

MEDICRIME VS VOLCANO

A practical case study
on how the Council of Europe
Convention could improve
the fight against
pharmaceutical crime



Domenico Di Giorgio
& Diana Russo
coordinating authors

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*In memory of our absent
friends who contributed to the
MEDICRIME convention:
Gen. Cosimo Piccinno,
Martijn ten Ham, Bart Wijnberg
and Roy Vancauwenberghe.*

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The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (the “Medicrime Convention”) was opened for signature in Moscow on 28 October 2011. This Convention was the fruit of constructive co-operation between experts from the European Directorate for the Quality of Medicines & HealthCare (EDQM) and the European Committee on Crime Problems (CDPC).

It is a dedicated international legal instrument that is designed to tackle this highly specialised criminal activity which presents a relatively low risk of detection and prosecution when compared to the potentially high financial gains. By using the internet to publicise and supply their products directly to patients and consumers around the world, criminals have established a safe and easy modus operandi for their activities which gives them global reach. The result is a serious and truly global threat to public health which also involves a complete and unacceptable disparity between the low risks incurred by criminals who falsify medical products and the enormous risks that this illicit behaviour may pose to the health of individuals worldwide.

*The “Medicrime” Convention
of the Council of Europe:
a powerful tool against falsification
of medical products.*

The Medicrime Convention is the first international criminal law instrument specifically designed to oblige States Parties to criminalise the manufacturing of falsified medical products, supplying and trafficking in falsified medical products, the unauthorised manufacturing or supplying of medicinal products, the placing on the market of medical devices which do not comply with conformity requirements and other related activities, such as falsification of documents. Not only natural persons but also “legal persons” (commercial enterprises, associations and similar legal entities) shall be liable for criminal actions performed on their behalf by anyone in a leading position or having failed to supervise an employee of the entity.

Together with the provisions of substantive criminal law, of at least equal importance is the framework provided by the Convention for national and

international co-operation in criminal matters and across the different sectors of public administration, the measures for co-ordination at national and international level, the preventive measures for use by public and private sectors and the protection of victims and witnesses.

The Convention is not restricted to the member states of the Council of Europe but is open to third countries. Furthermore, the Convention also foresees the establishment of a monitoring body to oversee its implementation by the States Parties.

Presented in this book, Operation Volcano is a clear example of how, had the Medicrime Convention been fully and correctly implemented by all the parties involved, the mechanisms of national and international co-operation it lays down would have greatly contributed to a more efficient resolution of the cases described and led to more appropriate sanctions which would have had a deterrent effect against the underlying criminal behaviour. Taking into account the widespread nature of pharmaceutical crime, the Convention sets the standards and represents a state of the art which should inspire national legislators and regulators and prompt its ratification by the greatest number of countries worldwide.

Lorenzo Salazar

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on Crime Problems (CDPC) of the Council of Europe

Chapter 1

Introduction

In the course of 2014, the Italian authorities carried out an impressive operation against an organisation facilitating the infiltration of falsified medicines (stolen/manipulated products obtained through robberies, mainly from Italian hospitals) into the parallel trade network, mostly in Germany, but also in Spain, The Netherlands and other countries: more than 100 different medicines and 17 countries were involved, and more than 3 000 transactions between operators were “polluted” by falsified medicines.

Although the harm caused to patients in these countries was not officially evaluated by the competent authorities, it is clear that during the “infiltration” period, which lasted at least from 2011 to 2014, public health was put at risk by manipulated products which possibly lacked pharmaceutical activity and quality – and it is well known that poor-quality medicines may compromise the treatment of chronic and infectious diseases, leading to disease progression, drug resistance, side effects and even fatalities.

In spite of the impressive results (more than 80 people arrested, and a 3-year dramatic reduction in such thefts in Italy), Operation Volcano did not act as a deterrent. This was due to many concurring factors, such as lack of proper specific sanctions for health professionals, different enforcement/investigative approaches in the European countries involved and poor cooperation between central/local authorities at national and international level, etc. Then, in 2018, other investigated cases replicated the features identified through Operation Volcano, proving once again that the criminals had simply transferred their activities from Italy, where the selling channels were shut down, to other EU Member States.

The aim of this study is to highlight the inadequacy of the current legal framework to tackle such a relevant phenomenon, the perfectibility of the traceability system, the fragmentation of proceedings related to pharmaceutical crime (such as handling of stolen goods) before different Italian judicial Authorities and the insufficient catalogue of accessory sanctions, also in disciplinary proceedings.

In addition, this study looks at how proper implementation of the MEDICRIME Convention could help in this matter. The study was carried out by Regulators and Prosecutors from Italy, Germany, UK, Belgium, the Republic of Armenia and the Republic of Serbia as part of CD-P-PH/CMED's activities and tries to answer the question by evaluating how the current regulation could be improved by appropriately implementing the Convention.

Note on the legal framework

The MEDICRIME Convention uses the term "counterfeit" and defines it as false representation as regards identity and/or source. This definition is consistent with the meaning of "falsification", used in the EU legislation, and hence the latter will be used through this whole document. It should be emphasised that issues with intellectual property rights are not covered, neither by the convention, nor by this study.

Chapter 2

The 2014 stolen medicines case

Following the initial report issued by Germany (April 2nd, 2014), stating that vials of the cancer medicine Herceptin® (trastuzumab), stolen from Italian hospitals, had been re-introduced into the supply chain under false credentials by unauthorised wholesalers, a number of Member States took action where required: falsified vials were seized by authorities in Germany, Finland and the UK. It was also demonstrated that the falsified vials had been distributed to other European Union (EU) Member States.

Upon further investigation by the Italian authorities, it was discovered that additional medicinal products identified as stolen in Italy had subsequently been re-introduced under false credentials into the supply chain. This was facilitated through “bogus” wholesalers operating in Cyprus, Hungary, Latvia, Romania, the Slovak Republic, Slovenia and Greece, which issued fake invoices in order to sell the stolen medicines to Italian and Maltese authorised operators. These authorised operators subsequently exported the medicines to other EU markets.

Since the “bogus” wholesalers were unauthorised operators, the products were considered “falsified”: given that it was impossible to establish whether they were safe or effective, their use was not allowed.

The Italian investigation demonstrated that there was a consolidated scheme: the criminal organisation behind this operation hired local criminals in Italy to break into hospitals and to hijack distribution trucks.

Stolen products were transferred to an Italian licensed wholesaler and falsified receipts were then provided for the shipments. Fake wholesalers were set up in numerous EU Member States, including Hungary, Latvia, Cyprus and the Czech Republic.

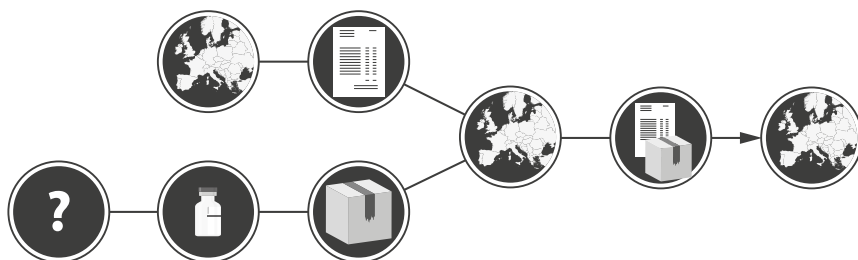
The Operation Volcano

“Operation Volcano” refers to a series of activities carried out after a German parallel distributor reported having received defective vials of the anti-cancer medicine Herceptin® 150 mg (trastuzumab) from a wholesaler in the UK.

During controls on medicines, the Authorities verified that the batch numbers printed on the primary and secondary packaging were not the same, as well as issues with the physical appearance of the products and suspected tampering.



Under the scheme set up, authorised wholesalers in Italy would receive a (fake) invoice from one of the “bogus wholesalers” in another country (e.g. Hungary); the shipment would then be sold on, for example to the licensed wholesaler in the UK. The non-Italian wholesalers, apparently, never asked for anything more than the Italian authorisation held by the legal wholesaler; they seemingly believed they had bought from a genuine wholesaler and sold the medicines to other Member States in that belief.



