P.Z. br. 655

HRVATSKI SABOR

KLASA: 022-03/19-01/93
URBROJ: 65-19-02

Zagreb, 19. lipnja 2019.

ZASTUPNICAMA I ZASTUPNICIMA
HRVATSKOGA SABORA

PREDSJEDNICAMA I PREDSJEDNICIMA
RADNIH TIJELA

Na temelju članaka 178. i 192. a u svezi članka 207.a Poslovnika Hrvatskoga sabora u prilogu upućujem ***Konačni prijedlog zakona o potvrđivanju Konvencije Vijeća Europe o krivotvorenju farmaceutskih proizvoda i sličnim kažnjivim djelima koja uključuju prijetnje javnom zdravlju,*** koji je predsjedniku Hrvatskoga sabora podnijela Vlada Republike Hrvatske, aktom od 19. lipnja 2019. godine.

Za svoje predstavnike, koji će u njezino ime sudjelovati u radu Hrvatskoga sabora i njegovih radnih tijela, Vlada je odredila prof. dr. sc. Milana Kujundžića, dr. med., ministra zdravstva, prim. Željka Plazonića, dr. med. i Tomislava Dulibića, državne tajnike u Ministarstvu zdravstva, te prof. dr. sc. prim. Vilija Beroša, dr. med., pomoćnika ministra zdravstva.

PREDSJEDNIK

Gordan Jandroković

P.Z. br. 655

VLADA REPUBLIKE HRVATSKE

Klasa: **022-03/19-11/34**
Urbroj: **50301-27/20-19-4**

Zagreb, 19. lipnja 2019.

REPUBLIKA HRVATSKA
65 - HRVATSKI SABOR
ZAGREB, Trg Sv. Marka 6

Primljeno: 19-06-2019	
Klasifikacijska oznaka:	Org. jed.
022-03/19-01/93	65
Urudžbeni broj:	Pril. / Vrij.
50-19-01	1 / 0

PREDSJEDNIKU HRVATSKOGA SABORA

Predmet: Konačni prijedlog zakona o potvrđivanju Konvencije Vijeća Europe o krivotvorenju farmaceutskih proizvoda i sličnim kažnjivim djelima koja uključuju prijetnje javnom zdravlju

Na temelju članka 85. Ustava Republike Hrvatske (Narodne novine, br. 85/10 – pročišćeni tekst i 5/14 – Oduka Ustavnog suda Republike Hrvatske) i članka 207.a Poslovnika Hrvatskoga sabora (Narodne novine, br. 81/13, 113/16, 69/17 i 29/18), Vlada Republike Hrvatske podnosi Konačni prijedlog zakona o potvrđivanju Konvencije Vijeća Europe o krivotvorenju farmaceutskih proizvoda i sličnim kažnjivim djelima koja uključuju prijetnje javnom zdravlju.

Za svoje predstavnike, koji će u njezino ime sudjelovati u radu Hrvatskoga sabora i njegovih radnih tijela, Vlada je odredila prof. dr. sc. Milana Kujundžića, dr. med., ministra zdravstva, prim. Željka Plazonića, dr. med. i Tomislava Dulibića, državne tajnike u Ministarstvu zdravstva, te prof. dr. sc. prim. Vilija Beroša, dr. med., pomoćnika ministra zdravstva.

PREDSJEDNIK

mr. sc. Andrej Plenković

VLADA REPUBLIKE HRVATSKE

KONAČNI PRIJEDLOG ZAKONA O POTVRĐIVANJU KONVENCIJE VIJEĆA EUROPE O KRIVOTVORENJU FARMACEUTSKIH PROIZVODA I SLIČNIM KAŽNJIVIM DJELIMA KOJA UKLJUČUJU PRIJETNJE JAVNOM ZDRAVLJU

Zagreb, lipanj 2019.

KONAČNI PRIJEDLOG ZAKONA O POTVRĐIVANJU KONVENCIJE VIJEĆA EUROPE O KRIVOTVORENJU FARMACEUTSKIH PROIZVODA I SLIČNIM KAŽNJIVIM DJELIMA KOJA UKLJUČUJU PRIJETNJE JAVNOM ZDRAVLJU

I. USTAVNA OSNOVA

Ustavna osnova za donošenje ovoga zakona sadržana je u članku 140. stavku 1. Ustava Republike Hrvatske (Narodne novine, br. 85/10 – pročišćeni tekst i 5/14 - Odluka Ustavnog suda Republike Hrvatske).

II. OCJENA STANJA I CILJ KOJI SE DONOŠENJEM ZAKONA ŽELI POSTIĆI

Republika Hrvatska primljena je u Vijeće Europe 6. studenoga 1996. godine, te je prijemom u tu međunarodnu organizaciju pristala promicati ciljeve Vijeća Europe, što uključuje ostvarivanje većeg jedinstva i suradnje između država članica.

Odbor ministara Vijeća Europe usvojio je 28. listopada 2011. godine u Moskvi Konvenciju o krivotvorenju farmaceutskih proizvoda i sličnim kažnjivim djelima koja uključuju prijetnje javnom zdravlju (u daljnjem tekstu: Konvencija) kojom se prvi put, na međunarodnoj razini, krivotvorenje lijekova i medicinskih proizvoda, kao i njihova proizvodnja i stavljanje u promet bez potrebnog odobrenja ili usklađenosti sa sigurnosnim zahtjevima, definiraju kao kaznena djela. Do danas, Konvenciju je potpisalo 14 država, od kojih su 12 države članice Vijeća Europe te je Konvenciju ratificiralo 15 država, od kojih su 12 države članice Vijeća Europe.

Konvencija je prvi međunarodni instrument kaznenog prava koji obvezuje države članice Vijeća Europe da inkriminiraju proizvodnju krivotvorenih lijekova i medicinskih proizvoda, opskrbu, ponudu i promet krivotvorenim lijekovima i medicinskim proizvodima, krivotvorenje dokumenata, proizvodnju, opskrbu i stavljanje u promet lijekova i medicinskih proizvoda bez potrebnih odobrenja ili usklađenosti sa zahtjevima.

Konvencija nudi učinkovitu platformu za zemlje diljem svijeta u identifikaciji mogućih rješenja, razmjeni dobrih praksi i uopće povećanju učinkovitosti svojih nastojanja u kontroli ovoga fenomena te u konačnici boljoj i učinkovitijoj zaštiti pacijenata od krivotvorenih lijekova.

Krivotvorenje lijekova i medicinskih proizvoda te slična kažnjiva djela moraju se kriminalizirati zbog rizika koji predstavljaju za javno zdravlje. Liječenje bolesti se odgađa zbog neučinkovitosti krivotvorenih lijekova i ilegalnih proizvoda te se odgovarajuće liječenje može pokazati beskorisno jer je započeto prekasno. Krivotvoreni lijekovi i slična kažnjiva djela su tihi ubojice jer pacijenti mogu umrijeti od neliječene bolesti kao rezultat neučinkovitog liječenja.

III. OSNOVNA PITANJA KOJA SE PREDLAŽU UREDITI ZAKONOM

S obzirom na sadržaj Konvencije ocjenjuje se korisnim postati njezinom strankom jer se njome osigurava jasan zakonski temelj za međunarodnu suradnju između zdravstvenih i zakonodavnih institucija u borbi protiv krivotvorenja lijekova i medicinskih proizvoda. Konvencija također daje okvir za nacionalnu i internacionalnu suradnju nadležnih tijela zdravstva, policije i carine na nacionalnom i internacionalnom polju, utvrđuje mjere za prevenciju kaznenih djela uključivanjem privatnog sektora i učinkovito procesuiranje krivaca te zaštitu žrtava i svjedoka.

Krivotvorenje lijekova i medicinskih proizvoda te slična kažnjiva djela su međunarodna kaznena djela koja prelaze granice i jurisdikcije pojedinih zemalja, stoga je neophodan međunarodni obvezujući ugovor za zaštitu zdravlja pučanstva.

Vlada Republike Hrvatske je 23. srpnja 2015. godine donijela Odluku o pokretanju postupka za sklapanje Konvencije. Stalni predstavnik Republike Hrvatske pri Vijeću Europe, izvanredni i opunomoćeni veleposlanik Miroslav Papa, dana 3. rujna 2015. godine, u ime Republike Hrvatske potpisao je Konvenciju.

Republika Hrvatska će prilikom polaganja svoje isprave o ratifikaciji kod depozitara na Konvenciju priopćiti rezervu u skladu s člankom 10. stavkom 4. Konvencije.

U članku 10. Konvencije uređena su pravila o nadležnosti za progon kažnjivih djela utvrđenih Konvencijom. Budući da su pravila o nadležnosti u dijelu koji se tiče progona vlastitih državljana i osoba koje imaju prebivalište na njenom državnom području u pravnom poretku Republike Hrvatske različita od onih koja se propisuju samom Konvencijom, ukazuje se potreba na te odredbe izjaviti rezervu. Izjavom rezerve na stavak 1. podstavak d. i stavak 2. članka 10. Konvencije postići će se jednoobraznost u postupanju tijela kaznenog progona Republike Hrvatske neovisno o kažnjivim djelima koja se progone budući će se u postupanju primjenjivati kazneno zakonodavstvo Republike Hrvatske i u njemu propisana rješenja o nadležnosti. Formulacija rezerve je dovoljno općenita da obuhvati i moguće izmjene kaznenog zakonodavstva Republike Hrvatske u budućnosti čime se pridonosi i pravnoj sigurnosti.

IV. OCJENA SREDSTVA POTREBNIH ZA PROVOĐENJE ZAKONA

Za provedbu ovoga zakona nije potrebno osigurati dodatna financijska sredstva u državnom proračunu Republike Hrvatske.

V. ZAKONI KOJIMA SE POTVRĐUJU MEĐUNARODNI UGOVORI

Temelj za donošenje ovoga zakona nalazi se u članku 207.a Poslovnika Hrvatskoga sabora (Narodne novine, br. 81/13, 113/16, 69/17 i 29/18), prema kojemu se zakoni kojima se, u skladu s Ustavom Republike Hrvatske, potvrđuju međunarodni ugovori donose u pravilu u jednom čitanju, a postupak donošenja pokreće se podnošenjem konačnog prijedloga zakona o potvrđivanju međunarodnog ugovora.

KONAČNI PRIJEDLOG ZAKONA O POTVRĐIVANJU KONVENCIJE VIJEĆA EUROPE O KRIVOTVORENJU FARMACEUTSKIH PROIZVODA I SLIČNIM KAŽNJIVIM DJELIMA KOJA UKLJUČUJU PRIJETNJE JAVNOM ZDRAVLJU

Članak 1.

Potvrđuje se Konvencija Vijeća Europe o krivotvorenju farmaceutskih proizvoda i sličnim kažnjivim djelima koja uključuju prijetnje javnom zdravlju, usvojena u Moskvi, 28. listopada 2011. godine, u izvorniku na engleskom i francuskom jeziku, a koju je Republika Hrvatska potpisala 3. rujna 2015. godine.

Članak 2.

