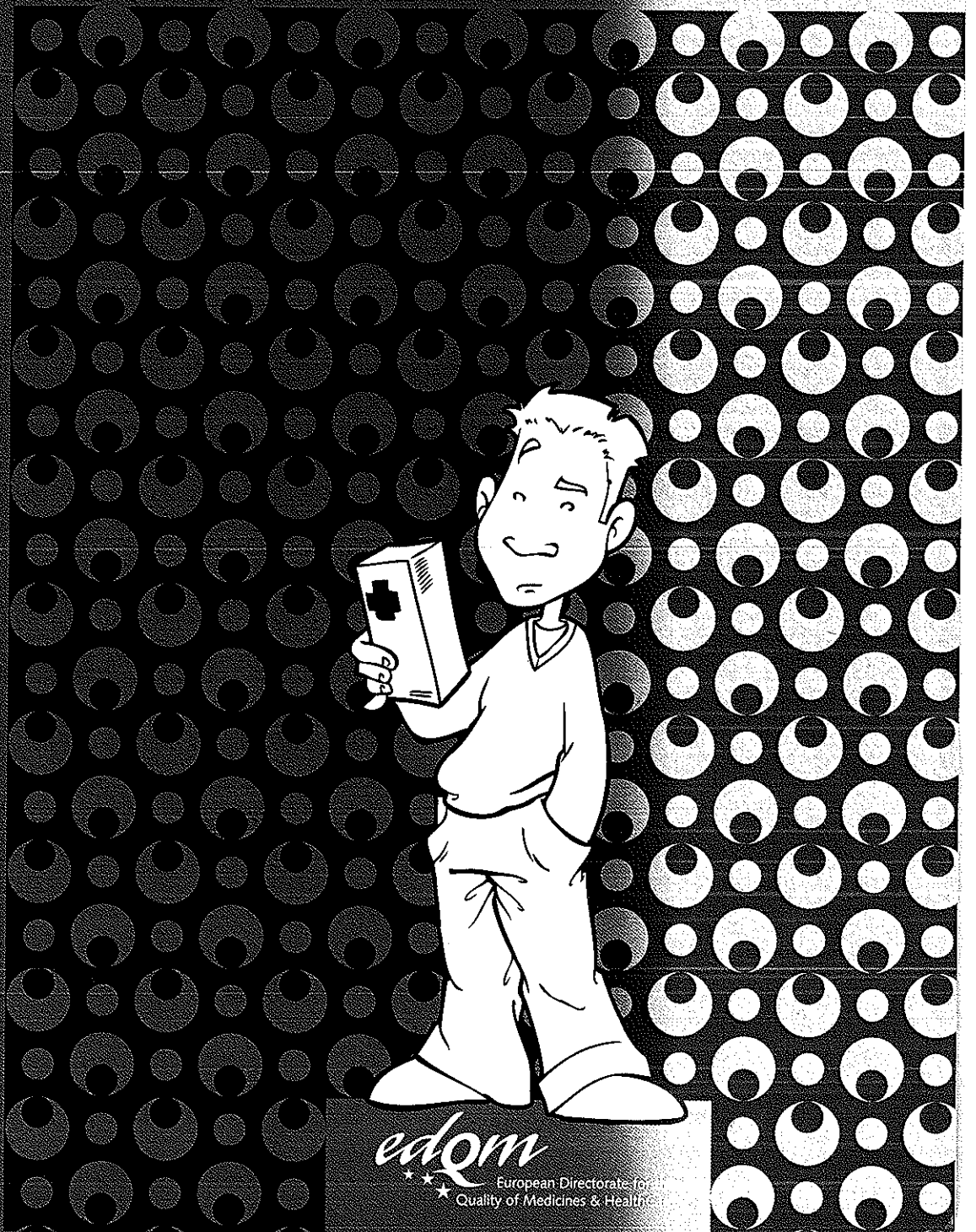
Counterfeit medicines
Facts and case studies

D. Di Giorgio Ed.



edqm
European Directorate for the Quality of Medicines & Healthcare

Counterfeiting of medicines and similar crimes present a serious threat to the health of particularly vulnerable persons, patients in Europe and worldwide. Timely, balanced information for the general public, avoiding undue anxiety, and the sharing of proven approaches between officials and healthcare professionals constitute the key for public health protection and for effectively fighting counterfeit medicines and similar crimes at national and international levels.

