

Detection and Investigation of Counterfeit Medical Products in Slovenia*

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Abstract: This article provides insights into the detection, investigation and prosecution of counterfeit medical products in Slovenia and abroad. The article summarizes the reports of Interpol and the European Union's activities in this area. It also uses the opinions and insights of experts in the field provided through interviews. While the scope of the problem surrounding counterfeit medical products has been increasing globally, the issue is not alarming in Slovenia. Counterfeit medical products (CFMP) were never found to enter the legal supply chain in Slovenia. In general, the incidence of counterfeit medical products in the scope of detection, investigation and prosecution is extremely low. The reasons for this may be in the ongoing debates about the definition of CFMPs and the continuing lack of public awareness about counterfeit medical products. If the public does not understand or even know about counterfeit medical products, they will fail to report potential encounters with them, thus making their detection even more

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difficult. The research study presented in this paper has (partly) confirmed that a sound and socially-oriented healthcare system in which the required medicines are widely available represents a deterrent against counterfeit medical products. Therefore, the legislative framework supporting such a system is most important.

Keywords: counterfeit medical products, detection, investigation, prosecution.

Suklastotų medicinos gaminių aptikimas ir tyrimas Slovėnijoje

Santrauka: Šiame straipsnyje pateikiamos išvalgos apie suklastotų medicinos gaminių aptikimą, tyrimą ir baudžiamąjį persekiojimą už juos Slovėnijoje ir kitose valstybėse. Straipsnyje apibendrinamos Interpolo ir Europos Sąjungos veiklos šioje srityje ataskaitos, taip pat naudojamos šios srities ekspertų nuomonės ir išvalgos, pateiktos šio straipsnio autorių atliktų interviu metu. Nors su suklastotais medicinos gaminiiais susijusios problemos mastas visame pasaulyje didėja, Slovėnijoje ši problema nesulaukio didelio dėmesio. Nebuvo rasta suklastotų medicinos gaminių, kurie patektų į legalaus tiekimo grandinę. Apskritai suklastotų medicinos gaminių aptikimo, tyrimo ir baudžiamojo persekiojimo apimtys yra labai mažos. To priežastys gali būti susijusios su vykstančiomis diskusijose dėl suklastotų medicinos gaminių apibrėžimo ir nuolatinio visuomenės informuotumo apie juos trūkumu. Jei visuomenė nesupranta ar net nežino apie suklastotus medicinos gaminius, ji nepraneš apie galimus susidūrimus su jais, todėl juos aptikti bus dar sunkiau. Šiame straipsnyje pateiktas tyrimas (iš dalies) patvirtino, kad patikima ir socialiai orientuota sveikatos priežiūros sistema, kurioje reikalingi vaistai yra plačiai prieinami, galėtų būti veiksminga atgrasymo priemonė suklastotų medicinos gaminių prekybai. Todėl svarbu vystyti tokią sistemą palaikančią teisinę bazę.

Pagrindiniai žodžiai: suklastoti medicinos gaminiai, suklastotų gaminių aptikimas, baudžiamasis tyrimas

Introduction

The consumption of pharmaceuticals is on the rise.¹ While the increased consumption of pharmaceuticals is, on one hand, linked to health-related issues of an ageing population (OECD, 2017), on the other hand, neoliberal consumerism propagates unneeded consumption, including the purchase of various products that, by using miraculous method(s), make a person generally and overall “better” (Kanduč, 2013). Because the demand is quite high and thus makes the

¹ This is evident from the data available at the OECD.Stat (2019) database, which shows an increasing trend in the use of almost every category of pharmaceuticals.

pharmaceutical market attractive, increased numbers of people are trying to profit from that demand. As a result, this flood of legitimate medical products,² legitimate food and dietary supplements, as well as genuine cosmetic and beauty products, also encompasses a segment of providers of counterfeit medicines, counterfeit medical products or/and counterfeit or/and harmful dietary supplements products, as well as harmful cosmetic and beauty products. Since the legitimate and legal market is extensive, illegal providers are able to hide easily.³ Numerous providers market and sell numerous products, among which there are products that are genuine in terms of their chemical composition, however, their origin is questionable or misrepresented. They provide products that are presented as genuine, albeit their chemical composition is not. The origin of ingredients may also be unsuitable. Products may use improper, recycled or counterfeit packaging (Hall & Antonopoulos, 2016; Harper & Gellie, 2006).