Tekst Konvencije iz članka 1. ovoga Zakona, u izvorniku na engleskom jeziku i u prijevodu na hrvatski jezik, glasi:

KONVENCIJA VIJEĆA EUROPE O KRIVOTVORENJU FARMACEUTSKIH PROIZVODA I SLIČNIM KAŽNJIVIM DJELIMA KOJA UKLJUČUJU PRIJETNJE JAVNOM ZDRAVLJU

Preambula

Države članice Vijeća Europe i druge potpisnice ove Konvencije,

uzimajući u obzir kako je cilj Vijeća Europe postići veće jedinstvo među njegovim članicama;

primjećujući da krivotvorenje farmaceutskih proizvoda i slična kažnjiva djela po samoj svojoj prirodi ozbiljno ugrožavaju javno zdravlje;

prisjećajući se Akcijskog plana usvojenog na Trećem sastanku na vrhu šefova država i vlada Vijeća Europe (Varšava, 16. - 17. svibnja 2005.), kojim se preporuča razvoj mjera za jačanje sigurnosti građana Europe;

imajući na umu Opću deklaraciju o ljudskim pravima koju je proglasila Opća skupština Ujedinjenih naroda 10. prosinca 1948., Konvenciju za zaštitu ljudskih prava i temeljnih sloboda (1950., ETS br. 5), Europsku socijalnu povelju (1961., ETS br. 35), Konvenciju o izradi europske farmakopeje (1964., ETS br. 50) i njen Protokol (1989., ETS br. 134), Konvenciju o zaštiti ljudskih prava i dostojanstva ljudskog bića u pogledu primjene biologije i medicine: Konvencija o ljudskim pravima i biomedicini (1997., ETS br. 164) i njezini Dodatni protokoli (1998., ETS br. 168, 2002., ETS br. 186, 2005., CETS br. 195, 2008. CETS br. 203) i Konvenciju o kibernetičkom kriminalu (2001., ETS br. 185);

imajući također na umu i drugi mjerodavan rad Vijeća Europe, prvenstveno odluke Odbora ministara te rad Parlamentarne skupštine, odnosno Rezoluciju AP(2001)2 o ulozi ljekarnika u okviru zdravstvene sigurnosti, odgovor koji je Odbor ministara usvojio 6. travnja 2005. i 26. rujna 2007. godine koji se odnosi na Preporuke Parlamentarne skupštine 1673 (2004.) „Krivotvorenje: problemi i rješenja" i 1794 (2007) „Kakvoća lijekova u Europi", kao i na odgovarajuće programe koje provodi Vijeće Europe;

imajući u vidu druge mjerodavne međunarodne pravne instrumente i programe koje prvenstveno provodi Svjetska zdravstvena organizacija, a naročito rad skupine IMPACT, i Europske unije, kao i foruma G8;

odlučne da na učinkovit način doprinesu postizanju zajedničkog cilja borbe protiv kriminala uključujući krivotvorenje farmaceutskih proizvoda i slična kažnjiva djela koja uključuju prijetnje javnom zdravlju, uvođenjem naročito novih kažnjivih djela i kaznenih sankcija koje se odnose na ta kažnjiva djela;

uzimajući u obzir da je svrha ove Konvencije sprečavanje i borba protiv prijetnji javnom zdravlju, provedba odredaba ove Konvencije koje se odnose na kazneno materijalno pravo mora uzeti u obzir njezinu svrhu i načelo proporcionalnosti;

uzimajući u obzir da se ova Konvencija ne nastoji baviti pitanjima koja se odnose na prava intelektualnog vlasništva;

uzimajući u obzir potrebu za izradom sveobuhvatnog međunarodnog instrumenta koji je usmjeren na aspekte vezane uz sprečavanje, zaštitu žrtava i kazneno pravo u borbi protiv svih oblika krivotvorenja farmaceutskih proizvoda i sličnih kažnjivih djela koja uključuju prijetnje javnom zdravlju te kojim se ustrojava specifičan mehanizam praćenja;

prepoznajući kako je za učinkovitu borbu protiv globalne prijetnje koju predstavlja krivotvorenje farmaceutskih proizvoda i slična kažnjiva djela nužno poticati usku međunarodnu suradnju između država članica Vijeća Europe i država koje nisu članice,

sporazumjele su se kako slijedi:

Poglavlje I. - Cilj i svrha, načelo nediskriminacije, područje primjene, definicije

Članak 1. - Cilj i svrha

1. Svrha ove Konvencije je sprečavanje i borba protiv prijetnji javnom zdravlju:

   a. inkriminiranjem određenih djela;
   b. zaštitom prava žrtava kažnjivih djela utvrđenih u skladu s ovom Konvencijom;
   c. poticanjem nacionalne i međunarodne suradnje.

2. Kako bi se osiguralo da stranke učinkovito provode njezine odredbe, ovom se Konvencijom uspostavlja specifičan mehanizam praćenja.

Članak 2. - Načelo nediskriminacije

Stranke osiguravaju provedbu odredaba ove Konvencije, a posebice uživanje mjera zaštite prava žrtava, bez diskriminacije po bilo kojoj osnovi kao što je spol, rasa, boja, jezik, dob, vjera, političko ili bilo koje drugo mišljenje, nacionalno ili socijalno podrijetlo, pripadnost nacionalnoj manjini, imovina, rođenje, seksualna orijentacija, zdravstveno stanje, invaliditet ili drugi status.

Članak 3. – Područje primjene

Ova Konvencija se odnosi na farmaceutske proizvode, bilo da su isti zaštićeni pravima intelektualnog vlasništva ili ne, da su generički ili ne, uključujući i pribor namijenjen korištenju zajedno s medicinskim proizvodima, kao i djelatne tvari, pomoćne tvari, sastavne dijelove i materijale koji su namijenjeni korištenju u proizvodnji farmaceutskih proizvoda.

Članak 4. - Definicije

Za potrebe ove Konvencije:

a. izraz „farmaceutski proizvod“ znači lijekovi i medicinski proizvodi;

b. izraz „lijek“ znači lijekovi za primjenu kod ljudi i životinja, koji mogu biti:

   i. svaka tvar ili kombinacija tvari prikazana sa svojstvima za liječenje i sprečavanje bolesti kod ljudi ili životinja;

   ii. svaka tvar ili kombinacija tvari koja se može upotrijebiti ili primijeniti na ljudima ili životinjama s ciljem obnavljanja, ispravljanja ili prilagodbe fizioloških funkcija farmakološkim, imunološkim ili metaboličkim djelovanjem, ili za postavljanje medicinske dijagnoze;

   iii. lijek namijenjen za istraživanje i razvoj;

c. izraz „djelatna tvar“ znači svaka tvar ili smjesa tvari namijenjena za proizvodnju lijeka te koja, kada se koristi u proizvodnji lijeka, postaje djelatni sastojak lijeka;

d. izraz „pomoćna tvar“ znači svaka tvar koja nije djelatna tvar ili gotov lijek, već je sastojak lijeka za primjenu kod ljudi ili životinja i ključan je dio cjelovitosti gotovog proizvoda;

e. izraz „medicinski proizvod“ znači svaki instrument, naprava, uređaj, programska podrška, materijal ili drugi predmet, koji je upotrebljen samostalno ili zajedno s nekim drugim predmetom, uključujući i programsku podršku, koju je njegov proizvođač namijenio specifično za dijagnostičke i/ili terapeutske svrhe i koja je nužna za njegovu pravilnu primjenu, namijenjen od proizvođača za uporabu kod ljudi radi:

   i. dijagnosticiranja, sprečavanja, praćenja, liječenja ili ublažavanja bolesti;

   ii. dijagnosticiranja, praćenja, liječenja, ublažavanja ili otklanjanja tjelesnog oštećenja ili nedostatka;

   iii. ispitivanja, nadomještanja ili preinake anatomije ili fiziološkog procesa;

   iv. kontrole začeća;

   te koji svoje glavno namjeravano djelovanje u ili na ljudskom tijelu ne postiže farmakološkim, imunološkim ili metaboličkim učincima, iako njegovo djelovanje može biti potpomognuto takvim učincima;

f. izraz „pribor“ znači proizvod koji nije medicinski proizvod, ali ga je proizvođač izričito namijenio za uporabu s medicinskim proizvodom te tako omogućio korištenje medicinskog proizvoda u skladu s namjenom medicinskog proizvoda koju je odredio proizvođač medicinskog proizvoda;

g. izrazi „sastavni dijelovi" i „materijali" znače svi sastavni dijelovi i materijali izrađeni i namijenjeni za uporabu za medicinske proizvode, a koji su ključan dio njihove cjelovitosti;

h. izraz „dokument" znači svaki dokument koji se odnosi na farmaceutski proizvod, djelatnu tvar, pomoćnu tvar, sastavni dio, materijal ili pribor, uključujući pakiranje, označivanje, upute za uporabu, potvrdu o podrijetlu ili bilo koju drugu popratnu potvrdu, ili koji je na bilo koji drugi način izravno povezan s proizvodnjom i/ili distribucijom istog;

i. izraz „proizvodnja" znači:

   i. u odnosu na lijekove, bilo koji dio postupka proizvodnje lijeka, ili djelatne tvari ili pomoćne tvari takvog lijeka ili dovođenje postupka proizvodnje lijeka, djelatne tvari ili pomoćne tvari u završnu fazu;

   ii. u odnosu na medicinske proizvode, svaki dio procesa proizvodnje medicinskog proizvoda kao i njegovih sastavnih dijelova ili materijala, uključujući dizajniranje medicinskog proizvoda, sastavnih dijelova ili materijala ili dovođenje postupka proizvodnje medicinskog proizvoda, njegovih sastavnih dijelova ili materijala u završnu fazu;

   iii. u odnosu na pribor, svaki dio procesa proizvodnje pribora, uključujući dizajniranje pribora ili dovođenje postupka proizvodnje u završnu fazu;

j. izraz „krivotvorenje" znači neistinito predstavljanje identiteta i/ili izvora;

k. izraz „žrtva" znači svaka fizička osoba koja pati od negativnih fizičkih ili psihičkih posljedica kao rezultat uporabe krivotvorenog farmaceutskog proizvoda ili farmaceutskog proizvoda koji je proizveden, isporučen ili stavljen u promet bez odobrenja ili bez da odgovara uvjetima sukladnosti kako su opisani u članku 8.

Poglavlje II. - Kazneno materijalno pravo

Članak 5. - Proizvodnja krivotvorina

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi utvrdila kao kažnjiva djela prema svojem unutarnjem pravu, namjernu proizvodnju krivotvorenih farmaceutskih proizvoda, djelatnih tvari, pomoćnih tvari, sastavnih dijelova, materijala i pribora.

2. U slučaju lijekova te, po potrebi, medicinskih proizvoda, djelatnih tvari i pomoćnih tvari, stavak 1. primjenjuje se i na krivotvorenje istih.

3. Svaka država ili Europska unija može u vrijeme potpisivanja ili prilikom polaganja svoje isprave o ratifikaciji, prihvatu ili odobrenju izjavom upućenom glavnom tajniku Vijeća Europe izjaviti kako zadržava pravo ne primjenjivati ili primjenjivati samo u posebnim slučajevima ili uvjetima stavak 1. u pogledu pomoćnih tvari, sastavnih dijelova i materijala, te stavak 2. u pogledu pomoćnih tvari.

Članak 6. - Isporuka, nuđenje isporuke i trgovanje krivotvorinama

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi utvrdila kao kažnjiva djela prema svojem unutarnjem pravu, kada su počinjena s namjerom, isporuku ili nuđenje isporuke, uključujući posredovanje, trgovanje, uključujući skladištenje, uvoz i izvoz krivotvorenih farmaceutskih proizvoda, djelatnih tvari, pomoćnih tvari, sastavnih dijelova, materijala i pribora.

2. Svaka država ili Europska unija može u vrijeme potpisivanja ili prilikom polaganja svoje isprave o ratifikaciji, prihvatu ili odobrenju, izjavom upućenom glavnom tajniku Vijeća Europe izjaviti kako zadržava pravo ne primjenjivati ili primjenjivati samo u posebnim slučajevima ili uvjetima stavak 1. u pogledu pomoćnih tvari, sastavnih dijelova i materijala.

Članak 7. - Krivotvorenje dokumenata

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi utvrdila kao kažnjiva djela prema svojem unutarnjem pravu, kada su počinjena s namjerom, izradu lažnih dokumenata ili čin neovlaštene izmjene dokumenata.

