Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2008/0261(COD)
Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products Amending Directive 2001/83/EC 1999/0134(COD) Subject 4.20.04 Pharmaceutical products and industry 4.60.02 Consumer information, advertising, labelling 4.60.08 Safety of products and services, product liability	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		
	Former committee responsible		
	ENVI Environment, Public Health and Food Safety		
	Committee for opinion	Rapporteur for opinion	Appointed
	ITRE Industry, Research and Energy		16/09/2009
		PPE SARTORI Amalia	
	IMCO Internal Market and Consumer Protection		14/09/2009
		PPE BASTOS Regina	
	Former committee for opinion		
	ITRE Industry, Research and Energy		
	IMCO Internal Market and Consumer Protection		
Council of the European Union	Council configuration	Meeting	Date
	Employment, Social Policy, Health and Consumer Affairs3019		07/06/2010
	Employment, Social Policy, Health and Consumer Affairs2980		30/11/2009
European Commission	Commission DG	Commissioner	
	Health and Food Safety	DALLI John	

Key events

10/12/2008	Legislative proposal published	COM(2008)0668	Summary
15/01/2009	Committee referral announced in Parliament, 1st reading		
19/10/2009	Committee referral announced in Parliament, 1st reading		

30/11/2009	Debate in Council	2980	Summary
27/04/2010	Vote in committee, 1st reading		Summary
07/05/2010	Committee report tabled for plenary, 1st reading	A7-0148/2010	
07/06/2010	Debate in Council	3019	Summary
15/02/2011	Debate in Parliament		
16/02/2011	Results of vote in Parliament		
16/02/2011	Decision by Parliament, 1st reading	T7-0056/2011	Summary
27/05/2011	Act adopted by Council after Parliament's 1st reading		
08/06/2011	Final act signed		
08/06/2011	End of procedure in Parliament		
01/07/2011	Final act published in Official Journal		

Technical information

Procedure reference	2008/0261(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amending Directive 2001/83/EC 1999/0134(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 114-p1
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/00148

Documentation gateway

Legislative proposal		COM(2008)0668	10/12/2008	EC	Summary
Document attached to the procedure		SEC(2008)2674	10/12/2008	EC	
Document attached to the procedure		SEC(2008)2675	10/12/2008	EC	
Economic and Social Committee: opinion, report		CES1191/2009	15/07/2009	ESC	
Committee draft report		PE430.883	07/01/2010	EP	
Amendments tabled in committee		PE439.406	12/03/2010	EP	
Amendments tabled in committee		PE439.407	12/03/2010	EP	
Amendments tabled in committee		PE439.409	12/03/2010	EP	
Amendments tabled in committee		PE439.860	12/03/2010	EP	
Committee opinion	ITRE	PE430.741	24/03/2010	EP	

Committee opinion	IMCO	PE438.139	06/04/2010	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0148/2010	07/05/2010	EP	
Text adopted by Parliament, 1st reading/single reading		T7-0056/2011	16/02/2011	EP	Summary
Commission response to text adopted in plenary		SP(2011)2217	16/03/2011	EC	
Draft final act		00003/2011/LEX	08/06/2011	CSL	
Follow-up document		COM(2018)0049	26/01/2018	EC	Summary
Follow-up document		COM(2024)0274	04/07/2024	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2011/62
OJ L 174 01.07.2011, p. 0074 Summary

Final legislative act with provisions for delegated acts

Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

PURPOSE: to prevent the entry into the legal supply chain of medicinal products which are falsified.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: there is an alarming increase in the EU of medicinal products which are falsified in relation to their identity, history or source. These products are, from the point of view of EU pharmaceutical legislation, illegal insofar as they do not comply with the Community rules for medicinal products. Moreover, the number of falsifications of innovative and life-saving medicines is increasing. In this way, in 2007, many thousand packs of falsified life-saving drugs reached patients in the EU.

