Criminal falsification of medicines in EU

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Abstract: *Falsified medicines (the term 'falsified' is used to distinguish the issue from IP violations, so-called 'counterfeits') are a major threat to public health and safety. As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year. Falsified medicines represent a serious threat to global health and call for a comprehensive strategy both at European and international level.*

Key words*:* "Falsified medicines", "health", "safety", "European Union", "international level"

Falsified medicines are fake medicines that pass themselves off as real, authorized medicines. Falsified medicines might contain ingredients, including active ingredients, which are of bad quality or in the wrong dose – either too high or too low. As they have not been properly evaluated to check their quality, safety and efficacy - as required by strict EU authorization procedures - this could be detrimental to your health. Falsified medicines (the term 'falsified' is used to distinguish the infringement to intellectual property rights, so-called 'counterfeits') are a major threat to public health. As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year.

Following adoption by the Council and the European Parliament, the new legislation

on falsified medicines was published on 1 July in the Official Journal of the European Union.

The new legislation will be applicable on 2 January 2013. This legislation is the outcome of the legal proposal that the Commission put forward in December 2008.

The new legislation introduces tougher rules to improve the protection of public health with new harmonized, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled.

To this end, these new measures include:

- An obligatory authenticity feature on the outer packaging of the medicines : this feature will be decided at a later stage via a delegated act;
- A common, EU-wide logo to identify legal online pharmacies. This would make it easier to distinguish between legal and illegal online pharmacies throughout the European Union;
- Tougher rules on the controls and inspections of producers of active pharmaceutical ingredients; and
- Strengthened record-keeping requirements for wholesale distributors

Member States have to transpose Directive 2011/62/EU by 2 January 2013 into national law. An overview of the transposition status of all Member States, together with a reference to the transposing national law

Directive 2001/83/EC of the European Parliament and of the Council (4) lays down the rules for, inter alia, manufacturing, importing, placing on the market, and the wholesale distribution of medicinal products in the Union as well as rules relating to active substances.There is an alarming increase of medicinal products detected in the Union which are falsified in relation to their identity, history or source. Those products usually contain sub-standard or falsified ingredients, or no ingredients or ingredients, including active substances, in the wrong dosage thus posing an important threat to public health.

Past experience shows that such falsified medicinal products do not reach patients only through illegal means, but via the legal supply chain as well. This poses a particular threat to human health and may lead to a lack of trust of the patient also in the legal supply chain. Directive 2001/83/EC should be amended in order to respond to this increasing threat.

The threat to public health is also recognised by the World Health Organisation (WHO), which set up the International Medical Products Anti-Counterfeiting Taskforce ('IMPACT'). IMPACT developed Principles and Elements for National Legislation against Counterfeit Medical Products, which were endorsed by the IMPACT General Meeting in Lisbon on 12 December 2007. The Union participated actively in IMPACT. IMPACT Planning Group members have taken note of the recent discussions of the World Health Organization's (WHO) Working Group on Substandard/Spurious/Falsely-Labeled/Falsified/Counterfeit (SSFFC) Medical Products, which recognized that the work undertaken thus far by the International Medical Product Anti-Counterfeiting Task Force (IMPACT) has delivered valuable results to countries around the world.

The Report of the Working Group on SSFFC Medical Products recognizes that WHO's key role in protecting public health has to include the fight against SSFFC medical products, notably in the areas of information exchange and awareness raising, in

developing/updating/promoting norms and standards, and providing technical support to countries to build and further strengthen national regulatory infrastructures and capacity. [1]

A definition of 'falsified medicinal product' should be introduced in order to clearly distinguish falsified. Persons procuring, holding, storing, supplying or exporting medicinal products are only entitled to pursue their activities if they meet the requirements for obtaining a wholesale distribution authorisation in accordance with Directive 2001/83/EC. However, today's distribution network for medicinal products is increasingly complex and involves many players who are not necessarily wholesale distributors as referred to in that Directive. In order to ensure the reliability of the supply chain, legislation in relation to medicinal products should address all actors in the supply chain. This includes not only wholesale distributors, whether or not they physically handle the medicinal products, but also brokers who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medicinal products.

Falsified active substances and active substances that do not comply with applicable requirements of Directive 2001/83/EC pose serious risks to public health. Those risks should be addressed by strengthening the verification requirements applicable to the manufacturer of the medicinal product.

There is a range of different good manufacturing practices that are suitable for being applied to the manufacturing of excipients. In order to provide for a high level of protection of public health, the manufacturer of the medicinal product should assess the suitability of excipients on the basis of appropriate good manufacturing practices for excipients. In order to facilitate enforcement of and control of compliance with Union rules relating to active substances, the manufacturers, importers or distributors of those substances should notify the competent authorities concerned of their activities.