In easily understandable language, the Guide takes a close look at the implications for public health of the criminal phenomenon of medicine counterfeiting in Europe. It gives an overview on counter-measures taken by international organisations, public administrations and stakeholders of the pharmaceutical production and distribution chain to safeguard public health in Europe.

The Guide provides, inter alia, a description of these vile phenomena, existing regulations, and practical advice, not only for the public, but also for non-specialised officials in public administrations and healthcare professionals in general.

The EDQM is a Directorate of the Council of Europe, an international organisation founded in 1949 that covers almost the entire continent of Europe. The Council of Europe aims to develop common democratic and legal principles based on the European Convention on Human Rights and other reference texts on the protection of individuals.

Director of the Publicat
Dr S. Ke

Copyri

European Directora
the Quality of Medicin
HealthCare (EDQ
7 allée K
CS 30
F-67081 STRASBOUR
FRA
Tel: +33 (0)3 88 41 30
Fax: +33 (0)3 88 41 27
E-mail: info@edqm
Internet: http://www.edqm

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

edqm European Directorate for the Quality of Medicines & HealthCare

The Editorial Board wishes to honour the work of all those actively engaged in fighting counterfeit medicines and protecting patient safety.

Sincere thanks are owed to all the experts and stakeholders supporting the Council of Europe medicine anti-counterfeiting activities whose names cannot be mentioned here, and in particular to Martijn Ten Ham, past chairman of the former Council of Europe Ad hoc Group on Counterfeit Medicines, and Paul Dietschy, delegate of the former Committee of Experts on Pharmaceutical Questions, who both launched the activities and contributed significantly to their progress and evolution.

Table of Contents

Chapter 3: Regulatory environment

The absence of the concepts of "counterfeit medicines" and "pharmaceutical crime" in European national regulation forced the authorities to use the available tools to try to face the emerging problems related to the easy circulation goods in the internet sphere. The following sections try to give an outline of the general framework and some practical examples on how the authorities are stretching the edges of existing regulation to better counteract the counterfeiters.

International initiatives such as the conventions and guidelines developed by international bodies (Council of Europe, WHO IMPACT) are aimed at co-ordinating the development of national regulations that could foster cooperation between all the interested stakeholders.

3.1. National legislation against counterfeit medical products

Axel F. Wenzel, TOPRA, and Dr Reiner Schwarz-Kaske, Institut für Chemie-Information, Germany

A physician of a mission hospital in Kenya reported, a few months ago, about patients who complained that their anti-malaria medication was "not working as expected". After a simple analysis, the pharmacists found out that the medicine contained only potato starch and a minimal concentration of the fever-lowering agent, paracetamol. This was not what was indicated on the labelling and in the patient information leaflet. Clearly, this combination had no effect whatsoever on malaria. Because the medicine had reduced the typical malaria fever for a few hours, the patients assumed it had a therapeutic effect and were encouraged to buy this medicine again. It was not mentioned, however, how many fatalities were caused by this counterfeit medicine.

Counterfeiting medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems. Considering their direct impact on health, counterfeiting of medicines should be combated and punished. Combating counterfeit medicines requires the co-ordinated effort of all public and private stakeholders that are involved and are competent for addressing the different aspects of the problem.

Counterfeiting of medicines is widespread and has increased to an extent that effective co-ordination and co-operation at international level are necessary to make regional and national strategies more effective. Traffic in counterfeit goods is a scourge that is taking the form of an epidemic, increasing in Europe in both range and volume by an estimated 20% every year. Counterfeiting is difficult to detect, to investigate and to quantify. So, it is difficult to know, or even estimate, the real extent of the problem. What is known is that it occurs worldwide and is more prevalent in developing countries. It is estimated that more than 10% of medicines are counterfeit worldwide. In some countries more than 50% of the medicine supply is counterfeit medicines. Furthermore, the World Health Organization (WHO) estimates that the annual profit from counterfeit medicines exceeds US$32 billion.