The underlying causes for falsified medicinal products remaining undetected in the legal supply chain are manifold, but can be reduced to four aspects: (i) falsified medicinal products can not always be easily distinguished from originals; (ii) the distribution chain has become very complex and is only as strong as its weakest link; (iii) there are legal uncertainties as to the regime applicable to products introduced into the EU while allegedly not being placed on the market; (iv) lastly, already the active pharmaceutical ingredients (API) entering the manufacturing process may be a falsification of the original API.

The existing provisions of Directive 2001/83/EC are in some respects insufficient to address these concrete causes. In view of the time span between the proposal for amendments to Directive 2001/83/EC and their effective implementation, there is a clear need for the Commission to act now.

CONTENT: in order to address the risk of falsified medicinal products entering the legal supply chain, the Commission proposes a number of amendments to Directive 2001/83/EC. These include:

- certain obligations for stakeholders other than wholesale distributors, who are involved in the distribution chain. These stakeholders are typically involved in the transactions without actually handling the products (for example, by auctioning or brokering products);
- a legal basis for the Commission to render obligatory specific safety-features (such as a serial number or a seal) on the packaging of prescription-medicines;
- a prohibition in principle of manipulating (i.e. removing, tampering with, or over-labelling) safety features on the packaging by stakeholders situated ?in-between? the original manufacturer and the last stakeholder in the distribution chain (typically the pharmacist) or end user (doctor/patient);
- compulsory audits of wholesale distributors of medicinal products in order to ensure reliability of business partners;
- strengthened requirements for imports of API from third countries if it could not 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;
- audits of manufacturers of API;
- stricter rules for inspections including increased transparency of inspection results through publication in the EudraGMP database managed by the EMEA.

Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

On the basis of progress reports, the Presidency informed the Council of the state of play in the negotiations on two parts of the "pharmaceutical package": preventing falsified medicines from entering into the legal supply chain of medicinal products and the strengthening and rationalising of the current pharmacovigilance system.

Under the Swedish Presidency, the preparatory bodies of the Council pursued their work with high priority on these two parts of the package.

1) Concerning the draft directive on preventing the entry into the legal supply chain of falsified medicinal products, the working group reached tentative agreement on a number of technical aspects, including:

- the definition of "falsified medicinal products";
- the proposed definition of "trading of medicinal products" has been changed to "brokering of medicinal products" and amended, thereby clarifying which actors in the supply chain should be subject to the responsibilities of brokers. The proposed introduction of obligations for brokers aim to reinforce the traceability of medicinal products;
- a clarification of the relationship between the proposed new provisions in Directive 2001/83/EC and Community legislation on intellectual property rights.

Other elements of the proposal still need further discussion, notably with regard to the strengthening of controls of non active substances used in pharmaceuticals (excipients) and the proposed safety features aiming to render falsification more difficult.

The proposal includes provisions requiring the accreditation of third party auditors of Good Manufacturing Practices and Good Distribution Practices. A majority of delegations object to accreditation, since they maintain that such a system could result in a transfer of responsibility from manufacturers and importers as well as make enforcement by national competent authorities more difficult. The Presidency has therefore proposed to delete the provisions regarding accreditation from the text. Some delegations have expressed an interest in the possibility of establishing third party accreditation at a national level.

2) Concerning the proposals for a regulation and a directive on strengthening the EU system for the safety monitoring of medicinal products ("pharmacovigilance"), the working group reached tentative agreement on a number of questions including:

- a clarification of the relation between the proposed new provisions in Directive 2001/83/EC and Regulation (EC) 726/2004 on the one hand and the Community legislation on protection of personal data on the other hand;
- a strengthening of the role of the Pharmacovigilance Risk Assessment Committee (PRAC) in relation to the Committee for Medicinal Products for Human Use and to the Coordination Group set up by Article 27 of Directive 2001/83/EC (CMD), including an obligation for these last two bodies to explain any differences in opinion compared to the PRAC;
- a change in the composition of the PRAC and in the method for nominating the PRAC members so that all Member States will be represented;
- the inclusion of a requirement for the Agency, in collaboration with the Member States and the Commission, to draw up functional specifications for the Eudravigilance database which will take account of the role and experience of national competent authorities for pharmacovigilance. The new reporting obligations to Eudravigilance will not apply until these specifications are met and to this end a transitional period is envisaged;
- the legal status of CMD opinions and how they are implemented in Member States. Here, text redrafting proposals are under legal scrutiny.