Products may be genuine, yet they may be not allowed to be sold on a specific market as they have not yet been properly registered and/or approved or are prescription-only medical products, etc. As a result, buyers seek other methods of acquiring them. The variety of combinations also affects the terminology that is used for labelling such products (Dégardin, Roggo, & Margot, 2014; World Health Organization [WHO], 2017). However, there are two predominant terms that are used, i.e. counterfeit medical products and falsified medical products. The first category includes products that represent an infringement of intellectual property rights, while the second category contains products that represent a health risk to consumers due to the improper mixture, quantity or quality of medical product components, its production, transportation, storage or any other reason (Lee et al., 2017; Planinšek, 2019). While the differentiation is important, in many cases, the term counterfeit medical product [henceforth: CFMP] is used to cover both categories. Following the example by Lee et al. (2017), the CFMP abbreviation is used in this paper for both counterfeit and falsified medical products, and when the discussion does not require any differentiation between them.

² Since reports (Interpol, 2016, 2017) indicate that apart from medicines, medical devices and health-related products are also subject to counterfeiting, the researchers decided to use the term *medical products* (MPs) instead of the term *medicines*.

³ As the COVID-19 pandemic shows, criminal actors were quick to abuse the global unease and try to generate profit by selling counterfeit medical products that would supposedly prevent or alleviate the symptoms of infection or could be used in the treatment against COVID-19 (Europol, 2020).

TABLE 1: Data about Interpol's Pangea operation (source: Europol 2014; Federal Agency for Medicines and Health Products, 2019; Interpol, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018b, 2019, 2020)

Year	Operation	Operation date	Number of participating countries ^a	Seized CFMP ^{a,b}	Type of seized CFMP ^{a,b}	Assessment of the value of seized CFMPs (in US\$)	Number of arrests	Number of closed-down web-sites ^a
2020	Pangea XIII	3–10 Mar 2020	90	4.4 million units	<i>Erectile dysfunction pills, anti-cancer medication, hypnotic and sedative agents, anabolic steroids, painkillers, nervous system agents, vitamins, surgical masks, "corona" spray, coronavirus packages, and coronavirus medicine, etc.</i>	14 million	121	2500
2019	Pangea XII	Jun–Jul 2019	In 2019, there was no international Pangea action week as over the years it became too predictable. In this year, operation Pangea collected and analysed annual data to raise awareness and to plan the next operation.					
2018	Pangea XI	9–16 Oct 2018	116	10 million units (almost one million packages inspected)	<i>Anti-inflammatory medication, painkillers, erectile dysfunction pills, anabolic steroids, slimming pills, medicines for treating HIV, Parkinson's and diabetes, contact lenses, hearing aids, etc.</i>	14 million	859	3671
2017	Pangea X	12–19 Sep 2017	123	25 million (some 715,000 packages were inspected)	<i>Dietary supplements, pain reduction pills, epilepsy medication, erectile dysfunction pills, anti-psychotic medication, nutritional products, contact lenses, condoms, syringes, etc.</i>	51 million	400	3584
2016	Pangea IX	30 May–7 Jun 2016	103	12.2 million (some 334,000 packages were inspected)	<i>Slimming pills, anti-malarial and cholesterol medication, erectile dysfunction pills, hair loss treatments, illicit anti-cancer medication, sleeping pills, pregnancy tests, etc.</i>	53 million	393	4932

Year	Operation	Operation date	Number of participating countries ^a	Seized CFMP ^b	Type of seized CFMP ^b	Assessment of the value of seized CFMPs (in US\$)	Number of arrests	Number of closed down web-sites ^a
2015	Pangea VIII	9–16 Jun 2015	115	20.7 million (some 150,000 packages were inspected)	Blood pressure pills, erectile dysfunction pills, cancer medication and nutritional supplements.	81 million	156	2414
2014	Pangea VII	13–20 May 2014	111	9.6 million	Weight loss pills, cancer drugs, erectile dysfunction pills, cholesterol medication, cough and cold medication, antimalarials, etc.	36 million	237	10,600
2013	Pangea VI	18–27 Jun 2013	Some 100 countries	9.8 million (some 522,000 packages were inspected)	Antibiotics, cancer medication, anti-depression pills, food supplements and erectile dysfunction medication.	41 million	58	more than 9000
2012	Pangea V	25 Sep–2 Oct 2012	100	3.75 million (some 133,000 packages were inspected)	Anti-cancer medication, antibiotics, erectile dysfunction pills, slimming and food supplements.	10.5 million	79	18,000
2011	Pangea IV	20–27 Sep 2011	81	2.4 million (some 45,500 packages were inspected)	Antibiotics, steroids, anti-cancer, anti-depression and anti-epileptic pills, slimming or food supplement pills.	6.3 million	55	almost 13,500
2010	Pangea III	5–12 Oct 2010	45	1 million (some 268,000 packages were inspected)	Antibiotics, steroids, anti-cancer, anti-depression and anti-epileptic pills, slimming or food supplement pills.	2.6 million	76	290
2009	Pangea II	16–20 Nov 2009	24	167,000 (more than 16,000 packages were inspected)	Antibiotics, steroids and slimming pills.	/	22	72
2008	Pangea I	12 Nov 2008	10	/	... relating to Internet sites believed to be selling unlicensed or prescription-only medicines claiming to treat conditions, such as diabetes, obesity and hair loss.	/	/	/

^a CFMP – counterfeit medical product.

