Opinion of the European Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source'

COM(2008) 668 final — 2008/0261 (COD)

Rapporteur: Mr MORGAN

On 12 February 2009 the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source


The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 22 June 2009. The rapporteur was Mr Morgan.

At its 455th plenary session, held on 15/16 July (meeting of 15 July), the European Economic and Social Committee adopted the following opinion by 150 votes to 2.

1. Conclusions and Recommendations

1.1 The EESC welcomes this initiative. Public health is a central concern of all the Committee's members. Nevertheless, we are fully conscious of the fact that, on its own, this Directive will not be effective. It forms one part of a multi-faceted effort involving criminal law, law enforcement, IPR protection, customs surveillance and international cooperation. The EESC urges Member States to strengthen enforcement measures.

1.2 The EESC proposes that more effort be made to harmonise the names and brands used for medicines in the EU as well as packaging (1) and identification coding for medicinal products throughout the EU. There are at least ten different coding systems in the EU and they have no particular focus on security issues in terms of batch and date of manufacture or expiry. A harmonised European standard should be introduced for the identification of medicinal products to allow tracking throughout the distribution chain up to the patient. Harmonisation will advance the internal market by opening the door to the secure free movement of medicinal products in the EU. It will also make it easier to authenticate medicinal products directly at the manufacturers at any time and in any place, at least in the EU internal market initially. Ultimately this could lead to a global initiative.

1.3 Technology can facilitate a significant advance in codes, identification and the authentication of medicinal products. Authentication and tracking are the central issues. These strategies should not exceed their set purposes, giving priority to direct checks (avoiding middlemen) in the official registers of manufacturers, the only parties able to certify the authenticity of their products. There are a number of identification systems including Radio Frequency Identification (RFID) and 2-dimensional bar code labelling (Data Matrix). Belgium has an individual registration system for packaging, using a sequence number and 1-dimensional bar code, introduced by the health insurance system to prevent multiple claims for one package under the third-party payment system. However, the Belgian system does not include either a batch number or an expiry date. Moving from the Belgian single bar code (Code Barres Unique - CBU) to DataMatrix labelling would fill the existing gaps with regard to tracking and authentication, as required by the Community code on medicinal products. Although these techniques could be applied readily and rapidly for a minimal cost, the Commission's position, paradoxically, is that it is too early to make a decision on identification coding and that more trials are needed. The longer the introduction of identification coding is put off, the more confused and fragmented the situation will become. Therefore the EESC proposes that an identification coding task force be put in place to assess the introduction of existing harmonised procedures, at least in the EU Internal Market initially. Ultimately this could lead to a global leadership opportunity.

1.4 The focus on the legal supply chain is not enough. If the Internet issue is not addressed, public health will be increasingly threatened. There is an important social dimension because illegal low cost medicines on the internet create a 2-tier health care system. The EESC urges the Commission to act.

(1) Change does not apply to English text.
1.5 The EESC supports a relentless attack on any actors who allow counterfeit drugs into the legal drug chain. The penalties should be draconian, ranging from fines to confiscation of the affected business. The EESC urges the Commission to publish sentencing guidelines for Member States.

1.6 The extent of counterfeiting and the sources of counterfeit medicines do not seem to be well understood. The draft directive should include plans to address these shortcomings in the systems of surveillance and supervision.

1.7 Following the WHO, the EESC would prefer that the Directive refer to 'counterfeit' products rather than 'falsified' products.

1.8 The complexity of the text, with so many past and present amendments, makes it difficult to comprehend. The EESC recommends that a subset of the base text together with the amendments be published so the text relating to counterfeit products can be read and understood.

2. Introduction

2.1 In November 2001 the EU introduced its Directive 2001/83/EC on the subject of The Community Code Relating to Medicinal Products for Human Use. This is an encyclopaedic compendium covering every aspect of the topic. It has subsequently been amended by one Regulation and five further Directives. It now runs to 70 pages comprising 130 Articles. There are another 44 pages of annexes.

2.2 The subject of this opinion is another amending Directive. It is concerned with the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source. This amending Directive is one of three such Directives being introduced at the same time to deal with different facets of the Community Code. In the view of the EESC it would have made more sense, at least for this Directive, if a relevant subset of the base Directive could have been produced, together with the amendments proposed in the current Directive, so that a short integrated, coherent and relevant text could have been available to interested parties. The present text is opaque and difficult to comprehend.

2.3 Counterfeit medicines are deliberately and fraudulently mislabelled with respect to identity or source; their quality is unpredictable as they may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients. In all cases counterfeit medicines are manufactured in clandestine laboratories with no possibility of control.

2.4 Counterfeit medicines pose a major threat to public health. They undermine EU pharmaceutical legislation and the EU pharmaceutical industry. The number of falsifications of innovative and life-saving medicines is increasing. Moreover, in order to increase the volume, these products are channelled towards the patient through the lawful supply chain.