The Working Party has continued to discuss other central provisions of the proposals, mainly in relation to the Community Procedure and Referrals, the Recording and Reporting of adverse reactions, the Periodic Safety Update Reports and the Post Authorisation Safety Studies.

A number of issues still require further examination, such as the recording and reporting of adverse reactions and the proposed list of medicinal products for human use under intensive monitoring.

At this stage, all delegations have a general scrutiny reservation on the entire proposal while the Danish, Maltese and United Kingdom delegations have parliamentary scrutiny reservations.

3) With regard to the third part of the "pharmaceutical package", the proposals for a regulation and a directive concerning information for the general public on medicinal products, the Presidency recalled the strong concerns of many Member States. The Commission made it clear that it is prepared to show flexibility in order to find a common basis for the future negotiations.

Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

The Committee on environment, public health and food safety adopted the report by Marisa MATIAS (GUE/NGL, PT) 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.

It recommended that the European Parliament?s position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

Definitions and responsibilities: Members want to establish precise and clear definitions on not only the scope but also on the different actions in the supply chain and their responsibilities. With this in mind, they introduced definitions for ?falsified medicinal products?, ?active substance used as starting material? and ?excipient?.

The amended text also introduces a distinction, in the definitions, between traders and brokers. For the system to be able to effectively protect public health, it is essential for the responsibilities of the various stakeholders to be clearly identified and for all stakeholders to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.

Excipients: falsified excipients can also present a serious risk for health and must also be included within the scope of the directive under examination. Both excipients and active pharmaceutical ingredients should be subject torelevant good manufacturing practices developed at the European level taking into accounttheir own specificities.

Obligations of the holder of the manufacturing authorisation: Members consider that it is necessary to require the holder of the manufacturing authorisation to i) inform the competent authorities of products he gets knowledge of which are or which are reliably suspected to be falsified in relation to the identity, history or source of products manufactured by him in the legal or illegal supply chain, including on the internet; ii) verify the authenticity and quality of the active substances and the excipients.'

The Commission shall submit every year to the European Parliament and to the Council a report with reliable and accurate data on the current situation and trends in the falsification of medicinal products. The report shall, as a minimum, include where, how and by whom the falsified products were detected, their origin, and an exact description of the nature of the falsification. That report shall clearly distinguish falsified medicinal products from patent infringements.

Third countries: Members consider that the protection offered in third countries should be at least equivalent to that in the Community. In the event of non-compliance, this information should be immediately supplied by the exporting third country to the Community.

Other means of preventing counterfeiting: the Commission shall study the possibilities for the authentication of individual dosage forms, as a method of detecting falsified medicinal products.

Safety features: the safety features should guarantee the identification, authenticity and uninterruptedtraceability of the medicinal product from the factory to the consumer. The identification, authenticity and traceability of medicinal products must be guaranteed in all circumstances. Furthermore, the additional costs should be as low as possible.

Where original safety features have been removed and replaced, Members consider that patients and other actors in the supply chain must be explicitly informed via a label on the pack.

Safety features shall be considered equivalent where they comply with the harmonised measures provided for in the Directive, which shall ensure that they are equally efficient in identifying, authenticating, tracing and preventing tampering with medicinal products, and that they are equally technically difficult to duplicate.

According to Members, the performance criteria for the safety features can be waived for certain generic medicinal products or product categories

The decision the advisability of extending the safety features to other categories of medicinal productsnot subject to medical prescription will depend on an assessment carried out by the Commission no later than four years following the entry into force of this Directive.