^b Text in italics is a direct citation from Interpol websites.

CFMPs may enter legal supply chains and/or are sold on the illegal market. The extent of the issues revolving around CFMPs is reflected in global statistics. For instance, data deriving from Interpol activities, most notably its Pangea operations (Table 1), show the global extent of the problem, while data from the European Commission (Table 2) show the status within the European Union. Table 1 shows one more concerning issue. Among confiscated CFMPs there are often products used for weight loss, muscle mass gain and overall improved sports performance. Doping is a highly dangerous, complex, but lucrative illegal business. Donati's (2007) report shows that products used in doping are manufactured in Pakistan, India or China, which are also the countries that are among the biggest producers of CFMP (OECD/EUIPO, 2017; Parfitt, 2006). The ambiguity of legislation pertaining to criminal prosecutions of persons involved in doping substances trafficking, evident in some countries (Donati, 2007), is similar to issues of legislation relating to prosecuting crimes relating to CFMP. Both doping and CFMP trafficking are linked to other "classical" illegal drug trafficking, as indicated in the report written by Donati (2007) since traffickers often use the same trafficking routes, modus operandi, are even the same perpetrators and, of late, are highly relayed on the internet for these sort of activities.

The internet is perhaps the most frequently used tool to purchase genuine or CFMPs (Europol, 2017; Hall & Antonopoulos, 2016; Interpol, 2018a; Leontiadis & Hutchings, 2015; Orsolini et al., 2015; WHO, 2018), although not all studies confirm this assumption (Festinger et al., 2016; Inciardi et al., 2010). Studies about the online sale of medical products (henceforth: MPs) indicate that one of the reasons why people decide to buy them over the internet – apart from reasons of convenience – is also related to the price of MPs and the sense of anonymity (Crawford, 2003; Hall & Antonopoulos, 2016; Orsolini et al., 2015). Perpetrators aim to reach as many buyers as possible; therefore, most of the sales "are carried out in the surface web (reachable by conventional search engines)" (Lavorgna, 2015: 234).

The purpose of this paper is to investigate the prevalence of the CFMP and its detection, investigation and prosecution in Slovenia, since all neighbouring countries, i.e. Austria (Interpol, 2016; Taylor, 2017), Hungary (XpatLoop, 2018), Italy (Agenzia Italiana del Farmaco, 2017; Gaudio et al., 2012) and Croatia (Tomić et al., 2010), also report about confiscated CFMPs.

TABLE 2: Statistics from the Reports on the EU Customs Enforcement of Intellectual Property Rights – Results at the EU Border (source: European Commission, 2011, 2012, 2013, 2014, 2015a, 2015b, 2017, 2018, 2019)

	2010	2011	2012	2013	2014 ^a	2015	2016	2017	2018
ALL CATEGORIES									
Detention cases	79,112	91,245	90,473	90,473	95,194	81,098	63,184	57,433	69,354
Procedures	-	-	-	-	105,488	95,313	77,705	74,706	89,873
No. of articles	103,306,928	114,772,812	39,917,445	35,940,294	35,568,982	40,728,675	41,387,132	31,410,703	26,720,827
Retail value (EUR)	1,110,052,402	1,272,354,795	896,891,786	768,227,929	617,046,337	642,108,323	672,899,102	585,142,267	738,125,867
MEDICINES AND OTHER PRODUCTS (condoms)									
Detention cases	1,812	2,494	2,530	1,175	-	-	-	-	-
Procedures	-	-	-	-	1,052	2	1,968	1,835	829
No. of articles	3,200,492	27,460,538	712,220	3,690,876	2,804,569	895,324	392,037	568,122	822,399
Retail value (EUR)	26,617,882	27,638,540	8,152,653	11,974,020	3,983,128	12,392,626	4,498,898	6,909,674	2,094,508

^a From 2014 onwards, a modified – more precise – reporting is used, which includes “the number of procedures that were initiated by customs. Each detention is referred to as a ‘case’ that may contain one or more articles. Each case may contain articles of different product categories and from different right-holders.” (European Commission, 2015a: 8).

