE
ACCESS TO MEDICINES

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Contents

Preface

This report was prepared by the WHO Regional Office for Europe as a background paper for a one-day consultation organized by the Ministry of Health of Lithuania in October 2018 to support a revision of the country's law on pharmaceuticals and, more specifically, regulation of community pharmacies. Other countries in the WHO European Region are facing similar challenges regarding the overall distribution of pharmacies and activities conducted by community pharmacies. The number of community pharmacies is rising in some areas, while in some rural areas pharmaceutical services are not available. The Regional Office supports Member States to develop, implement and monitor national medicines plans and policies that aim to ensure that affordable medicines of assured quality are reliably and consistently available for patients, through pharmaceutical consultation that will contribute to patient safety and to rational use of medicines.

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Abbreviations

CIS	Commonwealth of Independent States
CPD	continuing professional development
EU	European Union
FIP	International Pharmaceutical Federation
GPP	Good Pharmacy Practice (guidelines)
ILO	International Labour Organization
OTC	over-the-counter (medicine)
PGEU	Pharmaceutical Group of the European Union

Executive summary

Community pharmacists are the health professionals most accessible to the public and are a cornerstone of primary health care. The role of community pharmacists is expanding globally. The legal and regulatory framework for community pharmacies in the WHO European Region varies greatly across countries. It is usually defined by a series of legal provisions: either as a single pharmacy law or through a general law (on health or medicines, for example), complemented by a number of technical specifications or regulations defined by the ministry of health through several executive orders or decrees.

This report provides an overview of the diversity of the legal and regulatory framework, reflecting the specificities of pharmacies and the health care systems and the challenges that the legal and regulatory frameworks aim to correct. The legal and regulatory frameworks generally aim to support one or more of the following goals:

- The population should benefit from universal and appropriate access to community pharmacies, through:
  - enabling community pharmacy planning, which may be achieved through the licensing of (new) community pharmacies based on demographic and/or geographical criteria and/or economic incentives;
  - optimizing and expanding the outreach of existing pharmacies (for instance through the establishment of branch pharmacies).

- The population should benefit from the full potential of community pharmacies – for instance, by:
  - defining the roles and services to be provided by community pharmacies, aligned with the current and emerging health needs of the community they serve;
  - ensuring effective remuneration for these activities.

- The quality of services provided by the community pharmacy should be ensured – for instance, through:
  - criteria and conditions associated with issuing a licence for a community pharmacy (include ownership requirements), which can also help to support a stronger focus on health rather than non-health-related activities;
  - workforce requirements – at an individual level (to practise as a pharmacist or as a pharmacy technician) and at the pharmacy level (for example, setting minimum staffing levels and/or responsibilities and authority of the pharmacist and licencee of a pharmacy);
  - premises requirements to support the provision of high-quality services;
  - standards guiding the provision of services and quality assurance to ensure the reproducibility of the outcomes of these activities;
  - identification of deviations (such as through inspection), along with decisions on corrective or punitive measures and enforcement.

- The regulatory system should be rigorous, agile and responsive, through:
  - regulatory (government and/or professional) bodies with clearly defined functions and sustainable resources to fulfil their missions and duties towards the public;
  - professional bodies as actively involved organizations for the professional evaluation of practitioners, provision of continuing professional development and ethical aspects of the work;
  - appropriate, effective legal and regulatory provisions, publicly available and regularly updated according to the public health needs of the population and development of pharmaceutical branch.

Examples of options for legal and regulatory provisions are described in this report to allow policy-makers to draw from the experiences of other countries as they revise and improve their legal and regulatory framework. Adoption of provisions from other countries will often need to be adapted to the local context and adjusted to ensure coherence with the national framework.

1. Introduction

While many international analyses have been performed on the legal and regulatory provisions associated with medicines (such as marketing authorization or reimbursement), few publications offer information on the legal and regulatory frameworks for community pharmacies across the WHO European Region. This report aims to provide an overview of such frameworks so that policy-makers can consider the examples of other countries when revising their national frameworks, to support the objectives they set for the community pharmacy sector.

The report is based on national legal and regulatory texts framing community pharmacy practice in the Region. These were identified through peer-reviewed articles, public reports and online databases, as well as webpages of pharmacy regulators and recommendations of experts at the national level.

This overview focuses on legal and regulatory provisions in effect as of September 2018, unless otherwise specified. It does not consider their implementation: a country may allow the regulator to impose requirements, but this report does not consider whether this option has been employed. Likewise, it does not investigate the effective implementation of the provisions or the ways they may have been circumvented.

The legal and regulatory framework usually covers the following fields:

- the pharmacy workforce (pharmacists and, in most cases, pharmacy technicians and other pharmacy staff in contact with patients);
- the pharmacy licence, including ownership requirements;
- pharmacy operations (in terms of premises, processes and workforce);
- the types of services and activities provided in a community pharmacy and the associated remuneration.

The report refers to legal and/or regulatory provisions of the following countries in the Region: Albania, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, Monaco, Montenegro, the Netherlands, North Macedonia, Norway, Poland, Portugal, the Republic of Moldova, Romania, the Russian Federation, Serbia, Slovenia, Spain, Sweden, Switzerland, Tajikistan, Turkey, Turkmenistan, Ukraine, the United Kingdom and Uzbekistan.

The legal framework of pharmacy legislation across the Region has differences in administrative culture, type of legal tradition and approaches to regulate health professionals.

2. Regulation of the community pharmacy workforce

2.1 Pharmacists

The pharmacist is a university-trained health care professional with an important role in the health care system. A direct definition of a pharmacist is very rarely outlined in national legislation or regulations. The role is often defined indirectly, through education (as in Estonia *(1: article 11(1))*) or a list of activities only pharmacists can or are allowed to perform as in France *(2)*.

Three international descriptions of a pharmacist are worth mentioning, however. In 1994, WHO described community pharmacists as follows:

> *Community pharmacists are the health professionals most accessible to the public. They supply medicines in accordance with a prescription or, when legally permitted, sell them without a prescription. In addition to ensuring an accurate supply of appropriate products, their professional activities also cover counselling of patients at the time of dispensing of prescription and non-prescription drugs, drug information to health professionals, patients and the general public, and participation in health-promotion programmes. They maintain links with other health professionals in primary health care (3).*

The International Labour Organization (ILO) developed a set of norms for pharmacists in its International Standard Classification of Occupations *(4)*. This definition was developed primarily for statistical purposes and is reproduced below.

> ***Lead statement***
>
> *Pharmacists store, preserve, compound, and dispense medicinal products and counsel on the proper use and adverse effects of drugs and medicines following prescriptions issued by medical doctors and other health professionals. They contribute to researching, testing, preparing, prescribing and monitoring medicinal therapies for optimizing human health.*

Task statement

Tasks include:

- *receiving prescriptions for medicinal products from medical doctors and other health professionals, checking patients' medicine histories, and ensuring proper dosage and methods of administration and drug compatibility before dispensing;*
- *preparing or supervising the preparation and labelling of liquid medicines, ointments, powders, tablets and other medications to fill prescriptions;*
- *providing information and advice to prescribers and clients regarding drug interactions, incompatibility and contra-indications, side effects, dosage and proper medication storage;*
- *collaborating with other health care professionals to plan, monitor, review, and evaluate the quality and effectiveness of the medicine therapy of individual patients, and the effectiveness of particular drugs or therapies;*
- *maintaining prescription files and recording issue of narcotics, poisons and habit-forming drugs in accordance with legal and professional requirements;*
- *storing and preserving vaccines, serums and other drugs subject to deterioration;*
- *advising clients on and supplying non-prescription medicines and diagnostic and therapeutic aids for common conditions;*
- *supervising and coordinating the work of pharmacy technicians, pharmacy interns and pharmacy sales assistants;*
- *conducting research to develop and improve pharmaceuticals, cosmetics and related chemical products;*
- *conferring with chemists, engineering professionals and other professionals about manufacturing techniques and ingredients;*
- *testing and analysing drugs to determine their identity, purity and strength in relation to specified standards;*
- *evaluating labels, packaging and advertising of drug products;*
- *developing information and risks of particular drugs.*

Moreover, the Board of Pharmaceutical Practice of the International Pharmaceutical Federation (FIP) adopted the following definition:

> *A pharmacist is a scientifically trained graduate health care professional who is an expert in all aspects of the supply and use of medicines. Pharmacists assure access to safe, cost-effective and quality medicines and their responsible use by individual patients and health care systems. Pharmacists are specifically educated and trained health professionals who are charged by their national or other appropriate (e.g. state or provincial) authorities with the management of the distribution of medicines to consumers and to engage in appropriate efforts to assure their safe and efficacious use. There is also increasing recognition that providing consumers with medicines alone is not sufficient to achieve the treatment goals. To address these medication-related needs, pharmacists are accepting greater responsibility for the outcomes of medicines use and are evolving their practices to provide patients with enhanced medicines-use services (5).*

A pharmacist's education and training should be regulated in national legislation, as with other health professionals.

2.1.1 Regulation of education

2.1.1.1 Initial education

Legislation and regulations usually state that pharmacists are trained at a university. The regulations framing their education may refer to the duration of the training (theoretical and practical), the topics to be covered (or competency framework), quality assurance requirements and, in some countries including

France, the maximum number of students accepted to study pharmacy every year *(6)*. In many countries specialization or differentiation occurs at the master's degree level between community pharmacists and pharmacists specializing in regulatory affairs, industry or pharmaceutical sciences. This section focuses on the education of community pharmacists.

European Union (EU) directive 2005/36/EC *(7)* states that a pharmacist's education should be of at least five years' duration, including at least four years of full-time theoretical and practical training and a six-month traineeship in a pharmacy. The directive also lists the official qualification(s) for a pharmacist in each country. In the WHO European Region this is usually a five-year university degree obtained in a higher education establishment (university), with some country specificities.

Some countries, like Albania *(8)* and the Republic of Moldova *(9)*, only grant a diploma at the conclusion of the study, while others grant intermediate titles.

In countries of the Commonwealth of Independent States (CIS) pharmacy graduates receive a specialist pharmacist degree (including Armenia, Georgia, Kazakhstan, Tajikistan, Turkey and Turkmenistan) or a specialist *provizor* degree (Belarus *(10)*, Kyrgyzstan *(11)*, the Russian Federation *(12)* and Uzbekistan *(13, 14)*).

A bachelor's and master's degree are required in Azerbaijan (4 + 2 years) *(15)* and Ukraine (3 + 2 years) *(16)*, while a single master's degree is required in Poland, for example.

In most countries the duration of the compulsory internship varies from six months to 12 months and 10 weeks (in France) *(17)*. In some countries, such as the United Kingdom, this compulsory internship period (pre-registration training) is not included in the education but is a requirement of the pharmacy regulator.

In the United Kingdom a legal provision *(18: section 42)* allows the pharmacy regulator to issue standards for the initial education of pharmacists *(19)*. In Switzerland the law defines the learning objectives and competencies that pharmacists need to acquire by the conclusion of their training *(20: article 9)*.

In several countries, such as Belarus *(21)* and Ukraine *(22)*, a distance learning pharmacy degree is available, but this option was abolished in the Russian Federation in 2016. Distance learning practice has some historic background: some years ago a very limited number of universities offered a pharmacy degree, so distance learning was developed to cover the needs of pharmacists and to allow students to obtain the degree in a different region. After the dissolution of the USSR (Soviet Union), all independent countries created their own universities or faculties of pharmacy, so there was no longer a need for such distance learning programmes.

2.1.1.2 Postgraduate training and specialization

In some countries pharmacists can acquire a postgraduate specialization in community pharmacy. This is the case, for instance, in Germany *(23),* the Netherlands *(24)*, Switzerland (where it is mandatory*) (20)*, and the United Kingdom *(18)*. This specialization is usually organized and/or regulated by the pharmacy regulator. In Germany a postgraduate degree in community pharmacy is possible only in the area of general pharmacy. The specialization is available in various fields, including geriatric pharmacy, diabetes, homeopathy and others.

In the United Kingdom and some other countries a postgraduate qualification of clinical pharmacist is available and is a requirement to work as prescribing pharmacist. In some CIS countries (such as Ukraine *(25)*) postgraduate training in pharmacy management and economy (certificated) is a requirement for a specialist to become a pharmacy manager or head of pharmacy.

2.1.2 Regulation of entry and maintaining the right to practise

Almost all countries in the WHO European Region require either registration or a licence to allow community pharmacists to practise, subject to the fulfilling several criteria.

2.1.2.1 Pharmacist competency

2.1.2.1.1 Validation of competency at the beginning of practice and recognition of education

Pharmacists need to have a professional qualification – usually a diploma issued from an accredited university of the country in which they intend to practise.[1] Professional qualifications obtained from other countries may also be recognized. The most common method is via automatic recognition within the European Economic Area (and Switzerland), defined by EU Directive 2005/36 *(7)* and transferred into national legislation. Some countries have also established bilateral agreements with others, such as France and the province of Quebec in Canada *(26: article D4221-14-1)*.

For pharmacists who have a qualification from a country without a mutual or unilateral recognition agreement, the recognition procedure may require an assessment of the education received in the country of origin. The regulator assesses whether the initial education is equivalent to that of the destination country, as in Ireland *(27: article 16(2))*.

In addition to a qualification requirement, pharmacists may have to pass an exam. This is required at the conclusion of the pharmacist's education (and/or final internship) in Austria, Croatia, Cyprus, Germany, Ireland, Israel, the Netherlands *(24)*, North Macedonia, Switzerland, Ukraine and the United Kingdom *(28)*. In some countries, including France, an exam is only organized for pharmacists who received their qualification from a state without a (mutual) recognition agreement *(26: article D4221-7)*.

In some countries, within recognition of a foreign qualification, the pharmacy regulator may impose a requirement to practise under supervision for a fixed period, such as one year in Latvia *(29: section 38(3))* or three years in France *(26: article D4221-13)*. The duration of this supervised practice may also be determined based on the regulator's assessment, as in Denmark *(30: section 4)* and Ireland *(27: article 14(4))*. The requirement in terms of practice and examination may be determined on a case-by-case basis, in the Netherlands *(31)*. At the conclusion of the recognition process (including the exam and/or practice under supervision), a formal pharmacy practice authorization or accreditation is issued by the competent authority (such as the ministry of health), as in France *(26: articles R4221-13-1–D4221-13-4)* and Germany.

In case of interruption of pharmacy practice for a few years, some countries have in place a process guiding a return to practice. For instance, in Slovenia a pharmacist who has not worked in a pharmacy for more than three years must undergo a professional internship under the supervision of a pharmacist for up to six months *(32: article 73)*.

Finally, in Switzerland pharmacists need not only to have a diploma and pass a national exam but also to acquire a postgraduate title/specialization *(20: article 36)*.

2.1.2.1.2 Competency maintained through continuing education/continuing professional development

In many countries pharmacists have to follow continuing education programmes or CPD (Continuing Professional Development), as a legal and/or ethical provision (included within the code of ethics of pharmacists) *(28)*. Continuing education refers to education provided for adults after they have left the formal education system to maintain their knowledge and skills.

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[1] In most countries a diploma or degree enables pharmacy practice; in two (Ireland and the United Kingdom), pre-registration training – a six-month or one-year internship to gain practical experience – must be completed after graduation but before becoming a registered pharmacist.

FIP defines continuing CPD as "the responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes, to ensure continuing competence as a professional, throughout their careers" *(33)*. It relates to the process of tracking and documenting the skills, knowledge and experience that professionals gain both formally and informally as they work, beyond any initial training.

Continuing education and CPD vary greatly between countries; they may be regulated in national legislation on health care professionals or education. CPD is either a legal obligation or a professional right that might be organized and/or controlled by the government and/or professional bodies *(28)*.

In Belgium, the continuing education/CPD obligation aims to guarantee the quality of pharmaceutical care *(34: article 4)*. The requirement can be an individual requirement for the pharmacist, an obligation of the employer (in Estonia the employer needs to ensure that pharmacists receive no less than 40 academic hours' training in two years *(1: article 45(42))*) or an obligation for both the employer and the pharmacist as in Finland *(35: article 18; 36: article 56(1))*. It may be a requirement for issuance or renewal of a professional pharmacist's licence, as in Serbia *(37: article 182)*.

Fulfilment of the obligation can be based on continuing education credits (the most common system used), a portfolio summarizing the CPD cycle of a pharmacist, a combination of the two or peer-review *(28)*. The frequency of validation of credits varies from one year in Romania *(38)*, three years in France *(26: article L. 4021-1)* to five years in Portugal *(39: article 2)*. In Kazakhstan *(40)*, the Russian Federation *(41)* and Ukraine *(25)* a pharmacist who does not hold an up-to-date CPD certificate is not allowed to practise.

The pharmacy regulator in the United Kingdom has adopted a framework for CPD that includes *(18: section 43)*:

- the amount and type of CPD a pharmacist is required to undertake;
- the information to be provided by a pharmacist about the CPD undertaken and the form and manner in which it is to be provided;
- the times at which information about the CPD undertaken is to be provided (including any CPD that relates to an annotation with respect to a particular specialization to be recorded in the register);
- record-keeping on the CPD undertaken by pharmacists.

2.1.2.1.3 Linguistic competency

Given that community pharmacy practice requires ever-increasing interactions with patients during dispensing, counselling and other services, linguistic competency is usually a requirement applicable to all pharmacists and pharmacy technicians, as in Germany *(42: article 3(5))* and the Netherlands *(24: articles 6.f and 7.c)*. It is sometimes defined only if the pharmacist is not a national and/or has not studied pharmacy in the country. Such provisions are, for instance, included in France *(26: article R4112-1)*, Ireland *(27: article 14(1)g)* and Serbia *(37: article 168)*.

In Finland, this requirement is the responsibility of the individual pharmacist as well as the employer: "A health care professional must have adequate language skills required for the duties he or she carries out. The employer of a health care professional must ensure that the language skills of a health care professional are at an adequate level required by his or her duties" *(35: article 18a)*. In Slovenia a pharmacist managing a community pharmacy in an area with linguistic minority groups (Italian or Hungarian) must also have a good knowledge of this language *(32: article 13(2))*.

Linguistic competency can be assessed through different means (such as certificates of achievement from educational organizations or interviews with the regulator). In some countries, including Austria, linguistic competency is assessed by the pharmacy regulator and may be associated with a fee

(44: article 3b(2a)). In Great Britain[2] the regulator has issued guidance on evidence of English language skills *(45)*, defining four areas in which a pharmacist must demonstrate competency of English: reading, writing, listening and speaking. Several cases are described (based on the language and the country where the pharmacist studied).

2.1.2.2 Ability to practise

In several countries the laws and regulations have provisions that cover health conditions that prevent a pharmacist from practising safely and effectively (or make pharmacy practice dangerous). The regulator assesses whether a health condition (such as a disease or disability) prevents the pharmacist from practising and may impose a restriction on the activities the pharmacist can conduct or impose the assistance of another pharmacist. Such provisions are, for instance, defined in Belgium *(46: article 6)*, Finland *(35: article 28)*, France *(26: article R4112-1)*, Germany *(47: article 2(1)7)*, Great Britain *(18: article 51(c))* and Turkey *(48: article 4 C) and Ç))*.

In Iceland the regulation states that the pharmacy quality system should prevent any pharmacist rendered unsuitable because of an illness from performing duties *(49)*. Before the 2013 amendment, medical examinations were required for all pharmacy employees on an annual basis, to confirm that the pharmacy employee did not have any medical conditions that prevented them from practising *(50: article 44)*. In Austria a medical certificate is required to operate a community pharmacy *(44: article 3(1)6)*. In Israel a medical commission can assess whether a pharmacist's condition may impair their ability to practise. If deemed necessary, a pharmacist's licence can be suspended until the commission has finalized its assessment *(51: article 9c–9d)*. In the Netherlands a final court order to place a pharmacist under guardianship because of a physical or mental condition prevents them from being registered and therefore from practising *(24: article 6.b)*.

In most countries pharmacists can be subject to disciplinary sanctions or civil court decisions suspending their professional licence (or their ability to practise) for a defined period or permanently. The pharmacy regulator is usually responsible for the judiciary process leading to disciplinary sanctions, and is informed of any decisions of the courts suspending or cancelling a pharmacist's licence. If a pharmacist has practised in another country, however, the regulator is not always informed of this sanction by the regulator of the other country. This is why most countries, including Austria *(44: article 3c(7d))*, Ireland *(27: article 14(2))*, the Netherlands *(24: articles 6.e and 7.e)* and Turkey *(48: article 4B)* have adopted a provision to prevent an individual who is not allowed to practise in another country from practising on their soil.

2.1.2.3 Ethical practice

Some countries, like Malta *(52: article 13(2)(b))*, have set out that a pharmacist cannot be licensed unless of good conduct. Regulations and legislation assess moral criteria for a pharmacist to be able to practise through criminal records or similar official documents certifying that the pharmacist has not committed serious offences. Offences listed in criminal records vary across countries, however.

When registering, a pharmacist is obliged to provide a copy of any criminal record in a number of countries, such as Belgium *(53)*. In other countries, including France, the regulatory body charged with issuing a professional licence has direct access to a summary of criminal records *(54: article R79)*.

Some countries, like Turkey *(48: article 4A)*, define within their legislation the types of offence that prevent an individual practising pharmacy. Likewise, the Austrian regulation specifies, among other criteria, that a sentence of more than one year of imprisonment or specific types of offence are neither compatible with nor appropriate for pharmacy practice *(44: article 3b(2))*.

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[2] Note: "Great Britain" includes three nations of the United Kingdom: England, Scotland and Wales. Northern Ireland has a different pharmacy regulatory system.

When an individual has practised in a foreign country, a criminal record from the country (or certification from its regulatory body) is also sometimes requested, as in France *(26: article R4112-1)* and Austria *(44: article 3b(3a))*. However, the criminal record only reflects former offences that have received judgment. To cover ongoing cases, some regulators (including in France) ask for a solemn declaration stating that the pharmacist is not aware of any (civil) action or ongoing court cases against them that could have an impact on their professional licence *(26: article R4112-1)*.

Regulators may also impose disciplinary sanctions, which can limit the pharmacist's licence or suspend it temporarily or permanently, and have an impact on their ability to practise. These are usually based on professional and ethical standards, which are generally prepared by the pharmacy regulator. For professional standards, they may be specific to a topic or aim to cover the entire pharmacy practice. For example, Great Britain *(55)* has adopted an approach based on defining key principles and a giving description of how these are applied. Other countries have chosen a different approach, defining more precise rules, as in France *(26: articles R. 4235-1–R. 4235-77)* and Belgium *(56: annexe 1)*.

A code of ethics may cover different aspects of pharmacy practice, such as continuity of care; the relationship between pharmacists; professional confidentiality; and the relationships with, communication with and advertising to patients and other health care professionals. It may also define the responsibilities of the pharmacist, as well as provisions to ensure the independence of practice and the health (rather than commercial) focus of the profession.

In some countries, the code of ethics developed by the pharmacy regulator needs to be approved formally by the minister of health (or related government authority) to come into force. This is, for instance, the case in Belgium *(46: article 15)*, Monaco *(57: article 18.2)* and France *(26: article L4235-1)*. In other countries (like Romania *(38)*), the code of ethics can be adopted directly by the regulatory body.

When required, professional standards and codes of ethics may be associated with recommendations or guidance, to help create understanding of how to apply the principles defined in these documents to daily pharmacy practice, as in Great Britain *(58)*. Interpretation of the different professional and ethical standards is also built into case law from disciplinary courts and committees (which are part of the regulator) or through civil/penal courts.

2.1.2.4 Other criteria

Most countries have criteria related to nationality to allow pharmacists to practise. Three common situations can be distinguished.

- The pharmacist is a national of the country where they want to practise (or has a permanent residency permit).
- The pharmacist is a national (or in some cases a long-term resident) of a country with an agreement with the desired country of practice. Such an agreement is usually mutual. For instance, within the EU (and the European Economic Area) no distinction is made between nationals of any Member State *(7)*: these principles are included in the national legislation of all relevant countries.
- The pharmacist is a national of a country without a specific agreement with the desired country of practice. Countries consider this situation a diverse number of ways.