Medicinal products may be introduced into the Union while not being intended to be imported, i.e. not intended to be released for free circulation. If those medicinal products are falsified they present a risk to public health within the Union. In addition, those falsified medicinal products may reach patients in third countries. Member States should take measures to prevent these falsified medicinal products, if introducedinto the Union, from entering into circulation. When adopting provisions supplementing this obligation on Member States to take those measures, the Commission should take account of the administrative resources available and the practical implications, as well as the need to maintain swift trade flows for legitimate medicinal products. Those provisions should be without prejudice to customs legislation, to the distribution of competences between the Union and the Member States and to the distribution of responsibilities within Member States.

Safety features for medicinal products should be harmonised within the Union in order to take account of new risk profiles, while ensuring the functioning of the internal market for medicinal products. Those safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of tampering.

[1] http://www.who.int/impact/en/

The scope of these safety features should take due account of the particularities of certain medicinal products or categories of medicinal products, such as generic medicinal products. Medicinal products subject to prescription should as a general rule bear the safety features. However, in view of the risk of falsification and the risk arising from falsification of medicinal products or categories of medicinal products there should be the possibility to exclude certain medicinal products or categories of medicinal products subject to prescription from the requirement to bear the safety features by way of a delegated act, following a risk assessment. Safety features should not be introduced for medicinal products or categories of medicinal products not subject to prescription unless, by way of exception, an assessment shows the risk of falsification, which leads to serious consequences. Those medicinal products should accordingly be listed in a delegated act.

The risk assessments should consider aspects such as the price of the medicinal product; previous cases of falsified medicinal products being reported in the Union and in third countries; the implications of a falsification for public health, taking into account the specific characteristics of the products concerned; and the severity of the conditions intended to be treated. The safety features should allow the verification of each supplied pack of the medicinal products, regardless of how they are supplied including through sale at a distance. The unique identifier as well as the corresponding repositories system should apply without prejudice to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (1) and should retain clear and effective safeguards whenever personal data is processed. The repositories system containing information on safety features might include commercially sensitive information. This information must be appropriately protected. When introducing the obligatory safety features, due account should be taken of the particular characteristics of the supply chains in Member States. [2]

Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing auth orisation. In order for the safety features to be effective, a manufacturing authorisation holder who is not himself the original manufacturer of the medicinal product should only be permitted to remove, replace or cover those safety features under strict conditions. In particular, the safety features should be replaced in the case of repackaging by equivalent safety features. To this end, the meaning of the term 'equivalent' should be clearly specified. Those strict conditions should provide adequate safeguards against falsified medicinal products entering the supply chain, in order to protect patients as well as the interests of marketing authorisation holders and manufacturers.

Manufacturing authorisation holders who repackage medicinal products should be liable for damages in the cases and under the conditions set out in Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (2).

In order to increase reliability in the supply chain, wholesale distributors should

[2] OJ L 210, 7.8.1985, p. 29.

verify that their supplying wholesale distributors are holders of a wholesale distribution authorisation.The provisions applicable to the export of medicinal products from the Union and those applicable to the introduction of medicinal products into the Union with the sole purpose of exporting them need to be clarified. Under Directive 2001/83/EC a person exporting medicinal products is a wholesale distributor. The provisions applicable to wholesale distributors as well as good distribution practices should apply to all those activities whenever they are performed on Union territory, including in areas such as free trade zones or free warehouses.

In order to ensure transparency, a list of wholesale distributors for whom it has been established that they comply with applicable Union legislation by means of an inspection by a competent authority of a Member State, should be published in a database that should be established at Union level. The provisions on inspections and controls of all actors involved in the manufacturing and supply of medicinal products and their ingredients should be clarified and specific provisions should apply to different types of actors. This should not prevent Member States from performing additional inspections, where considered appropriate.

In order to ensure a similar level of protection of human health throughout the Union, and to avoid distortions in the internal market, the harmonised principles and guidelines for inspections of manufacturers and wholesale distributors of medicinal products as well as of active substances should be strengthened. Such harmonised principles and guidelines should also help to ensure the functioning of existing mutual recognition agreements with third countries whose application depends on efficient and comparable inspection and enforcement throughout the Union. Manufacturing plants of active substances should be subject not only to inspections carried out on the grounds of suspected non-compliance but also on the basis of a risk-analysis. The manufacture of active substances should be subject to good manufacturing practice regardless of whether those active substances are manufactured in the Union or imported. With regard to the manufacture of active substances in third countries, it should be ensured that the legislative provisions applicable to the manufacturing of active substances intended for export to the Union, as well as inspections of facilities and enforcement of the applicable provisions, provide for a level of protection of public health equivalent to that provided for by Union law.