2. Svaka država ili Europska unija može u vrijeme potpisivanja ili prilikom polaganja svoje isprave o ratifikaciji, prihvatu ili odobrenju, izjavom upućenom glavnom tajniku Vijeća Europe izjaviti kako zadržava pravo ne primjenjivati ili primjenjivati samo u posebnim slučajevima ili uvjetima stavak 1. u pogledu dokumenata koji se odnose na pomoćne tvari, sastavne dijelove i materijale.

Članak 8. - Slična kažnjiva djela koja uključuju prijetnje javnom zdravlju

Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi utvrdila kao kažnjiva djela prema svojem unutarnjem pravu, kada su počinjena s namjerom, u mjeri u kojoj takva aktivnost nije obuhvaćena člancima 5., 6. i 7., sljedeća djela:

a. proizvodnju, skladištenje za isporuku, uvoz, izvoz, isporuku, nuđenje isporuke ili stavljanje u promet:

   i. lijekova bez dozvole kada je takvo odobrenje potrebno prema unutarnjem pravu stranke; ili

   ii. medicinskih proizvoda koji ne odgovaraju zahtjevima sukladnosti, u slučajevima u kojima je takva sukladnost potrebna prema unutarnjem pravu stranke;

b. komercijalno korištenje izvornih dokumenata izvan okvira onoga za što su bili namijenjeni u legalnom opskrbnom lancu farmaceutskih proizvoda, kako je to određeno unutarnjim pravom stranke.

Članak 9. - Pomaganje ili poticanje i pokušaj

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi utvrdila kao kažnjiva djela kada su počinjena s namjerom pomaganja i poticanja na počinjenje bilo kojeg kažnjivog djela utvrđenog u skladu s ovom Konvencijom.

2. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi utvrdila kao kažnjivo djelo namjerni pokušaj počinjenja bilo kojeg kažnjivog djela utvrđenog u skladu s ovom Konvencijom.

3. Svaka država ili Europska unija može u vrijeme potpisivanja ili prilikom polaganja svoje isprave o ratifikaciji, prihvatu ili odobrenju, izjavom upućenom glavnom tajniku Vijeća Europe izjaviti kako zadržava pravo ne primjenjivati, ili primjenjivati samo u posebnim slučajevima ili uvjetima, stavak 2. u pogledu kažnjivih djela utvrđenih u skladu s člancima 7. i 8.

Članak 10. - Nadležnost

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi uspostavila nadležnost za svako kažnjivo djelo utvrđeno u skladu s ovom Konvencijom, u slučajevima kada je kažnjivo djelo počinjeno:

   a. na njezinom državnom području; ili
   b. na brodu koji plovi pod zastavom te stranke; ili
   c. u zrakoplovu registriranom prema propisima te stranke; ili
   d. od strane njenog državljanina ili osobe koja ima prebivalište na njenom državnom području.

2. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi uspostavila nadležnost za svako kažnjivo djelo utvrđeno u skladu s ovom Konvencijom kada je žrtva kažnjivog djela netko od njezinih državljana ili osoba koja ima prebivalište na njezinom državnom području.

3. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi uspostavila nadležnost za svako kažnjivo djelo utvrđeno u skladu s ovom Konvencijom kada se navodni počinitelj nalazi na njezinom državnom području te ne može biti izručen drugoj stranci zbog njezinog ili njegovog državljanstva.

4. Svaka država ili Europska unija može u vrijeme potpisivanja ili prilikom polaganja svoje isprave o ratifikaciji, prihvatu ili odobrenju, izjavom upućenom glavnom tajniku Vijeća Europe, izjaviti kako zadržava pravo ne primjenjivati ili primjenjivati samo u posebnim slučajevima ili uvjetima pravila o nadležnosti utvrđena stavkom 1. podstavkom d. i stavkom 2. ovoga članka.

5. Kada više od jedne stranke smatra da je nadležno za navodno kažnjivo djelo utvrđeno u skladu s ovom Konvencijom, dotične se stranke savjetuju gdje je primjenjivo, s ciljem određivanja najprikladnije nadležnosti za kazneni progon.

6. Ne dovodeći u pitanje opća pravila međunarodnoga prava, ova Konvencija ne isključuje bilo kakvu kaznenu nadležnost koju stranka ima u skladu sa svojim domaćim pravom.

Članak 11. – Odgovornost pravne osobe

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala da pravne osobe mogu biti odgovorne za kažnjiva djela utvrđena u skladu s ovom Konvencijom, kada ih je počinila bilo koja fizička osoba u njihovu korist, koja se u njoj nalazi na vodećem položaju djelujući samostalno ili kao dio tijela pravne osobe, na temelju:

   a. ovlasti za zastupanje pravne osobe;
   b. ovlasti za donošenje odluka u ime pravne osobe;
   c. ovlasti za provedbu kontrole unutar pravne osobe.

2. Osim slučajeva predviđenih stavkom 1., svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala da pravna osoba može biti odgovorna i kada je nedostatak nadzora ili kontrole od strane fizičke osobe iz stavaka 1. omogućio počinjenje kažnjivog dijela utvrđenog u skladu s ovom Konvencijom u korist te pravne osobe od strane fizičke osobe koja je djelovala pod njenom ovlasti.

3. Podložno pravnim načelima stranke, odgovornost pravne osobe može biti kaznena, građanska ili upravna.

4. Takva odgovornost ne dovodi u pitanje kaznenu odgovornost fizičkih osoba koje su počinile kažnjivo djelo.

Članak 12. - Sankcije i mjere

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala da su kažnjiva djela utvrđena u skladu s ovom Konvencijom kažnjiva učinkovitim, srazmjernim i odvraćajućim sankcijama, uključujući kaznene ili nekaznene novčane kazne, uzimajući u obzir njihovu ozbiljnost. Te sankcije uključuju, za kažnjiva djela utvrđena u skladu s člancima 5. i 6. kada su ih počinile fizičke osobe, kazne koje uključuju lišenje slobode koje može dovesti do izručenja.

2. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala da pravne osobe čija je odgovornost utvrđena u skladu s člankom 11. podliježu učinkovitim, srazmjernim i odvraćajućim sankcijama, uključujući kaznene ili nekaznene novčane kazne, a koje mogu uključivati i druge mjere kao što su:

   a. privremena ili trajna zabrana obavljanja poslovne djelatnosti;
   b. stavljanje pod sudski nadzor;
   c. sudski nalog za likvidaciju.

3. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi:

   a. omogućila zapljenu i oduzimanje:

i. farmaceutskih proizvoda, djelatnih tvari, pomoćnih tvari, sastavnih dijelova, materijala i pribora te roba, dokumenata i drugih instrumenata korištenih u počinjenju kažnjivih djela utvrđenih u skladu s ovom Konvencijom ili radi olakšavanja počinjenja istih;

ii. imovinske koristi ostvarene počinjenjem kažnjivih djela ili imovine čija vrijednost odgovara takvoj imovinskoj koristi;

b. omogućila uništavanje oduzetih farmaceutskih proizvoda, djelatnih tvari, pomoćnih tvari, sastavnih dijelova, materijala i pribora koji su predmet kažnjivog dijela utvrđenog u skladu s ovom Konvencijom;

c. poduzela odgovarajuće mjere kao odgovor na kažnjivo djelo, s ciljem sprečavanja budućih kažnjivih djela.

Članak 13. - Otegotne okolnosti

Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala da sljedeće okolnosti, u mjeri u kojoj one već ne čine sastavne dijelove kažnjivog djela, mogu, u skladu s mjerodavnim odredbama unutarnjeg prava biti uzete u obzir kao otegotne okolnosti pri određivanju sankcija u vezi s kažnjivim djelima utvrđenim u skladu s ovom Konvencijom:

a. kažnjivo djelo je uzrokovalo smrt ili narušavanje fizičkog ili mentalnog zdravlja žrtve;

b. kažnjivo djelo su počinile osobe koje su zlorabile povjerenje koje im je dano u svojstvu stručnjaka;

c. kažnjivo djelo su počinile osobe koje su zlorabile povjerenje koje im je dano kao proizvođačima i isporučiteljima;

d. kažnjiva djela isporuke i nuđenja isporuke počinjena je pribjegavanjem sredstvima široke distribucije, kao što su informacijski sustavi, uključujući i Internet;

e. kažnjivo djelo je počinjeno u okviru zločinačke organizacije;

f. počinitelj je već ranije osuđivan za kažnjiva djela iste prirode.

Članak 14. - Prethodne osude

Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala mogućnost da prilikom određivanja sankcija u obzir budu uzete pravomoćne presude koje je donijela druga stranka, u vezi s kažnjivim djelima iste prirode.

Poglavlje III. - Istraga, kazneni progon i postupovno pravo

Članak 15. - Pokretanje i tijek postupka

Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala da istrage i progon kažnjivih djela utvrđenih u skladu s ovom Konvencijom ne ovise o prijavi te da se postupak može nastaviti čak i u slučaju povlačenja prijave.

Članak 16. – Kaznene istrage

1. Svaka stranka poduzima potrebne mjere kako bi osigurala da su osobe, jedinice ili službe zadužene za kaznene istrage specijalizirane u području borbe protiv krivotvorenja farmaceutskih proizvoda i sličnih kažnjivih djela koja uključuju prijetnje javnom zdravlju ili da su osobe obučene za tu svrhu, uključujući financijske istrage. Takve jedinice ili službe moraju imati odgovarajuća sredstva.

2. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi, u skladu s načelima svog unutarnjeg prava, osigurala učinkovitu kaznenu istragu i progon kažnjivih djela utvrđenih u skladu s ovom Konvencijom, dopuštajući svojim nadležnim tijelima ako je to prikladno, mogućnost provedbe financijskih istraga, tajnih operacija, kontrolirane isporuke i drugih posebnih istražnih tehnika.

Poglavlje IV. - Suradnja tijela i razmjena informacija

Članak 17. - Domaće mjere suradnje i razmjene informacija

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala razmjenu informacija i suradnju predstavnika tijela nadležnih za zdravlje, carine, policije i drugih nadležnih tijela u skladu s domaćim zakonodavstvom s ciljem sprečavanja i učinkovite borbe protiv krivotvorenja farmaceutskih proizvoda i sličnih kažnjivih djela koja uključuju prijetnje javnom zdravlju.

2. Svaka stranka nastoji osigurati suradnju između svojih nadležnih tijela te trgovačkog i industrijskog sektora u pogledu upravljanja rizikom krivotvorenih farmaceutskih proizvoda i sličnih kažnjivih djela koja uključuju prijetnje javnom zdravlju.

3. Uz dužno poštivanje zahtjeva za zaštitom osobnih podataka, svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi uspostavila ili ojačala mehanizme za:

   a. dobivanje i prikupljanje informacija i podataka, putem nadležnog tijela za kontakt, na nacionalnoj ili lokalnoj razini te u suradnji s privatnim sektorom i civilnim društvom, u svrhu sprečavanja i borbe protiv krivotvorenja farmaceutskih proizvoda i sličnih kažnjivih djela koja uključuju prijetnje javnom zdravlju;

   b. stavljanje informacija i podataka koje su prikupila nadležna tijela za zdravlje, carina, policija i druga nadležna tijela na raspolaganje za suradnju među njima.

4. Svaka stranka poduzima potrebne zakonodavne mjere kako bi osigurala da su osobe, jedinice ili službe zadužene za suradnju i razmjenu informacija osposobljene za tu svrhu. Takve jedinice ili službe moraju imati odgovarajuća sredstva.

Poglavlje V. – Mjere za prevenciju

Članak 18. - Preventivne mjere

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi uspostavila zahtjeve kakvoće i sigurnost farmaceutskih proizvoda.

2. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala sigurnu distribuciju farmaceutskih proizvoda.