2.5 According to the World Health Organisation (WHO), the scale of the problem is as follows:

— less than 1 % in most industrialized countries and most of the EU;

— more than 20 % in much of the former Soviet Union;

— more than 30 % in parts of Asia, Africa and Latin America;

— more than 50 % from illegal internet sites.

With respect to the Internet, the Commission has stated that 'addressing illegal supply chains requires a separate problem definition, with separate underlying causes, separate objectives and separate policy options'. These are not addressed in the Directive being considered.

2.6 According to the Commission, the underlying causes for counterfeit medicinal products remaining undetected in the lawful supply chain are manifold, but can be reduced to four aspects:

— counterfeit medicinal products can not always be easily distinguished from the originals due to problems of tracking and identification;

— the distribution chain has become very complex and is only as 'strong as its weakest link';

— there are legal uncertainties as to the regime applicable to products introduced into the EU while allegedly not being placed on the market; and

— already the active pharmaceutical ingredients (API) entering the manufacturing process may be a falsification of the original API.


3.1 The aim of the base Directive, 2001/83/EC, as well as this proposed amendment, is to establish a functioning Internal Market for medicinal products in the EU while ensuring a high level of protection for public health. The main provisions of the amendment are detailed in the following paragraphs. Article references are to Article 1 of the amending directive.
Tracking and Identification

3.2 Audits of manufacturers of API. (4)

3.3 A legal basis for the Commission to make specific safety features such as an identification code or fixed seal obligatory on the packaging of prescription medicines in order to make it possible to identify, authenticate and trace medicinal products. (6), (8), (9)

3.4 A prohibition in principle of manipulating (i.e. removing, tampering with or over-labelling) safety features on the packaging by participants situated 'in between' the original manufacturer and the last point in the distribution chain – usually the pharmacist – or end user – the doctor/patient. Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing authorisation and be liable for any damage caused by falsified products (9), (10)

The Distribution Chain

3.5 Certain obligations for participants other than wholesale distributors who are involved in the distribution chain. Typical participants, such as brokers and auctioneers, can be involved without actually handling the products. (1), (14)

3.6 Rules supplementing existing good practice for distributors. (13)

3.7 Wholesale distributors will continue to require authorisation. (12), (13), (14)

3.8 Obligatory audits of wholesale distributors of medicinal products in order to ensure reliability of business partners. (15)

Legal Uncertainties

3.9 Elimination of legal uncertainties relative to import of medicinal products for re-export. (2), (7)

Falsification of the Original API

3.10 Certification by manufacturers of their API suppliers are compliant. (3), (5), (7)

3.11 Strengthened control of API imports from third countries when it cannot be established that the regulatory framework in the respective third country ensures a sufficient level of protection of human health for products exported to the EU. (4), (16)

General Provisions

3.12 Strengthened rules for inspections including increased transparency of inspection results through publication in the EudraGMP database. (12), (15)

3.13 Supervision will be carried out, and any necessary sanctions applied, by the competent authorities of the Member States. New guidelines will be issued by the Commission. (16), (17)

4. EESC Perspective

4.1 The EESC welcomes this initiative. Public health is a fundamental concern of the Committee.

4.2 The Committee notes that the World Health Organisation (WHO) describes 'falsified' products as 'counterfeit' products. We recommend that the Commission follow the lead of the WHO. 'Counterfeit' better communicates the criminality of this activity. In the words of the WHO, 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 life at risk and undermines the credibility of health systems (2).

4.3 In the legal supply chain, blocking the entry of counterfeit medical products relies on collaboration between trusted and reliable business partners. To improve collaboration there should be compulsory certification of all supply chain participants with the details available on a publicly accessible data base.

Tracking and Identification

4.4 The EESC believes that the Commission understates the problem of tracking and identification. 'Counterfeit medicinal products can never be easily distinguished from the originals in the absence of harmonised identification coding which leads to problems of tracking.'

4.5 The EESC proposes that more effort be made to harmonise the names and brands used for medicines in the EU as well as packaging (3) and identification coding for medicinal products throughout the EU. There are at least ten different coding systems in the EU and they have no particular focus on security issues in terms of batch and date of manufacture or expiry. A harmonised European standard should be introduced for the identification of medicinal products to allow tracking throughout the distribution chain up to the patient. Harmonisation will advance the internal market by opening the door to the secure free movement of medicinal products in the EU. It will also make it easier to authenticate medicinal products directly at the manufacturers at any time and in any place, at least in the EU internal market initially. Ultimately this could lead to a global initiative.

(3) See the IMPACT (International Medical Products Anti-Counterfeiting Taskforce) Report of the WHO updated in May 2008.

