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Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT Accompanying the document COMMISSION DELEGATED REGULATION (EU) No .../... supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

Delegations will find attached document SWD(2015) 188 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

COMMISSION DELEGATED REGULATION (EU) No .../...

supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

{C(2015) 6601 final}
{SWD(2015) 189 final}

1. INTRODUCTION AND PROBLEM DESCRIPTION

Fake medicines are a growing concern in the EU. Falsified medicines are medicines with a false identity (e.g. name, composition), history (e.g. batch number) or source and which are passed off as genuine, authorised products. They may contain ingredients which are of low quality or in the wrong dosage. Falsification concerns prescription and over-the-counter medicines, brand-name and generic medicines, albeit to a different extent.

The medicines distribution chain is very complex and involves many operators. This creates many potential points of entry for fake medicines in the legal supply chain.

Currently, there are no EU-wide obligatory technology solutions in place that prevent falsified medicines from entering the legal supply chain. The use of electronic record keeping combined with electronic means to identify medicines and acquire medicine information is not harmonised across the EU, creating inefficiencies in the traceability of medicines, including falsified medicines, and in the handling of expired or recalled medicines.

A second concern is that, despite coding systems being in place in certain Member States, most medicinal products are not checked for authenticity neither along the legal supply chain nor when supplied to patients, which increases the risk that fake medicines, but also recalled or expired medicines, are inadvertently supplied to patients.

To tackle this problem, Directive 2011/62/EU introduced obligatory ‘safety features' that encompass two distinct elements:

- ‘a unique identifier’, a sequence that is unique to a single pack, held by a ‘carrier’ (barcode);
- ‘an anti-tampering device’ to verify whether the outer packaging has been tampered with.

In addition, Directive 2011/62/EU requires the Commission[1] to set out the detailed rules for the safety features in a delegated act, following an analysis of the impact of the different options. To this end, this impact assessment report evaluates costs, benefits and cost effectiveness of:

(a) the technical options for the unique identifier;

(b) the options for the verification of the authenticity of the medicinal product bearing the safety features;

(c) the technical options for establishing and managing the repository system containing the safety features.

2. OBJECTIVES

The general objective of this initiative is to improve the protection of public health while promoting the internal market and the competitiveness of EU pharmaceutical companies.

The specific objectives of this initiative are:

[1] Art. 54a(2) of Directive 2001/83/EC

– to establish a framework for the unique identifier and its verification that is simple and cost-effective in safeguarding public health and which protects personal and commercial information;

– to limit the costs for all actors.

The first operational objective is to ensure efficient and effective characteristics and technical specifications of the unique identifier (objective 1).

The second operational objective is to introduce proportionate verification of the safety features in order to combat falsified medicines (objective 2).

The third operational objective is to ensure interoperability of the repository system, free movement of medicines and supervision by the competent authorities (objective 3).

3. ANALYSIS OF SUBSIDIARITY

Article 54(a)(2) of Directive 2001/62/EU requires the Commission to adopt a delegated act setting out, inter alia, the characteristics and technical specifications of the unique identifier, the modalities for the verification of the safety features and the provisions on the establishment and management of the repositories system containing the safety features.

The aim of the safety features is to harmonise the safety aspects of medicinal products on the EU market to ensure the equal protection of all European patients, without impeding the circulation of medicines across borders. Such objectives can only be achieved at EU level.

4. POLICY OPTIONS

4.1. Policy options for achieving objective 1: To ensure efficient and effective characteristics and technical specifications of the unique identifier

4.1.1. Policy option 1/1: Full harmonisation of the composition of the number and the data carrier to fight against falsified, recalled and expired medicines

This option proposes the full harmonisation of the composition of the unique identifier and the barcode carrying it. The identifier would contain the product code, serial number, national reimbursement number (where applicable) and, to facilitate return and recall procedures, the batch number and the expiry date. It would be carried by a two-dimensional barcode.

4.1.2. Policy option 1/2: Partial harmonisation of the composition of the number to fight against falsified medicines

This option requires the unique identifier to contain the product code and the serial number. It is up to the manufacturer to choose whether to include additional product-related information in the identifier and to choose the most appropriate carrier.