3. S ciljem sprečavanja krivotvorenja farmaceutskih proizvoda, djelatnih tvari, pomoćnih tvari, sastavnih dijelova, materijala i pribora svaka stranka poduzima potrebne mjere kako bi, između ostaloga, osigurala:

   a. osposobljavanje zdravstvenih radnika, dobavljača, policijskih i carinskih tijela te odgovarajućih regulatornih tijela;

   b. promicanje kampanja za podizanje svijesti usmjerenih prema široj javnosti koje donose informacije o krivotvorenim farmaceutskim proizvodima;

   c. sprečavanje nezakonite nabave krivotvorenih farmaceutskih proizvoda, djelatnih tvari, pomoćnih tvari, sastavnih dijelova, materijala i pribora.

Poglavlje VI. - Mjere zaštite

Članak 19. - Zaštita žrtava

Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi zaštitila prava i interese žrtava, posebice:

a. osiguravanjem da žrtve imaju pristup informacijama koje su mjerodavne za njihov predmet te koje su potrebne za zaštitu njihovog zdravlja;

b. pomaganjem žrtvama u njihovom tjelesnom, psihološkom i socijalnom oporavku;

c. osiguravanjem, u svojem unutarnjem pravu, prava žrtava na naknadu od počinitelja.

Članak 20. - Položaj žrtava u kaznenim istragama i kaznenom postupku

1. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi zaštitila prava i interese žrtava u svim fazama kaznene istrage i postupka, posebice:

   a. obavješćivanjem o njihovim pravima i uslugama koje su im na raspolaganju te, osim u slučajevima kada ne žele primati takve informacije, o poduzetim radnjama povodom njihove prijave, mogućim optužnicama, općem napretku istrage ili postupka te njihovoj ulozi u istima, kao i o ishodu njihovih predmeta;

b. omogućavanjem, na način koji je u skladu s postupovnim pravilima domaćeg prava, da budu saslušane, da podnesu dokaze te da odaberu način na koji će njihova viđenja, potrebe i brige biti iznesene, izravno ili putem posrednika, te razmotrene;

c. pružanjem odgovarajuće usluge podrške kako bi njihova prava i interesi bili dostojno izneseni i uzeti u obzir;

d. pružanjem učinkovitih mjera zaštite njihove sigurnosti, kao i sigurnosti njihovih obitelji i svjedoka u njihovu korist, od zastrašivanja i odmazde.

2. Svaka stranka osigurava da žrtve od prvog kontakta s nadležnim tijelima imaju pristup informacijama o mjerodavnim sudskim i upravnim postupcima.

3. Svaka stranka osigurava žrtvama pristup pravnoj pomoći, koja se pruža bez naknade tamo gdje je to zagarantirano, u slučajevima u kojima postoji mogućnost da imaju status stranaka u kaznenom postupku.

4. Svaka stranka poduzima potrebne zakonodavne i druge mjere kako bi osigurala da žrtve kažnjivog djela utvrđenog u skladu s ovom Konvencijom i počinjenog na državnom području stranke koja nije ona u kojoj prebivaju mogu podnijeti kaznenu prijavu nadležnim vlastima države njihovog prebivališta.

5. Svaka stranka zakonodavnim ili drugim mjerama, u skladu s uvjetima predviđenim domaćim pravom, osigurava skupinama, zakladama, udrugama, vladinim ili nevladinim organizacijama da pružaju pomoć i/ili podršku žrtvama uz njihov pristanak za vrijeme kaznenog postupka u vezi s djelima utvrđenim u skladu s ovom Konvencijom.

Poglavlje VII. - Međunarodna suradnja

Članak 21. - Međunarodna suradnja u kaznenim stvarima

1. Stranke međusobno surađuju u najvećoj mogućoj mjeri, u skladu s odredbama ove Konvencije te sukladno mjerodavnim primjenjivim međunarodnim i regionalnim instrumentima i mehanizmima dogovorenim na temelju jedinstvenog ili uzajamnog zakonodavstva i njihovog domaćeg prava, u svrhu istraga ili postupaka u vezi s kažnjivim djelima utvrđenim u skladu s ovom Konvencijom, uključujući zapljenu i oduzimanje.

2. Stranke međusobno surađuju u najvećoj mogućoj mjeri sukladno mjerodavnim primjenjivim međunarodnim, regionalnim i dvostranim ugovorima o izručenju i uzajamnoj pravnoj pomoći u kaznenim stvarima u vezi s kažnjivim djelima utvrđenim u skladu s ovom Konvencijom.

3. Ako stranka koja uvjetuje izručenje ili uzajamnu pravnu pomoć u kaznenim stvarima postojanjem ugovora zaprimi zahtjev za izručenjem ili pravnom pomoći u kaznenim stvarima od stranke s kojom nema takav ugovor, ona može djelujući u skladu sa svojim obvezama prema međunarodnom pravu te podložno uvjetima predviđenim unutarnjim pravom zamoljene stranke, ovu Konvenciju smatrati pravnim temeljem za

izručenje ili uzajamnu pravnu pomoć u kaznenim stvarima u odnosu na kažnjiva djela utvrđena u skladu s ovom Konvencijom.

Članak 22. - Međunarodna suradnja u sprečavanju i druge upravne mjere

1. Stranke surađuju na zaštiti i pružanju pomoći žrtvama.

2. Ne dovodeći u pitanje svoje unutarnje sustave izvješćivanja, stranke imenuju nacionalno nadležno tijelo za kontakt koje je odgovorno za prosljeđivanje i primanje zahtjeva za informacije i/ili suradnjom u vezi borbe protiv krivotvorenja farmaceutskih proizvoda i sličnih kažnjivih djela koja uključuju prijetnju javnom zdravlju.

3. Svaka stranka nastoji, tamo gdje je to moguće, integrirati sprečavanje i borbu protiv krivotvorenja farmaceutskih proizvoda i sličnih kažnjivih djela koja uključuju prijetnje javnom zdravlju u programe pomoći ili razvoja koji se pružaju u korist trećih država.

Poglavlje VIII. - Mehanizam praćenja

Članak 23. - Odbor stranaka

1. Odbor stranaka sastoji se od predstavnika stranaka Konvencije.

2. Odbor stranaka saziva glavni tajnik Vijeća Europe. Prvi će se sastanak održati unutar razdoblja od jedne godine od stupanja na snagu ove Konvencije za desetu potpisnicu koja ju ratificira. Nakon toga sastaje se kad god to zatraži najmanje jedna trećina stranaka ili glavni tajnik Vijeća Europe.

3. Odbor stranaka usvaja vlastiti poslovnik.

4. Odboru stranaka u obavljanju njegovih dužnosti pomaže Tajništvo Vijeća Europe.

5. Ugovorna stranka koja nije članica Vijeća Europe doprinosi financiranju Odbora stranaka na način o kojem će odlučiti Odbor ministara nakon konzultacija s tom strankom.

Članak 24. - Drugi predstavnici

1. Parlamentarna skupština Vijeća Europe, Europski odbor za probleme kriminala (CDPC) i drugi mjerodavni međuvladini ili znanstveni odbori Vijeća Europe u Odbor stranaka imenuju, svaki od njih, predstavnika kako bi doprinijeli višesektorskom i višedisciplinarnom pristupu.

2. Odbor ministara može pozvati i druga tijela Vijeća Europe da imenuju predstavnika u Odbor stranaka nakon konzultacija s istima.

3. Predstavnici mjerodavnih međunarodnih tijela mogu biti primljeni u Odbor stranaka kao promatrači nakon provedbe postupka utvrđenog mjerodavnim pravilima Vijeća Europe.

4. Predstavnici mjerodavnih službenih tijela stranaka mogu biti primljeni u Odbor stranaka kao promatrači nakon provedbe postupka utvrđenog odgovarajućim pravilima Vijeća Europe.

5. Predstavnici civilnog društva, naročito nevladinih organizacija, mogu biti primljeni u Odbor stranaka kao promatrači nakon provedbe postupka utvrđenog odgovarajućim pravilima Vijeća Europe.

6. Prilikom imenovanja predstavnika iz stavaka 2. do 5., osigurava se ravnomjerna zastupljenost različitih sektora i disciplina.

7. Predstavnici imenovani prema stavcima 1. do 5. sudjeluju na sastancima Odbora stranaka bez prava glasa.

Članak 25. - Dužnosti Odbora stranaka

1. Odbor stranaka prati provedbu ove Konvencije. Poslovnikom Odbora stranaka određuje se postupak za ocjenu provedbe ove Konvencije, primjenom višesektorskog i višedisciplinarnog pristupa.

2. Odbor stranaka također olakšava prikupljanje, analizu i razmjenu informacija, iskustava i dobre prakse među državama s ciljem jačanja njihovih kapaciteta za sprečavanje i borbu protiv krivotvorenja farmaceutskih proizvoda i sličnih kažnjivih djela koja uključuju prijetnje javnom zdravlju. Odbor može koristiti stručnost drugih mjerodavnih odbora i tijela Vijeća Europe.

3. Nadalje, Odbor stranaka, ako je to prikladno:

   a. olakšava učinkovito korištenje i provedbu ove Konvencije, uključujući i utvrđivanje bilo kojih problema i učinaka bilo koje izjave ili rezerve stavljene u skladu s ovom Konvencijom;

   b. izražava mišljenje o bilo kojem pitanju koje se odnosi na primjenu ove Konvencije te olakšava razmjenu informacija o značajnim pravnim, političkim ili tehnološkim dostignućima;

   c. strankama daje specifične preporuke koje se odnose na provedbu ove Konvencije.

4. Europski odbor za probleme kriminala (CDPC) se periodički izvješćuje o aktivnostima spomenutim u stavcima 1., 2. i 3. ovoga članka.

Poglavlje IX. - Odnos prema drugim međunarodnim instrumentima

Članak 26. - Odnos prema drugim međunarodnim instrumentima

1. Ova Konvencija ne utječe na prava i obveze koje proizlaze iz odredaba drugih međunarodnih instrumenata kojih su stranke ove Konvencije stranke ili će postati stranke, a koji sadrže odredbe o pitanjima koja uređuje ova Konvencija.

2. Stranke ove Konvencije mogu međusobno sklapati dvostrane ili mnogostrane ugovore o pitanjima kojima se bavi ova Konvencija, u svrhe dopune ili jačanja njezinih odredaba ili olakšavanja primjene u njoj sadržanih načela.

Poglavlje X. - Izmjene i dopune Konvencije

Članak 27. - Izmjene i dopune

1. Svaki prijedlog za izmjenu i dopunu ove Konvencije koji iznese stranka dostavlja se glavnom tajniku Vijeća Europe, a on ili ona ga prosljeđuje strankama, državama članicama Vijeća Europe, državama nečlanicama koje su sudjelovale u izradi ove Konvencije ili koje uživaju status promatrača u Vijeću Europe, Europskoj uniji i svim državama koje su pozvane da potpišu ovu Konvenciju.

2. Svaka izmjena i dopuna koju predloži stranka dostavlja se Europskom odboru za problem kriminala (CDPC) i drugim mjerodavnim međuvladinim ili znanstvenim odborima Vijeća Europe, koji Odboru stranaka dostavljaju svoja mišljenja o predloženoj izmjeni i dopuni.

3. Nakon razmatranja predložene izmjene i dopune i mišljenja koje je dostavio Odbor stranaka, Odbor ministara može usvojiti izmjenu i dopunu.

4. Tekst izmjene i dopune koji je usvojio Odbor ministara u skladu sa stavkom 3. ovoga članka prosljeđuje se strankama radi prihvaćanja.

5. Svaka izmjena i dopuna usvojena u skladu sa stavkom 3. ovoga članka stupa na snagu prvoga dana mjeseca koji slijedi nakon isteka razdoblja od mjesec dana nakon datuma na koji su sve stranke obavijestile glavnog tajnika Vijeća Europe da su istu prihvatile.