The growing phenomenon of counterfeiting in Europe points to substantial risks to public health and well-being and to the considerable losses incurred by the

economies of the Council of Europe member states. All member states of the Council of Europe are concerned either as countries of origin (the 'producers'), transit or end-destination for counterfeit goods. This multi-billion euro problem can no longer be ignored as marginal owing to the extent to which it undermines security, economic growth, employment, innovation, investment, competition, tax income and the reputation of branded goods.

One of the main difficulties is enforcement of legislation as the perpetrators are often residents of another country or members of a global criminal network. Under international law, EU member states are entitled to proscribe that an activity occurring in another state is a criminal offence under domestic law if the perpetrator or the victim of the offence is a national citizen. However, there is a need for the co-operation of the other state in order to prosecute the criminal offence.

The legislations of the member states of the Council of Europe were for a long time not ready to punish organisations or people that fake medicines. And there are many countries that still have to start to enact new legislation.

The evident risk to public health in Europe and the lack of commitment on the part of public and private sectors to tackle the problem, led the Council of Europe to entrust, in 2003, the Ad hoc Group on Counterfeit Medicines with a comprehensive risk management and prevention programme including a systematic review on applicable legislation. This was based on Resolution ResAP(2001)2 pointing out to the public health risks posed by counterfeit medicines and calling for multisectorial co-operation in Europe.

In addition to earlier activities to combat counterfeit medicines and substandard medicines, WHO set up the first global partnership known as the International Medicinal Products and Anti-Counterfeiting Task Force ("IMPACT") in February 2006. IMPACT is comprised of all 193 WHO member states on a voluntary basis and includes international organisations, enforcement agencies, national medicine regulatory authorities, customs and police organisations, non-governmental organisations, health professionals and patient groups.

These groups have joined their forces to improve co-ordination between the different countries to curtail the production, trade and sales of counterfeit medicines. IMPACT focuses on the following five areas: legal and regulatory infrastructure, regulatory implementation, enforcement technology and risk communication. It thereby aims at strengthening international collaboration among all concerned stakeholders for the purpose of effectively combating counterfeit medical products.

IMPACT stakeholders have gathered experience and information on national and international legislative instruments in different parts of the world. Although more study is necessary to further improve our understanding, some lessons have already been learned.

The Council of Europe has, moreover, started evaluating the feasibility of an international treaty in the criminal field targeted at counterfeiting of medicines. With its multidisciplinary approach, its political and legal authority and its pan-European membership (which is much larger than that of the European Union), the Council of Europe is ideally placed to motivate and mobilise European states to tackle the complex challenge and threat that counterfeiting represents. While

a legal instrument with a global reach would undoubtedly be desirable, it has to take into account the required urgency and the high standards to which European countries aspire.

3.1.1. Factors supporting counterfeiters

The most urgent problems are the following:

- a definition of counterfeit medical products is, in many a national legislation, still absent or inadequate;
- there is no consensus at all about the definition of a counterfeit medicine, not even within the EU;
- counterfeiting of medical products is not considered *per se* a serious crime or even a crime;
- where counterfeiting of medical products is considered a crime, sanctions are sometimes much lighter than those applicable to counterfeiters of products that have no implications for health such as T-shirts;
- counterfeiting of medicinal products is much more profitable, technically much easier to do, much more difficult to detect and, most importantly, to a much lesser extent, punished by legislation as trafficking of narcotics;
- sanctions are not linked to counterfeiting of medical products *per se* but to proof that counterfeits have actually resulted in harm or death;
- the responsibilities of those involved in the distribution system are not clearly defined;
- there are no provisions enabling effective co-ordination and exchange of information between the different authorities and other stakeholders at national, regional and international levels;
- there are no provisions enabling different authorities to provide information to other authorities (nationally, regionally and internationally) or to use, before the court, information obtained from other authorities (nationally, regionally and internationally);
- there are no provisions addressing the problem of trade in packaging materials, particularly labels, without the consent or upon order of the company whose name appears on these materials;
- insufficient provisions with regards to the confiscation and use of assets, equipment and other materials used for manufacture, trade and transportation of counterfeit products;
- lack of co-ordination among the different authorities in one given country and also within the EU, the Council of Europe member states and worldwide with other stakeholders (pharmaceutical industry).