Data protection: the measures contained in this Directive shall comply with the relevant provisions of Union law with regard to the protection of personal data.

Member States shall ensure that no collection or commercial processing of data takes place that would enable a link to be made between the medicinal products provided and the corresponding patients and shall ensure that the confidentiality of data generated by the use of safety features to authenticate medicinal products is safeguarded.

Internet sales: given that the internet is one of the main routes by which falsified medicinal products enter the European market, Members suggest that a distinction should be made between legitimate mail order or internet pharmacies and the illegal supply chain through non-controlled internet purchasing.

Internet pharmacies should, in Member States in which they are allowed to operate, require a special authorisation by the competent authority. The Commission shall adopt an EU logo for the front page of internet pharmacy sites, helping the public to identify whether a website offering to sell medicinal products is connected to an authorised pharmacy. The logo shall be linked to a central website at Member State level, to be established by the Member State, that allows the visitor to check the authenticity of the logo and that provides background information on the risks related to buying medicinal products on the internet.

Member States shall take the appropriate measures to ensure that all authorised pharmacy internet sites linked to pharmacies within their territory display the EU logo.

Member States shall also ensure that i) the internet is continuously monitored with regard to the selling of medicinal products; ii) all legitimate mail-order pharmacies operating in the internal market adhere to professional standards and guidance for internet pharmacy services, including a specific code of ethics.

Public awareness: Members call on the Commission, in cooperation with the European Medicines Agency (the ?Agency?) and Member State authorities, to launch campaigns informing and raising awareness among consumers of the risk involved in purchasing falsified medicinal products.

Inspections: in order to guarantee the safety of medicinal products, Members consider it vital to strengthen and extend the system of inspections. In this regard, it will be necessary to take into account all the actors throughout the supply chain and not simply the wholesale distributors.

Exports: the Directive should also seek to reduce the wholesale distribution of falsified medicines towards third countries. Members consider that applying less stringent rules to exports or products in transit to third countries would damage the Community?s credibility in its insistence on strengthening international cooperation in the combat against falsified medicines. This is why the report calls on the Member States to take all necessary measures to ensure that no falsified medicines are distributed or exported from their territory to third countries.

Sanctions: Members propose further strengthening the measures proposed by the Commission. They stress that the falsification of medicines is a serious criminal activity, which places human lives in danger and that appropriate sanctions are required. The threat that falsified or counterfeit medicines represent to human health needs to be taken into account when drawing up rules on the sanctions to be applied. These sanctions need to be equivalent to those typically applied for illegal acts related to narcotics.

Exchange of information and reports: Members call on the Commission to create a network between it, the Agency and the Member States? competent authorities and involve patients' and consumers' organisations to ensure the exchange of information on the measures taken to combat the falsification of medicinal products, including on the penalties systems in place. This network shall aim at defining best practices and shall contribute to increased cooperation in the area of prevention and enforcement. The Commission, the Agency and the competent authorities in the Member States shall report annually to this network on the actions they have undertaken.

International cooperation: the European Union should support the drafting of an international agreement increasing the penalties for falsifying medicinal products, and of an additional protocol to the United Nations Convention against Transnational Organised Crime (Palermo convention). In addition, the Commission and the Member States should cooperate closely with the Council of Europeon the establishment of a European Convention on the suppression of the falsification of medicinal products and trafficking in falsified medicinal products.

Lastly, many amendments adopted by Members seek to replace the ?old comitology procedure? by the new procedure foreseen in Article 290 of the Treaty on the Functioning of the European Union (delegated acts).

Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

The Council took note of a presidency progress report on the state of play in the negotiations on the prevention of falsified medicines from entering into the legal supply chain of medicinal products (doc. 10469/10).

The presidency also provided the Council with oral information on the progress in the discussions on the strengthening of the current pharmacovigilance system (aimed at protecting patients from adverse reactions to medicinal products). With regard to the pharmacovigilance part of the pharmaceutical package, the presidency will endeavour to reach an agreement at first reading with the European Parliament before the end of June.

Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

The European Parliament adopted by 569 votes to 12, with 7 abstentions, a legislative resolution 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.

Parliament adopted its position at first reading under the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise reached between the European Parliament and the Council. They amend the Commission?s position as follows:

Definitions: the amended text stipulates that a definition of ?falsified medicinal product? should be introduced in order to clearly distinguish falsified medicinal products from other illegal products, as well as from infringements of intellectual property rights. Furthermore, products with unintentional quality defects resulting from manufacturing or distribution errors should not be confused with falsified medicinal products. To ensure uniform application of this Directive, the terms ?active substance? and ?excipient? should also be defined.

Application of the legislation: 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. Given that the current distribution network for medicinal products is increasingly complex, the new legislation shall address all actors in the supply chain: this includes not only wholesale distributors, 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.

Obligations of the holder of the manufacturing authorisation: the holder of the manufacturing authorisation shall ensure that the excipients are suitable for use in medicinal products by verifying the appropriate good manufacturing practice on the basis of a formalised risk assessment. In this risk assessment, the holder of the manufacturing authorisation shall take into account the source and intended use of the excipients and previous incidents. The holder shall also, inter alia:

- inform the competent authority and the marketing authorisation holder immediately if he obtains information that medicinal products which come under the scope of his manufacturing authorisation are, or are suspected of being, falsified irrespective of whether those products were distributed in the legal supply chain or by illegal means, including sold illegally by way of information society services;
- verify that the manufacturers, importers or distributors from whom they obtain active substances are registered with the competent authority of the Member State in which they are established;
- verify the authenticity and quality of the active substances and the excipients.

Imports, third countries: Member States shall take appropriate measures to ensure that the manufacture, import and distribution on their territory of active substances, including active substances that are intended for export, comply with good manufacturing practice and good distribution practices for active substances.

Active substances shall only be imported if the active substances have been manufactured in accordance with standards of good manufacturing practice at least equivalent to those laid down by EU legislation. The active substances are accompanied by a written confirmation from the competent authority of the exporting third country of the following: (i) the standards of good manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the Union; (ii) the plant concerned is subject to regular, strict and transparent controls and to the efficient enforcement of good manufacturing practice, including repeated and unannounced inspections, ensuring a protection of public health at least equivalent to that in the Union. In the event of findings relating to non-compliance, that information is supplied by the exporting third country to the Union without any delay.

It should be noted that the requirements on information shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.

Safety features: safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of

tampering. The safety features shall not be partly or fully removed or covered, unless certain conditions are fulfilled. In particular, the safety features should be replaced in the case of re-packaging 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 distribution chain, in order to protect patients, as well as the interests of marketing authorisation holders and manufacturers.

Medicinal products subject to prescription should as a general rule bear the safety feature. However, in view of the risk 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 scope 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 medical 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.

Inspections: the competent authority of the Member State concerned shall, in cooperation with the Agency, ensure that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced. Manufacturers, located in the Union or in third countries, and wholesale distributors of medicinal products shall be subject to repeated inspections.

Sales at a distance to the public: 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 through such sale. This Directive should 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).

The natural or legal person or the body provided for by national law offering medicinal products for sale at a distance is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person or body is established. The authorised person or body shall communicate the following to the Member States: name or corporate name and permanent address of the place of activity from where the medicinal products are supplied; the starting date of the activity of offering medicinal products for sale at a distance by way of information society services; the address of the website used for that purpose and all relevant information necessary to identify that website.

Internet pharmacy sites will be required to display a common logo, which should be recognisable throughout the EU, so as to help the public to ascertain that they are linked to an authorised pharmacy. All authorised internet pharmacies will be linked to a central website in each Member State and will be listed on that website. The various national web sites will in turn be linked to an EU website. Citizens will also have to been informed about the risks involved in buying medicines via the internet.