AIFA coordinated a major verification campaign at EU level through the Fakeshare web platform, with the support of other Italian institutions (police forces such as Carabinieri NAS; Ministry of Health; Customs Agency), by coordinating (managing webinars and teleconferences, blacklists of products/operators and “investigative models” disseminated via Rapid Alert/Non Urgent Information documents, setting up web based databases and tools for the investigators), and helping other institutions (in the EMA and HMA/WGEO network) to recall suspicious products and inspect “contaminated” operators. All the results of Operation Volcano were published in real time, and transparency was a key factor for the success of the initiative: as a reference, with respect to the final results, it is important to note that, as reported in the AIFA White Paper regarding Operation Volcano, 14 Italian Prosecution offices used the available information for independent investigations – and more than 80 people were arrested.

If you need more details about Operation Volcano, the related White Paper and the follow up AIFA publication on medicines thefts are available for download from the AIFA website:

<http://www.aifa.gov.it/content/crimine-farmaceutico>

Results and sanctions

The substantial effort coordinated by AIFA ended the plague of hospital thefts: up to May 2014, Italy reported up to 3 such events per week, and from June 2014 until the end of 2015 there were no further thefts.

The combined efforts of AIFA, Carabinieri NAS and at least 14 different prosecutors in place during 2014 yielded impressive results: more than 80 people were arrested in 8 national operations (i.e. excluding the dozens of arrests related to local thefts), and the Italy-based criminal group supplying stolen medicines to the EU parallel trade network was disrupted.

However, despite these results, it is important to underline that all arrests were made on non-specific charges (e.g. theft, laundering, etc.): the charges brought against the health professionals (wholesalers, pharmacists) involved in the case were minor and administrative at best (e.g. fines, 1 or 2-month suspension of their licence), and this only where the failure to comply with regulations was really relevant and stipulated in the specific regulation, for instance, the purchase of medicines from non-licensed operators.

A specific case: Operation Pharmalab

“Operation Pharmalab” is one of the independent investigations carried out in connection with the framework of the “Operation Volcano”, and concerned the same type of criminal activity: we will use this concrete example to illustrate more clearly the practical implementation and enforcement of rules and sanctions in such a challenging situation.

The operation was launched after a large quantity of medicines (58,222 packages of medicines of different types, genres and origins, including hospital drugs, for an estimated market value of € 839,530) was seized by the Fiumicino (Rome) Guardia di Finanza (Italian financial police), in early June 2014. The stolen goods were discovered fortuitously in a storage warehouse in Arzano, which was used by two subjects (one of whom is a pharmacist).

The investigations initiated by the Public Prosecutor's Office in Napoli Nord (technical verifications aimed at clarifying the criminal provenance of the seized goods; observation, surveillance and monitoring; interceptions; questioning of the suspects) made it possible to identify the members of a criminal association receiving and handling stolen medicines (from hospital facilities and through robberies – mainly carried out against transport operators). False fiscal papers simulating their purchase from suppliers and/or Italian pharmacies by seemingly foreign companies were subsequently arranged for the stolen goods and they were then re-marketed.

To summarise, the criminal system proved to be organised into different stages:

- ▶ organisation and perpetration, throughout Italy, of burglaries (mostly in hospital pharmacies) and robberies (carried out against transport operators);
- ▶ storage of stolen goods in hidden warehouses (in the Campania region);
- ▶ cataloguing of medicines and arrangement of false documentation by expert co-participants;
- ▶ transfer to complicit subjects (pharmacies, wholesalers, distributors), dedicated to re-introducing the stolen medicines into the official channels.

Besides transferring the medicines to small, complicit pharmacies in Naples, the criminal organisation — entirely composed of Italians — also supplied official wholesalers who regularised the stolen goods by means of fictitious importations of medicines purchased, only upon paper, from bogus foreign companies. The goods could, therefore, be resold in Italy to unknowing pharmacies, thus introducing huge amounts of medicines into the retail system and defrauding the National Health System. As the conditions under which the medicines were stored and transported up to the time of their seizure (most likely inadequate and, certainly, not complying with environmental health concerns and storage temperatures) were unknown, these medicines represent a potentially serious threat to public health.

As part of the same investigation, in November 2014 a number of premises held by the suspects in the provinces of Naples and Caserta were searched, leading to the discovery and seizure of 3,117 additional packages of medicines,

many of them anti-cancer or anti-rheumatic drugs, also stolen from hospitals, with a market value of € 963,575.

Operation Pharmalab's substantive aspects: charged offences

Though the practices at issue in the proceedings are part of the wider and alarming phenomenon briefly described above, in this case it was possible to charge the suspects with the following offences:

- ▶ handling stolen goods (or goods which are the proceeds of a criminal offence, Art. 648 of the Italian Criminal Code): this offence is punishable by between 2 and 8 years' imprisonment and a fine of € 526 to € 10 329; moreover, charges were also brought for the aggravating circumstances laid down in Art. 61, N-o. 7 of the Criminal Code, in relation to the seriousness of the financial repercussions;
- ▶ possession of narcotic drugs (Art. 73, par. 1, also related to par. 4 of Italian Republic Presidential Decree No. 309/1990) with respect to some packages of medicines (1191) containing active substances which may feature in the Tables included in the Consolidated Law on Narcotic Drugs (specifically Table I section A and Table IV). The charge was, however, challenged by the defence, on the assumption that the Public Prosecutor referred to categories no longer in force, subsequent to the Constitutional Court's judgment no. 32/2014 (which ruled that the Fini – Giovanardi law was unconstitutional and reinstated the original version of Italian Republic Presidential Decree No. 309/1990 and its related table system) and the later introduction (via Decree No. 36/2014, passed into national legislation as Law No. 79/2014) of an ad-hoc Table for medicinal products ("Medicines Table"). Furthermore, each of Tables I to IV included in the Consolidated Law indicates, as substances to be considered as included in the same Table, "the preparations containing the substances listed in the present table, in compliance with the tables of medicinal products". As a consequence, the possession, without authorisation, of medicinal preparations containing active substances listed in the Tables of narcotic drugs, constitutes the offence described under Art. 73 of Italian Republic Presidential Decree No. 309/1990. The Judicial Review Court of Naples ruled accordingly, dismissing the objections and confirming the Public Prosecutor's assumption. This charge allowed the use of longer

terms of pre-trial detention and the extension of prescription times, upon consideration of a higher punishment limit (up to 20 years for the possession of the so-called “hard” drugs);

- ▶ criminal association for the purposes of committing the above mentioned crimes (Art. 416 of the Criminal Code);
- ▶ trade in and administration of faulty or defective medicines (Art. 443 of the Criminal Code): this charge was brought only because of expired medicines found in the stores of a purchasing pharmacy.

From a procedural point of view, the most relevant and, at the same time, problematic aspect of Operation Pharmalab concerns the evidence of the criminal source of the seized medicines.

Individuals who purchase or handle goods of criminal origin for profit can be charged with receiving and handling stolen goods.

It is up to the Public Prosecutor to prove the illicit origin of the goods.

It is presumed that the defendant is aware of the criminal origin of the products, in accordance with the case-law of the Court, when he or she provides no justification for possessing the goods.

In the present case, all the medicines detected and seized were catalogued with the support of the Pharmaceutical Department of the Local Health Authority NA1 and the distribution chain was reconstructed (traceability) with the support of Office IV of the Ministry of Health and of AIFA.

Operation Pharmalab’s substantive aspects: issues and operative proposals

Analysis of the Pharmalab case highlights critical issues in both the substantial and the procedural aspects.

Firstly, the inadequacies of the current legal framework, with regard to tackling such a relevant phenomenon, are immediately apparent; charging the perpetrators of these acts with such common offences as receiving and handling stolen goods appears highly reductive, in view of the risks such criminal activities pose for public health and particularly since the medicines involved are reintroduced onto the market after being held for a variable (and in all cases,

uncertain) period of time under inappropriate storage conditions. In that regard, it is interesting to note that, had the conduct been detected at a later stage of the “*iter criminis*”, those responsible could have been charged with receiving and handling stolen goods, in compliance with Art. 648 bis of the Criminal Code (common crime against property punishable by a prison sentence ranging from four to twelve years and a fine from € 5 000 to € 25 000), constituting the arrangement of false accounting documentation, an operation aimed at hindering the identification of the criminal origin of the medicines. Charging them with the special offence laid down by Art. 73 of the D.P.R. no. 309/1990, although undoubtedly more significant — also in terms of the penalty that may be inflicted — is only possible in the case of medicines containing narcotic or psychotropic active substances and, in any case, is provided to protect a different legal good. It should be emphasised that while, in the present case, the criminal activity of receiving medicines and re-releasing them on market had become a “professional” activity (i.e. not occasional) for most of those employed, this did not make the sanctions more effective, even when the “professionals” in question were caught in the act of storing stolen goods. Clearly, the sanctions currently applicable are not a good deterrent compared to the profitability of this criminal activity, and the investigative tools are poorly effective.