3.1.2. What is a counterfeit medicine?

In accordance with Black's law dictionary, the term "counterfeit medicine" may be used to describe a medicine made by someone other than the genuine manufacturer by copying or imitating an original medicine without authority or right, with a view to deceiving or defrauding, and then marketing the copied or forged medicine as the original. In reality, however, a counterfeit medicine is defined differently in different countries.

Before discussing the legislation applicable in Europe against counterfeiters of medicinal products, we have to find a clearer definition of what is a counterfeit medicine. The most known definition is the WHO definition of 1992:

"A medicine that is deliberately and fraudulently mislabelled with respect to source and/or identity". Counterfeiting can apply to both generic and branded products. Counterfeit medicines may include medicines:

- with the correct ingredients,
- with the wrong ingredients,
- without ingredients,
- with incorrect quantities of active ingredients,
- with fake packaging.

Looking into the different national legislations of the EU member states, in general a counterfeit medicine is considered a medication which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness. The colloquial term for a counterfeit medicine is „beat bag". A counterfeit medicine may be one which does not contain active ingredients, contains an insufficient quantity of active ingredients or contains entirely incorrect active ingredients (which may or may not be harmful) and which is typically sold with inaccurate, incorrect or fake packaging. Fake medicines which are deliberately mislabelled in order to deceive consumers are therefore counterfeit, while a medicine which has not received regulatory approval but consists of the correct active and inactive ingredients is often not considered as a counterfeit medicine.

3.1.3. Different approaches to tackle counterfeit medicines

Counterfeit pharmaceuticals enter the pharmaceutical production and distribution chain at at least three different stages.

- The first stage is the sourcing of counterfeit medicines. These include genuine pharmaceuticals that have been stolen, expired pharmaceuticals, manufactured counterfeit medicines and contraband products.
- The second stage involves the wholesale distribution of these counterfeit medicines that may or may not involve the packaging and repackaging of medicines. These medicines may be distributed to national health systems, hospitals, pharmacies or other legitimate or illegitimate distributors.
- The third stage is the distribution to the individual. This may occur through legitimate sources (many being unaware of the products or the source) through street markets in developing countries or over the Internet.

WHO carried out a study on counterfeit medicines between January 1999 and October 2000 (WHO 2005). During this period of time, 46 confidential reports from 20 countries were collected. Sixty per cent of these were from developing countries. This was not a rigorously controlled study but it showed a wide range of counterfeit medicines, including antibiotics, hormones, analgesics, steroids and antihistamines. The ways in which medicines were counterfeit can be grouped into seven categories:

1. products without active ingredients, 32.1%;
2. products with incorrect quantities of active ingredients, 20.2%;
3. products with wrong ingredients, 21.4%;
4. products with correct quantities of active ingredients but with fake packaging, 15.6%;

5. products with high levels of impurities and contaminants, 8.5%;
6. products with high levels of impurities and contaminants, 8.5%;
7. copies of an original product, 1%.

A patient who uses a counterfeit medicine may experience a number of dangerous consequences for health, such as unexpected side effects, allergic reactions, or a worsening of the disease. A number of counterfeit medicines do not contain any active ingredients but instead contain inert substances which do not provide treatment.

3.1.4. Lack of appropriate medicine legislation

Legislation and regulations form the basis for medicine regulation. Where legislation and regulations for adequate control of medicines do not exist, the otherwise criminal activity of counterfeiting of medicines is not prosecuted as crime. So far, only a few WHO member states have enacted special national legislation addressing the issue of counterfeit medicines. Moreover, sanctions imposed on counterfeiters are in most cases no deterrent. The absence of deterrent legislation encourages counterfeiters, since there is no fear of being apprehended and prosecuted.

Medicines need to be safe, effective and of good quality in order to produce the desired effect. These are the standard requirements for a marketing authorisation of a medicine. Ensuring these properties requires the running of a competent national medicine regulatory authority with the necessary human and other resources to control the manufacture, importation, distribution and sale of medicines. At present, only 20% of WHO member states, including Council of Europe member states, are known to have a well developed medicines regulation. Of the remaining member states, about 50% implement medicine regulations at varying levels of development and operational capacity. The remaining 30% have either no medicine regulation in place or a very limited capacity for enforcement that hardly works. Inadequate, ineffective or weak medicine regulatory control favours unregulated importation, manufacture and distribution of medicines, leading to the entering of counterfeit medicines into the national market.