Poglavlje XI. - Završne odredbe

Članak 28. - Potpisivanje i stupanje na snagu

1. Ova Konvencija je otvorena za potpisivanje državama članicama Vijeća Europe, Europskoj uniji i državama nečlanicama koje su sudjelovale u njezinoj izradi ili koje uživaju status promatrača u Vijeću Europe. Ona je također otvorena za potpisivanje po pozivu Odbora ministara bilo kojoj drugoj državi nečlanici Vijeća Europe. Odluka o pozivanju države nečlanice da potpiše Konvenciju donosi se većinom predviđenom člankom 20. d) Statuta Vijeća Europe te jednoglasnim glasovanjem predstavnika država ugovornica koje imaju pravo sjediti u Odboru ministara. Ta se odluka donosi nakon postizanja jednoglasnog dogovora ostalih država/Europske unije koje su izrazile svoj pristanak biti vezane ovom Konvencijom.

2. Ova Konvencija podliježe ratifikaciji, prihvatu ili odobrenju. Isprave o ratifikaciji, prihvatu ili odobrenju polažu se kod glavnog tajnika Vijeća Europe.

3. Ova Konvencija stupa na snagu prvoga dana mjeseca koji slijedi nakon isteka razdoblja od tri mjeseca nakon datuma na koji pet potpisnica, uključujući najmanje tri države članice Vijeća Europe, izrazi svoj pristanak biti vezane Konvencijom, u skladu s odredbama prethodnog stavka.

4. U odnosu na bilo koju državu ili Europsku uniju, koja naknadno izrazi svoj pristanak biti vezana Konvencijom, ona stupa na snagu prvoga dana mjeseca koji slijedi nakon isteka razdoblja od tri mjeseca nakon datuma polaganja njezine isprave o ratifikaciji, prihvatu ili odobrenju.

Članak 29. - Teritorijalna primjena

1. Svaka država ili Europska unija može u vrijeme potpisivanja ili prilikom polaganja svoje isprave o ratifikaciji, prihvatu ili odobrenju odrediti područje ili područja na koja se ova Konvencija primjenjuje.

2. Svaka stranka može bilo kojeg kasnijeg datuma izjavom upućenom glavnom tajniku Vijeća Europe proširiti primjenu ove Konvencije na bilo koje drugo područje određeno u izjavi, a za čije je međunarodne odnose ona odgovorna ili u čije je ime ona ovlaštena preuzimati obveze. U odnosu na takva područja Konvencija stupa na snagu prvoga dana mjeseca koji slijedi nakon isteka razdoblja od tri mjeseca nakon datuma kada glavni tajnik primi takvu izjavu.

3. Svaka izjava dana u skladu s prethodna dva stavka, može se u odnosu na bilo koje područje navedeno u takvoj izjavi, povući obaviješću upućenom glavnom tajniku Vijeća Europe. Povlačenje stupa na snagu prvoga dana mjeseca koji slijedi nakon isteka razdoblja od tri mjeseca nakon datuma kada glavni tajnik primi takvu obavijest.

Članak 30. - Rezerve

1. U odnosu na bilo koju odredbu ove Konvencije ne mogu se staviti rezerve, uz iznimku rezervi koje su izrijekom utvrđene.

2. Svaka stranka koja je stavila rezervu može se u svako doba povući, u cijelosti ili djelomično, obaviješću glavnom tajniku Vijeća Europe. Povlačenje stupa na snagu od datuma kada glavni tajnik primi takvu obavijest.

Članak 31. - Prijateljska nagodba

Odbor stranaka će, u bliskoj suradnji s Europskim odborom za probleme kriminala (CDPC) i drugim mjerodavnim međuvladinim ili znanstvenim odborima Vijeća Europe pratiti primjenu ove Konvencije te, tamo gdje je to potrebno, olakšati prijateljsku nagodbu svih poteškoća vezanih uz njezinu primjenu.

Članak 32. - Otkazivanje

1. Svaka stranka može u svako doba otkazati ovu Konvenciju obaviješću upućenom glavnom tajniku Vijeća Europe.

2. Takvo otkazivanje proizvodi učinak prvoga dana mjeseca koji slijedi nakon isteka razdoblja od tri mjeseca nakon datuma kada glavni tajnik primi obavijest.

Članak 33. - Obavijest

Glavni tajnik Vijeća Europe obavješćuje stranke, države članice Vijeća Europe, države nečlanice koje su sudjelovale u izradi ove Konvencije ili koje uživaju status promatrača u Vijeću Europe, Europsku uniju te sve države koje su pozvane da potpišu ovu Konvencije u skladu s odredbama članka 28. o:

a. svakom potpisivanju;

b. polaganju svake isprave o ratifikaciji, prihvatu ili odobrenju;

c. svakom datumu stupanja na snagu ove Konvencije u skladu s člankom 28.;

d. svakoj izmjeni i dopuni usvojenoj u skladu s člankom 27. te datumu stupanja na snagu takve izmjene i dopune;

e. svakoj rezervi stavljenoj u skladu s člancima 5., 6., 7., 9. i 10. te svakom povlačenju rezerve stavljene u skladu s člankom 30.;

f. svakom otkazivanju izvršenom sukladno odredbama članka 32.;

g. svakom drugom činu, obavijesti ili priopćenju koje se odnosi na ovu Konvenciju.

U potvrdu toga niže potpisani, za to propisno ovlašteni, potpisali su ovu Konvenciju.

Sastavljeno u Moskvi dana 28. listopada 2011., na engleskom i francuskom jeziku, pri čemu su oba teksta jednako vjerodostojna, u jednom primjerku koji se polaže u arhivu Vijeća Europe. Glavni tajnik Vijeća Europe dostavlja ovjerene preslike svakoj državi članici Vijeća Europe, državama nečlanicama koje su sudjelovale u izradi ove Konvencije ili uživaju status promatrača u Vijeću Europe, Europskoj uniji i svakoj državi koja je pozvana potpisati ovu Konvenciju.

COUNCIL OF EUROPE CONVENTION ON THE COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Preamble

The member States of the Council of Europe and the other signatories to this Convention,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members;

Noting that the counterfeiting of medical products and similar crimes by their very nature seriously endanger public health;

Recalling the Action Plan adopted at the Third Summit of Heads of State and Government of the Council of Europe (Warsaw, 16-17 May 2005), which recommends the development of measures to strengthen the security of European citizens;

Bearing in mind the Universal Declaration of Human Rights, proclaimed by the United Nations General Assembly on 10 December 1948, the Convention for the Protection of Human Rights and Fundamental Freedoms (1950, ETS No. 5), the European Social Charter (1961, ETS No. 35), the Convention on the Elaboration of a European Pharmacopoeia (1964, ETS No. 50) and its Protocol (1989, ETS No. 134), the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997, ETS No. 164) and the Additional Protocols thereto (1998, ETS No. 168, 2002, ETS No.186, 2005, CETS No. 195, 2008, CETS No. 203) and the Convention on Cybercrime (2001, ETS No. 185);

Also bearing in mind the other relevant work of the Council of Europe, particularly the decisions of the Committee of Ministers and work of the Parliamentary Assembly, notably Resolution AP(2001)2 concerning the pharmacist's role in the framework of health security, the replies adopted by the Committee of Ministers on 6 April 2005 and on 26 September 2007, concerning respectively, Parliamentary Assembly Recommendations 1673 (2004) on "Counterfeiting: problems and solutions" and 1794 (2007) on the "Quality of medicines in Europe", as well as relevant programmes conducted by the Council of Europe;

Having due regard to other relevant international legal instruments and programmes, conducted notably by the World Health Organisation, in particular the work of the group IMPACT, and by the European Union, as well as in the forum of the G8;

Determined to contribute effectively to the attainment of the common goal of combating crime involving counterfeiting of medical products and similar crimes involving threats to public health, by introducing notably new offences and penal sanctions relative to these offences;

Considering that the purpose of this Convention is to prevent and combat threats to public health, giving effect to the provisions of the Convention concerning substantive criminal law should be carried out taking into account its purpose and the principle of proportionality;

Considering that this Convention does not seek to address issues concerning intellectual property rights;

Taking into account the need to prepare a comprehensive international instrument which is centred on the aspects linked to prevention, protection of victims and criminal law in combating all forms of counterfeiting of medical products and similar crimes involving threats to public health, and which sets up a specific follow-up mechanism;

Recognising that, to efficiently combat the global threat posed by the counterfeiting of medical products and similar crimes, close international co-operation between Council of Europe member States and non-member States alike should be encouraged,

Have agreed as follows:

Chapter I – Object and purpose, principle of non-discrimination, scope, definitions

Article 1 – Object and purpose

1 The purpose of this Convention is to prevent and combat threats to public health by:

a providing for the criminalisation of certain acts;
b protecting the rights of victims of the offences established under this Convention;
c promoting national and international co-operation.

2 In order to ensure effective implementation of its provisions by the Parties, this Convention sets up a specific follow-up mechanism.

Article 2 – Principle of non-discrimination

The implementation of the provisions of this Convention by the Parties, in particular the enjoyment of measures to protect the rights of victims, shall be secured without discrimination on any ground such as sex, race, colour, language, age, religion, political or any other opinion, national or social origin, association with a national minority, property, birth, sexual orientation, state of health, disability or other status.

Article 3 – Scope

This Convention concerns medical products whether they are protected under intellectual property rights or not, or whether they are generic or not, including accessories designated to be used together with medical devices, as well as the active substances, excipients, parts and materials designated to be used in the production of medical products.

Article 4 – Definitions

For the purposes of this Convention:

a the term "medical product" shall mean medicinal products and medical devices;

b the term "medicinal product" shall mean medicines for human and veterinary use, which may be:

i any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;

ii any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

iii an investigational medicinal product;

c the term "active substance" shall mean any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product;

d the term "excipient" shall mean any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product;

e the term "medical device" shall mean any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:

i diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

iii investigation, replacement or modification of the anatomy or of a physiological process;

iv control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

f the term "accessory" shall mean an article which whilst not being a medical device

is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device;

g the terms "parts" and "materials" shall mean all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof;

h the term "document" shall mean any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof;

i the term "manufacturing" shall mean:

i as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;

ii as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;

iii as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state;

j the term "counterfeit" shall mean a false representation as regards identity and/or source;

k the term "victim" shall mean any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8.

Chapter II – Substantive criminal law

Article 5 – Manufacturing of counterfeits

1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.

2 As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof.

3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials, and paragraph 2, as regards excipients.

Article 6 – Supplying, offering to supply, and trafficking in counterfeits

1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories.

2 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials.

Article 7 – Falsification of documents

1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally.

2 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards documents related to excipients, parts and materials.

Article 8 – Similar crimes involving threats to public health

Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7:

a the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:

i medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or

ii medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;

b the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.

Article 9 – Aiding or abetting and attempt

1 Each Party shall take the necessary legislative and other measures to establish as offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention.

2 Each Party shall take the necessary legislative and other measures to establish as an offence the intentional attempt to commit any of the offences established in accordance with this Convention.

3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 2 to offences established in accordance with Articles 7 and 8.

Article 10 – Jurisdiction

1 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the offence is committed:

a in its territory; or
b on board a ship flying the flag of that Party; or
c on board an aircraft registered under the laws of that Party; or
d by one of its nationals or by a person habitually residing in its territory.

2 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the victim of the offence is one of its nationals or a person habitually resident in its territory.

3 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the alleged offender is present in its territory and cannot be extradited to another Party because of his or her nationality.

4 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, the jurisdiction rules laid down in paragraph 1, sub-paragraph d, and paragraph 2 of this article.

5 Where more than one Party claims jurisdiction over an alleged offence established in accordance with this Convention, the Parties concerned shall consult, where appropriate, with a view to determining the most appropriate jurisdiction for prosecution.