In several countries regulations state that pharmacists need to be able to practise independent of pressure or constraints. For instance, the French code of ethics of pharmacists (a component of the French regulation) mentions that the pharmacist should not be submitted to any constraint (such as financial, commercial, technical or moral constraint) that might affect the independence of their practice, including through contracts *(26: article R4235-18)*.

Independence of practice is considered more easily guaranteed in countries where ownership of community pharmacies is restricted to pharmacists, as they can be subject to disciplinary prosecution (which may result in the cancellation of their professional licence, meaning that they will have to sell their

community pharmacy – usually under unfavourable conditions) *(59)*. Additional criteria with regard to independence may be defined by regulation for the pharmacist responsible for a community pharmacy. These criteria are defined in section 3.6.1.

In most countries in the WHO European Region a pharmacist's professional licence is usually considered recognition of ability to practise pharmacy legally. A licence needs to be obtained prior to beginning to practise, and it may also be maintained when a pharmacist ceases to practise (such as on retirement or during a sabbatical year), provided other requirements are met.

In France, however, to have a professional licence (consisting of registration by the pharmacy regulator: the *Ordre national des Pharmaciens*), a candidate also needs to prove that they practise as a pharmacist within a pharmaceutical setting (such as a community pharmacy) by submitting a work contract. This means that when a pharmacist stops working as a pharmacist – for instance, on retirement or when changing career – they will automatically be removed from the registry. As such, the French registry only reflects practising pharmacists *(60)*.

Likewise, in Malta registered pharmacists should pursue at least one of the activities listed in the regulation, ranging from preparation of the pharmaceutical form of medicinal products and manufacture to dispensing and providing support to patients *(52: article 13(3))*.

In Belgium it is forbidden to practise as both a medical doctor and a pharmacist, even if the individual holds both degrees *(34: article 4bis)*. Likewise, in Malta concurrent practice of pharmacy and medicine is not allowed *(52: article 4)*. In the Netherlands this issue was discussed in the parliament discussion on the Medicines Act, but it was not included in the law. In practice, it is not possible to hold both professions because there of the prohibition on conflicts of interests *(61: article 11)*: prescribing medicines and earning from selling those medicines could be seen as such a conflict.

In most countries it is compulsory for pharmacists, pharmacy technicians and/or community pharmacies to have liability insurance. This obligation may be part of the legal requirements for a pharmacist licence, as in Austria *(44: article 4a)*, or it may be applicable to all health care professionals, as in France *(26: article L1142-2)*. Some countries, including Austria, ask for additional information in order to issue a licence, such as proof of residency *(44: article 3c(7d))*.

Moreover, a few countries, like the United Kingdom, have adopted specific provisions allowing foreign pharmacists to be registered quickly in the event of emergencies involving loss of human life or illness *(18: article 34)*. Such provisions ensure that registration will not unnecessarily delay the deployment of humanitarian support provided by foreign pharmacists in crisis situations.

2.1.3 Accessibility of proof of ability to practise

When all required criteria are met, the pharmacy regulator may either issue a professional licence or register the pharmacist. Validity of the licence or registration may be limited in time (for instance one year in Great Britain *(18: section 25)*, five years in most CIS countries or unlimited in Germany). It is usually subject to a fee to the pharmacy regulator, as in Great Britain *(18: section 36(1)(a))*.

Proof of licence or registration may take different formats: a certificate of registration, as in Ireland *(27: article 20)*, a professional card, as in Austria *(44: article 3e)* or inclusion of the pharmacist name (and other relevant details) on a public register, usually also available online, as in Albania *(62)* and Malta *(52: article 13(2)(c))*, or a register of the professional body, as in Kyrgyzstan *(63)*. The register may be specific to pharmacists or may be for all health care professionals (as in Switzerland *(64)*). The licence or registration is usually made public so that anyone (such as patients and potential employers) can verify that an individual is allowed to practise pharmacy: it is an important tool to ensure that only reliable specialists are able to practise.

If an individual is not registered but claims to be a pharmacist, the regulator may prosecute them, as is, for instance, the case in Great Britain *(18: section 38)*. In a few countries, the title "pharmacist" is protected and can only be used if an individual is registered or has a licence, as in Austria *(44: article 3f)* and France *(26: article L4223-5)*. In these countries, individuals holding a master's degree or doctorate in pharmacy can use their academic title even if they are not registered, but they cannot identify themselves as pharmacists unless they are registered.

In CIS countries the licence or registration information is usually not available – including in Azerbaijan, Belarus, Kazakhstan, the Republic of Moldova, Tajikistan and Ukraine – or has limited availability. For example, in the Russian Federation information about accreditation of pharmacists and pharmacy technicians is available through the website of the university where the professional was accredited, but the information is not easily accessible, as a search has to be conducted by name and year of accreditation *(65)*.

Some countries introduce the reverse procedure to ensure that unreliable pharmacists do not practise. In Uzbekistan *(66)* and Georgia *(67, 68)* a list of pharmacists who have violated the law is available on the website of the ministry of health.

2.1.4 Scope of practice

At the international level, the roles and functions of a pharmacist were described by WHO and FIP in 2011 *(69)*.

Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products

- *Function A: Prepare extemporaneous medicine preparations and medical products*
- *Function B: Obtain, store and secure medicine preparations and medical products*
- *Function C: Distribute medicine preparations and medical products*
- *Function D: Administration of medicines, vaccines and other injectable medications*
- *Function E: Dispensing of medical products*
- *Function F: Dispose of medicine preparations and medical products*

Role 2: Provide effective medication therapy management

- *Function A: Assess patient health status and needs*
- *Function B: Manage patient medication therapy*
- *Function C: Monitor patient progress and outcomes*
- *Function D: Provide information about medicines and health-related issues*

Role 3: Maintain and improve professional performance

- *Function A: Plan and implement CPD strategies to improve current and future performance*

Role 4: Contribute to improve effectiveness of the health-care system and public health

- *Function A: Disseminate evaluated information about medicines and various aspects of self-care*
- *Function B: Engage in preventive care activities and services*
- *Function C: Comply with national professional obligations, guidelines and legislations*
- *Function D: Advocate and support national policies that promote improved health outcomes*

The publication also lists standards that should be developed for each role and function.

The regular tasks of pharmacists were also described by ILO in its International Standard Classification of Occupations as pharmacists *(4: code 2262)*.

Pharmacists' scope of practice consists of two components:

- the exclusive scope of practice, usually justified by specific competencies required – for instance, in France the law defines what activities are reserved for pharmacists *(26: article L4211-1)*;
- the scope of practice allowed (and/or within the mission of pharmacists): this may be defined in general terms or with a precise list of activities (some of which can be performed by other health care professionals), as is the case in France *(26: article L5125-1-1 A)*.

The scope of practice of a health care professional may also be indirectly defined (and/or limited) through the exclusive scope of practice of other health care professionals (such as medical doctors and nurses). The scope of practice is sometimes defined through the definition of a pharmacist, as described earlier.

It should be noticed that the scope of practice of pharmacists may be different from the services provided in a community pharmacy; indeed, some countries allow other health care professionals (such as pharmacy technicians, nurses and nutritionists) to provide care in community pharmacies.

2.2 Pharmacy technicians

The definition of a pharmacy technician (and consequently the scope of practice) differs significantly across countries in the WHO European Region *(70)*. At the international level, ILO defined the tasks of a pharmacy technician (or pharmaceutical technician and assistant) in its International Standard Classification of Occupations as pharmaceutical technicians and assistants *(4: code 3213)*.

Lead statement

Pharmaceutical technicians and assistants perform a variety of tasks associated with dispensing medicinal products under the guidance of a pharmacist or other health professional.

Task statement

Tasks include:

- *preparing medications and other pharmaceutical compounds under the guidance of a pharmacist of other health professional;*
- *dispensing medicines and drugs to clients and giving written and oral instructions on their use, as prescribed by medical doctors, veterinarians or other health professionals;*
- *receiving prescriptions or refill requests from health professionals and verifying that information is complete and accurate according to medical record-keeping standards;*
- *maintaining proper storage and security conditions for drugs;*
- *filling and labelling containers with prescribed medications;*
- *assisting clients by answering questions, locating items or referring them to a pharmacist for medication information;*
- *pricing and filing prescriptions that have been filled and establishing and maintaining patient records, including lists of medications taken by individual patients;*
- *ordering, labelling and counting stocks of medications, chemicals and supplies, and entering inventory data into record-keeping systems;*
- *cleaning and preparing equipment and containers used for prepare and dispense medicines and pharmaceutical compounds.*

The official title "pharmacy technician" and the required education vary significantly across countries in the Region (Table 1).

Table 1. | **Examples of titles and education of pharmacy technicians in countries in the Region**

Country	Title	Level of education	Duration (years)
Azerbaijan	Фармацевт-ассистент (pharmacist assistant)	College degree	3
Belarus	Фармацевт (pharmacist)[a]	College degree	2–3
Croatia	Farmaceutski tehničar	Secondary level	4
Denmark	Farmakonom	Secondary level; post-secondary diploma	3
Finland	Lääketeknikko	Secondary level	3
France	Préparateur en pharmacie	Post-secondary diploma	2
Germany	Pharmazeutisch-technische Assistenten	Secondary level	2.5
Iceland	Lyfjatæknir	Secondary level	4
Ireland	Pharmacy technician	Post-secondary diploma	2
Kazakhstan	Фармацевт (pharmacist)[a]	College degree	3
Kyrgyzstan	Фармацевт-ассистент (pharmacist assistant)	College degree	3
Lithuania	Vaistininko padėjėjas (Farmakotechnikas)	Bachelor's degree	3
Malta	Pharmacy technician	Post-secondary diploma	2
Netherlands	Apothekersassitent	Secondary level	2
Norway	Apotekteknike	Post-secondary diploma	3
Poland	Technik farmaceutyczny	Post-secondary diploma	2
Portugal	Técnico de farmácia	Bachelor's degree	4
Republic of Moldova	Фармацевт-ассистент (pharmacist assistant)	College degree	3
Russian Federation	Фармацевт (pharmacist)[a]	College degree	3
Serbia	Farmaceutski tehnicar	Secondary level	4
Slovenia	Farmacevtski tehnik	Secondary level	4
Spain	Técnico en farmacia y parafarmacia	Secondary level	2
Sweden	Apotekstekniker	Post-secondary diploma	<2
Ukraine	Молодший спеціаліст фармації /Бакалавр (Young pharmacy specialist/bachelor)	College degree	3
United Kingdom	Pharmacy technician	Secondary level	2
Uzbekistan	Фармацевт-ассистент (pharmacist assistant)	College degree	3

[a] The profession is often called "pharmacist" to differentiate the role from specialists with higher education called "provizors".

Source: adapted from European Association of Pharmacy Technicians *(71)*.

Various regulatory options are in place to authorize an individual to practise as a pharmacy technician: some countries have an exam at the end of the education; some countries also issue a professional licence for pharmacy technicians to practise *(71)*.

Legal permission for pharmacy technicians to practise independently or under the effective guidance and/or supervision of a pharmacist also differs greatly across countries. In countries where such supervision is required, the number of pharmacy technicians per pharmacist in the pharmacy can be limited. For example, Belgium does not allow more than three pharmacy technicians per pharmacist *(56: article 7)*.

The scope of practice of pharmacy technicians can be limited to compounding (individual preparation of medicines in pharmacies according to prescriptions), dispensing over-the-counter (OTC) medicines or ensuring logistic functions. Some countries allow a wider scope of practice for pharmacy technicians who can also dispense prescription-only medicines, in line with their specific diploma. In majority of CIS countries pharmacy technicians (or holders of an equivalent degree) have broad professional rights. In Armenia *(72),* Belarus *(73)*, Georgia *(74)*, Kazakhstan *(40)*, Kyrgyzstan *(75)*, the Republic of Moldova *(76)*, the Russian Federation *(41)*, Tajikistan *(77)*, Ukraine *(25)* and Uzbekistan *(78)* specialists with college degrees can manage pharmacy points or pharmacy kiosks in rural or remote areas. To fulfil this function, their participation in continuing education programmes is mandatory (every five years), and attestation (in Kyrgyzstan and the Russian Federation) is required.

As a trained and educated health professional, a pharmacy technician should be able to work independently in a pharmacy. The overall responsibility of a pharmacy technician should reflect their level of training and education and be supported by an exact definition of professional rights.

3. Community pharmacy regulation

3.1 Community pharmacy definition

Each country's definition of community pharmacy differs, although most define it as a type of health care facility that provides specific services or with a given mission around medicines. These activities may be summarized or listed extensively.

For instance, community pharmacies are defined in Spain as "private health establishments of public interest, subject to health planning […] which must provide [a series of services]" *(79: article 1)*, outlining 10 essential services that pharmacies must deliver. In Serbia the definition is "a health care facility where pharmaceutical care is provided at primary level" *(37: article 100(1))*; in France it is "an institution in charge of the dispensing of medicines as well as other products [mentioned in another article] as well as compounding" *(26: article L5125-1)*.

In Germany pharmacies are defined as in charge of ensuring the proper supply of medicines to the public in the public interest *(47: article 1)*; in the Netherlands as a premises (or several premises) in which medicines are prepared, dispensed and kept in stock for the purpose of dispensing, or are only dispensed and kept in stock for this purpose *(80: article 1.1.oo)*.

The definition in Slovenia is "a public health service, which ensures the permanent and uninterrupted care of the population and health care providers with medicinal products and the pharmaceutical treatment of patients" *(32: article 5)*. Its purpose is to ensure "the quality and effective supply of medicines and other products to support treatment and health preservation and to advise on their safe, proper and effective use for patients and health care professionals" *(32: article 2)*.

In Finland, a pharmacy is defined as "an operating unit providing pharmaceutical services, including the retail sale, distribution and preparation of pharmaceutical products, as well as counselling and other services related to pharmaceutical products" *(36: article 38)*; in Lithuania as a legal entity "performing pharmaceutical activity including the acquisition, storage, sale (dispensing) of medicinal products to the ultimate consumer, the provision of pharmaceutical services and/or compounding and quality control of extemporaneous medicinal products" *(81: article 2.51)*.

3.2 Pharmacy licences

3.2.1 Granting a licence

A licence is needed to open and operate a community pharmacy in all countries in the WHO European Region. This can be provided by the national authority, as in Belgium *(56: article 1)*, Latvia *(29: section 37)* and Malta *(82: article 66(1))* and in the majority of CIS countries. In federal states, such as the Russian Federation and Switzerland *(83: article 30)*, provision of a pharmacy licence is regulated at the local level. Applications for licences can be made directly or through electronic government systems, as in Armenia, Azerbaijan, Georgia and Kazakhstan. Most licences are attached to a given location and premises, which may be subject to inspection prior to the licence being granted, as in Iceland *(50)* and Malta *(82: article 68)*.

Two different concepts govern pharmacy licences.

- A facility-based pharmacy licence is an authorization to operate a pharmacy in a specific location. The licence can be transferred (sold) automatically when the pharmacy is sold to another owner (provided the new owner meets all other requirements); it is therefore time unlimited and transferrable. This model is usually used in countries that combine limiting the establishment of community pharmacies (for health planning) with limiting ownership to pharmacists. This is the case, for instance, in Belgium, France *(26: article L5125-4)* and Malta, although when a new pharmacy is created in Belgium the licence can only be transferred five years after its creation *(34: article 4)*. In CIS countries licences are facility-based and non-transferable and most have to be re-issued in five-year terms (Armenia, Belarus, Kazakhstan, Russian Federation and Ukraine).
- A licence to operate a community pharmacy concerns the legal running of the pharmacy, which may be associated with a specific responsible pharmacist (as in Iceland). When the operator/responsible pharmacist changes, the licence is cancelled and a new one must be issued. This licence is personal and non-transferrable, as in Austria *(44: article 12(1))*. By definition, this licence is time limited (for example, expiring on the retirement or dismissal of the responsible pharmacist).

The issuance of a pharmacy licence can be associated with a fixed fee, as in Belgium *(84: article 4)*, and renewal may also be subject to a fee, as in Malta *(85)*. This fee may be the same for all pharmacies or may vary according to specific criteria (such as the size of the pharmacy in Malta *(85)*).

The documents and process for issuing a pharmacy licence are usually defined thoroughly, as in Belgium – where they encompass notification of request received and consultation of different organizations, including pharmacists' organizations *(84: articles 6 and 7)* – and Denmark *(86)*. When issuing a pharmacy licence, the regulator ensures that all requirements are met. It may also impose specific requirements or describe what the pharmacy owner is entitled to do, as in Denmark *(87: section 12)*.

In some countries, like Lithuania, different types of pharmacy licence are issued, based on whether the community pharmacy is allowed to compound or not *(81: article 35)*. In addition to a pharmacy licence, some countries allow pharmacies to have one or several pharmacy branches (see section 3.3.4). The conditions for granting a licence differ significantly from one country to another. These requirements are described in detail later in this chapter.

Belarus has five different types of pharmacy licence, which allow specific activities such as compounding and dispensing narcotics and psychotropic medicines *(88: article 3)*. In Georgia *(89)* three categories of pharmacies can be licensed: pharmacies that include in-house production of medicines; pharmacies without medicine production; and branch pharmacies located in hospitals and rural areas. There is no procedure for relicensing pharmacies due to the lack of pharmacy inspectors.

In many CIS countries the required space and capacity to compound medicines will define the type of pharmacy. To increase access to medicines in rural areas, national legislation allows pharmacy entities

with restricted requirements, such as pharmacy points and kiosks, to be opened. The major difference between pharmacy point and pharmacy kiosk is usually an issue of the space required, compared to a pharmacy. In Kyrgyzstan, for instance, a regular pharmacy requires 75–85 m^2, a pharmacy point only 20 m^2 and a pharmacy kiosk only 10 m^2 (see also section 3.6.2.1). A similar principle is applied in the Russian Federation, with requirements of 110 m^2 for a regular pharmacy, 34 m^2 for a pharmacy point and 10 m^2 for a pharmacy kiosk. A kiosk does not usually provide an entrance for customers: consultation and dispensing are performed through a small window while the customer stands outside. These restrictions on space and organization necessitate limited provision of pharmacy services, focusing on dispensing, with rare exclusions. For example, in small villages in Tajikistan *(77)* compounding is allowed in pharmacy points.

All entities need a licence to operate. Pharmacy points and kiosk are dependent entities: to get a licence the owner must have a regular pharmacy with a licence.

The Republic of Moldova has a specific accreditation procedure according to the local Good Pharmacy Practice (GPP) guidelines for opening a pharmacy point or kiosk *(76)*. In Armenia *(92)*, Kyrgyzstan *(90)*, the Republic of Moldova *(91)*, the Russian Federation *(41)*, Turkmenistan *(93)* and Uzbekistan *(78)* three categories of pharmacy exist: pharmacies (including finished dosage form; with compounding; with compounding of aseptic medical forms), pharmacy points and pharmacy kiosks (called branches of the first or second category in the Republic of Moldova). In Kazakhstan *(40)* and Ukraine (*25*) only two types of pharmacy are allowed: pharmacies (with or without compounding) and pharmacy points in hospitals.

Licensing of pharmacy kiosks in Ukraine has been prohibited since 2013. The application for a licence to open a pharmacy is dealt with by Ukraine's State Administration for Medicines and Control of Narcotics *(94)*. According to a new regulation, the owner of the licence should not have connections (or be influenced in their activities) by representatives of countries that offer military aggression to Ukraine.

In Turkey licensing and distribution of pharmacies are regulated by the government. To get a pharmacy licence, the pharmacist should submit an electronic application for a pharmacy manager position, fulfilling all requirements including a degree, work experience and certificate from the Chamber of Pharmacists. If successful, the premises are licensed *(48, 95)*.

Insufficient access to health care in remote areas is a critical concern in many countries. In Kazakhstan *(40)*, Turkey and Uzbekistan *(66)*, to increase access to medicines in rural areas, specific pharmacies can organize mobile pharmacy points, such as pharmacy buses. In Uzbekistan, a major distributor of pharmaceuticals runs mobile pharmacies to improve access to essential medicines in remote areas. Uzbekistan also recently provided medical vehicles serving as family clinics in the regions in need, aiming to reduce the burden of emergency medical services, which have been exploited due to a lack of access to primary health care services.

3.2.2 Cancelling a licence

A licence can expire if a community pharmacy ceases to operate or has not been created within a given time frame after issuance of the licence. Different practices exist among countries for cancelling or withdrawing licenses, such as if the owner does not use it at all or uses it only partially. In Denmark *(87: section 24)*, Finland *(36: article 48)* and Germany *(47: article 3(4))* if the licence is not used for one year (no pharmacy activity), it is withdrawn or cancelled. Similar provisions are in place in Belgium for a period of two years *(84: article 14)*. If a pharmacy is kept closed for a period of six months or for an aggregate period of six months within one calendar year in Malta, the licence is considered no longer valid *(96: article 3(4))*.

If the licence owner or pharmacy staff violate legislation on pharmacy practice (for example, by dispensing without a prescription) or licence requirements for community pharmacies (for example, with insufficient staff numbers or inadequate premises), the licence can be withdrawn or cancelled, either temporarily or permanently. Violation of pharmacy licence requirements in Georgia *(67)* or Armenia *(72)*,

causes high penalties for the licence owner, up to cancelling the licence. Examples of practices that can cause cancellation include employing staff without pharmacy degrees, dispensing rules violations and dispensing of falsified medicines. In Albania, a licence can be withdrawn in the case of violation of the code of ethics *(62)*.

In Azerbaijan, Kazakhstan, the Russian Federation, Tajikistan, Turkmenistan and Ukraine a violation of hygienic requirements or fire safety may cause a temporary withdrawal of the licence, while dispensing of psychotropic substances without prescription leads to permanent cancellation.

In Belarus *(73)* if licence requirements are not met, the licence owner may be given six months to improve before the licence is cancelled. A pharmacy can also receive a penalty if no stock of medicines from the essential list is available, produced in Belarus or the Russian Federation *(97)*.

In Kyrgyzstan *(63)* and the Republic of Moldova *(91)* a licence will be cancelled temporarily if GPP guidelines are not followed. In the Republic of Moldova, the licence will also be terminated in the absence of CPD certification for staff members or nonfulfillment of accreditation criteria *(76)*. In Ukraine a pharmacy licence will be cancelled if it is proved that the licence owner is influenced in their activities by representatives of countries that offer military aggression to Ukraine *(25)*.

In Uzbekistan a licence will be cancelled permanently if requirements are violated systematically (more than twice during the year): if the pharmacy has in stock medicines without quality certificate or falsified medicines, if the medicines are dispensed by a person without a pharmacy degree or if the head of a pharmacy does not have a pharmacy degree *(66)*.

Strict criteria are also implemented in Turkey *(48)* regarding the presence of pharmacist. If the pharmacist is absent or not fulfilling requirements, the pharmacy may be closed for 30 days. If the requirements are still not met, the licence will be cancelled. If pharmacy legislation is violated, the pharmacy will be closed and all pharmacists will be forbidden to apply for a licence for the next five years.

A requirement to inform the pharmacy regulator of a permanent or temporary closure of a community pharmacy is usual, as it can have an impact on pharmacy network planning. This is, for instance, the case in Belgium *(84: article 15 quater)*. To maintain continuity of access to pharmaceutical products and expertise, the pharmacy regulator can impose a requirement to maintain pharmacy activity for a short period until a new pharmacy is granted to another pharmacist, as in Denmark *(87: section 24)*.

Some countries include a comprehensive description of the process to be followed to cancel a pharmacy licence, as in Denmark *(87: section 25)*. In Germany, the licence can be withdrawn if the conditions for acquiring a licence (such as moral conditions and independence criteria) are no longer met *(47: article 4)*, which represents an impetus to professional and ethical behaviour.