Inadequate resources for drug regulatory activities and absence of training of national medicine regulatory authorities' staff may point to inefficiency and incompetence of national medicine regulatory authorities and consequently, counterfeit medicines will enter into national distribution channels.

Enacting deterrent anti-counterfeiting legislation alone will not solve the problem. It needs to be enforced. Where existing laws are not enforced, crime is perpetuated as criminals are not afraid of being arrested and prosecuted. Lenient sanctions for offences tend to encourage criminal activities such as medicines' counterfeiting, particularly if penalties for counterfeiting of non-medicinal goods are more severe. Moreover, disregarding intellectual property rights may encourage counterfeiting of medicines on a large scale.

3.1.5. Existing legislation for combating counterfeiting of medicines

International conventions are important tools for combating the counterfeiting of medicines. In the absence of such legal tools, legislation in force can be used to

prosecute this illegitimate trade. Existing legislation applicable to counterfeiting of medicines include for example, violation of intellectual property rights.

A counterfeit medicine may violate the intellectual property rights of the manufacturer of the genuine medicine. This can involve breach of a patent and/or trademark or involve the tort of passing off.

A pharmaceutical manufacturer can institute civil proceedings for violating the patent in case the counterfeit medicine has the same or similar ingredients as the genuine patent-protected medicine.

A pharmaceutical manufacturer or licensee can institute civil proceedings for violation of a trademark where the counterfeit medicine bears the trademark of the genuine medicine without the manufacturer's or licensee's consent. Police and customs authorities can also initiate criminal proceedings for the breach of a trademark.

A pharmaceutical manufacturer can also sue for the tort of passing off if the counterfeit medicine uses the same or similar name and product packaging as the genuine medicine (SmithKline Beecham plc v. Antigen Pharmaceuticals, High Court, McCracken J., 25th March, 1999). Legal proceedings for the violation of intellectual

property rights present difficulties. A pharmaceutical manufacturer can initiate civil proceedings if the counterfeit medicine causes a significant loss of sales of the genuine medicine or significant damage to the reputation of the genuine medicine. These facts may be difficult to establish.

There are also practical difficulties in identifying and locating the party responsible for violation of intellectual property rights, particularly if the violation has happened outside the country of residence of the rights' holder. This often gives rise to jurisdictional issues.

Many fake pharmaceuticals are produced in developing countries. The attitude of developing countries towards intellectual property rights has often been very negative. Intellectual property rights are considered to be responsible for the high price of medicines and are seen as a sign of foreign interests prevailing over domestic interests. However, membership in the World Trade Organization requires that member states enact these rights into domestic legislation. Progress in this area will be needed to facilitate co-operation between governments on several issues related to counterfeiting.

3.1.6. National examples from Europe

Austria

The Austrian legislation as regards counterfeiting of medicines was updated in 2006. Article 6 of the Austrian medicines act refers to intended misleading ("Irreführung"). It is not allowed to place medicinal products on the market that contain statements that do not correspond with the reality or that contain other misleading information, in particular:

- to claim effects that are not covered by scientific knowledge and/or experience,
- to claim a therapeutic action that can be expected with certainty,
- to claim total absence of side effects even after long-term use.

Sanctions comprise €25 000 (in repeated cases up to €50 000) or imprisonment of up to 3 years.

Bulgaria

Bulgaria, one of the oldest states in Europe, has recently joined the EU. Its medicines' legislation has been updated. In major legislation, like the Medicinal Products Act of 2007 supported by, for example, an administrative penal code and an administrative breach and Penalty Act, counterfeiting of medicines is clearly forbidden and the rule enforced.

Germany

Germany has recently updated the Medicines Act (AMG, Arzneimittelgesetz). Before the 12th amendment of the AMG, counterfeit medicines were considered as product piracy. Only in a few rare cases, for instance when harming a major part of the population, the Medicines Act could be used as basis for enforcement. In the new legislation reference can be made to section 8 of the 14th amendment of the medicines act dealing with prohibitions to prevent deception. Here, a counterfeit medicine is clearly defined.