Secondly, the current medicines tracking system does not, or not always, allow identification of the original owners of the drugs who would be entitled to restitution of the goods. There are relevant consequences both for evidentiary purposes (as the demonstration of the criminal origin, required by the offence of receiving and handling stolen goods, may be reached only upon deduction) and for the handling of the seized goods. Strengthening the implementation of traceability systems, and developing ad hoc tools aimed at facilitating the verifications performed by operators, health professionals and police forces (e.g. specific features clearly differentiating hospital packages from the corresponding pharmacy packages) could be a good support to the investigations.

This case clearly shows that there is a need to harmonise the authorisation systems to all actors involved in the medicines distribution chain in all EU Member States: the different levels of management (central and local) for the operators of this chain create possible “grey areas”, where the checks on illegal transit become more difficult and therefore they are carried out less frequently – often resulting in an ineffective level of control against the infiltration of illegal goods.

In addition, it is important to note that the proceedings related to falsification and/or handling of stolen goods are divided amongst different Italian judicial

authorities: the exchange of information between the police authorities and the Public Prosecutors Offices is entirely reliant on the good will of each office. In that regard, it should be noted that Art. 371 of the Italian criminal procedure code, which governs the relations between the different offices of the Public Prosecutor, provides for the possibility of coordination and connection in the investigations; this task is assigned to (and guaranteed by) the National Anti-mafia and Anti-terrorism Prosecutor as per Art. 371 bis of the criminal procedure code, and restricted to proceedings related to mafia-type organised crimes and similar crimes. Setting up a similar coordination scheme for investigations of pharmaceutical crime would definitely facilitate all the different exchanges of information and cooperation procedures advocated by the MEDICRIME Convention.

In this framework, it could be useful to set up ad hoc training processes for Prosecutors and high level officers of police forces: raising awareness about pharmaceutical crime in the judicial sector would prepare the way for the implementation of good practices with respect to information-sharing between prosecution offices, or to the specialisation of some “key” Public Prosecutors Offices that may act as coordination units in an investigation.

Finally, the catalogue of ancillary penalties that may be applied, also in disciplinary proceedings, to those who provide their expert contribution to the organisation as accessories to the crime (cataloguing the medicines, estimating their value, and enabling their re-entry into the distribution chain) turned out to be unsuitable (in the present case, a spontaneous report was received from the Order of Pharmacists of Salerno; when the prison sentence was enforced, the suspect was suspended from the Order). Nonetheless, the sanction was revoked as soon as the prison sentence was replaced by a less severe one, though the criminal proceedings against the subject were still pending.

On the basis of the above-mentioned considerations, the introduction of an ad hoc offence case or, at least, of an aggravating circumstance when medicines are concerned, appears desirable. Moreover, consistent ancillary penalties against professionals who, at any level, contribute to (or are involved in) the crime should be introduced, and permanent administrative sanctions (revocation of any authorisation for manufacturing, distributing or selling) should be applicable to the operators involved.

In parallel, it would be useful to envisage the possibility, or even an obligation, for public prosecutor offices, to notify the professional orders of the files of the proceedings, as soon as they can be disclosed.

Consideration could also be given to the possibility of notifying AIFA, always respecting the confidentiality of the investigation, of the files related to cases of falsification and/or illicit traffic of medicines, as soon as they can be disclosed; the Agency would then be able to inform the different public prosecutor offices about concomitantly pending proceedings against the same or some connected subjects, thus promoting coordination in the investigations or, certainly, a better understanding of the workings of this criminal activity.

Chapter 3

The AIFA/EDQM survey

In the light of the above, AIFA developed an ad hoc survey, summarizing some of the risky/criminal behaviours (“conducts”, see below) that were encountered during Operation Volcano – namely, the main behaviour that was evaluated and considered, as far as possible, in the prosecution of the Pharmedlab sub-operation: for each defined profile, the participants – national prosecutors and legal experts from Belgium, Germany, UK, Republic of Armenia and Republic of Serbia – were asked to report the applicable national regulation, in comparison to the legislation applied in the Italian case.

The survey submitted to the countries participating in this EDQM/Council of Europe project, looked into the conducts that emerged during the investigation performed in the framework of Operation Volcano. The respondents were asked to verify the possibility to bring charges for and sanction those conducts under the respective current national regulations, giving a full picture of the situation in their country.

In the case at hand, products were illegally obtained via thefts (“Acquisition”: conducts 1-4), then laundered through fake documentation and sold to authorised operators in Europe (“Sale”: conducts 5-9), in some cases after manipulation (conduct 10): the whole activity was managed by a structured group, including health professionals (“Background”: conducts 11-12), threatening public health at international level (“Damages”: conducts 13-15).

Acquisition	Conduct 1 - Theft of medicines
	Conduct 2 - Robbery
	Conduct 3 - Illegal possession of medicines
	Conduct 4 - Receiving stolen goods
Sale	Conduct 5 - Illegal export of goods
	Conduct 6 - Illegal export of medicines
	Conduct 7 - Sale of medicines purchased by an illegal operator
	Conduct 8 - Sale of medicines of illegal origin, purchased by a legal operator
	Conduct 9 - False invoices

Manipulation	Conduct 10 - Manipulation/falsification/counterfeiting/adulteration of medicines
Background	Conduct 11 - Violations to the “due diligence” of health professionals
	Conduct 12 - Criminal association (leaders and promoters, participants)
Damages	Conduct 13 - Damage caused (even lack of effect)/risk caused to patients
	Conduct 14 - Damage to company image
	Conduct 15 - Economic damage to hospitals and operators

In the text of the survey, the term “falsified medicines” is used with its regulatory definition; the term “illegal” refers to the broader concept of “not in compliance with regulations”, including falsified, adulterated and non-authorised medicines.

Conduct 1

Theft of medicines

Charge in Italy: Theft (ordinary crime, non-specific), possibly with violence or breaking and entering

- ▶ **BELGIUM.** Theft (Art. 461 and 463 Sw)
- ▶ **GERMANY.** Theft, aggravated case of theft (with violence or breaking and entering). Section 242 of the German Strafgesetzbuch (StGB)
- ▶ **UK.** Theft, ordinary crime
- ▶ **REPUBLIC OF ARMENIA.** Theft of medicinal products is an ordinary crime. In the Criminal Code, no specific punishment is listed for the theft of medicinal products
- ▶ **REPUBLIC OF SERBIA.** From one to ten years in prison, depending on the harm inflicted on the persons involved, Criminal Law ("Official Gazette of the Republic of Serbia", No. 85/2005, 88/2005 – ispr., 107/2005 – ispr., 72/2009, 111/2009, 121/2012, 104/2013, 108/2014 and 94 / 2016). Not specific to medicines, more regulations are required

Conduct 2

Robbery

Charge in Italy: Ordinary crime (no specific sanction if stolen goods are medicines taken from a hospital)

- ▶ **BELGIUM.** Theft with violence/threat (art .468-472 Sw). Aggravating circumstances: breaking and entering, night-time, two or more persons, use of car, victim was vulnerable, use of weapons, use of poison. No specific sanction when the stolen goods are medicines whether in hospital or not
- ▶ **GERMANY.** "Ordinary crime" as well, for all kind of goods
- ▶ **UK.** Ordinary crime. Robberies at hospital are not different

- ▶ **REPUBLIC OF ARMENIA.** Ordinary crime: no specific sanction if stolen goods are medicines taken from a hospital
 - ▶ **REPUBLIC OF SERBIA.** From one to ten years in prison, depending on the harm inflicted on the persons involved. No specific sanctions
-

- ▶ Thefts and robberies are usually judged under the “ordinary crimes” rules, without specific consideration either for the object of the theft, or for the expected objectives which, in the case of medicines, always include the infiltration of the stolen products into the legal distribution network under falsified credentials. Many different risk profiles are related, for instance, to the lack of compliance with Good Distribution Practices, possibly damaging the stolen medicines, making them less effective or dangerous for public health, as was confirmed for some of the samples analysed during Operation Volcano.