(4) Change does not apply to English text.
4.6 The EESC believes that it would reduce fraud if authentic packaging could be clearly identified. The EESC recommends that the Commission take the initiative to cause a visual data base of medicinal product packaging to be established.

4.7 The text of paragraph 3.4 appears to cut out parallel distributors. It could be more explicit to prohibit manipulation of safety features on packaging by any participant who does not hold a manufacturing authorisation. Parallel distributors need to repackage. They must not replace safety features in a way which could break the tracking chain.

4.8 Technology can facilitate a significant advance in codes, identification and the authentication of medicinal products. Authentication and tracking are the central issues. These strategies should not exceed their set purposes, giving priority to direct checks (avoiding middlemen) in the official registers of manufacturers, the only parties able to certify the authenticity of their products. There are a number of identification systems, including Radio Frequency Identification (RFID) and 2-dimensional bar code labelling (Data Matrix). Belgium has an individual registration system for packaging, using a sequence number and 1-dimensional bar code, introduced by the health insurance system to prevent multiple claims for one package under the third-party payment system. However, the Belgian system does not include either a batch number or an expiry date. Moving from the Belgian single bar code (Code Barres Uniques - CBU) to DataMatrix labelling would fill the existing gaps with regard to tracking and authentication, as required by the Community code on medicinal products. Although these techniques could be applied readily and rapidly for a minimal cost, the Commission's position, paradoxically, is that it is too early to make a decision on identification coding and that more trials are needed. The longer the introduction of identification coding is put off, the more confused and fragmented the situation will become. Therefore the EESC proposes that an identification coding task force be put in place to assess whether the existing harmonised procedures can be introduced, at least in the EU internal market initially. Ultimately this could lead to a global leadership opportunity.

4.9 Once medicine is packaged, it must be a criminal offence to repack it without the proper safeguards. Counterfeit packaging is the way in which counterfeit medicines enter the legal distribution chain. Packaging of medicines offered by legitimate internet pharmacies should be subject to inspection.

4.10 The EESC notes that the Directive proposes heavy penalties for failures to prevent the entry of falsified products into the distribution chain. The EESC recommends that sanctions be very severe. Businesses in default should be closed down.

Legal Uncertainties

4.11 The EESC is satisfied that legal uncertainties concerning import for export have been addressed in the draft Directive.

Falsification of Original API

4.12 As discussed in relation to the distribution chain, businesses complicit in falsification should be closed down.

The Illegal Supply Chain

4.13 The introduction of counterfeit products through the illegal supply chain is not addressed in this Directive. Yet the threat to public health is very serious, especially with respect to the Internet. The WHO statistics were given in paragraph 2.5. It was recently reported that in the UK one in four doctors had treated patients for the side effects caused by drugs bought online. Eight percent more may have done so, but were uncertain. In the Commission's recent Communication (4) there is reference to a 'Report on Community Customs Activities on Counterfeiting and Piracy' for 2007. Medicines seized by customs authorities increased by 628% between 2005 and 2007. They relate not only to 'lifestyle' products, but also to treatments against life threatening diseases.

4.14 The focus should be on the internet. Internet pharmacies are only legitimate if they are registered and approved in each Member State, with the registration easily accessible on a public data base as is already the case for traditional pharmacies. While, in this domain, there is an obvious need for European and international cooperation, each country makes its own rules for the internet. Furthermore, the retail trade is not presently regulated by the EU, so the scope for Community action is limited and should be extended in this domain as is already the case for wholesalers and wholesale distributors.

4.15 The reasons why patients turn to the internet rather than their doctors are easily understood. A given medicine may not be available in a particular jurisdiction, the price of a medicine, particularly a counterfeit medicine, may be less on the internet and, finally, it may be less embarrassing to buy some medicines directly on the internet rather than face a potentially difficult interview with the doctor. Furthermore, a patient cannot be prosecuted for buying medicines on the internet.

4.16 A communications campaign is needed in each Member State to direct the public towards registered internet pharmacies and away from criminal establishments. The campaign should highlight the potentially life threatening danger of products bought on the internet from unregistered sources. There should be publicity in every pharmacy, every doctor’s surgery, every hospital and every authorised web site.

4.17 Severe financial and criminal sanctions should be applied to anyone found to be engaged in the business of counterfeit medicines. Rather in the same way that sex is policed on the internet, collaboration could be envisaged between public authorities (as described in paragraph 4.3) and various stakeholders such as ISPs, search engines, freight services and credit card companies to better identify illegal participants in the counterfeit medicine trade. As the Commission has emphasised, its Directives are only one piece of a multi-faceted enforcement effort.

General Provisions

4.18 The extent of counterfeiting and the sources of counterfeit medicines do not seem to be well understood. The draft directive should include plans to address these shortcomings in the systems of surveillance and supervision.


The President
of the European Economic and Social Committee
Mario SEPI