1. Medicinal products shall be prohibited from being placed on the market

- if they are of a considerably reduced quality and deviate from recognised pharmaceutical standards,
- if they are incorrectly labelled with regard to their identity or origin (counterfeit medicinal products) or
- if they bear otherwise misleading designations, specifications or presentations. Deception shall be assumed, particularly if

– claims are made that certain medicinal products have a therapeutic efficacy or effects which they do not possess,

– the erroneous impression is given that success can be expected with certainty or that no harmful effects can be expected to occur if the medicinal product is used in accordance with its intended purpose or over a prolonged period,

– designations, specifications or presentations having an influence on the assessment of the medicinal product are used to mislead others with regard to its quality.

2. It shall be prohibited to market medicinal products which have expired.

Sanctions are laid down in articles 95 to 97. Persons that act against the above-mentioned sections of the law shall be liable to imprisonment for a term not exceeding three years or to a fine. The attempt to commit such acts is also punishable.

In particularly serious instances such as endangering the health of a large number of people, exposing people to the risk of death or the risk of serious injury or acquiring a considerable pecuniary gain for himself/herself or another person, the sanctions will comprise imprisonment from one to ten years.

In cases where violation of the Law is considered an administrative offence the offender may be liable to a fine not exceeding €25 000.

Italy

There are no specific articles dealing with the issue of counterfeit medicines; however, this matter is tackled by applying the regulation which deals with "Risks for Public Health", as stated in the Penal Code. This approach consists in identifying the existing regulation that can be used as a reference when dealing with cases of suspect counterfeit medicines (see Chapter 3.1.1 "A practical example: the Italian regulation").

Ireland

In Ireland, there are regulations for the manufacture, distribution, advertising and sale of pharmaceutical medicines (term used synonymously for medicinal products). It is a criminal offence to violate these regulations. The Irish Medicines Board is the enforcement authority for these regulations. A counterfeit medicine may violate these regulations in the following different ways:

- Importing, placing on the market or otherwise selling any medicinal product or procuring the manufacture for sale of any medicinal product without a licence granted by the Irish Medicines Board. [Medicinal Products (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998) Regulation 3];
- keeping, offering for sale, or selling by wholesale any medicinal product without a wholesale licence granted by the Irish Medicines Board. [Medical Preparations (Wholesale Licenses) Regulations 1993 (S.I. No. 39 of 1993) Regulation 4 and Medical Preparations (Wholesale Licenses) (Amendment) Regulations 1996. (S.I. No. 41 of 1996)];
- supplying certain medicinal products without a prescription. [Medicinal Product (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 5];
- certain medicinal products can be supplied without a prescription, but such products must be supplied in a pharmacy in accordance with the Pharmacy Act 1875 to 1977 and such supply must be effected or supervised by a pharmacist. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 6];
- failing to display required label information on a container or outer package of dispensed medicinal product. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 9];
- failing to provide certain information on the packaging and/or on a leaflet of a medicinal product. [Medical Preparations (Labelling and Package Leaflets) Regulations 1993 (S.I. No. 71 of 1993) Regulations 3-9 as amended by Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations 1994 (S.I. No. 440 of 1994) and Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations 1999 (S.I. No. 187 of 1999)];

- supplying of medicinal products for use as such after the expiry date of the medicinal product in question. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 18];
- supplying medicinal products by way of mail order [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 19];
- supplying certain homeopathic medicinal products and herbal substances in breach of the regulations. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 19, Medicinal Products (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998) Regulation 8, Medical Preparations (Licensing, Advertisement and Sale) Regulations, 1984 to 1994 and Medical Preparations (Labelling and Package Leaflets) Regulations, 1993 and 1994];
- advertising through any medium a medical preparation that does not have a product authorisation or is a product that requires a prescription. [Medical Preparations (Advertising) Regulations 1993 (S.I. No. 76 of 1993) Regulations 4 and 5.];
- placing dangerous products on the market. The safety of a product is determined by taking into account the characteristics of the product including its composition and packaging [Medical Preparations (Advertisement and Sale) Regulations 1958 (S.I. No. 135 of 1958)].