3.3 Pharmacy network planning – establishment and distribution

Many countries in the WHO European Region apply statutory provisions to regulate the establishment of new pharmacies. These are sometimes included in the definition of community pharmacies, as in Spain, where they are defined as "private health establishments of public interest, subject to health planning […]" *(79: article 1)*. These provisions are usually based on demographic and geographical criteria, and tend to be the same throughout the country, although they are sometimes adjusted to the specificities of a territory. This is the case, for instance, in Spain where the autonomous communities (regions) are allowed to adjust the criteria defined nationally to better meet their own peculiarities *(79: article 2)*. The planning of community pharmacies may also be defined at a more local level, as in Italy, where it is located by the city, charged with the *Pianta organica*.

These restrictions are often regulatory tools that assist the state in its health planning of community pharmacies. In Finland the law states that pharmacies must be in sufficient number to allow the general public, wherever possible, to access pharmaceutical products without difficulty *(36: article 39)*, thereby defining an objective for pharmacy network planning. The licence of a community pharmacy is thus often associated with the location of the pharmacy or a geographical unit, as mentioned in France *(26: article L5125-18)*.

To ensure fairness and allow transparent decision-making (and possible appeals) in countries with pharmacy planning, extensive descriptions of the criteria used for establishment and location of community pharmacies are usually included in laws or regulatory documents, as in Belgium *(84: articles 4–15bis)*, France *(26: articles L5125-18–L5125-22)* and Malta *(96)*. In some countries like Finland *(35: article 11)* and Turkey *(48: article 5)* public announcements are made when a licence for a community pharmacy becomes available.

In countries with community pharmacy planning, the relocation of an existing pharmacy is also subject to specific criteria. For instance, in Malta relocation is only possible within the same town or village, if better facilities are available, and if the new pharmacy is located no less than 300 m walking distance from any existing pharmacy or not more than 50 m from the current premises *(96: article 11)*. Likewise, in Portugal the transfer of a community pharmacy must "safeguard the accessibility of the population to the medicines, for their convenience as well as the economic viability of the pharmacy, whose location the owner intends to transfer" and "improve or increase of pharmaceutical services for health promotion and the well-being of users" *(98: article 26)*.

In countries where there is an attempt to stabilize or reduce the number of community pharmacies, some regulations and provisions are in place to support mergers, but at the same time to ensure that such mergers will not result in imbalances in access. For instance, in Belgium after the merger of community pharmacies it is not possible to open (or transfer) a new pharmacy within 1.5 km of the remaining one *(84: article 3)*. Moreover, the regulation states that it is not possible to increase the number of pharmacies for 20 years, as of 8 December 1999 *(84: article 1bis)*.

If a pharmacy licence is to be cancelled for pharmacy planning, the regulations may define compensation for the pharmacy owner, as in Denmark *(87: section 70)*.

3.3.1 Demographic restrictions

In several countries in the WHO European Region a licence to open a new pharmacy can only be issued if specific demographic criteria are met. The most common criterion is the number of inhabitants within a given city, county or administrative region. The criteria may differ for creation of the first pharmacy and establishment of additional pharmacies. Table 2 sets out some examples of the minimum number of inhabitants per pharmacy set by national regulations.

The demographic criteria are usually based on a census organized by the state. In some countries the ability to open a new pharmacy is made public; for instance, in Turkey such announcements are made at least twice a year *(48: article 5)*. The demographic criteria may not always, however, reflect the pharmacy needs of transiting passengers (as in airports, for example). The French regulation has set specific rules for determining the number of community pharmacies that can be authorized in an airport, based on the annual number of passengers. A first community pharmacy can open when there are more than 3 million passengers a year, with an additional pharmacy for each 20 million additional passengers *(26: article L5125-7)*.

Table 2. | **Examples of minimum numbers of inhabitants per new community pharmacy**

Country	Minimum number of inhabitants
Austria	5500 inhabitants *(44: article 10(2))*
Belgium	Maximum number of pharmacies instead based on the number of inhabitants divided by the following factors: 3000 for cities with more than 30 000 inhabitants; 2500 for cities between 7500 and 30 000 inhabitants; 2000 for cities with fewer than 7500 inhabitants *(84: article 1(2))*
France	2500 inhabitants for the first pharmacy; 4500 further inhabitants for any additional community pharmacy (although some criteria for are adjusted in specific regions, such as Guyane, Moselle, Bas-Rhin and Haut-Rhin *(26: article L5125-4)*)
Hungary	After creation of the new pharmacy, minimum number of inhabitants per pharmacy to be at least: 4000 for cities with more than 50 000 inhabitants 4500 for smaller cities *(99: article 49(A)2)*
Latvia	2000 inhabitants *(100)*
Malta	2500 inhabitants *(96: article 4(2))*
Poland	3000 inhabitants, although this criterion does not apply if the new pharmacy is located further than 1 km from any existing pharmacies *(101)*
Portugal	3500 inhabitants *(102)*
Republic of Moldova	Only for new pharmacies in cities: one per 3000–4000 inhabitants
Romania	3000 in Bucharest 3500 in county capitals 4000 in other cities No criteria in rural areas *(38)*
Slovenia	6000 inhabitants *(32: article 9)*
Spain	2800 (but the regulation can be adjusted at the regional level) *(79: article 2)*
Turkey	3500 *(48: article 5)*, although the demographic restriction is not applied if there are no pharmacies in the area, but the criteria would be applied again for resettlement of a pharmacy

3.3.2 Geographical criteria and restrictions

Several countries use geographical criteria to determine whether a pharmacy licence can be issued. This aims to prevent the concentration of community pharmacies in the same area. Some of these criteria are combined with the demographic criteria mentioned in the previous section.

A very commonly used criterion is the distance between the planned new pharmacy and existing ones. The calculation of this distance is sometimes clearly mentioned (for example, using a straight line calculated from the entrance of the existing pharmacy or walking distance). The distance varies from 100 m in North Macedonia to 5 km in Belgium *(84: article 1)* and Slovenia *(32: article 8)*. This distance can refer to other pharmacies within the limits of a city or village, but it may also refer to pharmacies in neighbouring towns or villages.

Many countries such as Belgium, Croatia and Hungary adjust the allowed distance between pharmacies based on the size of the city. For instance, in Croatia the minimum distance in large cities (over 500 000 people) is 200 m, while in smaller cities the minimum distance is 500 m. In Belgium the distance varies between 1 km, 3 km and 5 km, depending on the number of inhabitants (above 2500, above 2000 and above 1500, respectively) *(84: article 1)*. Table 3 gives examples of the minimum distances set by regulation between two pharmacies.

Table 3. | **Examples of minimum distances between new and existing pharmacies**

Country	Minimum distance
Austria	500 m *(44: article 10(2))*
Belgium	1 km, 3 km or 5 km, depending on number of inhabitants *(84: article 1(2))*
Croatia	200 m to 500 m, depending on number of inhabitants *(103)*
Hungary	250 m or 300 m, depending on number of inhabitants *(99: article 49A(2))*
Italy	200 m *(104: article 1)*
Latvia	500 m *(100)*
Malta	300 m *(96: article 4(1))*
Poland	500 m or 1 km *(101)*
Portugal	250 m *(102)*
Republic of Moldova	250 m from other pharmacies; minimum 500 m from pharmacies with in-house preparation of medicines
Slovenia	400 m in an urban area; 5 km in other areas *(32: article 8)*
Spain	250 m, but the regulation can be adjusted at the regional level *(79: article 5)*

Since the new Polish law was adopted in 2017, geographical criteria have been introduced for granting a new community pharmacy licence *(101)*. The minimum distance between existing pharmacies and a new pharmacy is:

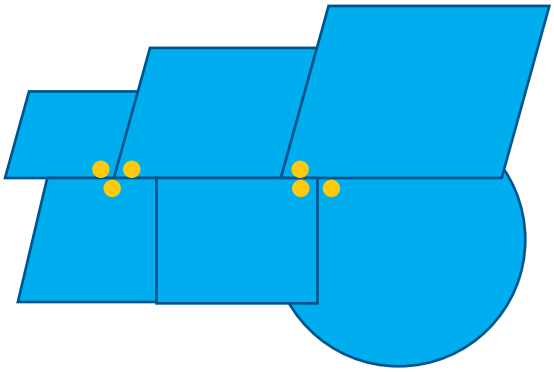
- 500 m if combined with demographic criteria (for example, if at the time of application the number of inhabitants in a given "voivodeship" (administrative region) is at least 3000 per pharmacy);
- 1 km without the demographic criteria.

Regulation sometimes relies on another geographical criterion: a geographical unit. This can be, for instance, a town or village, but it can also be a unit specifically set up for community pharmacy planning.

In Finland a community pharmacy licence is granted for a specific catchment area, typically a municipality. Large municipalities and cities may have several such pharmacy catchment areas, and each may have several pharmacies. Within a particular catchment area a pharmacy may be located without restrictions; for example, close to an existing pharmacy, without consideration of minimum distances *(105)*.

Even when the pharmacy location is based exclusively on geographical units (without a minimum distance), however, the way the units are drawn can also limit the possibility of multiple pharmacies in close proximity (Fig. 1).

Fig. 1. | Possible concentration of community pharmacies using geographical unit limitations



- In blue: fictitious geographical units
- In yellow: potential location of a community pharmacy (only one community pharmacy within a given geographical unit).

For these units, the maximum geographical concentration of community pharmacies is three (at the borders of their respective units).

Some criteria can be in place to prevent a monopoly in each village, as in the case of the Maltese regulation *(96: article 4(1))*, which states that "the number of pharmacies that may be licensed within the boundaries of any town or village shall not be less than two". Finally, in Portugal community pharmacies are not allowed to be closer than 100 m to a hospital or health care unit, except in municipalities with fewer than 4000 inhabitants *(102)*.

3.3.3 No restrictions

Some countries have no restrictions on the location of a new pharmacy, provided it complies with the other legal requirements. This is the case, for instance, in Bulgaria *(106)*, Czechia *(107)*, Germany *(23)*, Ireland, the Netherlands and Norway *(108)*, as well as Albania, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Russian Federation, Tajikistan, Ukraine and Uzbekistan.

Some countries never had these restrictions (like the Netherlands *(108)*), while others have discontinued them: rules for establishment of new pharmacies were introduced in Ireland in the 1990s but eventually revoked in 2002. In Norway establishment criteria were removed, further to the new law that came into force on 1 March 2001 *(108)*. The restrictions were also discontinued in CIS countries. In Ukraine a new law on medicines is under discussion, in which the geographical criteria can be introduced again: for opening a new pharmacy 500 m from other pharmacies *(109)*.

Such liberalization tends to increase the number of community pharmacies, but new pharmacies are primarily established in urban areas, which already have good access to medicines and pharmaceutical expertise, while no or few pharmacies are opened in rural localities with no existing pharmacies in place *(110)*.

3.3.4 Other ways to support universal access to medicines and pharmaceutical expertise

To ensure universal access to medicines and pharmaceutical expertise, countries in the WHO European Region use various strategies. Pharmacy entities (satellite and branch pharmacies) are allowed in several countries in the Region. In many CIS countries branch pharmacies are allowed in order to improve access to medicines, with fewer requirements for premises and staff.

3.3.4.1 Satellite/branch pharmacies

A branch pharmacy can be defined as an extension of a community pharmacy. It operates under the supervision and direct responsibility of the main pharmacy, which means that it is usually in the vicinity of or not too distant from the community pharmacy. A limited number of branch pharmacies per pharmacy are allowed in a few countries in the Region; they are usually considered to be under single rather than multiple ownership, as the branch pharmacies are all connected to and under the responsibility of a single pharmacy and do not operate separately *(110)*.

In Germany a community pharmacy can operate up to three branch pharmacies in the vicinity *(46: articles 1 and 2)*, each managed by a pharmacist acting as the branch manager *(23)*. In Austria each community pharmacy is allowed to run one branch pharmacy in a municipality where there is neither a community pharmacy nor a dispensing doctor *(44: section 24)*, but their number remains limited (23 in total) *(108)*.

In Denmark branch pharmacies and supplementary units are attached to the main pharmacy. At least one pharmacist is required to be present during opening hours in pharmacies, branch pharmacies and supplementary units *(108)*. Since 1 June 2015, pharmacies can establish up to eight separate branches within 75 km of the main pharmacy *(87: section 5)*. If needed, the National Health Board may oblige a pharmacy to maintain or establish a pharmacy branch, or may close a branch pharmacy *(87: section 7)*.

In Finland a pharmacy can operate up to three branch pharmacies, which can be created at the initiative of the pharmacy or the municipality *(36: article 52)*. If a branch pharmacy's turnover exceeds 50% of the average pharmacy turnover, however, it can be turned into an independent pharmacy *(36: article 54)*. A community pharmacy can be owned only by a professional with a master's degree in pharmacy; a branch pharmacy may also be managed by a professional holding a bachelor's degree in pharmacy *(36: article 52(4))*. A branch pharmacy may have shorter opening hours and a narrower selection of medicinal products than the main pharmacy *(36: article 52(5))*.

Norway allows branch pharmacies, subject to the authorization of the Norwegian Medicines Agency. They can be headed by a pharmacist or a bachelor of pharmacy (known as a "prescriptionist") as head, but remain under the supervision of the main pharmacy *(108)*. Uzbekistan also allows branch pharmacies *(111: article 20)*, and education requirements for the head of a branch are lower than for the head of a main pharmacy *(66)*.

In Latvia, a pharmacy can establish a branch in a county, city or parish where the number of inhabitants does not exceed 4000 and there are no other pharmacies or pharmacy branches within a radius of 5 km *(29: section 36(5))*. Not all activities in a community pharmacy can be performed in a branch pharmacy if no pharmacist is there *(29: section 35(2))*. In Estonia, branch pharmacies are allowed *(1: article 30)* but with the country's new regulations branch pharmacies in cities with more than 4000 inhabitants have to be turned into regular community pharmacies *(1: article 116[2])*.

Slovenia allows branch pharmacies, but they need to serve at least 2500 inhabitants. Their activities are the responsibility of a community pharmacy *(32: article 9)*. Iceland also allows branch pharmacies via four types of licence, depending of the level of service provided *(50: articles 63–75)*.

In Armenia *(72)*, Kyrgyzstan *(90)*, the Russian Federation *(41)*, Tajikistan *(113)* and Ukraine *(25)* licensing of pharmacy points and pharmacy kiosks (except in Ukraine) is allowed in rural areas. A pharmacy technician can manage a pharmacy branch. In the Russian Federation five years' work experience and an accreditation are required to manage a pharmacy branch *(41)*.

In CIS countries, despite current regulations on pharmacy points and pharmacy kiosks, their distribution is not appropriate. Indeed, the lack of geographical and demographic criteria to allow a pharmacy to be opened has led to a limited number of pharmacy points and pharmacy kiosks in rural areas but a high number in cities. Efforts to overcome inequalities in access to medicines in Uzbekistan contributed to development of the law on strategic development of social pharmacies in remote rural areas *(114)*. In Ukraine, a projected bylaw to increase access to pharmacies is under discussion. Aspects for consideration include increasing the number of pharmacies in rural areas (demographic restriction) and restructuring (de-monopolization).

3.3.4.2 Reimbursement/financial support for rural pharmacies

In addition to the regulatory criteria for establishment of a new community pharmacy (in areas of need), other approaches are used to encourage and guarantee universal access to medicines and pharmaceutical expertise. Compared to an approach exclusively based on regulation, these alternatives may mean a direct cost for the health insurance or government. Some are integrated into the remuneration models of community pharmacy.

In Estonia a one-off allowance (€15 000) is paid to pharmacists (or pharmacy assistants) who start work in a community pharmacy (or branch) located at least 10 km from a city or rural town and at least 5 km distant from another pharmacy or branch, provided that it is open at least 30 hours and five days a week *(1: article 62[1])*.

In Kazakhstan, the Republic of Moldova, the Russian Federation, Ukraine and Uzbekistan pharmacy graduates who study under sponsorship from the government (state budget) are required to work for three years in a state pharmacy after graduation, mostly in rural areas. Expenses for accommodation,

electricity and so on in the Republic of Moldova *(115)* and Ukraine are reimbursed by the municipality. Due to the reduction in the number of state pharmacies, however, this system is not proving effective in improving population access to pharmaceutical consultation.

In Spain smaller pharmacies are eligible to receive a monthly allowance calculated based on a target billing of €12 500 to the health insurance fund. This allowance can be up to €833 per month and is subject to meeting certain conditions (such as taking part in health-promotion activities) *(116)*.

In three nations of the United Kingdom (Scotland *(117)*, Northern Ireland *(118)* and Wales) a similar system of "essential small pharmacies" is established. These are usually subject to a minimum number of dispensing activities per month and a minimum distance to the nearest pharmacy. For Scotland, this minimum activity is 1400 medicines and appliances dispensed, and the distance to the nearest pharmacy is 2 miles (about 3 km). Under this scheme, the Scottish Government guarantees a minimum monthly income of £3804 for a community pharmacy open at least 30 hours a week. If a pharmacy does not reach this monthly income, the health insurance will cover the difference. The guaranteed income is adjusted to the number of opening hours. The schemes in Northern Ireland and Wales are based on the same concept. The system seems to have led to full coverage of the population, as there is currently a moratorium in Scotland on applications for new essential small pharmacies.

After the liberalization of the Swedish pharmacy sector, a fund was made available to support rural pharmacies meeting the following criteria: distance from another pharmacy of more than 20 miles, annual income from prescription-only medicines of between 1 000 000 and 10 000 000 Swedish kronor and open throughout the year *(119)*. The allowance is calculated based on annual turnover. A total of 30 community pharmacies benefit from this support, which accounted for 10 000 000 Swedish kronor in 2016 *(120)*.

The Finnish model takes a different approach: pharmacies are subject to a specific pharmacy tax to be paid to the state, based on their annual turnover of both OTC and prescription-only medicines. The tax rate increases with annual turnover. The smallest pharmacies do not pay any tax; the larger pharmacies may pay up to 10% of the turnover from sales of medicines. The effect of the pharmacy tax is that a small pharmacy will earn proportionally more than a large pharmacy from the sale of the same medicine *(105)*. In Lithuania the government and municipalities can exempt or reduce taxes and fees and provide other support for pharmacies located in rural municipalities *(81: article 41)*.

Outside the WHO European Region some Canadian provinces offer higher dispensing fees for community pharmacies in rural settings. For instance, in the province of New Brunswick, where the closest pharmacy is at least 25 km away, rural pharmacies receive an additional 2 Canadian dollars dispensing fee for the first 10 000 prescriptions dispensed annually *(121)*. In Australia a number of support measures for rural community pharmacies (in terms of monthly allowance, support for continuing education, replacement, internship and supporting rural students to study pharmacy) are an integral part of the Sixth Community Pharmacy Agreement *(122)*.

3.3.4.3 Other pharmacy entities beyond branch pharmacies

Some countries have developed additional approaches to ensure access to medicines and pharmaceutical care. In Germany pharmacies may request authorization to establish a prescription collection point, which cannot be established within a commercial company or at a health care professional's office *(42: article 23)*. These points allow patients to deposit their prescriptions in a sealed container; they can collect their medicines at the pharmacy or receive them via a courier *(42: article 17(2))*.

In Finland the regulator can grant permission to a community pharmacy to establish a pharmacy service point (*apteekin palvelupiste*) within the outlying districts of the pharmacy's own catchment area or beyond, in a neighbouring municipality or a village centre *(36: section 38(3))*. When requesting authorization, the pharmacy must define the range of medicines to be made available at the service point. It is usually OTC and sometimes some prescription-only medicines. Service points have primarily been established in scarcely populated areas *(105)*.

In Spain pharmaceutical points (*botiquines farmacéuticos* – literally "pharmaceutical first aid kits") have been authorized since 1944. They can be opened in factories, mines or other labour environments with more than 100 people that are further than 5 km from the nearest pharmacy *(123: article 16)*. Traditionally, they are only open a few hours per week and aim to serve local populations.

Romanian legislation allows the establishment by community pharmacies of local distribution points (*oficine locale de distribuție*) in localities lacking pharmaceutical services (typically rural areas) or in resorts at the seaside during the summer season *(124: article 13)*. Establishment is subject to authorization, which is discontinued if a community pharmacy opens in the locality of the distribution point.

In Slovenia pharmacies may establish a stock of medicines at a doctor's office if it is at least 10 km from the nearest pharmacy or branch pharmacy. This stock is managed by the community pharmacy. It requires the authorization of the local municipality *(32: article 11)*.

Another approach has been a roving community pharmacy, allowing patients to access a (branch) pharmacy through a vehicle with a determined schedule. This is the case in Estonia with the *apteegibuss* ("pharmacy bus") *(1: article 45[1])*, which needs to be accessible to patients with mobility impairments *(125: article 8[1](1))*. Pharmacy buses are also allowed in Hungary *(99: article 50(3))*.

In Kazakhstan *(40)*, Turkey and Uzbekistan *(66)*, to increase access to medicines in rural areas, specific pharmacies can organize mobile pharmacy points.

3.3.4.4 Dispensing by doctors/in other health facilities

In most countries in the WHO European Region medicine dispensing is done in pharmacies by pharmacy staff. Only Austria and Switzerland provide the legal option for doctors to dispense medicines in their offices for their patients. In Switzerland the cantons' regulations define whether doctors are allowed to dispense: some cantons allow it while others do not. It is estimated that dispensing doctors in Switzerland represent a market share of 24% in value of the total dispensing of prescription-only medicines *(126)*. A Swiss government report concluded that "dispensing by medical doctors leads to overlapping of activities carried out by doctors and pharmacists, and thus competition in the provision of primary care, which may undermine interprofessional collaboration. As such, dispensing by doctors has been identified as a barrier to collaboration between pharmacists and doctors" *(127)*.

In Austria dispensing doctors are in competition with the pharmacy network: for 1300 community pharmacies there are 940 dispensing doctors *(108)*. Overall, in EU countries with the exception of Austria, the number of dispensing doctors has been declining *(128)*.

In other countries dispensing doctors are authorized under very strict criteria and therefore limited in numbers. For example, in France medical doctors are not allowed to sell medicines, with some exceptions established by law *(26: article L.4127-21)*, which mean that only doctors established in municipalities without a community pharmacy can request authorization from the regional health authority to be a dispensing doctor (*médecin propharmacien*). If accepted, the authorization defines a geographical zone, and as soon as a community pharmacy is created within that area, the authorization is automatically cancelled *(26: article L.4211-3)*. Consequently, there are fewer than 100 dispensing doctors *(126)*, primarily established in remote areas (such as mountainous and island areas). The same situation can be found in Ireland, where 100 doctors are allowed to dispense *(108)*.

In the Netherlands the ministry of health can grant a licence for a doctor to dispense if the nearest pharmacy is at least 4.5 km and in some cases 3.5 km from the doctor's practice, the distance being measured by the road intended for motorized traffic *(80: articles 61.10 and 61.11)*. In some countries, dispensing doctors are sourced by a community pharmacy, such as Slovenia *(32: article 11)* and Belgium *(34: article 4)*.

Some countries allow hospital pharmacies to dispense to outpatients, such as Czechia, Lithuania *(128)* and the Netherlands, while others (like Estonia *(1: article 30(6))*) specifically prohibit hospital pharmacies

from dispensing medicines to outpatients. In the Netherlands it is estimated that every second hospital pharmacy sells medicines to outpatients *(108)*.

Dispensing by hospitals for outpatients may be allowed for all types of medicine or for only specific types (such as HIV and cancer medicines). In some cases, hospital pharmacies may have a monopoly on dispensing certain categories of medicines to outpatients.