The illegal sale of medicinal products to the public via the Internet is an important threat to public health as falsified medicinal products may reach the public in this way. It is necessary to address this threat. In doing so, account should be taken of the fact that specific conditions for retail supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty on the Functioning of the European Union (TFEU).

When examining the compatibility with Union law of the conditions for the retail supply of medicinal products, the Court of Justice of the European Union ('the Court of Justice') has recognised the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. The Court of Justice

has also held that health and life of humans rank foremost among the assets and interests protected by the TFEU and that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level may vary from one Member State to another, Member States must be allowed discretion[3] as regards the conditions for the supply on their territory of medicinal products to the public.

In particular, in the light of the risks to public health and given the power accorded to Member States to determine the level of protection of public health, the case-law of the Court of Justice has recognised that Member States may, in principle, restrict the retail sale of medicinal products to pharmacists alone[4].

The public should be assisted in identifying websites which are legally offering medicinal products for sale at a distance to the public. A common logo should be established, which is recognisable throughout the Union, while allowing for the identification of the Member State where the person offering medicinal products for sale at a distance is established. The Commission should develop the design for such a logo. Websites offering medicinal products for sale at a distance to the public should be linked to the website of the competent authority concerned. The websites of the competent authorities of Member States, as well as that of the European Medicines Agency ('the Agency'), should give an explanation of the use of the logo. All those websites should be linked in order to provide comprehensive information to the public. In addition, the Commission should, in cooperation with the Agency and Member States, run awareness campaigns to warn of the risks of purchasing medicinal products from illegal sources via the Internet.

Member States should impose effective penalties for acts involving falsified medicinal products taking into account the threat to public health posed by those products.

The falsification of medicinal products is a global problem, requiring effective and enhanced international coordination and cooperation in order to ensure that anti-falsification strategies are more effective, in particular as regards sale of such products via the Internet. To that end, the Commission and the Member States should cooperate closely and support ongoing work in international fora on this subject, such as the Council of Europe, Europol and the United Nations. In addition, the Commission, working closely with Member States, should cooperate with the competent authorities of third countries with a view to effectively combating the trade in falsified medicinal products at a global level. This Directive is without prejudice to provisions concerning intellectual property rights. It aims specifically to prevent falsified medicinal products from entering the legal supply chain.

The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to supplement the provisions of Directive 2001/83/EC, as amended by this Directive, concerning good

[3] Judgment of the Court of 19 May 2009 in Joined Cases C-171/07 and C-172/07 Apothekerkammer des Saarlandes and Others v Saarland ECR [2009] I-4171, paragraphs 19 and 31

[4] Judgment of the Court of 19 May 2009 in Joined Cases C-171/07 and C-172/07 Apothekerkammer des Saarlandes and Others v Saarland ECR [2009] I-4171, paragraphs 34 and 35.

manufacturing and distribution practices for active substances, concerning detailed rules for medicinal products introduced into the Union without being imported and concerning safety features. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

In order to ensure uniform conditions for implementation, implementing powers should be conferred on the Commission as regards the adoption of measures for the assessment of the regulatory framework applicable to the manufacturing of active substances exported from third countries to the Union and as regards a common logo that identifies websites which are legally offering medicinal products for sale at a distance to the public. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[5].The safety features for medicinal products introduced under this Directive require substantial adaptations to manufacturing processes. In order to enable manufacturers to make those adaptations, the time limits for the application of the provisions on the safety features should be sufficiently long and should be calculated as from the date of publication in the Official Journal of the European Union of the delegated acts setting out detailed rules in relation to those safety features. It should also be taken into account that some Member States already have a national system in place. Those Member States should be granted an additional transitional period for adapting to the harmonised Union system.

Since the objective of this Directive, namely to safeguard the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified medicinal products, cannot be sufficiently achieved by the Member States, and can, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective. It is important that the competent authorities of the Member States, the Commission and the Agency cooperate to ensure the exchange of information on measures taken to combat the falsification of medicinal products and on the penalties systems that are in place. Currently, such exchange takes place through the Working Group of Enforcement Officers. Member States should ensure that patients' and consumers' organisations are kept informed about enforcement activities to the extent that this is compatible with operational needs.In accordance with point 34 of the Interinstitutional Agreement on better law-making[6], Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

[5] OJ L 55, 28.2.2011, p. 13.

[6] OJ C 321, 31.12.2003, p. 1.

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2. OJ L 210, 7.8.1985
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