The vast majority of these regulations have been issued in order to bring Irish law into conformity with EU laws. The purpose of these EU laws is to remove differences in member states' laws regulating medicinal products so that the internal market in pharmaceuticals may function more effectively. The safeguarding of human health from medicines, genuine or otherwise, is an indirect benefit of these EU laws. Directives 2004/27 and 2004/24 make changes to this regulatory system. However, the current regulatory system does not directly attack the difficulty of counterfeit medicines from a patient safety perspective.

Irish and European laws make many aspects of counterfeit medicines illegal. This is achieved indirectly because counterfeit medicines breach the licensing and regulatory system for legitimate medicines. There is a need to tackle counterfeiting head on with a range of civil and criminal sanctions for those who engage in a trade that poses a significant and ever-increasing threat to global health.

Serbia

On which legal basis are the production and distribution of counterfeit medicines prosecuted in Serbia? In Serbia too this issue is not well regulated. Serbia is in the process of harmonising its legislation with EU legislation and regulations. The Serbian Law for Medicines and Medical Devices will be amended and harmonised with EU legislation in 2008/09. There are no articles in the current Law for Medicines and Medical Devices which could be applied to counterfeiting of medicines.

There is one article in the Serbian Criminal Law, Article 256, dealing with this issue. It says that whoever produces, distributes and puts on the market harmful products will be fined with a sentence of confinement from 3 months to 3 years.

United Kingdom

The Medicines and Healthcare products Regulatory Agency (MHRA) is the only regulatory authority in Europe that has its own dedicated enforcement and intelligence (E&I) group responsible for criminal investigations.

MHRA is the only national competent authority (NCA) that has developed its own Medicines and Healthcare products Regulatory Agency's (MHRA) Anti-Counterfeit Strategy. This document clearly sets out the MHRA's approach to combating the availability of counterfeit medicines and devices in the UK for the coming years[1].

The MHRA E&I is responsible for the national anti-counterfeiting strategy which was launched in November 2007. It monitors medicines and medical devices sold or distributed in the UK and has power which enables it to prosecute those who manufacture and distribute counterfeit medicines in the UK. It works closely with other law enforcement agencies such as the police, customs and trading standards authorities.

The E&I comprises of an intelligence, investigations, prosecutions and support unit of 42 staff members. The E&I is responsible for the investigation of breaches of the Medicines Act and associated legislation, including the MHRA response to counterfeit medicines in the legal and illegal supply chain. E&I staff have statutory powers to enter private and commercial premises in the furtherance of their duties and to seize goods suspected of being used in breaches of the Medicines Act and associated legislation. The E&I carries out investigations in accordance with relevant legislation and submits recommendations for prosecution to the solicitor of the Department of Work and Pensions (DWP).

Investigations concerning counterfeiting of medicine are usually complex, involving networks of companies and bank accounts, often overseas. The officials have a thorough knowledge as regards markets, different countries' supply arrangements procedures and laws. They will often try to exploit perceived weaknesses in supply chain arrangements. The extent of this type of criminal activity is serious and the types of cases are invariably referred to DWP solicitors recommending prosecution.

The E&I focuses mainly on the offences contained in the UK Medicines Act 1968 which carry a maximum of a two-year sentence and/or unlimited fine. Cases involving counterfeit medicines are also prosecuted using the Trademarks Act 19 carrying a maximum sentence of a 10- year imprisonment and the Proceeds of Crime Act 2002 with a maximum sentence of 14 years imprisonment. Consideration will now be given to using the Fraud Act 2006 for these types of cases. Civil injunctions have also been relied upon as appropriate.

3.1.7. Measures to combat counterfeit medicines

At national level, every country should therefore develop appropriate medicines policy options, legislation and enforcement strategies in the light of its own situation and availability of institutional framework, professional and financial resources. The policies should aim at involving the government, its agencies, the pharmaceutical industry, medicine importers and distributors, the pharmaceutical profession, non-governmental organisations, public interest groups and consumer groups, etc. in an effort to prevent the supply of counterfeit medicines. Measures are often more effective when carried out by all concerned working together.