In Lithuanian municipalities without a pharmacy, dispensing of medicinal products can be done by a pharmacy via the primary health care establishments located in rural localities, based on a contract and procedure established by the government *(81: article 41.2)*. In the Russian Federation medical practices may dispense in rural areas that do not have a community pharmacy *(41: article 55.1)*. In Armenia *(72)*, Kazakhstan *(40)*, Kyrgyzstan *(90)*, the Russian Federation *(41)*, Tajikistan *(77)*, Ukraine *(129)* and Uzbekistan *(66)*, staff with medical education (such as nurses) can dispense medicines in pharmacy entities in rural areas, in family medicine centres or in first medical aid points in rural areas. This is restricted to areas where no pharmacies are established.

Remuneration of dispensing by doctors may differ from that for dispensing performed in a community pharmacy.

3.4 Ownership

3.4.1 Pharmacy ownership restricted to pharmacists

Ownership of a community pharmacy is restricted to a pharmacist (or group of pharmacists) in many countries in the WHO European Region. The main reason is that it is considered by some to enable a high level of professional judgement by mitigating the risks of corporate ownership, which might give directives to favour profit over individual and population health.

Ownership restricted to pharmacists only (in Italy and Germany) was challenged ultimately in the European Court of Justice, which ruled in 2009 that it can be justified by the objective of ensuring that provision of medicinal products to the public is reliable and of good quality. In its judgement, the Court stated the following:

> *It is undeniable that a pharmacist, like other persons, pursues the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence.*
>
> *Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists.*
>
> *A Member State may therefore take the view, in the exercise of its discretion, that the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level.*
>
> *[…] The Court concludes that the freedom of establishment and the free movement of capital do not preclude national legislation which prevents persons not having the status of pharmacist from owning and operating pharmacies (130).*

3.4.1.1 Ownership by pharmacists

In several countries in the Region a pharmacy licence can only be owned by a pharmacist. It may be transferable – able to be sold to another pharmacist (or company of pharmacists) – provided the new owner meets defined legal requirements. This is, for instance, the case in Spain *(79: article 1)* and in Germany, where the owner of a pharmacy must always be a pharmacist, to emphasize the pharmacist's personal responsibility and liability, and to decouple the provision of pharmaceuticals from corporate profit goals *(23)*. The German regulation also includes specific provisions regarding ownership and contractual relationships (such as a loan or profit-oriented leases) to guarantee independence of practice *(47: article 8)*.

In Poland (new) pharmacy licences can only be issued and owned by pharmacists since 2017 *(101)*. In a few other countries, including Austria *(108)*, Hungary *(99: article 49(7) and article 74)* and Latvia *(29: section 36(2))*, the legislation only imposes the restriction that the majority of the shares must be owned by pharmacists.

Legal and regulatory provisions are sometimes in place to ensure that in case of extreme circumstances (such as the death of the owner) the pharmacy's operations can be maintained for a defined period to ensure its sale by the heirs. Such provisions exist in France: "After the death of a pharmacist, the spouse or the heirs can keep the pharmacy open for a maximum of two years with a managing pharmacist authorized by the Regional Health Director" *(26: article L5125-16)*.

Germany has similar provisions: after the death of the owner the heirs may have the pharmacy administered by a pharmacist for a maximum of 12 months *(47: article 13)* and, to ensure continuity of activity, if one of the children is younger than 23 years and studying pharmacy, the pharmacy may be managed externally until the heir becomes a pharmacist *(47: article 9)*.

3.4.1.2 Pharmacy licence as property of the state

While in most countries a pharmacy licence is owned by individuals (or a corporation), in a few countries in the Region the licence remains the property of the state, and as such is not transferable without the approval of the competent authority. In these countries, the situation may be seen as a non-transferrable "concession" of the pharmacy licences owned by the state.

In Finland the licence is granted by Fimea, the Finnish Medicines Agency, to a specified individual and may not be sold or leased out; nor may the licence obligations be transferred to a third party. A licence can be terminated or become vacant in two ways: when the proprietary pharmacist reaches 68 years or when they acquire a licence for a new pharmacy. When a licence becomes vacant, Fimea announces that it can be applied for, and grants it in line with the criteria defined in the Medicines Act. Fimea also makes decisions based on an assessment of need regarding the establishment of new pharmacies and subsidiary/branch pharmacies. This approach enables effective pharmacy planning, as Fimea can decide to create a new licence or cancel an existing licence with limited financial impact for the government *(105)*.

In Luxembourg most community pharmacies are run based on a concession system. When a concession is made available, its specifications are published by the ministry of health, detailing the location of the pharmacy, the timeline for opening it and specific provisions related to the granting and running of the concession *(131)*.

These two models require a fee paid to the government for the licence.

- In Finland pharmacies pay a pharmacy tax to the state. This represents an income to the state of around €175 million per year. The tax rate is based on annual turnover from the sales of prescription-only and OTC medicines and increases with turnover (see section 3.3.4.2) *(105)*.
- In Luxembourg the pharmacy tax (*redevance*) represents 2% of the adjusted annual turnover of the pharmacy (certain types of medicine are not integrated into the calculation of the yearly fee) *(132)*.

In Denmark the pharmacy licence is the property of the state and the pharmacy can only be owned by a pharmacist. The licence goes back to the state when a pharmacist has acquired a new pharmacy or when the owner dies *(87: section 22)*. In this model the regulation specifies the conditions under which the premises, equipment and stock may be taken over by a new licensee *(87: sections 28–30)*.

In Slovenia some pharmacies are subject to a concession, which can only be granted to pharmacists or to companies with 50% of the share capital owned by a pharmacist. The concession is given for a period ranging from 15 to 30 years *(32: article 39)*. In contrast to Finland and Luxembourg, the creation of a concession is decided at the local level by one or several municipalities. The law describes in detail the procedures involved in a call for tenders for a new concession and the decision-making process *(32: articles 39–61)*.

3.4.1.3 Transition to a pharmacist-owned pharmacy

Some countries have opened ownership to non-pharmacists (including Portugal and Italy in 2007 and 2016, respectively) while others, like Hungary, Estonia and Poland, moved from a liberalized system to restriction of community pharmacy ownership in 2009, 2015 and 2017, respectively.

In Hungary the transition of ownership was gradual: pharmacists needed to own at least 25% of the shares of the pharmacy by 2014 and 50% by 2017 *(99: article 83)*. In Estonia the new ownership regulations will be implemented gradually until 2020 *(1: article 116[3])*. In Poland the new legislation only came into effect for new community pharmacies, but the provisions also apply in case of a transfer of existing licences (in the case of company mergers other than partnerships between pharmacists) *(101)*.

3.4.2 Ownership opened to non-pharmacists

While much of the time professional obligations are the direct responsibility of a pharmacist (see section 3.6.1), some countries have also defined the responsibilities of owners or licensees who are not necessarily pharmacists. Examples of this are Estonia, through an article dedicated to the obligations of the owner *(1: article 45)*, and Malta *(82: article 74)*.

3.4.2.1 Private corporate ownership

In a number of countries, pharmacy ownership is not restricted to pharmacists: Albania *(133)*, Armenia *(72)*, Azerbaijan *(134)*, Belarus *(73)*, Belgium, Bulgaria *(106)*, Czechia *(107)*, Georgia *(67)*, Iceland, Ireland, Kazakhstan *(40)*, Kyrgyzstan *(90)*, Lithuania *(128)*, Malta *(82: article 67)*, the Netherlands, Norway *(108)*, the Republic of Moldova *(91)*, the Russian Federation *(41)*, Tajikistan *(77)*, Turkmenistan *(135)*, Ukraine *(129)*, the United Kingdom and Uzbekistan *(66)*. Since 29 August 2017 Italy has allowed corporations to own community pharmacies *(71)*.

In a few of these countries, however, there are some limitations on horizontal (or vertical) integration, as described in section 3.5.

3.4.2.2 State ownership

In a few countries some community pharmacies are owned (directly or indirectly) by the state or local governments (municipalities). In a few former Yugoslav republics, a substantial number of community pharmacies are still owned and operated by the state. In Croatia state-owned pharmacies represent around 20% of the total number *(28)*. In Slovenia they are called "public pharmacies" and are managed by an institution that is the property of one or several municipalities *(32: articles 27–38)*. Similar provisions and organizations exist in Serbia *(37: article 100)*.

In Italy municipalities own some community pharmacies, which are called *farmacie comunali*. These have historically been established by the municipality to serve areas without appropriate access to pharmacists; most are located in the central north of Italy. On average they represent about 20% of the total number of pharmacies, but in Cremona, for example, 14 of the 20 community pharmacies are owned by the city. Lately, these municipality-owned pharmacies have been sold to chains (as in Milan) which have bought 80% of their shares for a 99-year period. The risk of this (in a city like Cremona) is that it will create a monopoly for the benefit of the buyer, such as a pharmacy chain *(136)*.

In Sweden pharmacies were all state-owned by the public company Apoteket AB until 2009, when the government decided to liberalize the sector in a process called "re-regulation". As a consequence, about two thirds of all pharmacies are now owned by private companies through several chains. The remainder are still owned by the Swedish government through Apoteket AB *(108)*.

3.4.2.3 Special cases

In some countries pharmacies are owned by cooperatives; these may represent a significant share of the market, as in Belgium, where they represent 20% *(137)*.

France has historical exemptions to the ownership restriction of community pharmacies:

- 37 community pharmacies are owned by the Miners Health Insurance (*pharmacie minière*);
- 51 are owned by mutual insurers (*pharmacie mutualiste*) *(138)*.

These pharmacies originated at least 40 years ago and can only dispense to people insured by the owner companies.

In Finland the two universities (of Helsinki and of Eastern Finland) are allowed to own a pharmacy each, and Helsinki University's pharmacy can have up to 16 branch pharmacies *(36: article 42)*.

3.5 Integration and limitations

3.5.1 Horizontal integration and restrictions

Horizontal integration refers to a situation where a single person (or corporation) owns more than one community pharmacy. It may allow economies of scale, but it can also lead to limited competition and even monopolies when the same person or entity controls a significant share of the market through one or several chains of community pharmacies.

Many CIS countries, such as Albania, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan, have no horizontal restrictions in legislation, but several countries have adopted such restrictions. These are sometimes limited to a specific geographical zone (city, province or region) and/or cover minority stakes in pharmacies (beyond the first pharmacy owned). In the case of concentration of market share, competitive authorities may intervene.

The restrictions may have been organized prior to liberalization or to correct problematic issues. For instance, the limitation on horizontal integration in Norway followed an intervention of the Competition Authority after one group owned more than 80% of the pharmacies following liberalization *(110)*.

The new Polish law adopted in 2017 also prevents further horizontal integration, as an entity cannot have an additional licence for a new pharmacy if it controls more than 1% of the community pharmacies in a given region *(101)*. Table 4 offers an overview of the situation in a few countries in the Region.

Table 4. | **Examples of restrictions to horizontal integration**

Country	Restrictions to horizontal integration
Bulgaria	No more than four pharmacies to be owned by the same entity *(106)*
Denmark	Multiple ownership not allowed *(87: article 15)*
Estonia	No more than four pharmacies (or minority stakes in up to four community pharmacies) to be owned by the same individual or entity *(1: article 41)*
Finland	Multiple ownership not allowed *(36: article 44)*
France	Multiple ownership not allowed but minority stakes in up to four community pharmacies possible *(139)*
Germany	Multiple ownership forbidden *(23)*
Hungary	No more than four pharmacies controlled directly or indirectly by the same pharmacist/company *(99: article 75)*
Italy	Each pharmacy owner (including corporate entities) allowed, directly or indirectly, to control no more than 20% of the pharmacies located in a region or autonomous province *(71)*
Malta	An individual or company can only own one pharmacy in the same town or village *(96: article 5(1))*
Monaco	Multiple ownership forbidden *(57: article 29)*
Norway	No pharmacy chain allowed to own more than 40% of all pharmacies in Norway *(108)*
Poland	Ownership limited to a maximum of four pharmacies *(101)*
Portugal	Ownership limited to a maximum of four pharmacies directly or indirectly *(98: article 15)*
Spain	Multiple ownership forbidden *(108)*
Turkey	Multiple ownership forbidden *(48: article 18)*

3.5.2 Vertical integration and other limitations

In the context of community pharmacies, vertical integration refers primarily to the capability of a wholesaler or a pharmaceutical industry to own community pharmacies. It is only relevant from an economic perspective if it is also associated with horizontal integration (in other words, a wholesaler is unlikely to be interested in owning just one community pharmacy in a country).

The largest wholesalers in the WHO European Region (Walgreens Alliance Boots, McKesson-Celesio and Phoenix) own one or several chains of pharmacies in countries where vertical and horizontal integration are allowed.

In Estonia, with the new regulations to be implemented by 2020, vertical integration of wholesale companies and community pharmacies will no longer be allowed *(1: article 116[3])*. In Poland, further to the 2017 law, new licences will not be issued to non-pharmacists (and there will be a limit of four pharmacies in total (co-)owned by an individual). This will limit further vertical integration, as the licence will not be able to be passed on to other companies even in case of mergers *(101)*.

In addition to restrictions on vertical integration, it is common to find a ban on medical doctors and other prescribers owning a community pharmacy, to prevent potential conflicts of interest. This is the case in Denmark *(87: section 3)*, Estonia *(128)*, Iceland, Ireland, Malta *(96: article 3(2))*, Norway and Sweden *(110)*.

The same ban also applies even if the health care professional also holds a pharmacy degree in France *(26: article L5125-2)* and Spain *(140: article 4(3))*.

Pharmaceutical manufacturers, (private) hospitals and health insurance funds can also be prevented from owning community pharmacies to prevent potential conflicts of interest, including in Iceland, Norway and Sweden *(110)*.

In Armenia about 25% of pharmacies belong to pharmacy chains owned by wholesalers. According to information from the ministry of health, due to the high risks of monopolization and unfair competition, a draft law restricts vertical integration and is to be introduced in 2025 *(141)*.

3.6 Requirements to operate a pharmacy

To guarantee the proper functioning of a community pharmacy, legislation and regulations may set a number of requirements, especially in terms of opening hours, workforce, premises, equipment, processes, e-health and identification (among other things). In some countries these are gathered into a single set of rules defined by the pharmacy regulator, as in Ireland *(142)*.

In Austria pharmacy operations are guided by an ordinance providing a comprehensive description *(143)*. In Germany the legislation requires these regulations to take into account the principles laid down by WHO for the production and quality assurance of medicines, as well as the accepted rules of pharmaceutical sciences *(47: article 21)*. A comprehensive list of topics related to the operations of a community pharmacy that need to be covered by rules are also defined.

In Great Britain standards for pharmacies are set by the pharmacy regulator through a series of principles, each divided into a dozen standards *(144)*. Guidance on how to apply these principles and standards to specific issues of pharmacy practice is also provided *(145)*. In Malta the regulations for the opening of a pharmacy and for the operation of a pharmacy are established in the Medicines Act (*82: articles 66–89*)) and the relevant subsidiary legislation *(96)*.

In the Netherlands requirements for the operation of a pharmacy are formulated in the *Nederlandse Apotheek Norm*. This is not a law but the Dutch pharmacy norm: the common opinion of the Royal Dutch Association of Pharmacists. The national health care inspectorate uses it as a field norm when supervising and enforcing pharmacies and the work of pharmacists registered in the Netherlands, and it is used in implementation of GPP guidelines.

3.6.1 Workforce requirements

Almost all countries have adopted specific requirements for the pharmaceutical workforce (pharmacists and pharmacy technicians). Some regulators have adopted guidance to define how to set staffing levels and around leadership and management roles, as well as on the knowledge, skills and competence required of the pharmacy team, as in Great Britain *(146)*.

3.6.1.1 Pharmacy manager or responsible pharmacist

The professional activities of a community pharmacy are under the direct responsibility of a pharmacist in almost all countries in the WHO European Region. Sweden is an exception, as either a pharmacist or a *prescriptionist* with a pharmacy bachelor's degree can be responsible for a pharmacy *(108)*. Under specific conditions, a pharmacy technician (with a minimum level of experience) may manage a rural pharmacy *(29: section 38(1[1]))*.

Some countries, like Germany *(42: article 2)* and Iceland *(50)*, specify that the pharmacist is responsible for all professional activities in the pharmacy, while others define the responsibilities in detail, as in Ireland *(142: article 5)*, Malta *(82: article 75)*, Portugal *(102: article 21)* and Slovenia *(32: article 13)*. In Hungary, not only the responsibilities but also some of the powers concerning other staff members are listed: "The pharmacy manager is responsible for supervising the professional work in the pharmacy, including in branch pharmacies. Under their supervision, they have the right to ensure professional control and provide instructions to staff" *(99: article 62(3))*.

In countries where ownership of community pharmacies is limited to pharmacists, the owner is responsible for all activities in the pharmacy, as in Finland *(36: article 44(2))* and Germany, where the owner "must personally manage the pharmacy" *(42: article 2)*. In countries where non-pharmacists can own a pharmacy, the legislation and regulations require a pharmacist to be in charge.

There is diversity in the official title used to designate the responsible pharmacist, including "managing pharmacist" in Malta *(82: article 75)*, "technical director" in Portugal *(102: article 20)* and "superintendent" in the United Kingdom *(147: section 71)*.

In some countries provisions have been adopted to help to ensure that the responsible pharmacists have the authority and ability to meet their responsibilities effectively.

- In Switzerland the local pharmacy authorities have defined employment contract models for responsible pharmacists to support this aim.
- Slovenia requires a full-time contract for the responsible pharmacist *(32: article 13(2))*.
- In Hungary for decisions of the company related to professional activities to be effective they require the approval of the responsible pharmacist *(99: article 73)*.
- In Lithuania the pharmacy owner must "employ a pharmaceutical activity manager and confer on them sufficient powers enabling them to perform the duties entrusted to them" *(81: article 39.1)*.
- Similar provisions exist in Israel, where "the pharmacy owner shall act in matters related to professional activities of the pharmacy in accordance with the instruction of the responsible pharmacist and ensure that the responsible pharmacist has the necessary resources for the professional management of the pharmacy according to any law" *(51: article 11A)*.
- In the Netherlands pharmacists are not allowed to dispense prescription-only medicines if the responsible pharmacist is not registered with the authorities *(80: article 61.5)*. Moreover, a pharmacist may only work in one pharmacy. Each pharmacy should have a responsible pharmacist entered in the register of the inspectorate to be allowed to dispense *(80)*.
- Finally, in Malta the pharmacy licence owner shall "provide all the support and in no way interfere with the managing pharmacist's or a pharmacist's professional responsibilities in the performance of their duties as defined in by or under this Act or under any other law" *(82: article 78)*.

In several countries regulations specify that a pharmacist can only be the responsible person of a single community pharmacy, such as Belgium *(56: article 2)*, Hungary *(99: article 62(2a))*, Israel *(51: article 11)*, Latvia *(29: section 40(1))*, Malta *(82: article 75)*, Portugal *(102: article 20)* and Slovenia *(32: article 13(3))*. This limitation is also usually applied through the provisions on ownership (a pharmacy can only be owned by one pharmacist, and a pharmacist can only own one pharmacy). This is, for instance, the case in France *(139)*.

Experience, additional certification and further criteria can be applied to a responsible pharmacist. In countries where the owner of the pharmacy must be a pharmacist (and where the owner must manage the pharmacy), the minimum requirements for experience clearly apply to the owner/responsible pharmacist. Table 5 offers an overview of the situation in a few countries in the WHO European Region.

Table 5. | **Examples of experience required to manage a community pharmacy**

Country	Experience required to be the responsible pharmacist
Albania	Three years of professional practice under supervision of a skilled pharmacist
Armenia	Three years of experience and a specialist certificate
Austria	Equivalent to five years of full-time equivalent experience *(44: article 3(2) and 3(3))*
Belarus	CPD certification: for pharmacies with high turnover, the head of the pharmacy should have a postgraduate certificate in pharmacy management *(73)*
Denmark	Prior employment allows an individual to manage a pharmacy *(87: section 15)*
Georgia	A specialist certificate (minimum of one year of experience)
France	A minimum of six months of experience, only if the pharmacist has not done the six-month internship of pharmacy study in a community or hospital pharmacy *(26: article L5125-8)*
Hungary	Five years of experience *(99: article 56(2))*
Iceland	Three years of experience *(50: article 5)*
Ireland	Three years of experience *(142: article 5)*
Kazakhstan	A specialist certificate (minimum of one year of experience)
Poland	Five years of experience or three years of experience + additional pharmacy specialization *(148: article 88(2))*
Slovenia	Five years of experience *(32: article 13)*
Switzerland	Two years of experience *(20: article 36)*
Tajikistan	A specialist certificate (minimum of one year of experience) *(113)*
Turkey	One year of experience as an employed community pharmacist *(48: article 5)*; in order to get a pharmacy licence in highly developed regions, a pharmacist has to have higher qualification (holding a PhD or CPD certificate is an advantage)
Ukraine	Three years of experience and a CPD certificate as qualified pharmacist for pharmacy management *(25)*

To ensure the independence of the pharmacy manager's or responsible pharmacist's actions, some countries have introduced restrictions on obtaining positions or having shares in pharmaceutical wholesalers and industry. In Portugal the regulation defines a series of functions incompatible with the responsibilities of a responsible pharmacist, such as also being the qualified person of a pharmaceutical manufacturer or wholesaler, or the director of a hospital pharmacy *(102: article 20)*. Similar provisions exist in Latvia, preventing the responsible pharmacist from being the responsible pharmacist or deputy responsible pharmacist or department manager of a medicinal product wholesaler, or a head of production or head of control services of a medicinal product manufacturing undertaking *(29: section 40(1))*.

In the Russian Federation and Slovenia the responsible pharmacist cannot have interests in a pharmaceutical industry, such as working or contractual relationships or direct interests *(32: article 13(2))*. In Spain pharmacists owning a pharmacy are not allowed to have economic interests in the pharmaceutical industry or wholesalers *(140: article 4(2))*. Similar provisions exist in Estonia, where the pharmacy owner cannot be a shareholder of a pharmaceutical manufacturer or wholesaler *(1: article 42(3))*.

Many countries have also defined how a responsible pharmacist can be replaced (for example, during holidays and sick leave). The German regulation specifies that the pharmacy owner/manager can be represented by another pharmacist for a limited period of three months in a given year *(42: article 2(5))* and may be represented by a pharmacy engineer (a four-year degree, which used to be granted in East Germany, at the time of the former German Democratic Republic) for no more than four weeks per year. In Hungary the responsible pharmacist can be replaced for up to 60 days per year *(99: article 62(2)b)*; in Slovenia they can be replaced by their deputy *(32: article 13(3))*; in Finland, the pharmacy manager may

leave the management to a pharmacist (or a bachelor in pharmacy) for a maximum cumulative period of three months per year *(36: article 44(2))*.

In many countries certification or registration (managed by a national association/regulator) is a requirement of being a responsible pharmacist, as in Bulgaria *(106)* and Latvia *(100)*. It is sometimes also mentioned that whenever a pharmacist becomes the responsible pharmacist (or abandons such duties), the competent authority should be informed, as in Malta's regulations *(82: article 75(4))*.

To ensure full transparency, many countries require that the name of the responsible pharmacist is displayed at the pharmacy (inside and/or outside), as in Belgium *(56: article 2)*, Malta *(96: article 13(4))* and Serbia *(43: article 101(4))*, or on the certificate of registration, as in Ireland *(142: article 5)*. The name of the responsible pharmacist may also be included in the labelling of medicines dispensed by the pharmacy in Belgium, as well as in any professional documents *(56: article 2)*. In Israel the names of both the responsible pharmacist and the owner of the pharmacy must be visible from outside the pharmacy *(51: article 19)*. In the Netherlands, the name and legal status (title) of the established pharmacist (responsible pharmacist) has to be visible on the outside and near the entrance *(61: article 9)*.

3.6.1.2 Mandatory presence of a pharmacist

In almost all countries in the WHO European Region the presence of a pharmacist is a legal requirement whenever the pharmacy is open. This is the case, for instance, in Belgium *(56: article 5)*, Denmark, France *(26: article L5125-16)*, Germany, Malta *(82: article 75)*, Romania *(124: article 15)*, Spain *(79: article 5)* and Turkey *(48: article 14(1))*.