CFMPs in Slovenia

Slovenia is susceptible to the risks posed by CFMPs due to the fact that it is positioned on the Balkan trafficking route, that it is strongly connected to global markets, that it is part of the Schengen area, and that its citizens have excellent access to information–communication technology (ICT) and good Internet coverage/access (European Commission, n.d.). Back in 2006, studies have already shown that the internet was gaining popularity when it came to the purchasing of legal and illegal MPs (Harper & Gellie, 2006). While some research (e.g., Festinger et al., 2016; Inciardi et al., 2010) shows that the internet is not always the predominant method for acquiring prescription-only medicines without such a prescription, the experts (e.g., Hall & Antonopoulos, 2016; Leontiadis & Hutchings, 2015; Orsolini et al., 2015), institutional reports and publications (Interpol, 2013, 2015, 2018a; WHO, 2018), as well as law enforcement agency (henceforth: LEA) reports (Europol, 2017) predominantly conclude that most CFMPs are sold and bought online. The EU is also aware of this issue and has already started regulating the sale of MPs on the internet by mandating its Member States to develop policy and legislation regulating the online sale of MPs. The EU also helped in developing preventive measures, such as the introduction of a security logo that aims to show the legitimacy of an online website (Commission implementing regulation (EU) No 699/2014, 2014).

Slovenian legislation, which follows EU regulations, allows for nonprescription MPs to be sold online. Pharmacies or specialised retailers must obtain a licence for the online sale of MPs and are entered in a register published by the Ministry of Health on its website. They need to display a security logo, which contains a hyperlink to the aforementioned register. Buyers may – by clicking on the logo – verify if the online retailer is legitimate. Though some initial errors with registering pharmacies allowed to sell MPs online in Slovenia were present initially (Frangež & Slak, 2016), these irregularities were subsequently repaired.

The Slovenian Police participate in Interpol operations against illicit online sale of medicines and MPs (Interpol 2018a), however, the overall research interest in CFMP-related issues is rather limited and unsystematic in Slovenia. To investigate the issue of CFMPs more holistically, a research study was designed, which investigated several immensely intertwined scopes of issues related to CFMPs (online CFMP buying/selling in Slovenia; CFMP detection,

investigation and prosecution; and CFMP prevention). Research on the online CFMP buying/selling in Slovenia was presented in Frangež and Slak (2016), while the overview and status of Slovenian law enforcement in terms of investigating of CFMP-related crimes was presented in Miklič (2019). This paper presents additional research which examines how police and other institutions tackle CFMPs in Slovenia.

LEAs often rely on the successful work of others when it comes to CFMPs. Courier services, customs, etc. are usually the ones that are most often first to come into contact with the shipments of CFMPs, while inspection services are normally the ones detecting unregulated online sales or other irregularities in the formal markets. When CFMPs are discovered, the LEAs or prosecutors need experts from the field of medicine and pharmaceuticals to investigate and prosecute crimes related to CFMPs properly.

Research Methods

We conducted interviews to examine how police and other actors in Slovenia were prepared and motivated to tackle CFMPs. In March 2018, a letter was sent to 31 institutions that were selected based on a literature review and the experience of investigators, who were part of the research team (see Miklič, 2019). A request for cooperation was also sent to a further three institutions that were identified through additional research and in the scope of already completed interviews or were suggested by those who declined their participation in the interview. 34 letters were sent in total and recipients included eleven district state prosecutor's offices, eleven district courts, the Customs Administration and the Supervision Administration, which are both part of the Financial Administration of the Republic of Slovenia, the Post of Slovenia, the Market Inspectorate of the Republic of Slovenia, the Healthcare Directorate, the Slovenian Intellectual Property Office, the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, the Health Inspectorate of the Republic of Slovenia, the Centre for Clinical Toxicology and Pharmacology, the Port of Koper, the National Institute of Public Health and a department of the University Medical Centre Ljubljana.

The researchers received 20 negative replies to the requests, five positive ones, while nine institutions did not respond. These were then contacted by telephone to investigate whether the letter had been received and why they decided

not to reply. In most cases, the response from the courts and prosecutors' offices was negative merely because they had not (yet) encountered any cases involving counterfeit medicines in their work. In one case, a court reported that the person who tried a case involving counterfeit medicines no longer worked there, and in one case the proceedings were still ongoing, which is why an interview could not be conducted. Other institutions most commonly answered that their actual field of work did not cover the area of counterfeit medicines and that they were also not encountered in the scope of their work. One interviewee, who initially confirmed the participation, was not interviewed as, after a closer inspection of the attached questionnaire, he believed not to have sufficient experience. In the end, three structured interviews were conducted. Two individuals were participating in all three interviews. The interviews were audio-recorded, transcribed and analysed (using the Atlas.ti software). On average, the interviews lasted one hour. The information on the interviews is presented in Table 3 below.