The Agency´s website shall explicitly mention that the Member States´ websites contain information on persons or bodies authorised or entitled to supply medicinal products to the public and entitled to offer them for sale at a distance by way of information society services in the respective Member State.

Public awareness: the Commission shall, in cooperation with the Agency and the competent authorities of the Member State, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally to the public via the Internet and the function of the common logo, the Member States´ websites and the Agency´s website

Preventing dangerous medicines from reaching the patient: Member States shall have a system in place which aims at preventing medicinal products that are suspected to be dangerous from reaching the patient. With this aim the system shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products and cover recalls by marketing authorisation holders or ordered by national competent authorities from all relevant actors in the supply chain both during and outside normal working hours. The system shall also allow recalls from patients, who received them, where necessary with the assistance of health professionals.

If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which the product was first identified, shall without any delay transmit a rapid alert notification to all Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients.

International cooperation: 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 commercialisation of falsified medicinal products at a global level.

Penalties: the new Directive lays down penalties applicable to infringements of the national provisions. Those penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance.

Delegated acts: the Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU which concern: (i) good manufacturing and distribution practices for active substances; (ii) detailed rules for medicinal products introduced into the Union without being imported and (iii) concerning safety features.

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.

Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

PURPOSE: 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.

LEGISLATIVE ACT: Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on

the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

CONTENT: following an agreement in first reading with the European Parliament, the Council adopted a directive aimed at preventing falsified medicines from entering the legal supply chain. The Directive acts against the increase of falsified medicines detected in the EU and the public health risk which that poses. The main provisions of the new Directive are as follows:

Safety features: medicinal products subject to prescription must bear safety features which should allow verification of the authenticity and identification of individual packs throughout the supply chain, and provide evidence of tampering. Non-prescription medicines are normally exempt from this obligation. In the light of a risk assessment, it will, however, be possible to extend the scope of safety features to non-prescription medicines for which this turns out to be necessary and to exclude certain prescription medicinal products from the obligation to bear safety features. Re-packaging of medicinal products remains possible, but the safety features must be replaced by equivalent safety features.

Good manufacturing practice: the manufacture of active substances intended for use in medicinal products must follow good manufacturing practice regardless of whether these ingredients are manufactured in the EU or imported. In the case of manufacture in third countries of active substances which are intended for export to the European Union, the competent authority of the exporting third country must certify that the manufacturing plant concerned is subject to regular, strict and transparent controls so as to ensure a protection of public health at least equivalent to that in the Union.

Obligations of importers, manufacturers and distributors: in order to strengthen the protection of the legal supply chain, importers, manufacturers and distributors of active substances must be registered with the competent authority as well as must brokers of medicinal products.

Furthermore, the manufacturers of medicinal products must verify that the manufacturer and the distributor of the respective active substances comply with good manufacturing practice and good distribution practices. They must also ensure that the excipients used are suitable for use in medicinal products. Wholesale distributors must verify that their supplying wholesale distributors are authorised.

Obligation to inform competent authorities about suspect products: manufacturers will be obliged to inform competent authorities about medicinal products they suspect of being falsified. A legal basis is created for customs authorities in co-operation with competent authorities, to take measures aiming to prevent that medicinal products suspected of being falsified enter into circulation.

Inspections : the competent authority of the Member State concerned shall, in cooperation with the Agency, ensure that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced. Manufacturers, located in the Union or in third countries, and wholesale distributors of medicinal products shall be subject to repeated inspections.

Recall of dangerous products: Member States shall have a system in place which aims at preventing medicinal products that are suspected to be dangerous from reaching the patient. The system shall also allow recalls from patients, who received them, where necessary with the assistance of health professionals. If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which the product was first identified, shall without any delay transmit a rapid alert notification to all Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients.