The MEDICRIME Convention provides for the criminalisation of certain acts (Art. 1.1.a) which are described in Art. 5, 6, 7 and 8. The “theft of medicines” is not described in the Convention as an act that in itself constitutes an offence to be defined in national laws once the MEDICRIME Convention is ratified.

Nevertheless, at least within the European Union, the definition given in Directive 2011/62/EU could be taken into account. This includes (in the broader definition of falsified medicines) products whose identity, source and history have been falsified – such as stolen medicines sold with falsified documentation falsely certifying their origin.

Normally, the charge would be ordinary theft, but once the country bringing the charges has ratified the MEDICRIME Convention and integrated it into its legal system, the individuals involved would be accused of both theft and the charges laid down in Art. 6 and possible Art. 7, if they were caught supplying the stolen medicines (because the medicines could have been stolen for private use). From a legal point of view in terms of implementation of the Convention, it is recommended to specifically mention “theft/robbery of medicines intended to be distributed in the supply chain”.

Conduct 3

Illegal possession of medicines

Charge in Italy: this is sanctioned for narcotics only, hospital (Art 73 DPR 309/90, narcotics)

Comments: Non authorised warehouses are an infringement of the pharmaceutical code (Dir. 2001(83); illegal detention only applicable to narcotics, hospitals and specific categories

- ▶ **BELGIUM.** Possession of illegal substances (for narcotics: Drug law 21.02.19)
- ▶ **GERMANY.** Generally not a crime if medicines are not narcotics. If the person is found to be in possession of “larger amounts” of medicines, this may indicate the intention to sell or illegally deal them. This could be considered reasonable suspicion
- ▶ **UK.** Possession of controlled drugs is an offence. Possession of medicines with intent to supply without the necessary licence is also an offence
- ▶ **REPUBLIC OF ARMENIA.** No sanctions for medicines. Sanctions are established only for possessing psychoactive medicines according to Art. 268 of Criminal Code of RA. In the medicinal product lifecycle, only manufacturers and pharmacies are licensed. Distribution permits have only been necessary since 01 Aug 2019. This means that it would not be possible to bring charges against companies possessing medicines without the relevant authorisation
- ▶ **REPUBLIC OF SERBIA.** Only sanctioned for psychoactive drugs. Not specific enough

Conduct 4

Receiving stolen goods

Charge in Italy: Ordinary crime (no aggravating factors for drugs, aggravating for high value: Art. 61 c. 7 CP; L. 648)

Comments: Difficulty in identifying the “owner” of the stolen property

- ▶ **BELGIUM.** Possession of stolen goods (art. 505-1 Sw). General, not for medicines in particular
- ▶ **GERMANY.** Ordinary crime, no special sanctions for medicines. Section 259 of the German Strafgesetzbuch (StGB)
- ▶ **UK.** Ordinary crime. We prosecuted a case and the defendant got 3 years' imprisonment
- ▶ **REPUBLIC OF ARMENIA.** Ordinary crime: no aggravating factors for drugs, aggravating for high value
- ▶ **REPUBLIC OF SERBIA.** One year in prison. Not specific for medicines

Conduct 5 Illegal export of goods

Charge in Italy: Financial crimes

- ▶ **BELGIUM.** Depends on the type of goods
- ▶ **GERMANY.** Financial Crimes
- ▶ **UK.** Export of medicines to the EEA without the necessary licence is an offence
- ▶ **REPUBLIC OF ARMENIA.** Criminal sanctions are established only for cultural exports. Administrative offences are established for violating some rules relating to controlled and other goods without mentioning medicines. Nothing specific regarding medicinal products
- ▶ **REPUBLIC OF SERBIA.** Illicit trade, article 235 of the Criminal law, and article 236 – smuggling. A fine or prison sentence, but not specific for medicines

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- ▶ Whilst the above-mentioned connection between thefts and infiltration of stolen medicines into the legal supply chain cannot be taken for granted, it is nonetheless clear that storing illegal

medicines (conduct 3) should be considered under MEDICRIME Convention Art. 6 – “Supplying, offering to supply, and trafficking in counterfeits”: the purpose of illegal possession of medicines is always re-distribution.

Specific provisions against distribution and diversion of stolen/falsified medicines are necessary. According to the available data (such as those reported in the 2017 PSI counterfeit incident system report), the number of cases of illegal diversion (when a legitimate pharmaceutical product is approved and intended for sale in one market but is then illegally intercepted and sold in another market) of pharmaceutical products is growing, and is now higher than the figures for “traditional counterfeiting” (i.e. falsification of products and brand names).

The mere generic charges related to receiving stolen goods (conduct 4), and to illegal export of goods (conduct 5), would fall out of the scope of the MEDICRIME Convention, and only ordinary crime rules would be applicable: but when considering the specific charge related to medicines, since the aim of receiving and exporting illegal medicines is clearly their subsequent sale, it is clear that the implementation of the Convention would provide a proper solution.

“Intentionally keeping in stock counterfeit medicinal products” is a criminal act according to Art. 6.1 of the MEDICRIME Convention, and is not limited to controlled drugs. Those countries that have ratified, accepted or approved the MEDICRIME Convention must establish an equivalent offence under their domestic law (Art. 6).

Significant non-specific offences provided by regulations in force for other sector, e.g. for narcotics (such as Italian Art. 73 of Italian Presidential Decree No. 309/1990), are usually limited only to small groups of products (in the example, medicines containing narcotic or psychotropic active substances) and, anyhow, are aimed at targeting other kinds of illegal behaviour.

Conduct 6

Illegal export of medicines

Charge in Italy: Pharmaceutical wholesalers not authorised as described in Directive 2001/83 may be sanctioned; penal sanctions have been established for exporting/selling medicines without an authorisation as laid down in the pharmaceutical code ex Dir. 2001/83

- ▶ **BELGIUM.** Law 25.03.1964, Art. 12ter (and KB 14.12.2006 Art. 90-99bis). Export without authorisation is sanctioned
- ▶ **GERMANY.** Crime under the German Medicines Act. Section 73a) of the German Medicines Act (Arzneimittelgesetz)
- ▶ **UK.** Exporting medicines without the necessary licence is an offence
- ▶ **REPUBLIC OF ARMENIA.** No specific provisions: at the present time, wholesalers do not have to have a license
- ▶ **REPUBLIC OF SERBIA.** Illicit trade article 235 of the Criminal law, and article 236 – smuggling. A fine or prison sentence, but not specific for medicines

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- ▶ International conventions such as the MEDICRIME Convention could, in specific situations, go beyond EU Directives, but in this case, given that an EU law covering some of the MEDICRIME Convention's content is already in force (Directive 2001/83/EU) and has been transposed by all the EU Member States into their national law, it is possible that national amendments with respect to some points are not necessary – and this seems to be the case for illegal export of medicines. Non-EU Member States that ratified the Convention shall apply Art. 6.1 and transpose it into their national legislation as an offence.

It is worth mentioning that even if the specific point related to non-authorised trading of medicines is covered in the EU Directives (and has been transposed into national legislation in Belgium, Germany, UK and Italy), the related sanctions are not currently applied with regard to the "falsified medicines trading" point, which generally limits their impact to mere administrative fines: in the

Volcano/Pharmalab cases, the Italian operators involved in exporting illegal medicines had their licence suspended (not revoked) – a rather minor sanction but which is nonetheless more severe than those applied to non-Italian operators trading the same illegal medicines (who received small fines, at the most).