6 Without prejudice to the general rules of international law, this Convention shall not exclude any criminal jurisdiction exercised by a Party in accordance with its domestic law.

Article 11 – Corporate liability

1 Each Party shall take the necessary legislative and other measures to ensure that legal persons can be held liable for offences established in accordance with this Convention, when committed for their benefit by any natural person, acting either individually or as part of an organ of the legal person, who has a leading position within it based on:

a a power of representation of the legal person;
b an authority to take decisions on behalf of the legal person;
c an authority to exercise control within the legal person.

2 Apart from the cases provided for in paragraph 1, each Party shall take the necessary legislative and other measures to ensure that a legal person can be held liable where the lack of supervision or control by a natural person referred to in paragraph 1 has made possible the commission of an offence established in accordance with this Convention for the benefit of that legal person by a natural person acting under its authority.

3 Subject to the legal principles of the Party, the liability of a legal person may be criminal, civil or administrative.

4 Such liability shall be without prejudice to the criminal liability of the natural persons who have committed the offence.

Article 12 – Sanctions and measures

1 Each Party shall take the necessary legislative and other measures to ensure that the offences established in accordance with this Convention are punishable by effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, taking account of their seriousness. These sanctions shall include, for offences established in accordance with Articles 5 and 6, when committed by natural persons, penalties involving deprivation of liberty that may give rise to extradition.

2 Each Party shall take the necessary legislative and other measures to ensure that legal persons held liable in accordance with Article 11 are subject to effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, and may include other measures, such as:

a temporary or permanent disqualification from exercising commercial activity;
b placing under judicial supervision;
c a judicial winding-up order.

3 Each Party shall take the necessary legislative and other measures to:

a permit seizure and confiscation of:

i medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with this Convention or to facilitate their commission;

ii proceeds of these offences, or property whose value corresponds to such proceeds;

b permit the destruction of confiscated medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under this Convention;

c take any other appropriate measures in response to an offence, in order to prevent future offences.

Article 13 – Aggravating circumstances

Each Party shall take the necessary legislative and other measures to ensure that the following circumstances, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of domestic law, be taken into consideration as aggravating circumstances in determining the sanctions in relation to the offences established in accordance with this Convention:

a the offence caused the death of, or damage to the physical or mental health of, the victim;

b the offence was committed by persons abusing the confidence placed in them in their capacity as professionals;

c the offence was committed by persons abusing the confidence placed in them as manufacturers as well as suppliers;

d the offences of supplying and offering to supply were committed having resort to means of large scale distribution, such as information systems, including the Internet;

e the offence was committed in the framework of a criminal organisation;

f the perpetrator has previously been convicted of offences of the same nature.

Article 14 – Previous convictions

Each Party shall take the necessary legislative and other measures to provide for the possibility to take into account final sentences passed by another Party in relation to the offences of the same nature when determining the sanctions.

Chapter III – Investigation, prosecution and procedural law

Article 15 – Initiation and continuation of proceedings

Each Party shall take the necessary legislative and other measures to ensure that investigations or prosecution of offences established in accordance with this Convention should not be subordinate to a complaint and that the proceedings may continue even if the complaint is withdrawn.

Article 16 – Criminal investigations

1 Each Party shall take the necessary measures to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.

2 Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

Chapter IV – Co-operation of authorities and information exchange

Article 17 – National measures of co-operation and information exchange

1 Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.

2 Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.

3 With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

a receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

b making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.

4 Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

Chapter V – Measures for prevention

Article 18 – Preventive measures

1 Each Party shall take the necessary legislative and other measures to establish the quality and safety requirements of medical products.

2 Each Party shall take the necessary legislative and other measures to ensure the safe distribution of medical products.

3 With the aim of preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Party shall take the necessary measures to provide, *inter alia*, for:

a training of healthcare professionals, providers, police and customs authorities, as well as relevant regulatory authorities;

b the promotion of awareness-raising campaigns addressed to the general public providing information about counterfeit medical products;

c the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories.

Chapter VI – Measures for protection

Article 19 – Protection of victims

Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims, in particular by:

a ensuring that victims have access to information relevant to their case and which is necessary for the protection of their health;

b assisting victims in their physical, psychological and social recovery;

c providing, in its domestic law, for the right of victims to compensation from the perpetrators.

Article 20 – The standing of victims in criminal investigations and proceedings

1 Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims at all stages of criminal investigations and proceedings, in particular by:

a informing them of their rights and the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the

possible charges, the general progress of the investigation or proceedings, and their role therein as well as the outcome of their cases;

b enabling them, in a manner consistent with the procedural rules of domestic law, to be heard, to supply evidence and to choose the means of having their views, needs and concerns presented, directly or through an intermediary, and considered;

c providing them with appropriate support services so that their rights and interests are duly presented and taken into account;

d providing effective measures for their safety, as well as that of their families and witnesses on their behalf, from intimidation and retaliation.

2 Each Party shall ensure that victims have access, as from their first contact with the competent authorities, to information on relevant judicial and administrative proceedings.

3 Each Party shall ensure that victims have access, provided free of charge where warranted, to legal aid when it is possible for them to have the status of parties to criminal proceedings.

4 Each Party shall take the necessary legislative and other measures to ensure that victims of an offence established in accordance with this Convention committed in the territory of a Party other than the one where they reside can make a complaint before the competent authorities of their State of residence.

5 Each Party shall provide, by means of legislative or other measures, in accordance with the conditions provided for by its domestic law, the possibility for groups, foundations, associations or governmental or non-governmental organisations, to assist and/or support the victims with their consent during criminal proceedings concerning the offences established in accordance with this Convention.

Chapter VII – International co-operation

Article 21 – International co-operation in criminal matters

1 The Parties shall co-operate with each other, in accordance with the provisions of this Convention and in pursuance of relevant applicable international and regional instruments and arrangements agreed on the basis of uniform or reciprocal legislation and their domestic law, to the widest extent possible, for the purpose of investigations or proceedings concerning the offences established in accordance with this Convention, including seizure and confiscation.

2 The Parties shall co-operate to the widest extent possible in pursuance of the relevant applicable international, regional and bilateral treaties on extradition and mutual legal assistance in criminal matters concerning the offences established in accordance with this Convention.

3 If a Party that makes extradition or mutual legal assistance in criminal matters conditional on the existence of a treaty receives a request for extradition or legal

assistance in criminal matters from a Party with which it has no such a treaty, it may, acting in full compliance with its obligations under international law and subject to the conditions provided for by the domestic law of the requested Party, consider this Convention as the legal basis for extradition or mutual legal assistance in criminal matters in respect of the offences established in accordance with this Convention.

Article 22 – International co-operation on prevention and other administrative measures

1 The Parties shall co-operate on protecting and providing assistance to victims.

2 The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.

3 Each Party shall endeavour to integrate, where appropriate, prevention and combating of the counterfeiting of medical products and similar crimes involving threats to public health into assistance or development programmes provided for the benefit of third States.

Chapter VIII – Follow-up mechanism

Article 23 – Committee of the Parties

1 The Committee of the Parties shall be composed of representatives of the Parties to the Convention.

2 The Committee of the Parties shall be convened by the Secretary General of the Council of Europe. Its first meeting shall be held within a period of one year following the entry into force of this Convention for the tenth signatory having ratified it. It shall subsequently meet whenever at least one third of the Parties or the Secretary General so requests.

3 The Committee of the Parties shall adopt its own rules of procedure.

4 The Committee of the Parties shall be assisted by the Secretariat of the Council of Europe in carrying out its functions.

5 A contracting Party which is not a member of the Council of Europe shall contribute to the financing of the Committee of the Parties in a manner to be decided by the Committee of Ministers upon consultation of that Party.

Article 24 – Other representatives

1 The Parliamentary Assembly of the Council of Europe, the European Committee on Crime Problems (CDPC), as well as other relevant Council of Europe intergovernmental or scientific committees, shall each appoint a representative to the

Committee of the Parties in order to contribute to a multisectoral and multidisciplinary approach.

2 The Committee of Ministers may invite other Council of Europe bodies to appoint a representative to the Committee of the Parties after consulting them.

3 Representatives of relevant international bodies may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.

4 Representatives of relevant official bodies of the Parties may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.

5 Representatives of civil society, and in particular non-governmental organisations, may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.

6 In the appointment of representatives under paragraphs 2 to 5, a balanced representation of the different sectors and disciplines shall be ensured.

7 Representatives appointed under paragraphs 1 to 5 above shall participate in meetings of the Committee of the Parties without the right to vote.

Article 25 – Functions of the Committee of the Parties

1 The Committee of the Parties shall monitor the implementation of this Convention. The rules of procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention, using a multisectoral and multidisciplinary approach.

2 The Committee of the Parties shall also facilitate the collection, analysis and exchange of information, experience and good practice between States to improve their capacity to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health. The Committee may avail itself of the expertise of other relevant Council of Europe committees and bodies.

3 Furthermore, the Committee of the Parties shall, where appropriate:

a facilitate the effective use and implementation of this Convention, including the identification of any problems and the effects of any declaration or reservation made under this Convention;

b express an opinion on any question concerning the application of this Convention and facilitate the exchange of information on significant legal, policy or technological developments;

c make specific recommendations to Parties concerning the implementation of this Convention.

4 The European Committee on Crime Problems (CDPC) shall be kept periodically informed regarding the activities mentioned in paragraphs 1, 2 and 3 of this article.

Chapter IX – Relationship with other international instruments

Article 26 – Relationship with other international instruments

1 This Convention shall not affect the rights and obligations arising from the provisions other international instruments to which Parties to the present Convention are Parties or shall become Parties and which contain provisions on matters governed by this Convention.

2 The Parties to the Convention may conclude bilateral or multilateral agreements with one another on the matters dealt with in this Convention, for purposes of supplementing or strengthening its provisions or facilitating the application of the principles embodied in it.

Chapter X – Amendments to the Convention

Article 27 – Amendments

1 Any proposal for an amendment to this Convention presented by a Party shall be communicated to the Secretary General of the Council of Europe and forwarded by him or her to the Parties, the member States of the Council of Europe, non-member States having participated in the elaboration of this Convention or enjoying observer status with the Council of Europe, the European Union, and any State having been invited to sign this Convention.

2 Any amendment proposed by a Party shall be communicated to the European Committee on Crime Problems (CDPC) and other relevant Council of Europe intergovernmental or scientific committees, which shall submit to the Committee of the Parties their opinions on that proposed amendment.

3 The Committee of Ministers, having considered the proposed amendment and the opinion submitted by the Committee of the Parties, may adopt the amendment.

4 The text of any amendment adopted by the Committee of Ministers in accordance with paragraph 3 of this article shall be forwarded to the Parties for acceptance.

5 Any amendment adopted in accordance with paragraph 3 of this article shall enter into force on the first day of the month following the expiration of a period of one month after the date on which all Parties have informed the Secretary General that they have accepted it.

Chapter XI – Final clauses

Article 28 – Signature and entry into force

1 This Convention shall be open for signature by the member States of the Council of Europe, the European Union and the non-member States which have participated in its

elaboration or enjoy observer status with the Council of Europe. It shall also be open for signature by any other non-member State of the Council of Europe upon invitation by the Committee of Ministers. The decision to invite a non-member State to sign the Convention shall be taken by the majority provided for in Article 20.d of the Statute of the Council of Europe, and by unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers. This decision shall be taken after having obtained the unanimous agreement of the other States/European Union having expressed their consent to be bound by this Convention.

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five signatories, including at least three member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of the preceding paragraph.

4 In respect of any State or the European Union, which subsequently expresses its consent to be bound by the Convention, it shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 29 – Territorial application

1 Any State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 30 – Reservations

1 No reservation may be made in respect of any provision of this Convention, with the exception of the reservations expressly established.