In Belgium, Germany and the United Kingdom the regulations specify that if no pharmacist is in the community pharmacy, it must be closed during this absence *(56: article 5)*. In the Netherlands the pharmacist must organize a replacement in case of absence for a prolonged period *(80: article 61 section 4)*.

3.6.1.3 Sufficient workforce

In some countries the regulations aim to prevent the quality of pharmacy services being negatively affected by insufficient number of pharmacists. They may define a (minimum) number of pharmacists to meet a general objective or at a given time; they may also be adjusted, based on the level of activities of a pharmacy (expressed in annual turnover, total billing to health insurance funds or a total number of prescriptions dispensed).

3.6.1.3.1 Workforce requirement to perform pharmacy activities

In Germany the regulation states that the necessary pharmacy staff must be available in sufficient numbers to ensure the appropriate functioning of the pharmacy *(42: article 3(2))*. Likewise, in Switzerland the Association of Cantonal Chief Pharmacists has recommended similar provisions, such as "the pharmacy needs to have a qualified, competent staff, in sufficient number to fulfil the different tasks of a community pharmacy".

In Finland pharmacies and branch pharmacies must "have the required number of personnel with a pharmaceutical degree" *(36: article 56(1))*, and Kazakhstan's regulation states that a pharmacy need to be staffed with a sufficient number of qualified personnel to perform its basic functions *(150: article 10.1)*. In Estonia the pharmacy owner is required to employ a sufficient number of employees with requisite qualifications, taking account of the volume of work and business hours of the enterprise *(1: article 45(4))*.

In Great Britain, guidance provided by the pharmacy regulator to define the level of staff mentions various points to consider, including:

> *volumes of dispensing, the sale or supply of medicines over the counter, how and where medicines are supplied to patients (for example "hub and spoke" or internet pharmacies), the changing demands throughout the day, the population served by the pharmacy, including vulnerable patients, changes in*

the number of patients and their individual needs, the use of technology, including robotics, the range of different services provided, the different sets of skills, knowledge and experience within the team, the ongoing learning and development of the pharmacy team, previous incidents and errors, and the reasons for them … and feedback from patients and members of the public (146).

Other countries have adopted different approaches, defining the minimum number of pharmacists (and pharmacy technicians) at any time. In Iceland, it is expected that two pharmacists should be available at all time, although some exemptions can be granted – usually for smaller pharmacies *(50: article 34)*. Croatian regulations state that a minimum of one full-time equivalent pharmacist and one full-time pharmacy technician are required per eight-hour shift *(151: article 8)*. In Montenegro, a pharmacy should have at least one pharmacist and a pharmacy technician *(152)*. In Spain the regulation on the number of pharmacists required in addition to the pharmacy owner can be defined at the local level by autonomous communities *(79: article 5(2))*.

In Portugal at least two pharmacists should be working in a pharmacy (not necessarily at the same time), with some exceptions for pharmacies located in rural areas and with minimum income as defined by law *(153)*. This requirement is linked to the minimum number of opening hours of a pharmacy in Portugal, to ensure that there is always a pharmacist during these hours.

In Denmark, the number of pharmacists to be present in a community pharmacy is based on the number of branches. If it has up to two branches, one pharmacist should be present; for 3–5 branches, two pharmacists; and for 6–7 branches, at least three pharmacists *(149: section 16)*.

3.6.1.3.2 Workforce requirement based on pharmacy turnover

Other countries (like France and Turkey) have defined the minimum number of employed pharmacists (in addition to the owners, who must be pharmacists in these two countries), based on the level of pharmacy activities. The French regulation sets criteria based on the annual turnover (of all items sold in a community pharmacy, excluding value added tax) to calculate the minimum number of pharmacists to be employed. If the annual turnover is higher than €1 300 000, one or several employed pharmacists are required: for turnovers between €1 300 000 and €2 600 000, one employed pharmacist is required; for any additional €1 300 000 of turnover, an additional employed pharmacist is required *(6)*.

In Turkey the employment of another pharmacist (in addition to the pharmacy owner) is required when the total number of prescriptions dispensed annually is more than 80 000, or when the annual turnover of the community pharmacy is over 3 000 000 Turkish lira (excluding value added tax). For any additional 80 000 prescriptions (or 3 000 000 Turkish lira), an additional pharmacist is to be employed. The maximum number of employed pharmacists imposed by the law is three *(48: article 16(1))*.

3.6.1.3.3 Other requirements

Several countries have obligations regarding identification of pharmacy staff in the pharmacy. This requirement usually consists of a badge displaying compulsory information. In France the badge should only state the qualification (pharmacist or pharmacy technician) *(26: article L5125-29)*, while in Romania everyone involved in pharmaceutical activities in the community pharmacy must wear a badge with the person's full name, qualification and professional titles, as well as the name of the pharmacy *(124: article 16(4))*. Similar provisions are in place in Estonia, where pharmacy staff need to wear a badge with their name and education and, if relevant, a trainee position title *(125: article 12(1))*.

In Malta all pharmacists have to wear an identity tag issued by the pharmacy regulator, containing their name, designation and Pharmacy Council registration number. They are also obliged to wear a white coat when attending to their professional duties *(96: article 13(3))*. In Germany pharmacy staff may only be employed in accordance with their training and knowledge *(42: article 3(1))*.

3.6.2 Premises and equipment requirements

In many countries the requirements for pharmacy premises are described in detail, as in Belarus *(73)*. Belgium *(56: annexe 1)*, Estonia *(125)*, Iceland *(50: articles 17–31)*, Lithuania *(154)* and Malta *(96: articles 9 and 10)*. Some, like Finland *(36: article 56(2))*, state that the facilities should be appropriate for dispensing and storing medicines, as well as for compounding, or that the premises must be designed and equipped so that they are suitable for their activities, including being protected from burglary, like Denmark *(149: section 17)*. Likewise, in Lithuania *(154)* the size of the premises must be sufficient for pharmaceutical activities, proper storage of medicinal products and the provision of pharmaceutical services while ensuring confidentiality. Similar provisions are also in place in Kazakhstan *(150: article 8)*.

In a few countries, new community pharmacy premises (or existing ones that have undergone significant changes) have to be notified or approved, either through a premises inspection or via a review of submitted documents), as in Austria *(143: article 67)*, Denmark *(155)*, Finland *(36: article 15)*, Iceland *(50: article 18)* and some cantons in Switzerland.

The regulations may also specify that the required equipment (and records) need to be kept in accordance with national standards, as in Malta *(82: article 86)*. The standards in Northern Ireland, United Kingdom, consist of two types: essential standards (which are mandatory) and desirable standards (good practice standards, which should be followed in all normal circumstances) *(156)*.

3.6.2.1 Minimum area of operation for a pharmacy

Several countries have defined a minimum area for a pharmacy. This varies between countries and often depends on the pharmacy services performed. CIS countries and Turkey have alternative pharmacy entities with lower area requirements.

For instance, in Montenegro, the minimum space for a pharmacy is 50 m^2 *(152)*, while it is 55 m^2 in Romania *(124: article 16(2))*. In Germany, the minimum space is 110 m^2 *(42: article 4(2))* associated with the list of the different sections or rooms required. Moreover, depending on the services provided by the pharmacy, additional premises and equipment might be needed. Among these services required additional premises (separate area and storage): sterile production of medicines; supply of hospitals with medicines; supply and individual preparation of weekly dosages for nursing homes; automatic blister-services; selling medicines online and shipping medicines per post *(42)*.

In Lithuania, the minimum public section of a community pharmacy varies based on its location (25 m^2 versus 10 m^2 in rural settings), but the regulation specifies the different rooms based on the types of activities performed in the pharmacy, which all need to be adjacent and in the same building *(154)*. Similar requirements are in place in Estonia, where pharmacies in rural setting must be at least 50 m^2 while others must be at least 80 m^2 *(125: article 7(1))*. Smaller pharmacies can be authorized if they are located in the security control area of an airport *(125: article 7(3))*.

Table 6 gives detailed information on some countries in the WHO European Region.

Table 6. | **Examples of minimum area requirements**

Country	Minimum area of pharmacy (m^2)		Comments
	with compounding	without compounding	
Austria	120	–	Pharmacy licence not granted without space for compounding; minimum sizes of the different rooms in the pharmacy specified in the regulation *(143: article 27)*
Belarus	100	60	In rural areas: 15–20 m^2; minimum space varies from 15 m^2 to 100 m^2 based on the type of licence and activities of the pharmacy *(88: article 3)*
Croatia	85	–	Public area of at least 35 m^2, with additional minimum space for several areas (such as compounding area, storage, manager's room), meaning a minimum pharmacy space of 85 m^2 *(151: article 18)*
Estonia	80	–	In rural areas: 50 m^2 *(125: articles 7 and 8)*
Georgia	200	110	Pharmacy branches: 40 m^2
Germany	110	–	Pharmacy licence not granted without space for compounding; minimum sizes of the different rooms in the pharmacy specified in the regulation
Kazakhstan	110	55	No minimum requirements for rural and remote areas
Kyrgyzstan	75–85	35	In rural areas: 20 m^2; pharmacy points: 20 m^2; pharmacy kiosks: 12 m^2
Lithuania		10–25	Various requirements based on the location (city or rural) and other criteria
Montenegro	–	50	–
Republic of Moldova	98	50	In rural areas: 40 m^2; first category pharmacy branches: 20 m^2; second category pharmacy branches (usually located in local medical office): no required area
Romania	–	55	–
Russian Federation	110	60	Pharmacy points: 34 m^2; pharmacy kiosks: 10 m^2 (requirements may differ between regions)
Switzerland (Geneva)	105	–	The canton of Geneva regulation lists different sections of a community pharmacy, each with a minimum space, giving a minimum total of 105 m^2 *(157: article 35)*
Tajikistan	78	50	Second category pharmacy points: 36 m^2 in cities, 24 m^2 in small cities, 18 m^2 in rural areas, 12 m^2 in remote areas
Turkey	–	55	In areas where a natural disaster has recently taken place a pharmacy can be opened in smaller premises of 20 m^2 for a period not exceeding two years
Ukraine	110	50	In rural areas: 40 m^2; in small villages: 30 m^2
Uzbekistan	110	34–54	Branch pharmacies in rural areas (in rural medical care points): 8 m^2

3.6.2.2 Presence of a consultation room

With the development of new clinical services such as adult immunization, medicine use review and other cognitive services, an increasing number of countries require a room for private conversations and provision of these services *(126)*, as in Iceland *(50: article 25)* and Romania *(124: article 17(1))*. The Irish regulation includes a description of this room: "separate and designated area conveniently located within the pharmacy premises so that a pharmacist may review and discuss in private with the person

for whom a prescription has been issued, or with the carer of such a person, such matters relating to the medicine therapy as either of the said persons may request or as the pharmacist, in the exercise of his or her professional judgement, may deem necessary" *(142: article 4(3))*.

Another regulatory option for availability of a consultation room is through the requirements for delivery of specific (remunerated) services. For instance, in England, United Kingdom, the requirements for medicine use review include availability of a consultation area *(158)*. In France dispensing of wheelchairs (in pharmacies and elsewhere) requires accreditation associated with premises requirements *(159)*.

3.6.2.3 Other requirements

In many countries the pharmacy regulators have set up requirements associated with compounding (in terms of premises and equipment) *(126)*. For instance, in Germany sufficient equipment to compound a list of medicinal dosage in various forms is required *(42: article 4)*. Likewise, Belgium has extensive definitions of the required equipment for compounding *(56: article 12 and annexe III)*. Other requirements may include access to scientific information and legislation, as in Germany *(42: article 5)*.

In terms of accessibility, some countries have defined that the public section of a community pharmacy should be on a ground floor, as in Austria *(143: article 27(4))*, or that the pharmacy needs to be directly accessible to patients with a physical disability or accessible via a separate entrance, as in Kazakhstan *(150: article 8.7)*. In Tajikistan the counter in a pharmacy point must include a glass pane between the pharmacist and patients *(113)*.

3.6.3 Process requirements

3.6.3.1 Regulations on available products

A number of countries have regulations limiting the types of product (other than medicines and medical devices) that can be sold in a community pharmacy to ensure that they remain health care centres (and not shops). Some, like Denmark, have chosen a description: non-pharmaceutical products sold in community pharmacies need to be "naturally belonging to pharmacy" *(87: section 12)*. To illustrate this type of product, the executive order lists examples of products that can and cannot be sold in a community pharmacy, while highlighting that these are not exhaustive *(149: annex 1)*.

Most countries have adopted a positive definition or list: only the products referred to or listed can be sold. France has adopted a list of products allowed to be sold in a community pharmacy *(26: article L5125-24; 160)*, and a similar approach is used in Serbia, where the types of product that can be sold are subject to the decision of a professional body *(37: article 101(5))*. The German regulation also defines the types of product (in addition to those falling under the monopoly of pharmacies) that can be sold in a community pharmacy *(42: article 2(4))*, and states that these other products should not affect the proper operation of the pharmacy and the prime focus of pharmacy (which is medicines).

The Russian Federation has a list of items that community pharmacies are allowed to sell, which includes medical products; disinfectants; personal hygiene items; medical devices; products for the care of patients, neonates and children under the age of three years; eye glasses and care products; mineral waters; children's and dietary food; perfumes and cosmetics; and medical and health-related publications promoting healthy lifestyles *(41: article 55.7)*. Lists of goods that can be sold in a community pharmacy are also in place in Estonia *(1: article 31(5))*, Lithuania *(81: article 35.11)* and Uzbekistan *(111: article 21)*.

Finland does not have a defined list of products community pharmacies are allowed to sell, but the regulation states that when a pharmacy sells other products or provides services, it should not hinder the supply of pharmaceutical products or the counselling related to these products *(36: article 58a(2))*.

3.6.3.2 Stock

In a number of countries the regulations define requirements with regard to stock of medicines. These can be in general terms, as in Finland ("the amount of pharmaceutical products […] kept by a pharmacy must correspond to its usual customer needs" *(36: article 55(1))*) and Austria *(143: article 4)*.

Some countries' governments require all pharmacies (or some) to have a minimum stock of medicines (and other goods). This is, for instance, the case in Denmark *(87: section 41)*. The German regulation specifies that a pharmacy needs to keep in stock pharmaceutical products for a one-week supply for the population of a list of products *(42: article 15(1))*; other products on a second list can either be stocked or be procured at short notice *(42: article 15(2))*. Likewise, Belgian pharmacies have an obligation to stock a list of medicines *(56: article 12 and Annexe II)*.

Some countries include the conditions for storage within GPP guidelines; others define them separately, as in Germany *(42: article 16)*. Finally, in some countries, like Estonia, pharmacies must perform an inventory of medicinal products at least once a year *(125: article 19(3))*.

3.6.3.3 Regulations on opening hours

In many countries regular opening hours and the nearest on-duty pharmacy services must be displayed at the pharmacy (and visible from outside), as in Belgium *(56: article 10)*, Estonia *(125: article 11(1))* and Israel *(51: article 19)*. Several countries have defined a minimum number of operating hours for a community pharmacy. This may be done through the law, regulation but also through the collective agreement between community pharmacies and health insurance(s).

Opening hours also need to be considered in line with other operating requirements, including workforce requirements and workload. On this basis, it is possible to request the competent authority to allow fewer hours than the minimum (for instance, for the smallest pharmacies with only one pharmacist). In Finland, the pharmacy licence may be associated with minimum opening hours of the pharmacy to safeguard the availability of pharmaceutical products *(36: article 40(2))*. Table 7 offers an overview of the provisions in a few countries in the WHO European Region.

Table 7. | **Examples of minimum opening hours for a community pharmacy**

Country	Minimum opening hours
Denmark	47 hours per week, including at least four hours on Saturdays, although an exemption may be granted for smaller/branch pharmacies *(161)*
Estonia	40 hours per week in cities and areas with over 4000 inhabitants *(1: article 41.4[1])*
Hungary	30 hours per week *(99: article 53c)*
Iceland	09:00–18:00 on weekdays *(50: article 15)*
Malta	Minimum: 09:00–12:00 and 16:00–19:00, Monday to Saturday, although on Saturday afternoon the managing pharmacist may not open the pharmacy (according to the minimum number of pharmacies open, specified by a roster); a roster is also in place for pharmacies that need to open on Sunday mornings (the rules do not apply to a pharmacy at the airport) *(162)*
Portugal	44 hours per week: Monday to Friday at least 10:00–13:00 and 15:00–19:00 and Saturday 10:00–13:00 *(163)*
Spain	Based on local regulations of autonomous communities defining minimum opening hours *(79: article 6)*

Some countries, including Romania, have linked opening hours with the number of pharmacists employed in that pharmacy *(124: article 18(1))*.

Some have also defined maximum opening hours. In Austria the opening hours are defined by local authorities *(44: article 8)* but should not exceed 48 hours per week and should include a daily lunch break of approximately two hours. Pharmacies located in the same area must have the same opening hours.

3.6.3.4 On-duty services

Many countries have set up mandatory duty shifts for community pharmacies to guarantee continuous access to medicines and pharmaceutical expertise at night, during the weekend and on bank holidays, beyond the regular opening hours *(126)*. Such a system is in place in Belgium *(34: article 9(1))*, France *(26: article L5125-17)*, Germany *(46: articles 18–20)*, Portugal *(164)* and Romania *(124: article 18)*. Countries with on-duty services have organized information channels to ensure that patients are aware of the closest on-duty pharmacy. This is usually done through an obligation that pharmacies display a list of on-duty pharmacies or the nearest ones, as in Austria *(143: article 25; 44: article 8)*, Belgium *(56: article 10)*, Germany *(42: article 23(5))* and Malta *(162)*.

In Germany the on-duty shifts are organized by the local association of pharmacies. Pharmacies receive an allowance for on-duty services *(47: articles 18–20)*. The regulation also defines different ranges of on-duty services: for some it is acceptable that the pharmacist is in the direct vicinity and available to come to the pharmacy *(42: article 23)*. As the density of pharmacies varies across the country (and within a given region), it means that some pharmacies (especially in rural communities) perform these services more often than others *(24)*.

On-duty services in Belgium are also organized by the professional organizations *(34: article 9(1))*. They are available from 19:00 until 08:00 the next day, as well as on Sundays and bank holidays. If a pharmacy that is not on an on-duty shift opens during the on-duty period, it needs to be open for the whole duration of the shift *(56: article 6)*.

The number of on-duty community pharmacies may differ based on foreseen needs. For instance, in the Geneva canton in Switzerland there are always five pharmacies involved with on-duty services, but their opening hours differ: two only need to be open from 08:00 to 21:00; two need to be open from 08:00 to 23:00 and the final one is responsible for the on-duty service at night, from 23:00 to 08:00 *(157: article 25)*.

In Austria, in locations where there is only one public pharmacy, the pharmacy manager or another pharmacist must be reachable quickly, even outside operating hours, for the supply of medicinal products in urgent cases *(44: article 8(3))*. In Portugal on-duty service planning considers other sources of medicines in the vicinity, such as hospitals. In Romania, certain pharmacies located in malls (that cannot operate outside the mall's opening hours) are exempted from on-duty services *(124: article 18(3))*.

France makes specific provision for airport community pharmacies: if there are more than two community pharmacies in an airport, one must be open (or available for on-duty services) whenever the airport is open *(26: article L5125-7-2)*. In Malta the restrictions on opening hours do not apply to the pharmacy at Malta International Airport *(162)*. Moreover, the pharmacy in the main public hospital operates 24/7 and sells emergency supplies of medicines during the hours that community pharmacies are closed.

3.6.4 Dispensing

Dispensing processes and requirements may be described in regulations, either through GPP guidelines or a dedicated regulation or guidelines. For instance, in France the pharmacist must provide the different components of the act of dispensing, including:

- pharmaceutical analysis of the prescription (if there is one);
- preparation of unit dose dispensing (if required);
- provision of information and advice to ensure responsible use of medicines *(26: article R4235-48)*.

Some countries, including France *(165)*, have adopted Good Dispensing Practices, detailing the different steps leading to high-quality dispensing.

3.6.4.1 Recording

In most countries regulations and legislation require that community pharmacies maintain records of medicines dispensed from a prescription and/or the medicines compounded. In Austria, the regulation lists the information to be recorded for medicines compounded in a community pharmacy and medicines dispensed by the pharmacy. It also defines how long the records must be kept: at least five years from the last entry *(143: article 8)*.

Similar provisions are described in detailed in Belgium *(56: articles 34–43)*. Belgian pharmacists must record the number of fills and refills done for a prescription, the date of dispensing, the full names of the prescriber and patient, the national number of the medicine, the quantity of medicine dispensed and the batch number of the medicine. The dispensing records must be reviewed at least once a year and be kept for 10 years. Belgian pharmacies must also keep a record of their medicine purchases (and the sources). Additional requirements are imposed for specific types of medicine (like narcotics and psychotropics). Access to these records requires the approval of the patient except in the case of certain authorities (such as health authorities and police). These records can be electronically archived and must be kept for at least 10 years.

The Estonian regulation lists the different records (and the information required for each) to be kept at the pharmacy, such as the records of:

- medicinal products subject to medical prescription that have been dispensed;
- medicinal products withdrawn from the market;
- medicinal products received as foreign aid.

Such reports must be submitted once a quarter. In addition, the community pharmacy must submit information on the activities of the pharmacy such as total turnover, number of prescriptions, total turnover of medicinal products (prescription-only and OTC), total turnover of distance sales, purchase prices of the medicinal products sold and personnel data *(125: article 27)*.

In some countries the pharmacy must also keep the prescription for a defined period (for example, three months in Malta) after medicines have been dispensed *(96: article 12)*.

3.6.4.2 Labelling of medicines

The regulations of a number of countries specify the information to be included in the label prepared by the pharmacy and stuck on the medicine packages, including Belgium *(56: article 15)*, Germany *(42: article 14)* and Israel *(51: article 30)*.

3.6.4.3 E-health and data linking

In some countries pharmacists can access (and sometimes write on) the electronic patient file developed by the government. In such cases, the legal and regulatory framework may be defined by a dedicated e-health law. Some countries have granted access (and sometimes writing) rights to patients records for pharmacists. For instance, in England, United Kingdom, community pharmacies have had access to the summary care records of their patients since 2017 *(166)*.

In Estonia, pharmacists (and other health care professionals) can access an agreed data set about a patient, using the patient's identity card. Data are extracted from various health systems and can be viewed through an online portal *(166)*. In the Netherlands pharmacists can consult and store laboratory results supporting safe dispensing and better care of the patient, with patients' consent *(80: article 66a)*.

The professional bodies in France and Belgium have developed a shared pharmaceutical patient file among all community pharmacies, allowing any pharmacy to integrate in their dispensing software the data of all medicines dispensed over the few last months (including by other pharmacies) and to send

the data of their last dispensing activity. Access to these common files requires the consent of the patient *(166)*. The development of this shared pharmaceutical patient file has required the introduction of legal provisions in France *(26: article L1111-23)*. Not all countries with an electronic patient record have yet granted an access or writing rights to pharmacists, however.

Finally, a number of countries have implemented electronic prescribing and transfer of prescriptions to pharmacies. This is, for instance, the case in Nordic countries (Denmark, Finland Iceland, Norway and Sweden) and in Croatia, Estonia and the Netherlands *(167)*. The transfer of e-prescriptions can be done through a server or via a secure health care mail system.

Armenia and Georgia have also introduced e-prescription systems recently. One of the requirements for a pharmacy is integration with government systems.

Electronic prescribing may bring significant benefits, including:

- easier access to prescribing data for the government, including prescribing patterns and numbers of unfilled prescriptions;
- systematic use of software to assist prescribing, which can alert on potential interactions when prescribing, integrate clinical guidelines and costs and support decisions in the prescribing process;
- prevention of alteration (and/or fraud) of prescriptions by patients;
- safer dispensing of medicines by solving the issue of deciphering a prescriber's handwriting;
- accessibility of prescriptions, and enabling retrieval of copies (including of past prescriptions);
- integrating prescription data into community pharmacy dispensing software.