Conduct 7

Sale of medicines, purchased by an illegal operator

Charge in Italy: Not in compliance with the Pharmaceutical code (Legislative Decree 219/06, implementing Dir. 2001/83), requesting supplier qualification

Comments: It could also be possible to apply Criminal Code references to expired drugs and to the sale of drugs of illegal origin). “Caveat emptor” principle: operators buying at low prices are possibly aware that the goods are of illegal origin (no “careless purchase” – as the line of defence of the accused)

- ▶ **BELGIUM.** Law 25.03.1964 Art. 12ter. Sale and purchase of medicines requires licences
- ▶ **GERMANY.** Those may fulfil the definition of falsified medicines according to Section 4 (40) of the Medicines Act. Similar to the situation in Italy as under “comments” above
- ▶ **UK.** Failure to notify MHRA of suspected falsified products. If the seller knows that the medicines should not be sold, other offences may be committed too
- ▶ **REPUBLIC OF ARMENIA.** No specific provision
- ▶ **REPUBLIC OF SERBIA.** No specific reference in the Criminal law and few articles mention this but it is not clearly defined in the Law on medicines and medical devices (“The Official Gazette of the Republic of Serbia”, 30/2010; 107/2012 and 113/2017 laws). New law on medicines will introduce provisions in line with EU, Council of Europe, WHO and other relevant international legislation and standards in this area by the end of 2019, and hopefully the signing of the MEDICRIME Convention will help expedite this procedure and maybe introduce changes in Criminal law as well in the near future

Conduct 8

Sale of medicines of illegal origin, purchased by a legal operator

Charge in Italy: Not in compliance with the Pharmaceutical code (Legislative Decree 219/06, implementing Dir. 2001/83), requesting supplier qualification

Comments: "Careless purchase" (fault or malice) applicable only if there are grounds for suspicion (prices, availability). "Caveat emptor" principle: operators buying at low prices may be aware that the goods are of illegal origin (no "careless purchase" – as the line of defence of the accused)

- ▶ **BELGIUM.** Law 25.03.1964 Art. 16, §3,4 and Art. 94 KB 14.12.2006. To get a conviction it will be necessary to prove that the legal operator knew, should have known or could have known (suspected) that the medicines were illegal (e.g. very low prices can be an indicator)
- ▶ **GERMANY.** These may fulfil the definition of falsified medicines according to Section 4 (40) of the Medicines Act. This definition includes a false identity or origin or falsified shipment papers
- ▶ **UK.** Failure to notify MHRA of suspected falsified products. If the seller knows that the medicines should not be sold, other charges may also be applicable
- ▶ **REPUBLIC OF ARMENIA.** No specific provision
- ▶ **REPUBLIC OF SERBIA.** No specific reference in the Criminal law and few articles mention this but it is not clearly defined in the Law on medicines and medical devices ("The Official Gazette of the Republic of Serbia", 30/2010; 107/2012 and 113/2017 laws). New law on medicines will introduce provisions in line with EU, Council of Europe, WHO and other relevant international legislation and standards in this area by the end of 2019, and hopefully the signing of the MEDICRIME Convention will expedite this procedure and maybe introduce changes in Criminal law as well in the near future

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- ▶ With regard to Good Distribution Practices, the EU regulation mentioned above clearly states that medicines should be traded only

between authorised operators. Moreover, Directive 2011/62/EC also defines as “falsified” all medicines distributed through documentation falsely certifying their history and origin, and calls for specific sanctions against operators trading in falsified medicines. Here, according to the EU rules, both conducts are covered and subject to sanctions: but in spite of this framework, none of the non-Italian operators involved in trading the falsified medicines in the Volcano case was sanctioned, and even in more recent cases investigated during 2018, the majority of the operators illegally trading in medicines with non-authorised operators escaped the sanctions, pretending to be victims of a fraud – the “caveat emptor” principle was not applied (up to now).

Since the MEDICRIME Convention calls for a specific criminalisation of any conduct leading to the distribution of counterfeit (falsified) medicines, the general rules of the Convention could be applied.

Moreover, the case could fall under Art. 6 of the Convention, if it can be proven that the acts were intentional – i.e. that the trader knew that he/she was buying from an illegal operator – or even Art. 8, if it may be linked to the black market (see explanatory report Art. 8).

As a general remark, it is important to underline that the charging the perpetrators of these acts with common offences such as theft, receiving and handling of stolen goods is short sighted, given the serious repercussions they may have on public health. For instance, it is necessary to consider that stolen medicines reintroduced into the market after being stored for a variable (and in all cases uncertain) period of time, no doubt under unsuitable storage conditions, may represent a danger far beyond that expected for the other kinds of laundered goods considered in the regulation.

Conduct 9 False invoices

Charge in Italy: Financial crimes

- ▶ **BELGIUM.** Art. 196-197, 213 and 214 Sw. General article for falsifications of documents

- ▶ **GERMANY.** Those fulfil the definition of section 4 (40) and are therefore falsified medicines under Section 8 of the Medicines Act
- ▶ **UK.** Fraud
- ▶ **REPUBLIC OF ARMENIA.** Criminal Code defines sanctions for falsification of documents: no specific provisions regarding falsification of invoices with a view to the sale of medicinal products
- ▶ **REPUBLIC OF SERBIA.** Some provisions in the Criminal law, 6 months to 5 years and a fine. Not specific enough

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- ▶ The “*falsification of documents*” is a criminal act under Art. 7 of the MEDICRIME Convention. Those countries that have ratified, accepted or approved the MEDICRIME Convention shall establish an equivalent offence under their domestic law.

Conduct 10

Manipulation/falsification/counterfeiting/adulteration of medicines

Charge in Italy: Specific reference in Criminal Code (Art. 440, 443)

- ▶ **BELGIUM.** Art. 498 Sw (general) and Law 25.03.1964 Art. 16,§3,3 specific reference (falsification of medicines), and Law 25.03.1964 Art. 12bis (a manufacturing permit is required for medicines). This is more a general article concerning fraud related to sold goods (not specifically on medicines) and Law 25.03.1964 is specific for medicines
- ▶ **GERMANY.** Specific reference in the German Medicines Act, Sections 8 and 95. Manufacturing and trafficking or dealing in falsified medicines
- ▶ **UK.** Breach of trademark. MHRA have prosecuted using this offence many times
- ▶ **REPUBLIC OF ARMENIA.** Criminal Code stipulates up to 3 years' imprisonment for the manufacture, preparation in a pharmacy and sale of falsified medicines

- ▶ **REPUBLIC OF SERBIA.** No specific reference in the Criminal law and few articles mention this but it is not clearly defined in the Law on medicines and medical devices (“The Official Gazette of the Republic of Serbia”, 30/2010; 107/2012 and 113/2017 laws). New law on medicines will introduce provisions in line with EU, Council of Europe, WHO and other relevant international legislation and standards in this area by the end of 2019, and hopefully the signing of MEDICRIME Convention will help expedite this procedure and maybe introduce changes in Criminal law as well in the near future
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- ▶ The “*manufacturing of counterfeit medicinal products and any adulteration thereof*” is a criminal act according to Art. 5.1 and Art. 5.2 of the MEDICRIME Convention, whilst falsification of documentation (a key element in the EU definition for falsified medicines, in particular with respect to Operation Volcano) is considered under art. 7. States that have ratified, accepted or approved the MEDICRIME Convention shall establish an equivalent offence under their domestic law.

The offence is considered from many different points of view in the existing regulation, and Dir. 2011/62/EU also lays down specific sanctions with respect to manufacturing falsified medicines: nonetheless, the mere conduct is not easy to be sanctioned as such, since the applicable rules consider as a key element the damage to patients (as for the Italian Criminal Code), or breach of trademark (as for the MHRA-UK reference – an element openly excluded from Directive 2011/62/EU scope), whilst implementation of the MEDICRIME Convention would make it directly chargeable.

Conduct 11

Violations to the “due diligence” of health professionals

Charge in Italy: Only infringements to the Penal/Pharmaceutical Code are sanctioned (fine or administrative sanction)

Comments: Even the obligation to report offences to Professional Orders is absent: an operator clearly involved in a criminal scheme may maintain his/her qualification/licence

- ▶ **BELGIUM.** Does not exist in Belgium. There are possible sanctions for specific infractions mentioned in the Law, but there is no general 'due diligence' rule
- ▶ **GERMANY.** As in Italy, above. There are of course certain rules of professional conduct, but no criminal sanctions. Very difficult to prove a mistake or lack of due diligence
- ▶ **UK.** If the violation is an offence, it will be prosecuted. There is no obligation to report to professional regulators, but a report will usually be made, and the professional may be struck off
- ▶ **REPUBLIC OF ARMENIA.** No specific provision
- ▶ **REPUBLIC OF SERBIA.** No specific reference in the Criminal law and few articles mention this but it is not sufficiently defined in the Law on medicines and medical devices ("The Official Gazette of the Republic of Serbia", 30/2010; 107/2012 and 113/2017 laws). Not specific enough, other legislation might need to change as well

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- ▶ A specific extension of the catalogue of accessory sanctions for health professionals supporting pharmaceutical crime activities, also in terms of disciplinary proceedings, would be extremely useful. Operators providing their expertise to the criminal organisation (for instance by cataloguing the medicines, estimating their value, assisting their re-entry into the distribution chain) should be specifically sanctioned also with respect to their professional role.