TABLE 3: Structure of interviews

Inter-view No.	No. of participants	Institution	Interviewee code ^a
1	2	Prosecution	Prosecution 1
			Prosecution 2
2	2	Financial Administration of the Republic of Slovenia [FARS] ^b	Fars 1
			Fars 2
3	2	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia [AMPD]	Ampd 1
			Ampd 2
Total No.:	6	3	6

^a In order to protect the anonymity of interviewees, no other data are provided and the male gender form is used in this paper regardless of the actual or preferred gender of the interviewee.

^b FARS combines both the Customs and the Tax Administration; however, when sending the requests for cooperation, an interlocutor from the Customs Administration and the Supervision Administration was sought, and both Administrations were invited separately. Nevertheless, interviewees from both Administrations were interviewed together.

The National Institute of Public Health declined their cooperation in the study, however, its reply consisted of a letter containing 398 words, the content of which was found suitable for qualitative analysis. Their letter was included in the analysis, and is coded as "NIPH".

Results

CFMP detection in Slovenia

The Customs Administration of the Financial Administration of the Republic of Slovenia (hereinafter: CA-FARS) is considered the primary actor in charge of tackling CFMPs. The interviews conducted with FARS staff, who are part of the CA-FARS, clearly show that they recognise the importance of the role they play. They tackle CFMPs independently or in tandem with other institutions, bodies, agencies and companies. Most notably they do it with the Post of Slovenia and particularly with the Slovenian Police, when they detect a shipment indicating that a crime was potentially committed, is taking place or will be committed (e.g., when the size of the detected shipment of CFMPs indicates that further trafficking is likely to take place). The detection of shipments relies on following the necessary procedures that are used by customs offices worldwide, on using proper tools (e.g., risk assessment tools) and pooling (exchanging) information between countries. While the Fars 1 interviewee stated that he has limited-to-none field experience, the Fars 2 interviewee reported having more insight and stated that experience gathered on the job is crucial for a successful detection of problematic shipments.

FARS provided statistical data (Table 4) that shows a relatively low number of detention cases involving medicines.

Similarly, low numbers of CFMP cases were reported from the AMPD and the prosecutor's offices. The former reports that their employees have never encountered a CFMP in the legal supply chain and that they come across very few cases even in the informal market. However, they attribute this to the fact that they are rarely informed about such cases from other actors or the general population. More cases are identified with respect to the marketing of CFMPs, where websites selling them are often found; however – according to the Ampd 1 – the search for such websites is not conducted systematically. Interviewees see the internet as the predominating channel for selling and purchasing CFMPs. They were informed that some CFMPs containing ingredients for the treatment of erectile dysfunctions had been sold to minors. The AMPD themselves find many examples of advertisements promoting certain products, including those that could be classified as counterfeit medicines. The legislative framework of the AMPD does not provide for a proper reaction to

TABLE 4: Slovenian customs statistics of detention cases

	2012	2013	2014	2015	2016	2017	2018 ^a	First half of 2019 ^a
ALL CATEGORIES								
Detention cases	555	1,334	4,053	2,669	1,089	746	435	259
No. of articles	830,867	198,340	506,460	3,188,323	1,289,706	196,930	701,048	202,760
Retail value (EUR)	4.3 million	18.9 million	12.5 million	28.9 million	4.9 million	4 million	51 million	4.5 million
MEDICINES								
Detention cases	35	57	34	44	21	11	none ^b	none ^b
No. of articles	1,749	4,818	4,152	2,198	676	272		
Retail value (EUR)	8,745	138,090	21,060	10,990	3,500	1,930		

^a The data for 2018 and 2019 were provided in a follow-up query. In the initial interview, data were only provided for the 2012–2017 period.

^b The employees of the General Financial Office of the CA-FARS provided the following explanation about zero detected cases: “The number of detentions has decreased in the recent years due to the effects of the newly adopted Medicinal Products Act, which prohibits the import or export of medicines by individuals in Slovenia”.

the identified advertisements, since advertising inspection is in the domain of other inspectorates and agencies. According to the Ampd 2 interviewee, other countries have a much better and sophisticated system of monitoring and responding to such advertisements, which means that they are also more successful in closing down websites promoting and selling counterfeit medicines. Such a low detection rate is, in turn, reflected in the workload of prosecutors (explicit statement made by Prosecution 1). The interviewed prosecutors report that they received up to five cases related to CFMPs in the 2005–2018 period. One case went to trial, and resulted in a conviction. No evidence of a crime could be found in other cases. The prosecutor’s offices have not yet encountered any cases where CFMPs would be detected in the legal supply chain.