3.6.5 Identification of a community pharmacy

3.6.5.1 A unique symbol for pharmacies

In several countries in the WHO European Region a protected national symbol for community pharmacy enables patients to identify a pharmacy easily. For instance, France has two symbols: the predominant one is a green cross, which is a collective brand owned by the pharmacy regulator and accessible only to pharmacists according to defined rules. The second is a caduceus *(168)*.

In Germany the pharmacy symbol is a red "A" (with chalice and snake). This is a registered trademark of the German Pharmacists Association, which enjoys special legal protection in Germany (and Europe) *(23)*. In Romania the symbol is defined in law *(124: article 17(2))* as: "a cross symbol with equal-sized limbs, green on white sides, intersected at right angles". In Lithuania the design of the pharmacy symbol is part of the regulation on pharmacy premises *(154)*.

In Albania the pharmacy symbol is a cross with a snake. In Kyrgyzstan since 2012 a unique symbol identifies community pharmacies *(75)*: a green cross on a white background, with green lettering denoting "pharmacy", "pharmacy point" or "pharmacy kiosk" in the official languages (Kyrgyz and Russian), the name of the pharmacy and its opening hours.

In Turkey the Pharmacy Chamber provides guidance for a special sign that should be placed at a defined height outside the pharmacy. Information about the owner, opening hours and the phone number and address of on-duty (24/7) pharmacies are also required.

3.6.5.2 Pharmacy signs

To identify pharmacies easily, national legislation in many countries describes a special designated sign to be used for a pharmacy, pharmacy point and pharmacy kiosk (when applicable) in detail. For instance, Romanian legislation mentions that the sign for the community pharmacy should include the term

"pharmacy" and, where appropriate, a name to distinguish it from other community pharmacies *(124: article 17)*. Likewise, in Estonia pharmacy premises must display the word *Apteek* ("pharmacy" in Estonian), accompanied by the name of the pharmacy *(1: article 30(2))*.

A sign defining the form of the pharmacy (pharmacy, pharmacy point or pharmacy kiosk), the licence owner, opening hours and information about on-duty pharmacies is obligatory in Armenia *(72)*, Azerbaijan *(134)*, Belarus *(73)*, Georgia *(74)*, Kazakhstan *(150)*, the Republic of Moldova *(76)*, the Russian Federation, Tajikistan, Turkmenistan *(93)* and Ukraine *(25)*.

A pharmacy sign should be present in two languages (national and Russian) in Belarus and Kazakhstan. In Ukraine if the owner of the licence would like to put a special sign on the pharmacy (logo), it should be registered with the ministry of health *(25)*.

4. Activities and services provided in a community pharmacy

4.1 Role of the pharmacist, essential and professional services

The pharmaceutical activities and services provided to patients in community pharmacies in countries in the WHO European Region are usually defined by the law (for example, within the definition of "community pharmacy"); listed in licensing requirements and/or defined indirectly in the scope of practice of pharmacy professionals. Many countries have followed the Joint FIP/WHO Guidelines *(69)* and established a national framework of quality standards and guidelines for GPP, defining essential and professional pharmacy services.

FIP and WHO defined the pharmacy practice mission as contributing to health improvement and helping patients with health problems to make the best use of their medicines. This consists of six major components:

- being readily available to patients with or without an appointment;
- identifying and managing or triaging health-related problems;
- health promotion;
- assuring effectiveness of medicines;
- preventing harm from medicines; and
- making responsible use of limited health care resources.

GPP is the practice of pharmacy that responds to the needs of the people who use pharmacists' services to provide optimal, evidence-based care. To support this, it is essential that an established national framework of quality standards and guidelines is in place.

International GPP standards recommend that a number of roles and functions are considered for pharmacists and reflected in the activities of a community pharmacy (see section 2.1.4). These can contribute to the development of specific actions, services or programmes *(69)*.

It is possible to differentiate between two general groups of pharmacy services. The first group – essential (or core) services – are usually those that should be provided in all pharmacies in the country and include dispensing of OTC and prescription-only medicines, pharmaceutical consulting, pharmacovigilance and health promotion. These are provided, for example, in all CIS countries.

In countries with high implementation of pharmaceutical care, such as Belgium, France, the Netherlands and the United Kingdom, core pharmacy services include additional aspects. The Pharmaceutical Group of the European Union (PGEU) *(169)* defines the following core pharmacy services, focusing on expertise in medicines:

- dispensing (including repeat dispensing and homecare);
- compounding;
- medication management (unit dose packaging, new medicines service, medicine use review);
- emergency care (including emergency contraception) and minor ailment management.

The second group includes professional pharmacy services, defined as "an action or set of actions undertaken in or organized by a pharmacy, delivered by a pharmacist or other health practitioner, who applies their specialized health knowledge personally or via an intermediary, with a patient/client, population or other health professional, to optimize the process of care, with the aim to improve health outcomes and the value of health care" *(170)*. Many professional pharmacy services – including chronic disease management; early screening and testing; vaccination; smoking cessation; and measurement of blood pressure, cholesterol and glucose – are considered advanced services and pharmacies are not obliged to provide them, and/or may need special accreditation or certification to do so.

A wide diversity of services is provided across countries. Some variation exists in the structure, process and outcome measures for similar services, as well as the names used for them, which makes international comparison challenging. Table 8 presents the results of international surveys of national associations of pharmacists *(126, 174)*, using the framework developed by FIP and WHO *(69)*.

4.2 Regulation of pharmacy activities and services

Provision of pharmacy services is directly referred to in legislation in Austria *(143: article 1)*, France *(26: article L5125-1-1 A)*, Latvia *(29: section 35)*, Portugal *(172; 173)*, Serbia *(37: article 100 (5))* and Slovenia *(32: articles 6 and 7)*. The Finnish definition of a community pharmacy lists the types of essential activity ("the retail sale, distribution and preparation of pharmaceutical products as well as counselling and the provision of other services related to pharmaceutical products" *(36: article 38(1))* and adds a few additional services, including health and well-being promotion and prevention of disease. It states, however, that these activities should prevent irrational overuse of pharmaceutical products *(36: article 58a(1))*.

A few countries also define the obligation to provide services in a community. This can be a condition of the community pharmacy licence, as in Denmark *(87: section 11)*. It can also be a contractual obligation defined in the collective agreement between community pharmacies and the health insurance fund, as in England, United Kingdom, where pharmacies with a contract with the National Health Service must provide a set of core services defined as "essential services", including dispensing, repeat dispensing, disposal of unwanted medicines, promotion of healthy lifestyles (public health), signposting and support for self-care.[3] These are provided under a clinical governance framework that includes clinical audit and information governance requirements *(174)*.

In Albania pharmacy services are defined as essential services (dispensing medication with and without prescriptions; contributing to pharmacovigilance; promoting and participating in disease prevention campaigns and health education) and special services (blood pressure and glucose level measurement) *(133)*. In Armenia *(72)*, Azerbaijan *(175)* and Georgia *(67)*, pharmacy services are restricted to OTC and prescription-only medicines dispensing, provision of information about medicines and pharmacovigilance. In Georgia pharmacists are allowed to dispense only to private people (not hospitals or companies).

[3] Note: English community pharmacies are not limited to these compulsory services. A second list of "advanced services" is also compensated.

Table 8. | **Overview of community pharmacy services**

Service	European level *(30 countries)*	Global level *(74 countries and territories)*
1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products		
A: Prepare extemporaneous medicine preparations and medical products	*Not surveyed*	Compounding medicines: 59 countries
B: Obtain, store and secure medicine preparations and medical products	*Not surveyed*	*Not surveyed*
C: Distribute medicine preparations and medical products	*Not surveyed*	*Not surveyed*
D: Administration of medicines, vaccines and other injectable medications	Flu vaccination: 40% Other vaccination: 17%	Vaccination: 24 countries
E: Dispensing of medical products	Dispensing prescriptions: 100% Night/out-of-hours services: 93% Homecare services: 47% Manual preparation of personalized dosage systems: 37%	Opioid substitution treatment: 24 countries Tuberculosis Directly Observed Treatment, Short Course: 20 countries Repeat dispensing: 26 countries Home care: 31 countries Adherence aids: 32 countries
F: Dispose of medicine preparations and medical products	Disposal of medicines: 90%	Collecting expired medicines: 48 countries
2: Provide effective medication therapy management		
A: Assess patient health status and needs	Medication review: 53% Blood pressure measurement: 90% Weight measurement: 90% Blood glucose measurement: 77% Cholesterol measurement: 73%	HIV test: 12 countries Medicine use review: 50 countries Medicines reconciliation: 44 countries
B: Manage patient medication therapy	Asthma/chronic obstructive pulmonary disease management: 43% Diabetes management: 43% Hypertension management: 37%	Adjusting prescribed treatments: 27 countries Asthma management: 36 countries Hypertension management: 42 countries Diabetes management: 42 countries Management of anticoagulants: 35 countries New medicines service: 40 countries
C: Monitor patient progress and outcomes		
D: Provide information about medicines and health-related issues	Information to patients on conditions/ treatments: 57% New medicines service: 27%	
Role 3: Maintain and improve professional performance		
A: Plan and implement CPD strategies to improve current and future performance	*Not surveyed*	*Not surveyed*
Role 4: Contribute to improve effectiveness of the health-care system and public health		
A: Disseminate evaluated information about medicines and various aspects of self-care	*Not surveyed*	*Not surveyed*
B: Engage in preventive care activities and services	*Not surveyed*	Health-promotion initiatives: 51 countries
	Smoking cessation: 70%	Smoking cessation: 39 countries
	Needle and syringe exchange: 27%	Syringe exchange: 19 countries
C: Comply with national professional obligations, guidelines and legislations	*Not surveyed*	*Not surveyed*
D: Advocate and support national policies that promote improved health outcomes	*Not surveyed*	*Not surveyed*

Sources: PGEU *(171)*; FIP *(126)*.

In Ukraine *(176)* pharmacies are described as health care facilities where pharmaceutical care for patients and clinical pharmacy services must be provided. Pharmacies are also obliged to provide blood pressure measurement. Legislation in Tajikistan *(77)* and Turkmenistan *(93)* defines pharmacy services as dispensing OTC and prescription-only medicines; provision of reliable information about medicines, medical products and their prices, and about rational drug use for responsible self-medication; pharmaceutical consulting; and production of medicines. In most countries, however, pharmacies are also allowed to offer additional services beyond the ones listed as part of their monopoly.

In many countries community pharmacies are allowed (or even have an ethical duty) to provide care when facing a health-threatening situation. For example, in France pharmacists have an obligation to provide assistance to a person in danger, to the best of their abilities and competencies *(26: article R. 4235-7)*. In some countries, including Switzerland *(83: article 24)*, the regulation clearly specifies the possibility of dispensing prescription-only medicines without a prescription at the individual patient level in defined situations. In Israel a pharmacist may dispense a prescription-only medicine without a prescription for "immediate and urgent need" of a patient, following the conditions listed in the regulation *(51: article 26)*. Similarly, in the Netherlands pharmacists can dispense a prescription-only medicine without a prescription in urgent cases and when they have sufficient assurance that there is no danger of abuse *(80: article 61.10)*.

FIP also suggests a number of provisions to allow regulatory flexibility in the event of a disaster, to allow regular pharmacists to provide exceptional care in such situation *(177)*. For instance, Israel's legislation allows the ministry of health to issue an executive order to adjust the regular pharmacy legal provisions in emergency situations *(51: article 68)*.

4.3 GPP standards

As recommended by the Joint FIP/WHO Guidelines, many countries have adopted national GPP standards defining the activities and services provided in community pharmacies. The advantage is that these standards are often the only detailed definition provided of pharmacy services, their provision, evaluation and quality management. Definitions of core and professional services in the GPP standards are key texts designating the professional position of a pharmacist in the health care system. The scope of GPP standards varies across countries, highlighting national features. National GPP guidelines can be stand-alone documents, as in Belarus *(88)*, Belgium *(56)*, Kazakhstan *(150)*, Lithuania *(178)* and the Russian Federation *(179)*, or integrated into a regulation covering all requirements of community pharmacies, as in Austria *(143)*.

GPP standards are obligatory in Belarus *(88)*, Kyrgyzstan *(75)*, the Republic of Moldova *(76)* and the Russian Federation *(179)*. They include requirements for a pharmacy structure and processes and define in detail structural, process and outcome-related requirements for provision of core services: dispensing OTC and prescription-only medicines; provision of reliable information about medicines, medical products and their prices, and about rational drug use for responsible self-medication; pharmaceutical consulting; production of medicines; and documentation. Services should be provided in compliance with professional ethics. National GPP guidelines in the Republic of Moldova also list blood pressure measurement *(76)*.

According to national GPP guidelines in Kazakhstan *(150)*, primary pharmacy services are dispensing of controlled, prescription-only and OTC medicines; production of medicines; quality control of medicines; and storage. Additional pharmacy services are pharmaceutical consulting to patients and health care professionals; taking phone orders; home delivery of (OTC) medicines; renting patient care tools; promotion of healthy lifestyles and prevention of diseases; and pharmacovigilance. Despite the declaration of compounding of medicines as a primary pharmacy service, there is no obligation to provide it. According to the licensing requirements, compounding of medicines in pharmacies or pharmacy entitles has additional requirements (area, equipment and staff) and is rarely present in CIS countries nowadays.

GPP guidelines in Uzbekistan *(180)* are recommendations (and not obligations) for pharmacies and describe core services as dispensing of medicines, consultation on minor alignments, providing information about

medicines and health promotion. According to national GPP guidelines in Turkey, core pharmacy services are dispensing of controlled, prescription-only and OTC medicines; production of medicines; quality control of medicines; and storage. Additional pharmacy services include pharmaceutical consulting to patients and health care professionals, promotion of healthy lifestyles, prevention of diseases and pharmacovigilance.

The Belgian GPP guidelines cover three major types of activity:

- activities related to the compounding, preparation and dispensing of medicines (and other health products);
- activities associated with treatment monitoring;
- activities aiming to promote health and well-being of patients and the population, and to reach health objectives *(56: annexe I)*.

In Lithuania *(81: article 39.5)*, Serbia *(37: article 83)* and Slovenia *(32: article 22(1))* the legislation specifically refers to GPP standards to be adopted by the pharmacy regulator; in Serbia GPP guidelines must ultimately be approved by the ministry of health *(43: article 83)*. In Lithuania a reverse strategy is in place. The pharmacy must define the services offered to patients.[4] Each must be described according to a format defined by the regulation, including its purpose, the selection criteria for patients, competencies required, premises and equipment requirements, information sharing with the physician and process, among others *(181)*.

France and Portugal are among the countries that have updated the list of services that can be provided by a community pharmacy. In addition to activities on which they have a monopoly (such as dispensing prescription-only medicines), Portuguese pharmacies are allowed to provide the following services:

- home support;
- administering first aid;
- administration of medicine;
- use of auxiliary diagnostic and therapeutic methods;
- administration of vaccines not included in the national vaccination scheme;
- pharmaceutical care programmes;
- nutrition consultation;
- programmes for adherence, medicines reconciliation and unit dose dispensing, as well as education programmes on appropriate use of medical devices;
- rapid tests for HIV, and hepatitis B and C screening, including counselling prior to and after the test, as well as patient referral to the appropriate hospital in the case of positive results, based on procedures adopted by the ministry of health;
- simple nursing care, including wound care and care to patients with a stoma;
- level 1 care for preventing and treating diabetic foot problems, according to ministry of health guidelines.

Pharmacies can also take part in campaigns and programmes on health promotion and education, disease prevention and healthy lifestyles *(172, 173)*.

In October 2018 the French government updated the list of community pharmacists' missions *(26: articles L5125-1-1 A and R. 5125-33-6)*. It now has strong focus on collaborative practice, involvement of the pharmacist in pharmaceutical monitoring, active participation in patient education and screening of infectious and non-infectious diseases. Duties include the following, where appropriate:

- contributing to primary health care;
- participating in cooperation between health care professionals;
- participating the public service mission of continuity of access to care;
- supporting health monitoring and protection activities organized by public health authorities;
- taking part in patients' therapeutic education and support;

[4] These include provision of information about the pharmaceutical services; collection, analysis and evaluation of patient data; development of an individual pharmaceutical care plan; monitoring of the implementation of the care plan; and evaluation of the results achieved through the services.

- acting as the pharmacist for a nursing home;
- being appointed the referent pharmacists within an interprofessional team – as such, renewing prescriptions for chronic treatment, adjusting dosage if needed and providing medicine use reviews to improve the effects of the treatment, at the request or with the approval of the doctor;
- offering advice and services aiming to improve or maintain the health status of individuals, such as:
  - activities of pharmaceutical monitoring and patient support to prevent medicine-related illness, guarantee responsible use of medicines and monitor adherence by analysing patient data (including on treatment) – recommendations are formalized and shared with the medical doctor unless the patient objects;
  - implementation of health-promotion and prevention actions on the domains identified by the national health strategy, contributing to awareness and information campaigns on public health topics, sharing scientifically validated information on disease prevention with different audiences, with particular attention to delivering an appropriate message to the public;
  - participating in assessment of medicines, medical devices and innovations, based on observational/real-world data in collaboration with health authorities;
  - participating in screening of infectious and noncommunicable diseases;
  - participating in coordination of care in collaboration with all health care professionals, supporting coordinated care delivery through a doctor.

4.4 Quality of pharmacy services

Evaluation of the quality of pharmacy services is an important aspect of maintenance and continuous improvement of care provided to patients. Many international organizations provide recommendations on such evaluation using various tools and indicators, such as the European Directorate for Quality of Medicines and Health care *(182)*. Requirements for quality assurance of pharmacy services are usually included in GPP guidelines (where applicable) or are an integral part of the quality management system required for all pharmacies.

Quality management systems for all pharmacy activities are an obligation in many countries, such as Germany *(42: article 2a)*, Iceland *(50: article 48)*, Slovenia *(32: article 22)*, Switzerland and the United Kingdom. In Iceland the pharmacy's quality manual must be finalized at least one month before its scheduled opening, as part of the licence granting procedure *(50)*. In some countries, including Germany, the regulator may issue guidelines to support a quality management system *(23)*, pharmacies should have self-inspection *(42: article 2a)* and may also order external inspections to get a quality certificate that is usually needed to collaborate with other health care facilities (to supply to nursing homes and hospitals).

In Estonia pharmacies must have written internal work procedure rules for operations that affect the quality of and relate to the handling of medicinal products *(125: article 13(1))*. A list of the minimum required operating procedures is defined *(125: article 13(2))*. Moreover, Estonian pharmacies must undertake an internal audit at least once a year to monitor implementation of and compliance with legislation and standard operating procedures. The audit should include proposals for action and must be formalized into a report *(125: article 19(1))*.

In Slovenia the procedures and processes should be in accordance with the standards and GPP guidelines adopted by the pharmacy regulator *(32: article 22(1))*. In Kazakhstan the regulation refers to a quality assurance *(150: articles 14.1–14.4)* and lists the standard operating procedures that must be developed in a community pharmacy *(150: article 11.2)*, as well as obliging pharmacies to perform regular self-inspections *(150: articles 13.1–13.6)*. A quality management system is an obligation and a requirement for renewal of a pharmacy licence.

In Denmark the regulation states that pharmacists should establish service targets for the dispensing of medicines and provision of pharmacy services – including waiting times, service levels and objectives for

professional counselling and information – and report on achievement of these targets *(149: section 27)*. In the Netherlands the Dutch Pharmacist Association provides a comprehensive list of quality indicators for pharmacy services *(183)*.

4.5 Regulatory restrictions on pharmacy activities

Regulatory restrictions on pharmacy activities are usually described in pharmacy practice legislation. This can be done either by explicitly limiting the activities performed to those listed (positive list) or by listing all the activities that cannot be performed (negative list), thereby allowing all activities not listed. Some countries set out very strict differentiation between functions and professional rights of health care professionals that should also be taken into account. In the case of violation of allowed services or activities, government inspectors may apply fines or penalties, or even withdraw a licence temporarily or permanently.

In Serbia pharmaceutical care is provided according to laws regulating health care, the field of medicines and medical devices and health insurance, as well as GPP guidelines established by the Pharmaceutical Chamber of Serbia. Regulations restrict selling medicines and medical devices that: do not have marketing authorization; are manufactured without a licence; are not labelled according to the law; do not have adequate documents about their quality; have expired; are sold via the Internet; or are prescription-only medicines without a prescription. Fines are imposed on pharmacies and pharmacists selling medicines against the regulations, and the relevant pharmaceutical chamber could also withdraw the pharmacist's licence *(37)*.

In Monaco the legislation states that pharmacies are not allowed to display or sell products outside the pharmacy premises, such as at fairs or markets *(57: article 58)*. Additional activities (such as soliciting orders from patients directly or through intermediaries) are also forbidden *(57: articles 56 and 57)*.

In Turkey local health authorities carry penalties according to the Law of Misdemeanour. For example, fines are imposed on pharmacies if antibiotics are sold without prescription. However, the same level of fine is imposed on repeated misconduct and there is no penalty other than fines, such as suspension of the pharmacist's licence. Evidence in Turkey shows that penalties were imposed more often in urban than rural settings. Differences in inspection practices between urban and rural settings were also observed: Inspections were conducted less frequently in urban than in rural settings due to insufficient human resources. Inconsistency in inspection practices creates concerns among pharmacies – some that follow the law may lose customers, while others that break it may gain customers.

In Armenia *(72)*, according to the Law of Medicines, pharmacists are not allowed to provide medical services (such as blood glucose measurement) or deal with narcotics and psychotropic substances without licence. They are not allowed to provide false information about medicines, or dispense falsified medicines or those of poor quality. The law defines the very high penalties and describes the criteria for penalties in different ways: very clearly (for example, for dispensing of falsified medicines or prescription-only medicines without prescription) and less concretely (such as for not registering side-effects or failing to provide sufficient information about available generics).

In Azerbaijan the list of products that can be available in pharmacies is defined by the law. It is forbidden to sell products outside this list, or to provide medical advice and conduct medical practices (including blood glucose measurement and all other activities defined as medical practice) *(134)*. Pharmacists are also not allowed to provide medical services, deal with narcotics and psychotropic substances without a licence or provide false information about medicines in Belarus, Kazakhstan *(40)*, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan *(135)* and Ukraine. In Kazakhstan the GPP guidelines describe some diagnostic services but explicitly mention that these are "provided by the doctor or medical staff" – pharmacy owners often offer doctors a consultation room next to pharmacy premises in the country.

In Georgia the Law on Drugs and Pharmaceutical Activity defines dispensing rule for medicines, which are categorized into three groups, and specifies penalties in cases of misconduct. Fines are imposed

on pharmacies for sales of prescription-only medicines without prescription, and the fine increases with repeated violations. The law also specifies fines for sales of prescription-only medicines without prescription to underaged people. Although about 2500 pharmacies can sell prescription-only medicines in the country, only 10 inspectors are in place to undertake pharmaceutical inspection, and this lack of human resources makes it difficult to conduct inspections. Pharmacists are not allowed to provide medical services, deal with narcotics and psychotropic substances without licence, provide false information about medicines or dispense falsified medicines of those of poor quality. The penalties are very high. It is also forbidden to employ staff without a pharmacy degree, violate dispensing rules (with a penalty of about €160 for the first and about €300 for subsequent cases), dispense falsified medicines (with a penalty of about €6500) or sell medicines to companies and institutions.

When a regulation lists the services that can be provided by a community pharmacy, it usually means that all other unlisted services may not be provided. This represents a challenge to develop and test new services before they are included in the official list of services. In such cases a generic provision to allow testing or piloting may be included in the law, and piloting may be further defined in a decree, as in the Netherlands, where testing of a new service can take up to five years *(24: article 36a.1)* or through the adoption of a specific law for each test, as in France for flu vaccinations in community pharmacies *(184: article 66)*.