Due diligence of health professionals as such is not covered by the MEDICRIME Convention either as a definition or as an act that could be penalised. However, there is Art. 13 of the MEDICRIME Convention, which lays down "Aggravating circumstances". "Abusing the confidence" might be associated with the term "due diligence" and Art. 13 could apply only if an offence mentioned in Art. 5, 6, 7 or 8 has been committed.

Conduct 12

Criminal association (leaders and promoters, participants)

Charge in Italy: Ordinary crime (Art. 416 Criminal Code), no specific charges if the criminal organisation deals with medicines

Comments: A structure with several operators of different levels (i.e. someone *placing an order* for the drugs, someone *stealing* the medicines, someone *recycling/laundering* them, someone *exporting* them) is an organisation, but this must should be demonstrated (via wire tap, for instance) in order for charges to be brought.

- ▶ **BELGIUM.** Art. 323-324 Sw (association) or 324bis Sw (criminal organisation). In general, not specific for medicines
- ▶ **GERMANY.** Sanctioned under section 129 of the German Strafgesetzbuch (criminal law). Again, most difficult to prove and gather evidence
- ▶ **UK.** Conspiracy. This is used frequently to prosecute cases where people have agreed to commit an offence
- ▶ **REPUBLIC OF ARMENIA.** Ordinary crime, no specific provisions related to medicinal products in terms of criminal associations
- ▶ **REPUBLIC OF SERBIA.** Up to 8 years in prison, article 346 of the Criminal law. Not specific to medicines

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- ▶ Also with respect to this conduct, the considerations already reported with respect to thefts of medicines (conducts 1 and 2) may be repeated: Art. 6 and 7 of the MEDICRIME Convention could apply, and possibly also Art. 9, for those persons aiding or abetting the commission of any of the offences described in Art. 5, 6, 7 or 8. Additionally, it is important to highlight that Art. 11 “Corporate liability” penalises cooperate liability under four conditions only if one or more of the MEDICRIME offences is committed. According to the Explanatory Report to the MEDICRIME Convention “the intention is to make commercial companies, associations and similar legal entities (“legal persons”) liable for criminal actions performed on their behalf by anyone in a leading position in them”.

Given that the operation described made it possible to uncover networks fostering trade in falsified medicines, it would be important to apply similar offences such as those provided in Italy by Art. 74 of the D.P.R. no. 309/90 (association with the purpose of illicit drug trafficking), also considering specific provision of Art. 443 Italian Criminal Code as “Commerce of administration of faulty medicines or falsified medicines”. Stressing the “criminal organisation” aspects would strengthen the coordination and connection in the investigation provided by specific regulations such as Art. 371 of Italian Criminal Procedure Code, not only related to mafia type organised crime, but also for international trafficking in falsified medicines.

Conduct 13

Damage caused (even lack of effect)/risk caused to patients

Charge in Italy: Pharmaceutical crime is not among the alleged “dangerous” crimes. Damage must be proven, in order to apply the charges listed in Criminal Code (Art. 440)

Comments: Damage is difficult to evaluate: in this case, it would be up to the country of destination of the products

- ▶ **BELGIUM.** Art. 421 Sw: administration of substances that can harm (or kill). Risk alone is not enough, there has to be a real damage (even though the effect may only be clear years later)
- ▶ **GERMANY.** Similar to the situation in Italy, damage to be proven under Criminal law (Strafgesetzbuch)
- ▶ **UK.** Assault, murder etc. A person who causes a harmful medicine to be taken is considered to have done so intentionally or recklessly if harm was caused
- ▶ **REPUBLIC OF ARMENIA.** There are provisions in Criminal Code related to harm to patients caused by falsified medicinal products
- ▶ **REPUBLIC OF SERBIA.** Up to 12 years (in case of death) in prison, article 121 of the Criminal law. Not specific to medicines

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- ▶ One of the objectives of the MEDICRIME Convention is the protection of victims of the offences established under the Convention itself. Art. 19 and 20 of the Convention introduce measures for the protection of “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 conformity requirements”.

The “risk” caused to patients is not openly covered by the Convention – it falls under ordinary crime if it can be proven: nevertheless, the criminalisation of the conducts related to falsification requested in the implementation of the Convention is, by matter of fact, a criminalisation of the risk caused.

Conduct 14

Damage to company image

Charge in Italy: Companies (and any insurance companies) may form a civil party in proceedings

Comments: Compensation at the end of the process. There is no obligation to be a party in the trial

- ▶ **BELGIUM.** Only civil (specific procedure based on art .1382 BW) or companies may form a civil party in penal proceedings
- ▶ **GERMANY.** Same as in Italy
- ▶ **UK.** Civil action for defamation. This only applies if something is published which defames someone
- ▶ **REPUBLIC OF ARMENIA.** No specific provision
- ▶ **REPUBLIC OF SERBIA.** Up to one year in prison or a fine, Criminal law, article 239. Hard to prove, needs more specification

Conduct 15

Economic damage to hospitals and operators

Charge in Italy: Hospitals and operators (and any insurance companies) may form a civil party in the proceedings

Comments: Compensation at the end of the process. There is no obligation to be a party in the trial

- ▶ **BELGIUM.** Only civil (specific procedure based on art .1382 BW) or companies may form a civil party in penal proceedings
- ▶ **GERMANY.** Same as in Italy
- ▶ **UK.** Action for damages. This would be a civil law matter
- ▶ **REPUBLIC OF ARMENIA.** No specific provision
- ▶ **REPUBLIC OF SERBIA.** No specific article in the Criminal law. Hard to prove, needs more specific legal provisions

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- ▶ Indirect economic damage is out of the main scope of the MEDICRIME Convention: nevertheless, the general conducts may be criminalised in the civil proceedings, since any action for damages could be better supported if the origin of the possible damage is officially defined as an “illegal behaviour”.

Chapter 4

Conclusions

Inadequacy of the current regulatory framework

As far as the current legislation against pharmaceutical crime is concerned, in Italy (but also in the other countries that were involved in this study) it is generally agreed that the law is inadequate, in particular with respect to sanctions and deterrent measures: all penalties related to the pharmaceutical codes may be reduced to mere fines, even for conducts that could be related to criminal activities.

Even in the cases where the criminal law is applicable (e.g. the Italian Criminal Code, Art. 443 c.p. "Commerce or administration of defective medicines"), the poor coordination between old rules (aimed at sanctioning a proven damage) and the recent evolution of pharmaceutical codes may cause difficulties in enforcement: "falsified medicines" (as defined by Directive 2011/62/EU and Legislative Decree of transposition 17/2014) are not considered to be the dangerous goods that call for strong penalties under Criminal Law.

More recent developments in counteracting pharmaceutical crime address the lack of specific and tailored preventive measures, include provisions such as those laid down in Dir. 2011/62/EU (the "Falsified Medicines Directive"), focusing on the use of tools such as traceability systems, protecting the legal distribution network from possible infiltrations of illegal medicines.

It is worth mentioning that the application of non-specific regulations aimed at protecting public health, such as the medicines traceability systems in place in Italy, already proved to have a limited effect, when used in tackling such a challenging infiltration: the traceability system, tracking and tracing all medicines on the Italian market in their journey from the manufacturer to the final destination (pharmacy/patients, hospital) blocked the infiltration of products into the Italian distribution network, but the loopholes in traceability, caused by ad hoc exporting practices, for example, already made it possible to avoid verification of stolen products exported to the European Parallel Distributors' network. This is related to the design of these systems: the Italian traceability

system was set up with specific goals related to reimbursement and pharmacovigilance, the protection of the network from the infiltration of falsified medicines being a “side effect”.

At the current state of play, the information in the Italian system of traceability provided by supply chain stakeholders (transport operator, pharmacy or health structure, etc.) exclusively indicates some key data (name, batch number and quantity), without any specifics regarding the unique identifiers of the stolen medicines. The missing information makes it extremely difficult to reconstruct the distribution chain of the stolen medicines as well as the identification of the subject entitled to the restitution.