2 Each Party which has made a reservation may, at any time, withdraw it entirely or partially by a notification addressed to the Secretary General of the Council of Europe. The withdrawal shall take effect from the date of the receipt of such notification by the Secretary General.

Article 31 – Friendly settlement

The Committee of the Parties will follow in close co-operation with the European Committee on Crime Problems (CDPC) and other relevant Council of Europe intergovernmental or scientific committees the application of this Convention and facilitate, when necessary, the friendly settlement of all difficulties related to its application.

Article 32 – Denunciation

1 Any Party may, at any time, denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 33 – Notification

The Secretary General of the Council of Europe shall notify the Parties, the member States of the Council of Europe, the non-member States having participated in the elaboration of this Convention or enjoying observer status with the Council of Europe, the European Union, and any State having been invited to sign this Convention in accordance with the provisions of Article 28, of:

a any signature;

b the deposit of any instrument of ratification, acceptance or approval;

c any date of entry into force of this Convention in accordance with Article 28;

d any amendment adopted in accordance with Article 27 and the date on which such an amendment enters into force;

e any reservation made under Articles 5, 6, 7, 9 and 10 and any withdrawal of a reservation made in accordance with Article 30;

f any denunciation made in pursuance of the provisions of Article 32;

g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done in Moscow, this 28th day of October 2011, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention or enjoy observer status with the Council of Europe, to the European Union and to any State invited to sign this Convention

Članak 3.

Prilikom polaganja isprave o ratifikaciji Republika Hrvatska priopćit će na Konvenciju iz članka 1. ovoga Zakona sljedeću rezervu:

REZERVA

vezana uz članak 10. stavak 4. Konvencije

U skladu s člankom 10. stavkom 4. Konvencije, Republika Hrvatska zadržava pravo primjenjivati pravila o nadležnosti iz članka 10. stavka 1. podstavka d. i stavka 2. Konvencije pod uvjetima koje propisuje kazneno zakonodavstvo Republike Hrvatske.

Članak 4.

Provedba ovoga Zakona u djelokrugu je središnjih tijela državne uprave nadležnih za poslove zdravstva, unutarnjih poslova, pravosuda, poljoprivrede i financija.

Članak 5.

Na dan stupanja na snagu ovoga Zakona Konvencija iz članka 1. ovoga Zakona nije na snazi za Republiku Hrvatsku, te će se podaci o njezinom stupanju na snagu objaviti sukladno odredbi članka 30. stavka 3. Zakona o sklapanju i izvršavanju međunarodnih ugovora (Narodne novine, broj 28/96).

Članak 6.

Ovaj Zakon stupa na snagu osmoga dana od dana objave u Narodnim novinama.

OBRAZLOŽENJE

Uz članak 1.

Ovim člankom utvrđuje se da Hrvatski sabor potvrđuje Konvenciju u skladu s odredbama članka 140. stavka 1. Ustava Republike Hrvatske i članka 18. Zakona o sklapanju i izvršavanju međunarodnih ugovora, čime se iskazuje formalni pristanak Republike Hrvatske da bude vezana Konvencijom, na temelju čega će taj pristanak biti izražen i na međunarodnoj razini.

Uz članak 2.

Ovaj članak sadrži tekst Konvencije u izvorniku na engleskom jeziku i u prijevodu na hrvatski jezik.

Uz članak 3.

Ovim se člankom utvrđuje rezerva koju će Republika Hrvatska prilikom polaganja isprave o ratifikaciji priopćiti na Konvenciju iz članka 1. ovoga Zakona.

Uz članak 4.

Odredbom ovoga članka određena je nadležnost središnjih tijela državne uprave za provedbu ovoga Zakona.

Uz članak 5.

Ovim se člankom utvrđuje da na dan stupanja na snagu ovoga Zakona Konvencija nije na snazi u odnosu na Republiku Hrvatsku, te će se podaci o njezinom stupanju na snagu objaviti naknadno sukladno odredbi članka 30. stavka 3. Zakona o sklapanju i izvršavanju međunarodnih ugovora.

Uz članak 6.

Odredbom ovoga članka utvrđeno je stupanje na snagu ovoga Zakona.

Prilog:

- preslika teksta Konvencije Vijeća Europe o krivotvorenju farmaceutskih proizvoda i sličnim kažnjivim djelima koja uključuju prijetnje javnom zdravlju, u izvorniku na engleskom jeziku.

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Council of Europe Treaty Series - No. 211

Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health *

Moscow, 28.X.2011

Preamble

The member States of the Council of Europe and the other signatories to this Convention,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members;

Noting that the counterfeiting of medical products and similar crimes by their very nature seriously endanger public health;

Recalling the Action Plan adopted at the Third Summit of Heads of State and Government of the Council of Europe (Warsaw, 16-17 May 2005), which recommends the development of measures to strengthen the security of European citizens;

Bearing in mind the Universal Declaration of Human Rights, proclaimed by the United Nations General Assembly on 10 December 1948, the Convention for the Protection of Human Rights and Fundamental Freedoms (1950, ETS No. 5), the European Social Charter (1961, ETS No. 35), the Convention on the Elaboration of a European Pharmacopoeia (1964, ETS No. 50) and its Protocol (1989, ETS No. 134), the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997, ETS No. 164) and the Additional Protocols thereto (1998, ETS No. 168, 2002, ETS No.186, 2005, CETS No. 195, 2008, CETS No. 203) and the Convention on Cybercrime (2001, ETS No. 185);

Also bearing in mind the other relevant work of the Council of Europe, particularly the decisions of the Committee of Ministers and work of the Parliamentary Assembly, notably Resolution AP(2001)2 concerning the pharmacist's role in the framework of health security, the replies adopted by the Committee of Ministers on 6 April 2005 and on 26 September 2007, concerning respectively, Parliamentary Assembly Recommendations 1673 (2004) on "Counterfeiting: problems and solutions" and 1794 (2007) on the "Quality of medicines in Europe", as well as relevant programmes conducted by the Council of Europe;

Having due regard to other relevant international legal instruments and programmes, conducted notably by the World Health Organisation, in particular the work of the group IMPACT, and by the European Union, as well as in the forum of the G8;

(*) Text corrected in accordance with the Committee of Ministers' decision (1151st meeting of the Ministers' Deputies, 18-19 September 2012).

Determined to contribute effectively to the attainment of the common goal of combating crime involving counterfeiting of medical products and similar crimes involving threats to public health, by introducing notably new offences and penal sanctions relative to these offences;

Considering that the purpose of this Convention is to prevent and combat threats to public health, giving effect to the provisions of the Convention concerning substantive criminal law should be carried out taking into account its purpose and the principle of proportionality;

Considering that this Convention does not seek to address issues concerning intellectual property rights;

Taking into account the need to prepare a comprehensive international instrument which is centred on the aspects linked to prevention, protection of victims and criminal law in combating all forms of counterfeiting of medical products and similar crimes involving threats to public health, and which sets up a specific follow-up mechanism;

Recognising that, to efficiently combat the global threat posed by the counterfeiting of medical products and similar crimes, close international co-operation between Council of Europe member States and non-member States alike should be encouraged,

Have agreed as follows:

Chapter I – Object and purpose, principle of non-discrimination, scope, definitions

Article 1 – Object and purpose

1 The purpose of this Convention is to prevent and combat threats to public health by:

a providing for the criminalisation of certain acts;
b protecting the rights of victims of the offences established under this Convention;
c promoting national and international co-operation.

2 In order to ensure effective implementation of its provisions by the Parties, this Convention sets up a specific follow-up mechanism.

Article 2 – Principle of non-discrimination

The implementation of the provisions of this Convention by the Parties, in particular the enjoyment of measures to protect the rights of victims, shall be secured without discrimination on any ground such as sex, race, colour, language, age, religion, political or any other opinion, national or social origin, association with a national minority, property, birth, sexual orientation, state of health, disability or other status.

Article 3 – Scope

This Convention concerns medical products whether they are protected under intellectual property rights or not, or whether they are generic or not, including accessories designated to be used together with medical devices, as well as the active substances, excipients, parts and materials designated to be used in the production of medical products.

Article 4 – Definitions

For the purposes of this Convention:

a the term "medical product" shall mean medicinal products and medical devices;

b the term "medicinal product" shall mean medicines for human and veterinary use, which may be:

i any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;

ii any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

iii an investigational medicinal product;

c the term "active substance" shall mean any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product;

d the term "excipient" shall mean any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product;

e the term "medical device" shall mean any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:

i diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

iii investigation, replacement or modification of the anatomy or of a physiological process;

iv control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

f the term "accessory" shall mean an article which whilst not being a medical device is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device;

g the terms "parts" and "materials" shall mean all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof;

h the term "document" shall mean any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof;

i the term "manufacturing" shall mean:

i as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;

ii as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;

iii as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state;

j the term "counterfeit" shall mean a false representation as regards identity and/or source;

k the term "victim" shall mean any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8.

Chapter II – Substantive criminal law

Article 5 – Manufacturing of counterfeits

1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.

2 As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof.

3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials, and paragraph 2, as regards excipients.

Article 6 – Supplying, offering to supply, and trafficking in counterfeits

1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories.

2 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials.

Article 7 – Falsification of documents

1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally.

2 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards documents related to excipients, parts and materials.

Article 8 – Similar crimes involving threats to public health

Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7:

a the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:

i medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or

ii medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;

b the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.

Article 9 – Aiding or abetting and attempt

1 Each Party shall take the necessary legislative and other measures to establish as offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention.

2 Each Party shall take the necessary legislative and other measures to establish as an offence the intentional attempt to commit any of the offences established in accordance with this Convention.

3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 2 to offences established in accordance with Articles 7 and 8.

Article 10 – Jurisdiction

1 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the offence is committed:

a in its territory; or
b on board a ship flying the flag of that Party; or
c on board an aircraft registered under the laws of that Party; or
d by one of its nationals or by a person habitually residing in its territory.

2 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the victim of the offence is one of its nationals or a person habitually resident in its territory.

3 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the alleged offender is present in its territory and cannot be extradited to another Party because of his or her nationality.

4 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, the jurisdiction rules laid down in paragraph 1, sub-paragraph d, and paragraph 2 of this article.

5 Where more than one Party claims jurisdiction over an alleged offence established in accordance with this Convention, the Parties concerned shall consult, where appropriate, with a view to determining the most appropriate jurisdiction for prosecution.

6 Without prejudice to the general rules of international law, this Convention shall not exclude any criminal jurisdiction exercised by a Party in accordance with its domestic law.

Article 11 – Corporate liability

1 Each Party shall take the necessary legislative and other measures to ensure that legal persons can be held liable for offences established in accordance with this Convention, when committed for their benefit by any natural person, acting either individually or as part of an organ of the legal person, who has a leading position within it based on:

a a power of representation of the legal person;
b an authority to take decisions on behalf of the legal person;
c an authority to exercise control within the legal person.

2 Apart from the cases provided for in paragraph 1, each Party shall take the necessary legislative and other measures to ensure that a legal person can be held liable where the lack of supervision or control by a natural person referred to in paragraph 1 has made possible the commission of an offence established in accordance with this Convention for the benefit of that legal person by a natural person acting under its authority.

3 Subject to the legal principles of the Party, the liability of a legal person may be criminal, civil or administrative.

4 Such liability shall be without prejudice to the criminal liability of the natural persons who have committed the offence.

Article 12 – Sanctions and measures

1 Each Party shall take the necessary legislative and other measures to ensure that the offences established in accordance with this Convention are punishable by effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, taking account of their seriousness. These sanctions shall include, for offences established in accordance with Articles 5 and 6, when committed by natural persons, penalties involving deprivation of liberty that may give rise to extradition.