Interviewees from prosecutor's offices and the AMPD emphasised the need for some kind of an awareness-raising campaign, while the NIPH stated it was motivated to cooperate in such campaigns.

CFMP investigation in Slovenia

A multidisciplinary approach and cooperation are essential when investigating CFMPs, as was underlined in all interviews. Interviewees from the AMPD explained that they cooperate with the CA-FARS daily, mainly in assessing the legality and to conduct verifications of imported products. This was confirmed in the interviews conducted with the FARS, who listed the AMPD and the Slovenian Police as the most common partners. Prosecutors cooperate with the Police, which is logical, as well as with the AMPD and the Market Inspectorate of the Republic of Slovenia. Paradoxically, the Market Inspectorate of the Republic of Slovenia refused to participate in the study stating that it "does not have the authority to supervise the detection and investigation of counterfeit medicinal products", and this was the task of other actors. This paradox was not explored further – it was marked as the lack of motivation to partake in academic research or as miscommunication. Cooperation is important, also because the CA-FARS may conduct undercover purchases with a lesser burden of proof than the Slovenian Police. According to the Ampd 2, some examples of good practices derive from their cooperation with the CA-FARS, and the fact that the latter may enter the investigation as an undercover buyer.

Cooperation, in general, could go even further, as the interviewed prosecutors expressed their interest in obtaining statistical data regarding seizures or work carried out by the AMPD, the CA-FARS and others, even if these cases were not referred to the Police or the prosecutor's office. The interviewed prosecutors have not yet cooperated with private companies. The AMPD stated that overall cooperation could be slightly more formalised. International cooperation is useful for information sharing, albeit none of the cases encountered by the interviewees required international cooperation. In terms of cooperation regarding the issues of prevention, it was reported that awareness-raising was lacking.

One of the critical questions, which were recognised in the preliminary inquiry into the investigation of CFMPs (also discussed in Miklič, 2019), is who among the LEAs should be in charge of investigating CFMP-related crimes.

Interviewees were asked to categorise CFMP-related crimes according to the type of criminality (e.g., organised crime, economic crime, etc.). While the Fars 1 interviewee listed crimes related to CFMPs as offences linked to organised crime, it was explained that the majority of shipments they discovered were low scale and that the detected CFMPs were ordered by individuals, which is why no evidence of organised crime involvement could be found. However, the whole process of the production, sale and shipment has certain traits of organised crime. The opinion of the AMPD was similar, as the Ampd 2 interviewee reported that their fellow (including CA-FARS) inspectors received threats, and therefore recognised that CFMP-related crimes were carried out by criminal groups.

CFMP prosecution in Slovenia

The interviewed prosecutors commented that the criminal legislation regulating CFMPs should be amended. Most notably, the problem lies in the criminalisation of CFMP trafficking. The current legislation is suitable for prosecuting individuals, whose conduct within the MPs legal supply chain endangers people's health, however, it does not properly criminalise the trafficking in CFMP on the illegal market. More specifically, it lacks the definition of the concept "harmful to human health" in relation to CFMPs. The FARS also made a similar observation, as the Fars 2 interviewee suggested that the criminal legislation should be more precise in explaining what exactly is meant when the phrase "harmful to human health" is used in the relevant Article of the Criminal Code criminalising the production of and trafficking in harmful medicines. The Ampd 2 interviewee also reported a similar experience. The interviewed prosecutors thus made a recommendation to amend the legislation by inserting a new article or amending the current ones, so that they would follow the example of drug trafficking and criminalise CFMP trafficking in a similar manner (to include possession, criminalise marketing, intention to sell, etc.).

It is generally believed that the legislation covering the work of the CA-FARS is, according to the Fars 1 interviewee, suitable and that they do not wish to gain more powers. The AMPD has already been working on the amendments to their legislation, as well as the rules used by other inspection services with respect to websites. Only a limited number of inspections services

in Slovenia has the power to shut down websites, and many of them have no competences in CFMP-related topics. The interviewees also share the view that the legislation regulating the legal supply chain is suitable. According to the Fars 2 interviewee, the low number of CFMP occurrences in Slovenia may partly also be attributed to the well-established, public and socially-oriented healthcare system.

The Ampd 1 interviewee observes that Slovenia's small size is a beneficial preventive factor, as Slovenia represents a small market for CFMPs, however, this also means that legal producers are not interested in importing to the Slovenian market. Thus, some medicines are not officially available and are perhaps sought on unofficial markets. Slovenia also does not (yet) use parallel imports. However, interviewees also agreed that the situation regarding (food) supplements is even more problematic, and warned that they remain a grey area. According to the Ampd 2, some products that are declared as supplements contain ingredients that are part of medical products and thus represent a health hazard. There is a lack of motivation among policymakers to adequately address the issue of legislation, control, supervision and categorisation.