Once again, since the regulation was not specifically set up with pharmaceutical crime in mind, its application in the described framework is subject to limitations. With respect to preventive measures, a specific regulation on the use of traceability data in counteracting pharmaceutical crime would definitely be useful, since it would trigger a change in approach, possibly leading to results at a strategic level, e.g. procedures for data aggregation aimed at developing intelligence materials, but also to “tactical”, practical goals. For instance, a quick “decommissioning” of the unique identifiers related to stolen products could help the police forces identify as “stolen” any suspicious product bearing a “decommissioned” identifier.

Practical implementation of the MEDICRIME Convention concepts: the Italian case study

Italy invested substantial resources in addressing this specific type of pharmaceutical crime, by deploying and using tools for cooperation in investigation and intelligence and for an efficient exchange of information, as proposed in the MEDICRIME Convention (Art. 16 and 17), with impressive results: the number of thefts in Italian hospitals suddenly decreased with Operation Volcano (2014), and the creation of the web tools for authorities and operators “closed” the recycling channels, stopping the phenomenon. The effect of the investigation and of the preventive measures put in place through Operation Volcano also had an impact on the phenomenon of thefts as a whole: the number of packages stolen during transportation clearly decreased.

Italy applied the MEDICRIME core concepts in spite of the delay in regulatory implementation of the text. However, the proper transposition of the Convention in national law, together with the 19 March 2015 guidelines on principles of Good Distribution Practice of active substances for medicinal

products for human use (Text with EEA relevance 2015/C 95/01), would have helped AIFA and the other stakeholders in preventing and counteracting the criminal infiltration of the network.

Good implementation practices for the MEDICRIME Convention

It is clearly apparent that, with respect to the cases discussed here, efficient implementation of the MEDICRIME Convention could help strengthen the regulatory framework. However, this is contingent upon taking into account some specific points, some of which are related to existing regulations.

- ▶ **Art. 4 — Definition.** Definition of “counterfeit” should take into account the definition of “falsified medicines” as in Directive 2011/62/EU: medicines may be considered as falsified in terms of identity, source, history.
- ▶ **Art. 6 — Supplying, offering to supply, and trafficking in counterfeit.** Specific provision with respect to the distribution of stolen medicines and the related falsification, as well as to the “diversion” of medicines (i.e. when a legitimate pharmaceutical product is approved and intended for sale in one market but is then illegally intercepted and sold in another market) should be defined.
- ▶ **Art. 12 — Sanctions and measures.** It must be possible to sanction all activities related to falsified medicines, when intentional, with the revocation of any authorisation (for manufacturing, distributing, selling) of the involved operators.
- ▶ **Art. 16 — Criminal investigations.** Investigations against pharmaceutical crime should access all special investigative techniques provided by the law (in Italy, L. 146/2006, nr. 146 Art. 9). A higher level of priority and a strengthening of the investigation tools are necessary in order to speed up the investigations and to avoid falling into prescription. In this context, judicial procedures could allow AIFA, and consequently AIC holders if necessary, to be informed (while respecting the confidentiality of the investigation) and provide assistance to the investigation of the prosecutor’s office/law enforcement in case of thefts of medicines. This greater implication of technical administrations and private stakeholders in the investigation could promote an “investigative culture”. The security department/quality/supply chain department could act as

reference point to maintain a mutually beneficial partnership with law enforcement/judicial authority, allowing a multidisciplinary approach to the investigation: in this context, regulatory agencies and private sectors could provide precious support to law enforcement, on condition that specific judicial procedures allowing the pharmaceutical regulatory authorities to access the details of the investigations, are also defined.

- ▶ **Art. 17 — Cooperation between stakeholders and information exchange.** Cooperation is one of the instruments for preventing and fighting falsified medicines; public and private stakeholders know how much cooperation contributes to achieving common results. The MEDICRIME Convention encourages cooperation and information exchange between stakeholders, also considering the global vision typical of private multinationals: in setting up Operation Volcano through its Fakeshare web platform, AIFA already managed tools such as those defined in the Convention, with impressive results. Pharmaceutical companies had the opportunity to exchange information quickly with the authorities, and the national cooperation results convinced the international network (MAH headquarters, EU authorities) to support the effort by sharing information and cooperating in a more efficient way.

- ▶ **Art. 17.2 — Cooperation and involvement of commercial and private sector.** Practical indications on how to enhance collaboration, at both private and public level (“create collaboration through connection”), could be useful: partnerships can be developed through periodic meetings and webinars organised by the national competent authority, aimed at enhancing cooperation between regulatory authority/law enforcement/judicial authorities. As already discussed under the previous article, information sharing is the best way to prevent and fight the problem. Regulatory authorities should promote cooperation, organizing meetings with stakeholders aimed at fostering the sharing of information and points of view, as well as at drafting shared “best practice” guidelines, such as those already developed in Italy. These include the “AIFA Guidelines on Pharmaceutical Thefts”, which define the key steps in developing and managing signals, or the “PADLOck project” documents regarding the adaptation of hospital pharmacy safety levels against the risk of theft, and definition of technical standards.

Despite their complexity, coordinated public/private scientific investigations can provide useful support to the Authorities, in particular in investigating new criminal models, and in the evaluation of criminal networks. Using analytics and innovative technologies to protect the integrity of the distribution chain can help fight the phenomenon.

- ▶ **Art. 18.1 — Quality and Safety requirements of medical products.** The MEDICRIME Convention could encourage the use of technologies aimed at preserving the integrity of packages, as well as ensure security of medicines during transportation. Serialisation, if applied in a homogeneous manner, is considered an effective means of preventing the infiltration of falsified medicines into the pharmaceutical supply chain.
- ▶ **Art. 18.2 — Measures to ensure safe distribution of medical products.** Complete tracking of some types of medicines (such as those described in Dir. 2011/62/EU, calling for cooperation between private and public stakeholders through ad hoc structures) could be an excellent deterrent and could greatly reduce the risk of theft and diversion, with health professionals working closely to provide quality and security expertise to improve the integrity of the supply chain.

The MEDICRIME Convention could also encourage the enhancement of quality and security audits of pharmaceutical supply chain stakeholders (depositories, distributors, pharmacies) by the national and regional competent authorities: the safe distribution of medical products could also be obtained by stepping up verifications of the companies trading at international level. On the other hand, it would be helpful to simplify the “first check” performed by operators receiving the goods, for instance, by differentiating the packages of the products for specific restricted channels, e.g. for hospitals and similar institutions, in order to raise the number of reports from the field to the competent national authorities, according to Dir. 2001/83/EC art. 80(i).

From a technological/forensic investigation point of view, new technologies (mobile technologies, RFID tag, Blockchain) also help improve the integrity of the supply chain; on the other hand, a more balanced distribution of prices of medicines amongst countries in

the same area, as well as guidelines allowing safer access to parallel import networks, could reduce the differences between markets.

- ▶ **Art. 18.3 — Training of healthcare professionals and awareness-raising campaigns.** Greater involvement of all actors in the supply chain, in view of the specific criticalities of operators such as wholesalers and hospital pharmacists, could help prevent pharmaceutical crime in general, and thefts of medicines in particular. Knowledge and awareness can be strengthened through ad hoc training for professionals (pharmacists and physicians, but also prosecutors), and awareness campaigns targeting the public. Campaigns focusing on the key issue of the dangers related to any purchase of medicines through non-controlled/authorised channels (e.g. illegal websites) may also promote positive behaviours, such as reporting illegal offers to the competent authorities, facilitating studies on and analysis of this illegal phenomenon.

In the academic context, awareness of the falsified medicines issue may be heightened through training sessions on quality, logistics and distribution to future pharmacists/physicians, but also to future prosecutors, by including law faculties among the target audiences. International cooperation concerning training activities on international case management of trafficking falsified medicines should also be encouraged: case studies on practical investigations, public/private task forces, definition of information data flows may also be developed through training projects fostered by the implementation of MEDICRIME.

Chapter 5

Good implementation practices: the Switzerland case study

Switzerland actively collaborated in the development of the MEDICRIME Convention and was among the first countries to sign the Convention in Moscow. Although the ratification process took some considerable time, all the authorities involved were pleased to announce the ratification in October 2018. The additional legal provisions in the Swiss Therapeutic Products Act (TPA) have been in force since 1 January 2019.