Distance selling to the public: the new directive also contains provisions aimed at protection patients from receiving falsified medicines through the sale of medicines via the internet. Websites offering medicines must be linked to the website of the respective competent authority on which a list of all persons or bodies in that Member State that are authorised to offer medicinal products for sale via internet must be available. Furthermore, such web pages must, in order to facilitate identification, display a common logo. These new provisions are without prejudice to Member States' right to regulate retail sales of medicinal products.

Public awareness: the Commission shall, in cooperation with the Agency and the competent authorities of the Member State, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products.

Sanctions: Member States must impose effective penalties inter alia for the manufacturing, distribution, import and export of falsified medicinal products.

ENTRY INTO FORCE: 21/07/2011.

TRANSPOSITION: 02/01/2013.

DELEGATED ACTS: the Commission is empowered to adopt delegated acts in accordance with Article 290 TFEU which concern good manufacturing and distribution practices for active substances, detailed rules for medicinal products introduced into the Union without being imported and safety features.

Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

The Commission adopted a report on the Member States transposition of Article 118a of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2011/62/EU of the European Parliament and of the Council.

As a reminder, Directive 2011/62 / EU (Falsified Medicines Directive) was adopted to address growing concerns about the presence of falsified medicines in the legal supply chain. In 2014, falsified vials of Herceptin (trastuzumab), a cancer treatment, were discovered in several EU markets. Falsification also affects medicines for sexual dysfunction and hepatitis C.

The Falsified Medicines Directive introduces mandatory safety features on prescription medicines from February 2019 (unless explicitly exempted), and establishes an EU-wide logo to allow the identification of legal online retailers of medicines (applicable from 1 July 2015).

Article 118a of Directive 2001/83/EC requires Member States to lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to the Directive and to take all necessary measures to ensure that those penalties are implemented. The

penalties must be effective, proportionate and dissuasive.

This report provides an overview of the Member States transposition measures and a qualitative assessment of their effectiveness. The Commission was aided in its assessment by the TRANSPOSE study conducted by an external contractor.

Transposition of Article 118a in Member States: the main conclusion of the report is that the transposition by Member States of Article 118a is satisfactory. A total of 26 Member States have introduced changes to their legislation in relation to penalties for the falsification of medicines, active substances and excipients in order to transpose Article 118a.

All 28 Member States apply criminal penalties in the form of imprisonment for the falsification of medicines. In 21 Member States, falsification per se is penalised, without the need to prove that the product is dangerous to health. For active substances, 23 Member States apply criminal penalties. For excipients, 14 Member States apply criminal penalties.

Where criminal penalties apply for the falsification of medicines, the maximum prison sentence is at least three years in 20 Member States. All Member States apply fines for the falsification of medicines.

Effectiveness: many of the national legal experts consulted as part of the TRANSPOSE study were unable to provide estimates of the effectiveness of specific penalties in relation to falsified medicines, active substances and excipients. Experts in 10 Member States considered that all of the penalties in place (criminal, civil and administrative) had at least some effect in reducing the presence of falsified medicines in the legal supply chain. Overall, administrative sanctions were rated as effective more often.

To further reinforce measures in place and strengthen their overall effectiveness, the report concludes that certain Member States could consider introducing additional criminal penalties or administrative sanctions in relation to falsified medicines, active substances or excipients.

Member States should ensure that adequate resources and personnel are allocated to enforcing penalties in place (e.g. by training new enforcement officers). Given the difficulties in obtaining accurate estimates of the extent of falsification in the EU market, the Commission considers that increased monitoring and data collection could allow for more accurate assessment of the effectiveness of specific national provisions.

Next steps: the Commission will continue to support Member States implementation of the Falsified Medicines Directive, in particular the medicine authentication system, which becomes applicable in the Member States in February 2019.

Furthermore, the EU logo for online pharmacies should ensure that consumers do not unknowingly buy medicines from illegal suppliers and should assist Member States in their enforcement efforts.

The report stresses the importance of continued cooperation, sharing of best practices and effective monitoring of the legislation in place to discourage the falsification of medicines through suitable penalties.