More specifically, governments of each country should show political will and commitment for developing and implementing programmes to combat counterfeit medicines. Political will and commitment should be demonstrated by:

- enacting new medicine laws or updating the existing ones to include provisions for prohibiting counterfeit medicines as demonstrated in the foregoing chapter;
- establishing institutions for the regulation of medicines and clearly setting out the powers, duties and responsibilities of the institution(s) in the medicine laws;
- training of staff, including enforcement officers, in medicine surveillance;
- making available necessary financial and other resources;
- ensuring that the medicine laws are enforced; and
- fostering international cooperation in the control of pharmaceuticals and entering into bilateral and multilateral agreements with other governments and with international organisations such as the Council of Europe (conventions in the criminal field), WHO, Interpol and the World Customs Organization (WCO).

Judicial procedures and policies should reflect the seriousness of the problem and the offence. Courts should, without delay, dispose of cases involving counterfeit medicines and impose appropriately severe sanctions on convicted offenders. In addition, courts should order the confiscation/forfeiture and destruction of counterfeit medicines.

Combating counterfeiting of medicines is a shared responsibility to which all interested parties have to contribute. Non-governmental organisations or community-based organisations, such as consumer associations, should be informed in a balanced way about the problem of counterfeiting and the possible presence of counterfeit medicines in the national distribution chain without causing undue anxiety. They should be provided with information and methods for detection so that they are able to report cases to the national medicine regulatory agencies.

The general public should be encouraged to support the fight against medicine counterfeiting. Education and information campaigns directed at the general public should be established and the public should be advised to buy medicines from legitimate sources rather than from peddlers and hawkers or from market places and streets or via doubtful sites on the internet. Consumers should also be encouraged and advised to report to their prescribers or physicians any lack of improvement in their health in spite of treatment or of any adverse reactions experienced.

More privatisation and liberalisation of the world economy, more extensive opening of borders to trade, and increased promotion and sale of medicines through the Internet will all lead to the increased circulation of counterfeit medicines on national and international markets. This means greater co-operation between countries at sub-regional, regional and international levels will be needed to combat counterfeit medicines in the future. Co-operation should include developing common strategies, timely exchange of information and harmonisation of measures to prevent the spread of counterfeit medicines. Co-operation would improve if all countries adopt a common definition of counterfeit medicines.

At global level,a more effective response to the threat of counterfeit medicines c
be the development of an international convention to control trade in counterf
and substandard medicines.

3.1.8 References Chapter 3.1

[1] http://www.mhra.gov.uk/home/groups/ei/documents/websiteresources/con2033156.pdf

List of Authors

Cristina BACCARELLI
GMP Inspector
Agenzia Italiana del Farmaco (AIFA)
Via Sierra Nevada 60
I-00144 ROME
Italy

Luc BESANÇON
Project Coordinator
International Pharmaceutical Federation (FIP)
P. Box 84200
Andries Beckerweg 5
NL- 2508 AE THE HAGUE
The Netherlands

Hugo K. BONAR
Enforcement Manager
Irish Medicines Board
Earlford Center, Earlsford Terrace
IR-DUBLIN, 2
Ireland

Dr Maurizio BONATI
"Mario Negri" Institute for Pharmacological Research
Via Eritrea, 62
I-20157 MILAN
Italy

Professor Hendrik DE JONG
Chairman of the European Pharmacopoeia Commission
Council of Europe
European Directorate for the Quality of Medicines and HealthCare (EDQM)
7 allee Kastner, CS 30026
F- 67081 STRASBOURG
France

Dr Domenico DI GIORGIO
Editor
Senior Chemist Officer
Anti-counterfeiting Activities Manager
Agenzia Italiana del Farmaco (AIFA)
Via Sierra Nevada 60
I- 00144 ROME
Italy

Dr Sabine WALSER, Dipl. Tox., MPH
Administrative Officer
Council of Europe
European Directorate for the Quality of Medicines and HealthCare (EDQM)
Biological Standardisation, OMCL Network & HealthCare Department (DBO)
7 allee Kastner, CS 30026
F-67081 STRASBOURG
France

Dr Axel F. WENZEL, PhD, MSc, BSc.
Past President
Board of Directors, TOPRA,
c/o P.SS.T
Kreillerstr 65
D–81673 MÜNCHEN
Germany

Eleni ZACHARI, Lawyer, LL.M. in European Food Law
8 rue Marcel Pagnol
F-67205 OBERHAUSBERGEN
France