Although Swiss legislation enabled Swissmedic (Swiss Agency for Therapeutic Products) to combat illegal medicines quite efficiently before 2019, the ratification made it possible to introduce even more elements into the fight against this kind of crime and to include a number of important new articles in Swiss legislation.

Below we present three examples of such new provisions, which help combat the infiltration of illegal medicines as discussed in this study.

Article 17 of the Convention gives grounds to formalise and strengthen the national authorities' existing system of Single Points of Contact (SPOC). In the TPA, a direct connection to the Convention was made and Swissmedic was appointed as the national SPOC [1].

The drug regulatory authority is ideally placed to act as the national SPOC because of its ability to assess the impact on public health, to manage and prevent risks, to supervise administrative and criminal procedures and to alert the public to hazards. As Swissmedic has been active as national SPOC – especially

1 Therapeutic Products Act Art. 69 para. 4: “The Agency is the national central and contact point pursuant to Articles 17 para 3 and 22 para 2 of the ‘Council of Europe Convention of 28 October 2011 on the counterfeiting of medical products and similar crimes involving threats to public health’. It shall maintain contacts with the designated contact points in other countries.”

in the European network of Enforcement Officers – for more than 15 years, the exchange of information was already established. The national SPOC informs relevant SPOCs on cases, assesses trends and organises meetings of the national network.

Communication with the pharmaceutical industry had to be a strictly one-way process because the TPA did not allow the disclosure of any confidential data to companies. Article 17 of the Council of Europe's MEDICRIME Convention lays down provisions that may for instance enable the exchange of information between authorities and industry.

The Convention has helped Switzerland to introduce an unusual but important new article into its own legislation, specifically for the disclosure of confidential data to industry in order to detect and combat suspected illegal trading.

In serious and complex cases of illegal trading in therapeutic products, the companies that manufacture the authorised product and place it on the market will play a central role in the investigations and measures taken to protect public health. They possess the relevant information about their therapeutic products and the legal sales channels. In some cases, moreover, they undertake their own investigations in order to defend their rights and counter hazards that could arise in connection with falsification of their therapeutic products.

Thus, the disclosure of information by the authorities to the companies concerned can substantially reinforce the protection of public health. For example, a manufacturer that receives information about a falsified product via the delivery channels can initiate the withdrawal of the legally distributed therapeutic product abroad – something the Swiss authority is unable to enforce.

The new Article 62b TPA [2] empowers the authorities to disclose confidential data, i.e. data relating to administrative and criminal proceedings and sanctions, to the involved parties.

2 Art. 62b Collaboration with the private sector: 1 – Following due consideration of the interests concerned, the Agency and the Federal Customs Administration are **entitled in specific cases to disclose confidential data** gathered in accordance with this Act to the holder of an establishment licence or of a medicinal product authorisation or to any person who places a medicinal product on the market, including data enjoying special protection pursuant to Art. 3.c.4 of the Federal Act of 19 June 1992 on Data Protection, provided such action is deemed necessary **in order to detect and combat suspected illegal trading** in therapeutic products; 2 – Personal patient data must not be disclosed.

Furthermore, it was important to introduce an obligation to report illegal trading and the discovery of falsified medicines. With reference to the EU Guidelines on Good Distribution Practices (Article 6.4 [3]), some provision had already been made, but only in the appendix to an ordinance. In the ratification process, it was helpful to incorporate clearly this obligation in the law [4]. The new article in the law also includes a reporting form together with notes explaining what to report, similar to the instructions on reporting quality defects.

To enhance the visibility of the national point of contact, a new website was created that is linked to the Swissmedic website: www.medicrime.ch. As contact point, the email address medicrime@swissmedic.ch has been established.

An example of a case which applied and combined the above-mentioned new provisions is that of falsified Iclusig®.

On 8 January 2019, a Swiss licensed wholesaler reported that it had been involved in trading in potentially falsified Iclusig® (a medicine against leukaemia containing the active ingredient ponatinib). The wholesaler had learned from a communication issued by the EMA (European Medicines Authority) that the batch it had purchased was suspected to be falsified. The Swiss wholesaler reported to Swissmedic that it had bought 6 packs from a Turkish wholesaler at the end of 2018 and had sold one pack to an Argentinian customer. Swissmedic requested that the remaining 5 packs be sent to the Swissmedic OMCL laboratory. Within a short time, the lab detected that the falsified tablets contained low-dose paracetamol instead of ponatinib. Because of the serious health risk, Swissmedic sent the Turkish SPOC full details of the supplier and issued a European rapid alert. In contact with the market authorisation holder of Iclusig®, information about the supply chains for the falsified batches were exchanged and Swissmedic was able to disclose the name of the Turkish wholesaler to the marketing authorisation holder (MAH). Also in collaboration with the MAH and Swissmedic, WHO issued an international alert [5], which helped to reveal further falsifications of the same medicine.

3 Art. 6.4 of EU GDP (2013/C 68/01): "Wholesale distributors must immediately inform the competent authority and the marketing authorisation holder of any medicinal products they identify as falsified or suspect to be falsified."

4 TPA Art. 59 Abs. 3bis: "Any person who manufactures or places on the market therapeutic products must report to the Agency any suspicion of illegal trading in therapeutic products by third parties that come to its knowledge in connection with its activities, its products or their components."

5 https://www.who.int/medicines/publications/drugalerts/drug_alert-2-2019/en/

Chapter 6

Take home message: there is a need for a framework regulation against pharmaceutical crime

Pharmaceutical crime is one of the most lucrative illicit activities, and one of the main investment areas for organised crime: in recent years, alongside falsification there has been a significant increase in pharmaceutical product-related crimes, such as thefts and robberies targeting hospitals or lorries, aimed at re-marketing the stolen products in Italy or abroad, on-line or through infiltration of the legal distribution chain.

In spite of this situation, the survey referred to in this study clearly underlines that the absence of specific regulatory measures aimed at deterring and preventing pharmaceutical crime is an issue in all countries that did not implement a framework regulation such as the MEDICRIME Convention.

A specific implementation of MEDICRIME Convention as a framework regulation, through proper references to Pharmaceutical Codes and Criminal Law, seems therefore to be highly desirable. This would act as a trigger for more severe and easily applied deterrent penalties, and for structured cooperation schemes between stakeholders, allowing more refined intelligence activities aimed at counteracting and preventing criminal schemes: not just those discussed in this study, but also the forthcoming developments triggered by the joint efforts of administrations and private stakeholders, counteracting the criminal organisations that are targeting the sector.

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In the course of 2014, the Italian authorities carried out Operation Volcano, an impressive campaign against a criminal organisation facilitating the infiltration of falsified medicines (stolen/manipulated products obtained through robberies, mainly from Italian hospitals) into the parallel trade network, mostly in Germany, but also in other European countries: more than 100 different medicines and 17 countries were involved, and more than 3 000 transactions between operators were “polluted” by falsified medicines.

Although the harm these activities caused to patients was not officially measured, it is clear that during the “infiltration” period (2011–2014), public health was put at risk by manipulated products which possibly lacked pharmaceutical activity and quality – and it is well known that poor-quality medicines may compromise the treatment of chronic and infectious diseases, leading to disease progression, drug resistance, side effects and even death.

In spite of the impressive results (more than 80 people arrested, and a three-year dramatic reduction in thefts in Italy), Operation Volcano did not have a deterrent effect. This was due to many concurring factors such as lack of proper specific sanctions for health professionals, different enforcement/investigative approaches in the European countries involved and poor cooperation between central/local authorities at national and international level, etc. Then, in 2018, other investigated cases reproduced the features identified through Operation Volcano, proving once again that criminals had simply transferred their activities from Italy, where the selling channels had been shut down, to other EU Member States.

This study looks at how proper implementation of the MEDICRIME Convention could help in this matter. It was carried out by Regulators and Prosecutors from Italy, Germany, the UK, Belgium, the Republic of Armenia and the Republic of Serbia as part of the EDQM Committee of Experts on Minimising the Public Health Risks Posed by Falsification of Medical Products and Related Crimes (CD-P-PH/CMED) activities and tries to answer the question by evaluating how current legislation could be improved through a proper implementation of the Convention.

The Council of Europe is the continent’s leading human rights organisation. It comprises 47 member states, including all members of the European Union. The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a directorate of the Council of Europe. Its mission is to contribute to the basic human right of access to good quality medicines and healthcare and to promote and protect public health.