Discussion and Conclusion

The results of a study, as well as data available in the Harper and Gellie (2006) survey, various papers (Crawford, 2003; Miklič, 2019), research conducted by Hall & Antonopoulos (2016), and Orsolini et al. (2015), as well as reports published by Europol (2017) and Interpol (2017), enabled the researchers to map the life cycle of CFMPs in a manner similar to that of Dégardin, Roggo, & Margot (2015), and Leontiadis and Hutchings (2015). Key elements have been identified, which have, either independently or in combination with others, a certain heuristic value – they represent a potential element facilitating the detection of CFMPs. The summarised life cycle of CFMPs is, together with the key pre-dispositive elements, illustrated in Figure 1.

Figure 1 demonstrates several elements that may facilitate both detection and investigation. Cooperation among several stakeholders is crucial, as has been continuously recognised in research studies (Harper & Gellie, 2006). Individual actors will not be able to gain data or properly contextualise such data, if manufacturers, health institutions, customs, LEAs, etc. will not share their data, information, intelligence and financial support or provide help with

their analysis. To unburden the LEA budgets, an analysis of the CFMP could sometimes be done by the manufacturer of the original MP. However, such steps must consider the demands of national criminal procedure legislation, particularly if convictions are sought. The interviewed prosecutors expressed interest in obtaining statistical data regarding CFMPs from other actors, even if the detected shipment, case, advertisement, etc. was not referred to the police or the prosecutor's office. The question is whether this results solely from the greater engagement of the interviewees and whether other members of the Slovenian prosecutors' offices share this view, particularly considering the low prevalence of CFMP-related crimes in Slovenia.

From a criminological standpoint, multiple theories can be used to explain the behaviour patterns of perpetrators on the one hand and then buyers, policymakers, and LEA on the other. The most applicable is Rational choice theory. In contrast to illegal drug trafficking, the penalties for CFMP trafficking are severely lower (if present) (as discussed in Miklič, 2019), making this high-profit-low-risk offence. The risk of apprehension is even lower in the case of online sales of CFMP. On the other hand, Merton's (1938) strain theory which is easily linked to consumerism (Hayward, 2004), can be used to explain why people want to buy medicine online even though they perhaps know that it is illegal. Kanduč (2013) and Hayward (2004), in their explorative criminological works, connect consumerism as a factor connected to crime, often strongly building on ideas of cultural criminology. Hayward (2004), in his essay, describes the importance of immediate gratifications and/or satisfaction and sensation gathering in connecting criminality to consumer culture. If we build on that thought, as shown, CFMPs that fall in the lifestyle category (e.g., MP for treating an erectile disorder, weight loss pills etc.) are most frequently bought, and this is because they are also bought by persons who do not need such MP. However, they seek weight loss shortcuts or ways of prolonging and improving sexual intercourse, which is a form of immediate gratification and/or satisfaction and sensation gathering. The question remains whether these buyers know about the risk related to CFMP (and if they do – do they care?). In contrast, if they are unaware of the illegality of their behaviour, then the purchase of CFMP is a form of rational economic behaviour, seeking the best option to gain access to otherwise expensive medicines. Here Alfred Schütz (1946) notion of the social distribution of knowledge is informative. In the

modern world, there are numerous fields where people lack the knowledge to make informative decisions. Schütz (1946) makes an argument that in the modern world, people shift among three knowledge modes. Of an expert on the one end, the man on the street on the other and a well-informed citizen, who is placed between them. The man on the street is equipped with knowledge to accomplish the most typical tasks deemed of him or her through life, while the expert poses in depth knowledge of certain fields. And while one can be an expert in one field, (s)he can have limited knowledge of the other fields (Imber, 1984). Thus, the man on the street making perfect example of CFMP buyer, who is uninformed about illegality or dangers of such purchases. However skilful enough to make such a purchase. They also form public opinion that is used to shape policymaking. A well-informed citizen however would possess knowledge about illegality or dangers of CFMP, thus being reluctant to make purchases without some guarantees of genuineness and legality of MP. It is therefore on the experts of the CFMP to alarm and inform on the dangers of the CFMP and make informed citizens. The demand for further research is self-evident, as it contributes to the development of detection (data mining) algorithms, forensic approaches, etc. Research studies, such as those conducted or supported by renowned institutions and policymakers, i.e. the Harper and Gellie (2006), are an excellent tool for detecting gaps, problematic areas or good practices, and for devising relevant recommendations following further analyses. While much has improved (e.g., internet pharmacies have been appropriately addressed), some issues remain problematic. Among them, the continuing lack of public awareness about CFMPs is perhaps the most distressing. If the public does not understand or even know about CFMPs, then they will also fail to report potential encounters with CFMPs, thus making their detection even more difficult. Studies related to community policing show that residents in Slovenia are willing to cooperate in crime prevention and policing activities (Nalla, Meško, & Modic, 2018). There are ongoing debates about the definition of CFMPs, which also affects the detection, investigation and prosecution of CFMP-related crimes. Suitable legislation is a necessary predisposition for a successful prosecution, however, if the general public are not aware of the extent of the problem, there is no pressure on the national policymakers to amend the legislation governing LEAs and other issues to properly tackle CFMPs. In Slovenia, the Criminal code (2008) does not properly criminalise the trafficking of CFMPs on the illegal market and lacks the definition of the