Since 2012 several groups of antibiotics have been included in the OTC medicines list in Belarus *(185)*. The maximum amount to be dispensed is set for all medicines including antibiotics (not more than 50 single doses or not more than two packages). A new list of OTC drugs is under discussion by the ministry of health but contains no changes regarding antibiotics compared with the 2012 bylaw *(185)*. At the same time, antibiotic resistance in Belarus has increased significantly since 2012, according Central Asian and Eastern European Surveillance of Antimicrobial Resistance data *(186)*. Government initiatives to improve access to medicines have resulted in an increase in antibiotic resistance since the regulation's introduction due to insufficient regulation (no restriction of maximum daily and treatment doses of antibiotics available as OTC medicines) and an absence of targeting (for example, antibiotics only available OTC for rural areas).

4.6 Remuneration for community pharmacy services

The remuneration model for community pharmacies needs to consider the activities and services expected by the health care system, their values (to the payer and the health care system) and the total costs for delivery of these services (and requirements for additional investment). It should provide positive incentives to achieve optimal health outcomes through pharmaceutical products and services *(187)*. In most countries the model relies on one (or several) components specifically designed to remunerate specific activities or outcomes.

The first component relates to dispensing (which represents the sole or predominant share of community pharmacy remuneration in most countries). The commonest formats are a margin (linear or regressive),[5] a maximum reimbursement price[6] and one or several dispensing fees (per box dispensed, per line of prescription, per prescription and/or per visit to the pharmacy, sometimes adjusted by the complexity of the treatment). In 2013 the General Secretary of PGEU presented an overview of the types of remuneration for dispensing within most countries in the WHO European Region (Fig. 2).

A second component relates to provision of other clinical services, ranging from administration of medicines (including vaccination) to cognitive services (such as medicine use review, medication therapy management and minor ailments programmes). This may consist of a fee for services, a capitation fee and/or a fee for performance.

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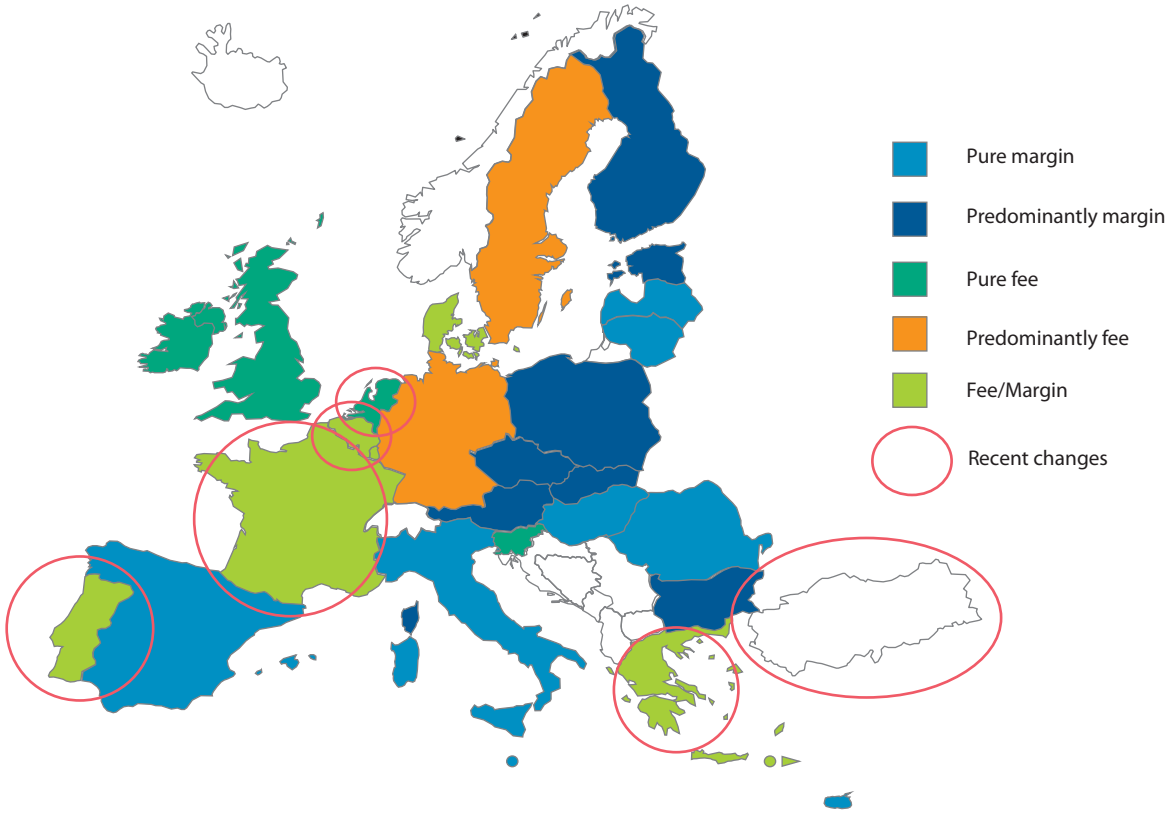
[5] In this case, the margin of medicines reimbursed by the health insurance fund is defined by the regulation. It may be based on a (variable) percentage of the ex-factory price (or the final price) and/or a mark-up.

[6] As in the United Kingdom; it is usually associated with regular review of the pharmacists' profits derived from this scheme, to adjust the maximum price set regularly.

Fig. 2. | **PGEU overview of pharmacy remuneration related to dispensing, 2013**



Source: Chave *(188)*.

A third component may support (or sustain) an appropriate network of pharmacies to meet local needs. These measures usually target specific pharmacies whose financial sustainability is at risk under the standard scheme but that are deemed essential to provide equitable and good access to medicines and pharmaceutical expertise *(189)*.

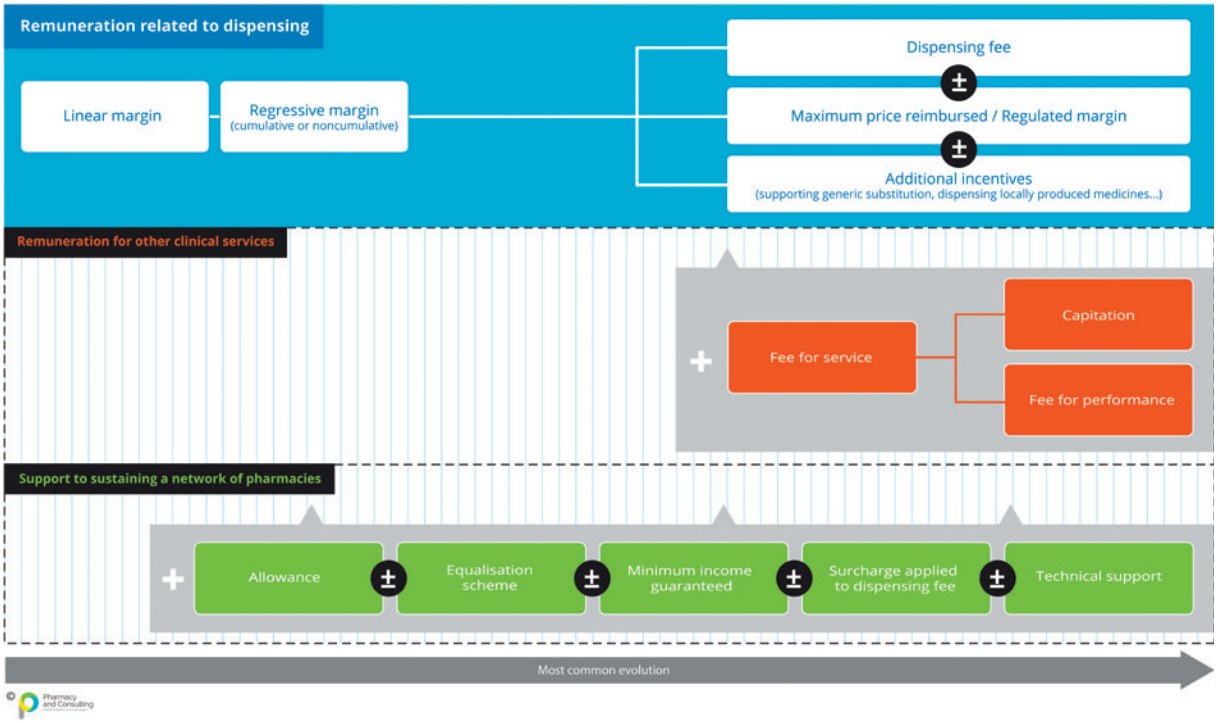
Community pharmacy remuneration evolves to reflect the evolution of pharmacy practice and to provide incentives for delivery of new needed services (Fig. 3).This evolution partly aims to disconnect remuneration (for dispensing) from the price of medicines (as illustrated in the blue part of the image), meaning that community pharmacy remuneration is less affected by reductions in medicine prices. This is particularly relevant as the decision/negotiation of the medicine price does not involve pharmacists' representatives, although it will affect their remuneration.

As new clinical services are adopted, they may be compensated by a fee for service, a fee for performance (such as when achieving a target in generic substitution in France) or a capitation fee (as for the minor ailment scheme in Scotland, United Kingdom). As noted above, some measures may also be considered to provide (financial) incentives to maintain a network of community pharmacies, especially in areas with weak access to medicines and pharmaceutical expertise (usually rural areas).

Whenever a remuneration model change is considered, it should be based on several considerations. Operation costs for a community pharmacy (to deliver pharmaceutical services) usually include:

- fixed assets (such as stock of medicines, including the capital cost);
- structure (the minimum equipment and premises required for delivery of services and dispensing);
- activities (these costs usually grow with the level of activity and consist, for instance, of staff costs and consumables), as well as investments by and fair remuneration for the owner.

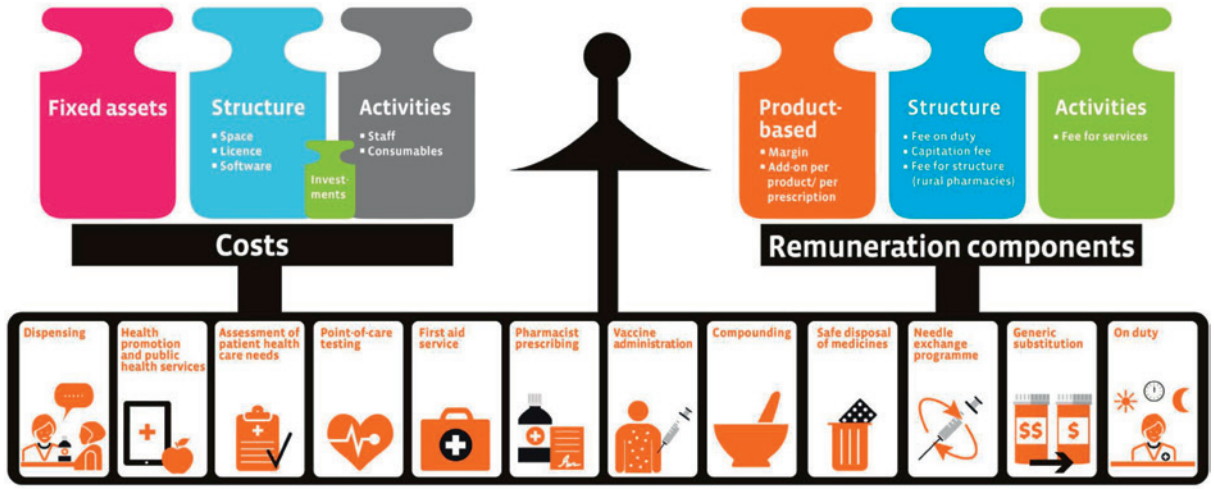
Fig. 3. | **Summary of the most common evolution of community pharmacy remuneration**



Source: adapted from Besançon *(189)*.

Further, the way the community pharmacy is remunerated for services expected from the health authorities may take different formats, as described above. These considerations are summarized in Fig. 4.

Fig. 4. | Overview of considerations for community pharmacy remuneration model



Source: adapted from FIP *(187)*.

The decision about whether to remunerate additional services and activities is often based on evidence on the impact and value of such services. This may come from research done in the country or in other countries. Such studies allow assessment of the impact of new services, their costs and values, providing a solid foundation for determining remuneration.

5. Alternative forms of dispensing medicines

5.1 OTC medicines

OTC medicines are usually defined as medicines that can be dispensed or sold without a prescription. Access to OTC medicines is generally based on the combined effect of two regulations *(110)*:

- existence of a monopoly on dispensing (OTC) medicines in a community pharmacy;
- classification of OTC medicines, for which several approaches – a single category of medicines or multiple categories – are available.

Many countries have adopted a community pharmacy monopoly on dispensing all medicines, such as Belgium, France, Germany, Greece, Malta *(82: article 76)*, Romania *(190)* and Uzbekistan *(111: article 20)*. A few countries have adopted a monopoly with a few exceptions: this is, for instance, the case in Finland, where the community pharmacy monopoly does not include traditional herbal medicinal products, homeopathic products or nicotine replacement products *(36: article 38a)*. Finally, a few countries have allowed the sale of (some) OTC medicines outside community pharmacies *(110)*.

The classification of medicines is usually based on a risk assessment that considers scientific evidence, as well as particularities of the local health care system, population literacy and culture affecting the potential use (and misuse) of OTC medicines *(191)*. The classification may reflect patients' ability (or inability) to select medicines independently *(126)*, age limits (as in Denmark *(192)*) and the premises where medicines can be obtained (especially when the country has not granted a monopoly to community pharmacies).

In a very few countries, such as the Netherlands *(80: article 1.1.qqq)* and Switzerland *(83: article 25)*, health professionals called "druggists" (respectively *drogists* and *droguistes/drogisten/droghisti*) receive dedicated vocational training to sell OTC medicines. They operate independently from any pharmacy or pharmacist. These countries have lists of OTC medicines that can only be sold by a druggist or in a pharmacy.

The Council of Europe has long been concerned with the supply conditions for medicines for human use and the harmonization of national legislation in this field. The availability of medicines with or without a medical prescription has implications for patient safety, accessibility of medicines to patients and responsible management of health care expenditure. Decisions on prescription status and related supply conditions are a core competency of national health authorities. The conditions of the supply of medicines vary considerably in Council of Europe Member States, since the provisions are interpreted and implemented differently by countries, and important additional classification criteria are not harmonized.

In continuing the programme of activities carried out under the aegis of the former Partial Agreement in the Social and Public Health field, the Committee of Experts on the classification of medicines as regards their supply reviews classification practices at the national level and issues recommendations on the classification of medicines and their supply conditions to health authorities of Council of Europe Member States that are parties to the European Pharmacopoeia Convention *(191)*.

If community pharmacies have a monopoly on dispensing medicines, regulators can define access by specifying the following groups of OTC medicines:

- those that can placed for free access for customers in the pharmacy shopping area;
- those that can be placed in an area where customers can see them, but that are available only from pharmacy staff after pharmaceutical consultation;
- those that cannot be placed in an area where customers can see them, but that are available from pharmacy staff without prescription after pharmaceutical consultation.

If there is no community pharmacy monopoly on dispensing medicines, regulators can restrict access to OTC medicines by defining:

- whether OTC medicines can be sold in any premises or whether the setting should be authorized by the authorities (for example, via druggists);
- the categories of OTC medicines that can be sold to all customers or only to customers older than 18 years (or above).

5.2 Online sales of medicines

The dispensing (or sale) of some medicines over the Internet is authorized within the EU, as specified in Directive 2011/62/EU *(193)*.

5.2.1 Types of medicine that can be sold online

Development of sales of OTC medicines over the Internet started in around 2000 in the WHO European Region. For instance, it has been authorized in Sweden since 2002 and in Spain and Ireland since 2006 *(108)*. Further to EU Directive 2011/62/EU, most EU Member States allow the sales of OTC medicines in community pharmacies *(193)* and have usually defined specific rules to protect patient safety.

Some countries have authorized the sale of prescription-only medicines over the Internet, as in Estonia *(1: article 31(5[1]))*, Finland *(36: article 52b(2))*, Germany *(23)*, Sweden *(108)* and Switzerland *(83: article 27)*. Facing potential challenges around the transmission and authentication of a prescription (especially if sent electronically by a patient to an online pharmacy), the e-prescription can offer a technical solution for prescription-only medicines, but this move should be considered from public health, economic and social perspectives.

The public health perspective focuses on:

- technical implementation of the regulation on online sales
- technical possibilities for control of fulfilment of regulatory requirements
- potential risks for the existing pharmacy network and its further development.

The economic perspective includes the following points for consideration:

- potential loss of government revenue from community pharmacy taxes due to turnover reduction if foreign pharmacies are allowed to enter the market;
- potential loss of working places due to related closure of community pharmacies;
- potential risks for national producers of medicines, especially OTC medicines.

The social perspective includes:

- risks of falsified medicines and medicines of insufficient quality;
- access to prescription medicines without prescription;
- risks for patient safety from illegal pharmacies and lack of availability of pharmaceutical consultation;
- restrictions of access to medicines in the case of an emergency due to a reduction in community pharmacy density.

Only a few countries (like Germany) specifically allow mail-order trade in prescription-only medicines from a limited list of other countries in the WHO European Region *(24)*. The potential risks for existing pharmacies and the public health system are unpredictably high, however, as Germany discovered. In 2016 the total share of online sales in the German market was 0.9% for prescription-only and 13% for OTC medicines. According to data from the German Pharmacies Association, further growth in online sales of prescription-only medicines is expected to be 10% in the medium term and up to 25% in the long term *(194)*. Sales of prescription-only medicines represent the largest income source for German pharmacies, and since the introduction of online medicine sales and the entry of foreign pharmacies onto the prescription-only market the number of community pharmacies has decreased continuously, reaching the lowest level of the past 30 years in 2017 *(194)*. The introduction of e-prescribing may also accelerate this process by making it easier to order online medicines.

Whenever an online pharmacy dispenses to a patient established in a different country or jurisdiction than the country of establishment and operation of the online pharmacy, the online pharmacy usually has to comply with the legal requirements of both jurisdictions. Some regulations highlight, for instance, that it is the responsibility of the online pharmacy to ensure that the product is authorized in both countries, as specified in the guidance from the British regulator *(195)*.

Finally, some countries have also excluded (directly or indirectly) medicines from online sales. For instance, in Belgium medicines for veterinary use or compounded at the pharmacy cannot be sold online *(56: article 29)*. In Northern Ireland (United Kingdom), some prescription-only medicines (such as schedule 2 and 3 controlled drugs) cannot be dispensed over the Internet, even with a valid prescription *(196)*.

5.2.2 Requirements for community pharmacies to sell online

5.2.2.1 Activity authorized or declared

In countries that allow the sale of medicines online (from a community pharmacy), this activity is usually subject to either authorization from the regulatory body (prior to starting selling medicines) – as in Germany *(24)*, Estonia *(1: article 31(5[2]))*, France *(26: article R5125-71)* and Switzerland *(83: article 27)* – or notification of the regulatory body by the community pharmacy, as in Belgium *(56: article 29.13)*and Ireland *(197)*. This authorization or notification may be subject to a fee and valid for a limited period (€160 for 12 months in Ireland, for instance *(197)*).

Some countries, including France, prohibit community pharmacies from receiving medicines ordered via brokers and third parties *(26: article L5424-4)*.

5.2.2.2 Processes for dispensing and shipping medicines

In most countries similar requirements to regular dispensing apply when dispensing medicines over the Internet, as in Belgium *(56: article 29.4)* and France *(165)*. In some countries additional requirements are described in a dedicated section of the Good Dispensing Practice guidance, as in Estonia *(198: article 6²)* and France *(165: section 7)*, or in a dedicated document, as in Northern Ireland, United Kingdom *(196)*.

The regulation usually specifies that the process is the responsibility of a pharmacist, as in Belgium *(56: article 29)*, France *(165: section 7.3)* and Great Britain *(195)*. In some countries the regulation specifies that dispensing must be done from community pharmacy premises, as in Belgium *(56: article 29.8)*.

In France no medicine can be dispensed without the opportunity for the patient to interact with a pharmacist. This interaction cannot take place through an automated answer service, as this would not allow the pharmacist to give the patient personalized and relevant advice *(165)*. Likewise, in Estonia free-of-charge individual advice from a pharmacist or a pharmacy technician on the rational and safe use and the preservation of the medicinal product must be ensured in connection with distance sales of medicinal products. Provision of such advice must take place before confirmation of the order *(125: article 12¹(7))*.

Specific requirements may be described to ensure that the delivery will not affect the quality or efficacy of medicines, as in Belgium *(56: article 29.7)*, where the regulation also states that the following information should be included on the medicines and with them in the parcel *(56: articles 29.8 and 29.10)*: medicine labelling, information on the pharmacy, a notice that medicines cannot be sent back (except if defective), the list of pharmaceutical care services offered after dispensing and any information required for their responsible use.

In Estonia the regulation describes the requirements for shipping and the information associated with the parcel extensively. It states that a shipment document must be attached to the parcel and include the following information: the name of the person ordering the product, the order number, the name and contact details of the pharmacy, the business name of the holder of the licence, the name of the person who verified the contents of the parcel and, in the case of a medicinal product subject to prescription, the prescription number *(198: article 6²(3))*. The parcel must include a warning message that the product(s) must not be used if the parcel does not match the order, if it is open or damaged, or if there is any chance that the product may be defective. It must also include a note advising the recipient to read the package leaflet before using the product *(198: article 6²(4))*. Further, the parcel should not bear any reference to a particular medicinal product, and information concerning storage conditions, place of delivery, latest delivery time and the order number must be entered on the parcel in terms that can be understood clearly by the person delivering the products. Until delivery is complete, the pharmacy that issued the products remains responsible for them *(198: article 6²(6))*. Delivery of the package is made to the recipient or a representative appointed by the recipient against their signed receipt or other mark allowing personal identification *(198: article 6²(7))*.

Some countries have defined a standard (maximum) delivery time (which may be adjusted by the patient), such as Belgium, where the parcel must reach the patient within two working days of the order *(56: article 29.9)*. In Estonia the parcel must reach the patient no later than three working days after the order *(1: article 31(5⁵))*.

In France, an order should not exceed one month's treatment under the recommended dosage or full treatment of acute ailments *(165)*.

5.2.2.3 Availability of advice after online dispensing

In most countries pharmacies need to be available for advice after dispensing (usually after the patient has received the medicine), as in Belgium *(56: article 29.7)* and Northern Ireland, United Kingdom *(196)*. In Estonia the online pharmacy website needs to state the options available for receiving advice on medicinal products *(125: article 12¹(4))*.

5.2.3 Requirements for the website

5.2.3.1 Identification of the legitimate websites

In countries where online pharmacy sales are authorized, regulations have adopted tools to help patients identify legitimate and authorized online pharmacies, such as:

- a list of authorized online pharmacies kept up to date by the regulatory body, usually available on its website;
- a logo for authentication of legitimate online pharmacies – within the EU there is a single model for this logo, and when clicking on it the consumer/patient is redirected to the list of authorized online pharmacies, where they can check for the presence of a pharmacy, in line with EU Directive 2011/62/EU *(193, 199)*.

Pharmacies are usually obliged to display the logo and to link it to the list of authorized pharmacies, as in Belgium *(56: article 29.6)* and Great Britain *(195)*.

In the United States of America a different approach is used to identify legitimate pharmacies: use of a dedicated generic top-level domain name, which is the last part of a website address (such as.com,.eu,.int,.de and.fr). The domain name ".pharmacy" is managed by the National Association of Boards of Pharmacy (the association of state regulatory bodies for pharmacy). When an online pharmacy is certified, it can acquire a domain name ending with ".pharmacy" (as with www.walgreens.pharmacy). The certification proof is therefore the address itself, which is much harder to falsify than a logo.

5.2.3.2 Specifications of the website

The website content requirement may be defined thoroughly in the regulation. Some countries allow pharmacies to sell medicines through a portal, as in Northern Ireland, United Kingdom *(196)*, while others require the pharmacy to operate its own website, as in France *(200)*.