2 Each Party shall take the necessary legislative and other measures to ensure that legal persons held liable in accordance with Article 11 are subject to effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, and may include other measures, such as:

a temporary or permanent disqualification from exercising commercial activity;
b placing under judicial supervision;
c a judicial winding-up order.

3 Each Party shall take the necessary legislative and other measures to:

a permit seizure and confiscation of:

i medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with this Convention or to facilitate their commission;

ii proceeds of these offences, or property whose value corresponds to such proceeds;

b permit the destruction of confiscated medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under this Convention;

c take any other appropriate measures in response to an offence, in order to prevent future offences.

Article 13 – Aggravating circumstances

Each Party shall take the necessary legislative and other measures to ensure that the following circumstances, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of domestic law, be taken into consideration as aggravating circumstances in determining the sanctions in relation to the offences established in accordance with this Convention:

a the offence caused the death of, or damage to the physical or mental health of, the victim;

b the offence was committed by persons abusing the confidence placed in them in their capacity as professionals;

c the offence was committed by persons abusing the confidence placed in them as manufacturers as well as suppliers;

d the offences of supplying and offering to supply were committed having resort to means of large scale distribution, such as information systems, including the Internet;

e the offence was committed in the framework of a criminal organisation;

f the perpetrator has previously been convicted of offences of the same nature.

Article 14 – Previous convictions

Each Party shall take the necessary legislative and other measures to provide for the possibility to take into account final sentences passed by another Party in relation to the offences of the same nature when determining the sanctions.

Chapter III – Investigation, prosecution and procedural law

Article 15 – Initiation and continuation of proceedings

Each Party shall take the necessary legislative and other measures to ensure that investigations or prosecution of offences established in accordance with this Convention should not be subordinate to a complaint and that the proceedings may continue even if the complaint is withdrawn.

Article 16 – Criminal investigations

1 Each Party shall take the necessary measures to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.

2 Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

Chapter IV – Co-operation of authorities and information exchange

Article 17 – National measures of co-operation and information exchange

1 Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.

2 Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.

3 With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

a receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

b making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.

4 Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

Chapter V – Measures for prevention

Article 18 – Preventive measures

1 Each Party shall take the necessary legislative and other measures to establish the quality and safety requirements of medical products.

2 Each Party shall take the necessary legislative and other measures to ensure the safe distribution of medical products.

3 With the aim of preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Party shall take the necessary measures to provide, *inter alia*, for:

a training of healthcare professionals, providers, police and customs authorities, as well as relevant regulatory authorities;

b the promotion of awareness-raising campaigns addressed to the general public providing information about counterfeit medical products;

c the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories.

Chapter VI – Measures for protection

Article 19 – Protection of victims

Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims, in particular by:

a ensuring that victims have access to information relevant to their case and which is necessary for the protection of their health;

b assisting victims in their physical, psychological and social recovery;

c providing, in its domestic law, for the right of victims to compensation from the perpetrators.

Article 20 – The standing of victims in criminal investigations and proceedings

1 Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims at all stages of criminal investigations and proceedings, in particular by:

a informing them of their rights and the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the possible charges, the general progress of the investigation or proceedings, and their role therein as well as the outcome of their cases;

b enabling them, in a manner consistent with the procedural rules of domestic law, to be heard, to supply evidence and to choose the means of having their views, needs and concerns presented, directly or through an intermediary, and considered;

c providing them with appropriate support services so that their rights and interests are duly presented and taken into account;

d providing effective measures for their safety, as well as that of their families and witnesses on their behalf, from intimidation and retaliation.

2 Each Party shall ensure that victims have access, as from their first contact with the competent authorities, to information on relevant judicial and administrative proceedings.

3 Each Party shall ensure that victims have access, provided free of charge where warranted, to legal aid when it is possible for them to have the status of parties to criminal proceedings.

4 Each Party shall take the necessary legislative and other measures to ensure that victims of an offence established in accordance with this Convention committed in the territory of a Party other than the one where they reside can make a complaint before the competent authorities of their State of residence.

5 Each Party shall provide, by means of legislative or other measures, in accordance with the conditions provided for by its domestic law, the possibility for groups, foundations, associations or governmental or non-governmental organisations, to assist and/or support the victims with their consent during criminal proceedings concerning the offences established in accordance with this Convention.

Chapter VII – International co-operation

Article 21 – International co-operation in criminal matters

1 The Parties shall co-operate with each other, in accordance with the provisions of this Convention and in pursuance of relevant applicable international and regional instruments and arrangements agreed on the basis of uniform or reciprocal legislation and their domestic law, to the widest extent possible, for the purpose of investigations or proceedings concerning the offences established in accordance with this Convention, including seizure and confiscation.

2 The Parties shall co-operate to the widest extent possible in pursuance of the relevant applicable international, regional and bilateral treaties on extradition and mutual legal assistance in criminal matters concerning the offences established in accordance with this Convention.

3 If a Party that makes extradition or mutual legal assistance in criminal matters conditional on the existence of a treaty receives a request for extradition or legal assistance in criminal matters from a Party with which it has no such a treaty, it may, acting in full compliance with its obligations under international law and subject to the conditions provided for by the domestic law of the requested Party, consider this Convention as the legal basis for extradition or mutual legal assistance in criminal matters in respect of the offences established in accordance with this Convention.

Article 22 – International co-operation on prevention and other administrative measures

1 The Parties shall co-operate on protecting and providing assistance to victims.

2 The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.

3 Each Party shall endeavour to integrate, where appropriate, prevention and combating of the counterfeiting of medical products and similar crimes involving threats to public health into assistance or development programmes provided for the benefit of third States.

Chapter VIII – Follow-up mechanism

Article 23 – Committee of the Parties

1 The Committee of the Parties shall be composed of representatives of the Parties to the Convention.

2 The Committee of the Parties shall be convened by the Secretary General of the Council of Europe. Its first meeting shall be held within a period of one year following the entry into force of this Convention for the tenth signatory having ratified it. It shall subsequently meet whenever at least one third of the Parties or the Secretary General so requests.

3 The Committee of the Parties shall adopt its own rules of procedure.

4 The Committee of the Parties shall be assisted by the Secretariat of the Council of Europe in carrying out its functions.

5 A contracting Party which is not a member of the Council of Europe shall contribute to the financing of the Committee of the Parties in a manner to be decided by the Committee of Ministers upon consultation of that Party.

Article 24 – Other representatives

1 The Parliamentary Assembly of the Council of Europe, the European Committee on Crime Problems (CDPC), as well as other relevant Council of Europe intergovernmental or scientific committees, shall each appoint a representative to the Committee of the Parties in order to contribute to a multisectoral and multidisciplinary approach.

2 The Committee of Ministers may invite other Council of Europe bodies to appoint a representative to the Committee of the Parties after consulting them.

3 Representatives of relevant international bodies may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.

4 Representatives of relevant official bodies of the Parties may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.

5 Representatives of civil society, and in particular non-governmental organisations, may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.

6 In the appointment of representatives under paragraphs 2 to 5, a balanced representation of the different sectors and disciplines shall be ensured.

7 Representatives appointed under paragraphs 1 to 5 above shall participate in meetings of the Committee of the Parties without the right to vote.

Article 25 – Functions of the Committee of the Parties

1 The Committee of the Parties shall monitor the implementation of this Convention. The rules of procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention, using a multisectoral and multidisciplinary approach.

2 The Committee of the Parties shall also facilitate the collection, analysis and exchange of information, experience and good practice between States to improve their capacity to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health. The Committee may avail itself of the expertise of other relevant Council of Europe committees and bodies.

3 Furthermore, the Committee of the Parties shall, where appropriate:

a facilitate the effective use and implementation of this Convention, including the identification of any problems and the effects of any declaration or reservation made under this Convention;

b express an opinion on any question concerning the application of this Convention and facilitate the exchange of information on significant legal, policy or technological developments;

c make specific recommendations to Parties concerning the implementation of this Convention.

4 The European Committee on Crime Problems (CDPC) shall be kept periodically informed regarding the activities mentioned in paragraphs 1, 2 and 3 of this article.

Chapter IX – Relationship with other international instruments

Article 26 – Relationship with other international instruments

1 This Convention shall not affect the rights and obligations arising from the provisions of other international instruments to which Parties to the present Convention are Parties or shall become Parties and which contain provisions on matters governed by this Convention.

2 The Parties to the Convention may conclude bilateral or multilateral agreements with one another on the matters dealt with in this Convention, for purposes of supplementing or strengthening its provisions or facilitating the application of the principles embodied in it.

Chapter X – Amendments to the Convention

Article 27 – Amendments

1 Any proposal for an amendment to this Convention presented by a Party shall be communicated to the Secretary General of the Council of Europe and forwarded by him or her to the Parties, the member States of the Council of Europe, non-member States having participated in the elaboration of this Convention or enjoying observer status with the Council of Europe, the European Union, and any State having been invited to sign this Convention.

2 Any amendment proposed by a Party shall be communicated to the European Committee on Crime Problems (CDPC) and other relevant Council of Europe intergovernmental or scientific committees, which shall submit to the Committee of the Parties their opinions on that proposed amendment.

3 The Committee of Ministers, having considered the proposed amendment and the opinion submitted by the Committee of the Parties, may adopt the amendment.

4 The text of any amendment adopted by the Committee of Ministers in accordance with paragraph 3 of this article shall be forwarded to the Parties for acceptance.

5 Any amendment adopted in accordance with paragraph 3 of this article shall enter into force on the first day of the month following the expiration of a period of one month after the date on which all Parties have informed the Secretary General that they have accepted it.

Chapter XI – Final clauses

Article 28 – Signature and entry into force

1 This Convention shall be open for signature by the member States of the Council of Europe, the European Union and the non-member States which have participated in its elaboration or enjoy observer status with the Council of Europe. It shall also be open for signature by any other non-member State of the Council of Europe upon invitation by the Committee of Ministers. The decision to invite a non-member State to sign the Convention shall be taken by the majority provided for in Article 20.d of the Statute of the Council of Europe, and by unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers. This decision shall be taken after having obtained the unanimous agreement of the other States/European Union having expressed their consent to be bound by this Convention.

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five signatories, including at least three member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of the preceding paragraph.

4 In respect of any State or the European Union, which subsequently expresses its consent to be bound by the Convention, it shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 29 – Territorial application

1 Any State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 30 – Reservations

1 No reservation may be made in respect of any provision of this Convention, with the exception of the reservations expressly established.

2 Each Party which has made a reservation may, at any time, withdraw it entirely or partially by a notification addressed to the Secretary General of the Council of Europe. The withdrawal shall take effect from the date of the receipt of such notification by the Secretary General.

Article 31 – Friendly settlement

The Committee of the Parties will follow in close co-operation with the European Committee on Crime Problems (CDPC) and other relevant Council of Europe intergovernmental or scientific committees the application of this Convention and facilitate, when necessary, the friendly settlement of all difficulties related to its application.

Article 32 – Denunciation

1 Any Party may, at any time, denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 33 – Notification

The Secretary General of the Council of Europe shall notify the Parties, the member States of the Council of Europe, the non-member States having participated in the elaboration of this Convention or enjoying observer status with the Council of Europe, the European Union, and any State having been invited to sign this Convention in accordance with the provisions of Article 28, of:

a any signature;

b the deposit of any instrument of ratification, acceptance or approval;

c any date of entry into force of this Convention in accordance with Article 28;

d any amendment adopted in accordance with Article 27 and the date on which such an amendment enters into force;

e any reservation made under Articles 5, 6, 7, 9 and 10 and any withdrawal of a reservation made in accordance with Article 30;

f any denunciation made in pursuance of the provisions of Article 32;

g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done in Moscow, this 28th day of October 2011, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention or enjoy observer status with the Council of Europe, to the European Union and to any State invited to sign this Convention.