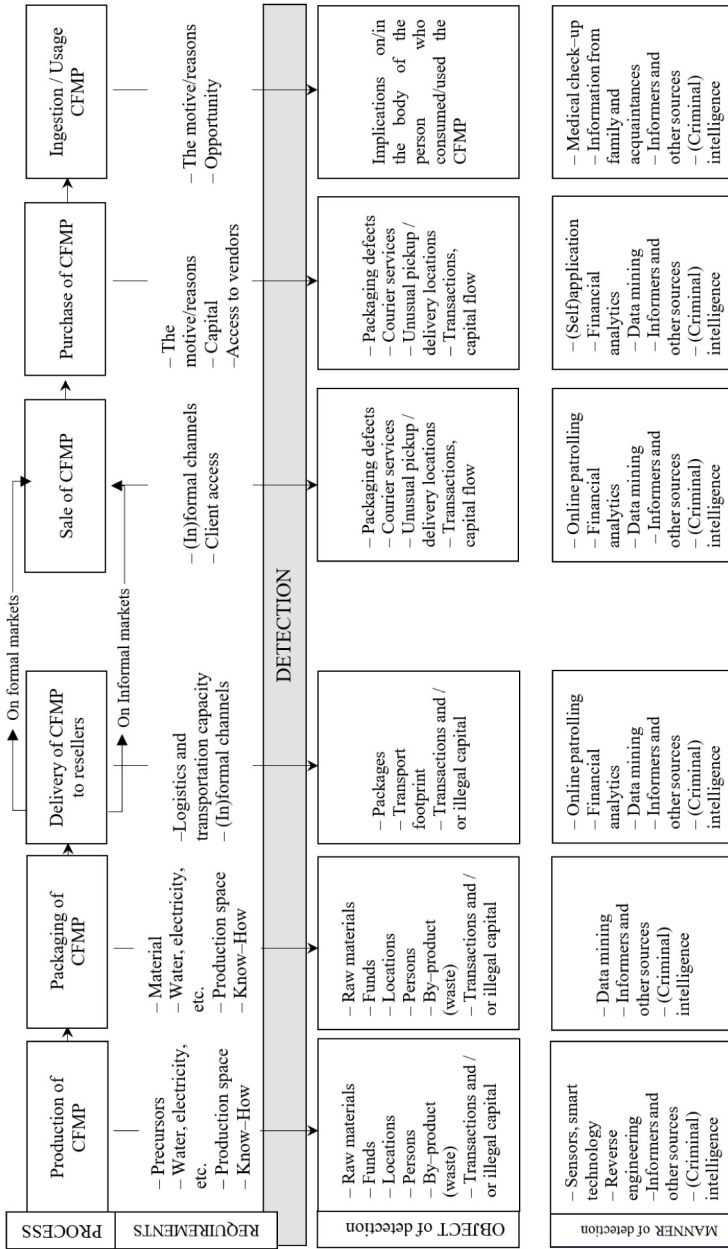


FIGURE 1: The CFMP (counterfeit medical product) life cycle and the means of detecting CFMPs. Research findings complemented with the findings presented by the Harper & Gellie (2006), Crawford (2003), Dégardin et al. (2015), Europol (2017), Hall & Antonopoulos (2016), Interpol (2017), Leontiadis & Hutchings (2015), Miklič (2019) and Orsolini et al. (2015)

concept of “harmful to human health” concerning CFMPs. Therefore, incentives for legislative amendments must come from abroad – and here we return to the importance of research –, as incentives for such amendments must be based on and supported by science.

Finally, with respect to the legislation, the research study presented in this paper has, similarly to Leontiadis & Hutchings (2015) or Orsolini et al. (2015), (partly) confirmed that a sound and socially-oriented healthcare system in which the required medicines are widely available, represents a deterrent against CFMPs. Therefore, the legislative framework that supports such a system must be maintained.

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