5.2.3.2.1 Information about the community pharmacy

In Northern Ireland, United Kingdom, websites must include the following information about the pharmacy: the name of the responsible pharmacist(s) and the phone number, licence number, physical address and name of the pharmacy *(196)*. Similar requirements are implemented in Estonia *(125: article 12[1])* and in Belgium, where the website must also include the pharmacy's opening hours *(56: article 29.6)*.

5.2.3.2.2 Presentation of medicines

In Belgium all OTC medicines marketed on the Belgian market must be listed on the website, even if some are not sold by this community pharmacy's website *(56: article 29.6)*. Moreover, the website must be built in a way that supports rational use of medicines and medical devices, including by presenting products in an objective and non-deceptive manner, without exaggerating their therapeutic properties *(56: article 29.5)*; information extracted from patient leaflets should also be included *(56: article 29.6)*. The price of medicines (all taxes included) and possible delivery fees must also be clearly stated, as well as the validity of the price of medicines and any offers *(56: article 29.6)*.

In France medicines should be presented in a dedicated section/tab, separated from other products sold on the website (such as cosmetics). The EU common logo should only be displayed in this medicines section. Links used in the medicines section may only refer to the institutional websites of health authorities and of pharmacy regulators *(200)*. The regulation lists the information that must be included when presenting a medicine:

- the brand name and international nonproprietary name;
- therapeutic indication(s) as stated in the marketing authorization;

- the dosage form and number of dosage units;
- the price, which must be displayed in the same way for all medicines so that no specific medicine is promoted, and must not be in bold or flashing text;
- a note that information on warnings and precautions, as well as the recommended dosage, are available on the patient leaflet (available in a pdf printable format);
- a link to the summary of product characteristics hosted in the public medicines database or the European Medicines Agency;
- pictures of the packaging, with the same size image for all medicines.

Extracts or simplification of patient leaflets and summaries of product characteristics are not allowed, as this would deprive patients of comprehensive information. Data must be updated regularly *(200)*.

When a patient orders a medicine from a French online pharmacy, consultation of the patient leaflet is compulsory during the ordering process, either by asking the patient to confirm they have read the patient leaflet or by opening a page containing the patient leaflet *(165)*.

In Estonia the website used for distance sale of medicinal products may not display references or links designed to give preference to particular proprietary medicinal products or them to be ordered under anything other than the usual terms and conditions *(125: article 12[1](4))*.

5.2.3.2.3 Patient information and data

In most countries the regulation details the requirements (which may not be specific to pharmacies) to ensure the security of the data collected, especially with regard to patient data, as in Belgium *(56: article 29.3)*, France *(200)*, Great Britain *(195)* and Northern Ireland, United Kingdom *(196)*.

To ensure confidentiality, the French regulation requires that only accredited hosting companies host personal health data (and therefore the website). Exchanges with patients must be secured using ciphering processes *(200)*. Moreover, the French regulation specifies that patients must have access to a section entitled "My account", where all previous orders and communication with pharmacists are available. To create such an account, patients must provide their full name, date of birth and email address *(200)*. Similar requirements apply in Belgium: the pharmacy must ask the patient for contact details, age, gender and any other relevant information *(56: article 29.6)*.

French pharmacies must also ask for specific patient data to validate every order and dispensing. These are collected through an online questionnaire (to be filled in and/or updated by the patient before every dispensing), which includes age, weight, height, gender, current treatment, allergies, counter-indications and, when appropriate, information on pregnancy or breastfeeding *(165)*.

In France the patient can print out all exchanges with the pharmacist. Public discussion forums are not allowed on websites offering medicines, given the potential risks associated with disclosure of patient personal data during discussions *(200)*.

5.2.3.2.4 Language requirements

For multilingual countries (like Belgium) the website must state the language(s) available and explicitly ask the patient's desired language for communication with the pharmacy *(56: article 29.6)*.

In France the regulation states that the content of the website must be provided in French, while translation into other languages may also be available *(200)*.

5.2.3.2.5 Other requirements

In France the domain name of the website should not aim to be promotional, mislead the patient on the content of the website or be whimsical. Inclusion of links to websites of pharmaceutical companies is also forbidden *(200)*.

In Estonia the website needs to include contact information for the State Agency of Medicines, as well as the terms and conditions for ordering and dispensing medicines, including the time required for the confirmation of orders, the methods of delivery of medicinal products and the amount of the shipping fee *(125: article 12[1])*.

French community pharmacies are forbidden to pay to appear in search engines or price comparison sites *(200)*. It is also illegal to require or suggest a minimum purchase: the patient should have the option to buy only one box of medicine *(165: section 7.2)*. Likewise, in Estonia the delivery fee for medicinal products must not vary based on the total amount of the order, the medicines dispensed or the consignments to the client *(1: article 31(5[6]))*.

5.2.4 Overview of online medicine sales

In 2017 FIP made a global study of the ability to sell medicines over the Internet, covering 73 countries and territories. Table 9 provides highlights of the results.

Table 9. | **Global overview of legal framework for online medicine sales**

Type of medicine	Prescription-only medicines	Non-prescription medicines
Available online only through the websites of "bricks and mortar" (physical) community pharmacies	16 countries	14 countries
Available online and not restricted to the websites of physical community pharmacies	11 countries	29 countries
Not available/not allowed online	46 countries	30 countries

Source: FIP *(126)*.

Whenever international comparison is made of the legality of online medicine sales, it is important to also consider the classification of OTC medicines and the monopoly of community pharmacies on OTC medicines; this explains some of the differences observed among countries in the table above.

Beyond the online sale of medicines are multiple hybrid options, such as "click and collect" *(195)*, through which patients can pre-order medicines to be delivered to a local pharmacy from where they can collect in person. In these cases medicines are usually not considered to be sold online (as long as payment is made at the pharmacy when dispensing occurs).

Of the CIS countries, only Kyrgyzstan has adopted legislation covering online sale of medicines as a retail option *(90)*.

Regulators need to pay intensive attention and make strong efforts to define online sales and their objectives, to ensure access to high-quality medicines for patients.

6. Regulatory systems

The regulation and enforcement systems for community pharmacies vary greatly across countries, in terms of the type of regulators and their functions *(201)*.

6.1 Functions of regulators

In each country regulators may be responsible for some (or all) of the following functions related to community pharmacists (and sometimes other pharmacy staff):

- accreditation of the pharmacist's initial education;
- registration/licensing and relicensing of a pharmacist;
- specialization of community pharmacists;
- accreditation of continuing education/CPD;
- defining the rules and standards a community pharmacist must follow (as a responsible pharmacist or as an employee);
- ensuring that the pharmacist complies with the rules (through inspection and disciplinary action, for example) *(201)*.

In a global study covering five professions (medical doctors, pharmacists, nurses, dentists and physiotherapists), of the aggregated respondents the following proportions indicated that health care professional regulators were involved in: registration (96%), discipline (81%), investigation (72%), recertification (70%), regulation of practice guidelines (61%), specialization (by organizing training or granting certification) (53%), accreditation of initial education (45%) and accreditation of continuing education (43%) *(201)*.

The study defined a hierarchy of functions, indicating that across systems of regulation for all professions (including for pharmacists), a clear pattern of the specific functions engaged in by regulators is based on the number of functions in their scope. For example, almost all regulatory bodies – even those that only engage in one or two functions – handle registration. As systems of regulation broaden their scope and undertake additional functions, new responsibilities are generally added in the following order: discipline, investigation and recertification. Only complex regulatory systems covering seven or eight functions are likely to accredit continuing education and to regulate practice guidelines *(201)*.

It appears that some functions are more frequently ensured by certain types of regulator. For instance, discipline, investigation, recertification, regulation of practice guidelines and specialization appear to be more frequently conducted if the regulators include a professional body *(201)*.

In some countries regulation of individuals (pharmacists) and premises (pharmacies) are not performed by the same body. The following functions can be defined for regulation of community pharmacies:

- defining the rules under which a community pharmacy must operate;
- granting authorization to open/operate a pharmacy (usually through a licence for the community pharmacy and/or the pharmacy owner);
- ensuring that the pharmacy is complying with the rules (such as through inspections);
- defining the economic framework for the community pharmacy (for example, agreements for community pharmacy remuneration).

6.2 Regulatory bodies

Several bodies are usually involved in the regulation of community pharmacies (and pharmacists). The starting-point of the regulation is a legal provision, adopted by the national (or local) parliament. Implementation of the legal provision relies on regulatory schemes that are developed and administered by government bodies, like ministries of health or other government agencies (such as a medicines agency), professional bodies (whose governance is mainly ensured by elected members of the profession) or a combination of entities. Table 10 sets out the types of regulator in the WHO European Region for five professions: doctors, pharmacists, nurses, dentists and physiotherapists.

Table 10. | **Types of regulator in the Region**

Identity of the regulator	Number in the Region
Government (e.g. ministry of health or dedicated government agency)	38 (56%)
A combination of entities	13 (20%)
Professional body	14 (20%)
Unknown	3 (4%)
Total number of systems of regulation	68

Source: adapted from Besançon et al. *(201)*.

Across the professions, there is little variation in the type (government, professional body, combination) of regulatory body within the same country. The organization of regulatory bodies differs between federal and non-federal countries. Non-federal countries are more likely to have systems of regulation conducted at the national level than federal countries. In contrast, a large proportion of systems of regulation in federal countries are conducted at the state or provincial level, or a combination of subnational and national levels *(201)*, as in Switzerland *(83)*.

6.2.1 Parliament

Some countries have a single law dedicated to pharmacy, like Slovenia *(32)*, while others have an overarching law on medicines and their distribution, of which pharmacy is a part, as in Malta *(82)*. Others have a series of laws that cover transversal topics, like Switzerland's laws on medical products *(83)* and health professions *(20)*. Finally, countries like France gather the different provisions into a code of health or pharmacy *(26)*.

The value of a single law containing all the legal provisions associated with pharmacy and its practice is that it easier to have a comprehensive overview of the legal framework. It ensures coherence among the different provisions but not necessarily with other provisions (such as medicines). Some countries have very detailed legal provisions; others only provide key general principles, which can be complemented extensively by rules adopted by regulatory bodies and by case law.

6.2.2 Government body

In most countries the ministry of health is involved in the regulation of community pharmacies and pharmacists. It may be the sole regulator or may share this responsibility with other bodies (government or professional bodies).

The internal organization of the ministry of health varies greatly. The regulation of community pharmacies may be the responsibility of the department in charge of pharmaceuticals (and other health care products), or that in charge of health care professions and/or facilities. In many countries the ministry in charge of the university (such as the ministry of higher education) is actively involved in regulation of the initial education of pharmacists. This responsibility is often shared with other regulators like the ministry of health. In some countries regulation of the community pharmacy sector is under the direct responsibility of the medicine agency. This is, for instance, the case in Finland *(36)*.

In Great Britain and Ireland the regulators are dedicated government agencies called the General Pharmaceutical Council and the Pharmaceutical Society of Ireland, respectively. The objectives of the General Pharmaceutical Council are defined as follows *(18: article 6)*:

> *The over-arching objective […] in exercising its functions is the protection of the public.*
>
> *The pursuit by the Council of its over-arching objective involves the pursuit of the following objectives:*
>
> *a) to protect, promote and maintain the health, safety and well-being of the public;*
> *b) to promote and maintain public confidence in the professions regulated under this Order;*
> *c) to promote and maintain proper professional standards and conduct for members of those professions; and*
> *d) to promote and maintain proper standards in relation to the carrying on of retail pharmacy businesses at registered pharmacies.*

It is also noted that the regulator should have proper regard to the interests of people using or needing the services of pharmacists/pharmacies, and the interests of pharmacists and pharmacy technicians, as well as pharmacy owners. The functions of the regulator are *(18: article 4)*:

- to establish and maintain a register of pharmacists, pharmacy technicians and pharmacies;
- to set and promote standards for the safe and effective practice of pharmacy;
- to set requirements by reference to which pharmacists/pharmacy technicians must demonstrate that their fitness to practise is not impaired;
- to promote the safe and effective practice of pharmacy by pharmacists and pharmacy technicians (including, for example, by reference to any code of conduct for, and ethics relating to, pharmacy);
- to set standards and requirements in respect of the education, training, acquisition of experience and CPD;
- to ensure the continued fitness to practise of pharmacists/pharmacy technicians.

Members of the governing body of the General Pharmaceutical Council are all appointed by the government.

The Pharmaceutical Society of Ireland functions in a similar way *(27: article 7)*. The major difference in terms of governance is that nine of the 21 members of its governing bodies are selected by the members of the Society (meaning registered pharmacists), allowing some level of representation of the profession in the governing body *(27: article 10)*.

6.2.3 Professional bodies

A professional (pharmaceutical) body can be defined as an organization in which a majority (or all) of its governing body is elected by pharmacists. In many countries in the WHO European Region a professional body is involved in regulation of the profession, often as the pivotal regulatory body. These are sometimes referred to as "self-governing bodies" but results from the global study covering five professions *(201)* challenge this, as most of the time rules and regulations (including those on the way they operate and their governance) are defined by the ministry of health, other government agencies or parliament (through a dedicated law).

At the global level rules and laws are solely determined by legislation or government decrees in 41% of the cases. Only 35% of professional body-affiliated regulators set their own rules, and 24% use a combination of self-determined and government rules *(201)*. For instance, in Austria the roles, responsibilities, powers and governing rules for the *Österreichische Apothekerkammer* [Austrian Chamber of Pharmacists] are defined in a dedicated law *(202)*; likewise in Portugal for the *Ordem dos Farmacêuticos* [Pharmaceutical Society] *(203)*. In Slovenia, the rules of the professional regulatory body (*Lekarniška zbornica Slovenije*) [Pharmaceutical Chamber of Slovenia] are defined by the Pharmacy Act *(32: articles 95–111)*.

Based on the nature of the country (federal or non-federal), there may be a unique body (as in Slovenia), a federation of local professional regulatory bodies (as in Belgium with the *Ordre des Pharmaciens* [Chamber of Pharmacists], in Germany with the *Bundesapothekerkammer* [Federal Chamber of Pharmacists], in Italy with the *Federazione Ordini Farmacisti Italiani* [Federation of Italian Pharmacists Chambers] and in Spain with the *Consejo General de Colegios Oficiales de Farmaceuticos* [General Council of Official Chambers of Pharmacists]), which may operate under regional/local regulations.

In France the professional regulatory body (*Ordre national des pharmaciens* [National Chamber of Pharmacists]) is made up of several sections (each section includes pharmacists working in the same type of pharmacy practice).[7] In Portugal the *Ordem dos Farmacêuticos* has three geographical sections. The professional regulatory body is allowed to develop its own specific regulations (for instance on implementation of continuing education) *(39)*.

The Order of Pharmacists of Albania *(62)* and Chamber of Pharmacists in Turkey *(48)* are in charge of CPD and certification of pharmacists. In many CIS countries professional bodies, when they exist, have the status of nongovernmental organizations and may not be involved or may not have advisory functions for regulators, as in the Republic of Moldova, the Russian Federation, Ukraine and Uzbekistan. One exception is Kyrgyzstan, where the nongovernmental organization Professional Association of Pharmaceutical Workers of Kyrgyzstan provides CPD and attestation of pharmacists with university and college degrees *(63)*.

[7] For instance, section A includes pharmacy owners; section B pharmacists working in the pharmaceutical industry; section C pharmacists working in wholesalers; section D pharmacists employed in community pharmacies (and other types of practice); section E pharmacists working in overseas departments and territories; section G pharmacists working in clinical biology labs; section H hospital pharmacists.

6.3 Regulation enforcement

6.3.1 Inspection

Inspection is a part of the quality assurance system, which evaluates the fulfilment of legal and regulatory requirements and compliance with professional and/or ethical standards. The primary object of the inspection might be a pharmacy or an individual pharmacist. An inspection of a community pharmacy might be:

- planned before a new community pharmacy opens (as in Iceland *(50)*);
- performed on a regular basis (for example, at least every five years in Austria *(143: article 68)*) or when it is felt appropriate (usually based on a complaint from a patient or a report from a pharmacist or the pharmacy regulator);
- focused on particular pharmacy activity, such as turnover of controlled substances;
- focused on medicines (storage, dispensing or documentation);
- focused on provision of pharmacy services (compliance with GPP standards).

In some countries pharmacy inspectors evaluate selected or all areas of pharmacy practice and may perform unannounced inspections.

The result of the inspection might be granting a licence or renewal of a licence if requirements are met. If the pharmacy does not qualify, an inspector might temporarily or permanently withdraw the licence, or apply disciplinary measures or fines depending on the country. For example, in the United Kingdom the pharmacy regulator (inspectorate) is also responsible for defining disciplinary sanctions *(18: article 8)*. In the Netherlands the Inspectorate for Healthcare and Youth is responsible for inspection of pharmacies and is granted powers to close a pharmacy if the "necessary guarantees for the safe preparation, storage or dispensing of medicines are not met" *(80: article 115.1.c)*.

Other countries have preferred to split the responsibilities, applying the concept of separation of executive and judiciary powers. One body is in charge of the inspection, while another is in charge of disciplinary sanctions, as in France *(26: articles L5127-1–L5127-6)*.

Further, the body charged with the inspection can be in charge of inspection of only community pharmacy, as in the United Kingdom, of the whole pharmaceutical sector (community pharmacy, industry, wholesaler and so on), as in France, or even covering the whole health care sector, as in the Netherlands. Specific provisions may also be defined to prevent pharmacy inspections from being carried out by a relative of the pharmacy owner, as in France *(26: article L5127-6)*.

In the majority of CIS countries the inspectorates are integrated parts of the ministries of health, as in Kazakhstan and Kyrgyzstan, or represent a separate agency, as in Georgia (from 2019) and Ukraine *(94)*. The inspections are carried out before a pharmacy is opened and regularly to renew the licence (every five years) or if the licence requirements change. Some countries have structured networks of regional inspectorates, such as the Russian Federation and Ukraine *(94)*. In others, the lack of trained inspectors and geographical restrictions, as in Georgia and Tajikistan, leaves areas for further improvement.

For implementation of community pharmacy legislation and to ensure compliance with legal and professional standards it is essential to define the inspectorate functions clearly, including types and frequency of inspections, as well as objects of evaluation (for example, quality of pharmacy services). The best practice is to provide inspectors with checklists (as in Ireland). The regulators should define the impact of the results of the inspection precisely to improve objectivity and equality.

6.3.2 Discipline and fines

Most countries define the maximum (and sometimes minimum) penalties faced by an individual who does not comply with the legal and regulatory framework, as well as the obligation to withdraw a licence as the highest disciplinary measure (for more information see section 3.2.2). In all countries the civil and penal judiciary systems are competent to decide on fines, damages and, in the most extreme cases, imprisonment for any individuals and legal entities, whether they are pharmacists, pharmacy owners or others. The fines are usually defined through a (range of) fixed amounts, but they could also be expressed as a percentage of total turnover.

Many countries have also granted the pharmacy regulator disciplinary power towards individuals and entities registered by the regulator. The entity entrusted with disciplinary power is usually specific to pharmacists and can usually decide on a formal warning, an official reprimand, a fine or a temporary or permanent prohibition of pharmacy practice, as in the Netherlands *(24: article 48)*. Additional sanctions may also include the inability of a pharmacist to claim reimbursement for health products and services provided to patients, as in France *(204)*.

Prohibition of pharmacy practice for the pharmacy owner may have other consequences: in countries where pharmacies can only be owned by a (registered) pharmacist, a provision usually defines the maximum duration for which the pharmacy owner/responsible pharmacist can be replaced by another pharmacist. If the prohibition of pharmacy practice is longer than this, the pharmacy owner will have to sell the community pharmacy. Indeed, as mentioned in the Opinion of Advocate General Bot delivered on 16 December 2008 on the Joined Cases C-171/07 and C-172/07: "In addition to the consequences under disciplinary provisions, a pharmacist's professional misconduct puts his economic existence at stake, which is a further inducement for him to give priority to public health requirements in the management of his pharmacy" *(205)*.

The decision of the disciplinary committee can be subject to appeal, through the regulator, as in Great Britain *(18: section 40)* and France *(26: articles R4234-15–R4234-25)*, and/or through the relevant national court, as in Great Britain *(18: section 41)*.

In most countries the disciplinary committee's decision does not need approval from other authorities. In Monaco, however, the most severe sanctions (temporary or permanent suspension of the pharmacist's licence) require publication of an executive order of the ministry of health, based on the recommendation of the disciplinary committee *(57: article 23(2))*. The process guiding disciplinary committee activity (from initiation of the process to implementation of the final decision) is usually described in regulations, as in France *(26: articles R4234-1–R4234-39)*, Great Britain *(18: part 6)*, Israel *(51: articles 56–58)* and the Netherlands *(24: articles 65–74)*.

The composition of the disciplinary committee varies across countries, based on the type of pharmacy regulator. It may be chaired by a professional judge, as in France *(26: articles L4234-3 and L4234-4)* or Israel *(51: article 56b(B)1)*, to ensure that the legal good judiciary processes are followed. In the Netherlands the chair and deputy chairs of the regional disciplinary committees are appointed for life (until they reach the age of 70 years) and are the same across the different health care professions *(24: chapter VII)*.

Accessibility of the decisions of a disciplinary committee varies across countries: decisions may only be visible (and able to be shared) with the public and/or other foreign regulators when they are active (for example, if suspension of a licence is ongoing) or may be permanently accessible.

7. Conclusions

The legal and regulatory framework for community pharmacies in the WHO European Region varies greatly across countries. It is usually defined by a series of legal provisions, either as a single pharmacy law or through a general law (on health or medicines, for example), complemented by a number of technical regulations and specifications defined by the pharmacy regulator (usually the ministry of health).

The framework structure partly reflects the legal system of the country: the civil law approach is predominant in the Region, while the common law approach is used in the United Kingdom and in countries formerly associated with the United Kingdom (such as Cyprus or Ireland), and some countries (like Malta) use a combination of both. Moreover, the framework tends to be influenced by whether the country is a federal state or not. Non-federal countries are more likely than federal countries to have systems of regulation defined and implemented at the national level. In contrast, a large proportion of systems of regulation in federal countries are defined and implemented at the state or provincial level, or a combination of subnational and national levels *(201)*, as in Switzerland *(83)*.

The diversity of the legal and regulatory framework also reflects the specificities of the development of pharmacies and the health care system as a whole, including the challenges they have encountered in the past and what the framework aimed to correct. In some countries, especially those outside the EU, it may also reflect the limited capacity for oversight and regulation of the sector. The legal and regulatory framework usually covers the following fields:

- the pharmacy workforce (pharmacists and, in most cases, pharmacy technicians and other pharmacy staff in contact with patients);
- the pharmacy licence, including ownership requirements;
- pharmacy operations (in terms of premises, processes, workforce and so on);
- the types of service and activities provided in a community pharmacy and the associated remuneration.

Many countries also include provisions supporting the planning of a relevant pharmacy network to ensure universal access to medicines and pharmaceutical expertise. Such provisions may be based on demographic or geographical criteria, or a combination of both. Similarly, some countries allow alternative forms of dispensing (such as dispensing doctors or online medicine sales); the extent of these varies greatly.

Implementation of the legal framework relies on one or several pharmacy regulators, usually including the ministry of health (or a government agency). In many countries it also relies on a professional body with delegated powers and responsibilities from the ministry of health, funded through the licence fee and other sources of incomes.

Overall, the legal and regulatory framework of any country needs internal coherence. Adoption of provisions from other countries will often need to be adapted to the local context and adjusted to the coherence of the national framework. The framework also needs regular revision to adjust to current and future pharmacy practice. Some countries – including Denmark, Estonia, Hungary and Poland – have revised and updated their legislation recently. To be effective, such revisions should be based a strategic approach, aiming to set a series of objectives for the community pharmacy network and to reflect the future and desired roles of community pharmacies in the health care system.

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