4.2. Policy options for achieving objective 2: To introduce proportionate verification of the safety features in order to combat falsified medicines

4.2.1. Policy option 2/1: Systematic verification of the unique identifier at the dispensing point — 'end-to-end verification system'

In this option, the pack is scanned or checked out following the reading (scanning) of the unique identifier at the end of the supply chain, i.e. by the retailer, hospital pharmacy, community pharmacy or general practitioner.

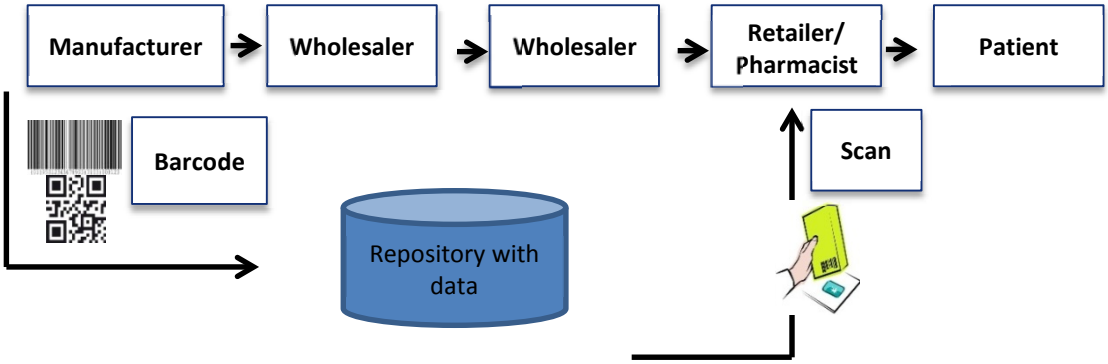

Figure 1. Illustration of an end to end verification system. The manufacturer places the unique identifier on the outer packaging and enters the number in a repository system at time of manufacture. The pharmacist checks the unique identifier against the repository system before dispense to the patient.

4.2.2. Policy option 2/2: Systematic verification at the dispensing point and risk-based verification by wholesale distributors

In this option, the pack is verified at the dispensing point as in option 2/1 and, additionally, by wholesale distributors on the basis of risk.

4.3. Policy options for achieving objective 3: To ensure interoperability of the repository system, free movement of medicines and supervision by the competent authorities

In order to verify the authenticity of the medicinal product, the unique identifier has to be checked against the information stored in a repository system. According to Directive 2011/62/EU, the delegated act must contain provisions on the establishment and management of and access to the repository system. Directive 2011/62/EC also lays down that the costs of the repository systems are to be borne by the manufacturers.

4.3.1. Policy option 3/1: Establishment and management by stakeholders with supervision by the relevant competent authorities

This policy option provides for the establishment and management of the repository system by stakeholders. It defines the obligations of the system, but would leave the choice of the appropriate infrastructure for the repository system to the relevant actors, and the right to supervise the system to the national competent authorities.

4.3.2. Policy option 3/2: Establishment and management by a public authority at EU level

This policy option provides for the establishment and management of the repository system by an EU body.

4.3.3. Policy option 3/3: Establishment and management by public authorities at national level

This policy option involves the establishment of repositories managed by national competent authorities. The national databases will need to be interconnected in order to allow intra-EU trade.

5. ASSESSMENT OF THE SOCIAL, ECONOMIC AND ENVIRONMENTAL IMPACTS

Objective 1: To ensure efficient and effective characteristics and technical specifications of the unique identifier

Social impact: Harmonisation offers a greater positive impact by protecting patients not only form falsified medicines but also from recalled and returned products, and from the involuntary administration of inappropriate medicines.

Economic impact/costs: In both options, total annual costs for originator companies would range from €20 million to €110 million, and for generics companies from €30 million to €210 million. However, option 1/1 can partly offset those costs by:

- replacing different national product coding systems, thus avoiding multiple manufacturing lines to comply with individual national obligations;
- increasing the legitimate sales of medicines;
- reducing the cost of handling recalls and returns.

Benefits: Harmonisation would avoid the costs of different packaging standards and processes and facilitate implementation, reimbursement and surveillance activities, including product recalls. Moreover, wholesale distributors and pharmacies would only need to invest in one piece of software and one reader. Partial harmonisation is convenient for manufacturers that produce only for those markets where a system of authentication is already in place. It will also allow marginal savings for a limited number of companies using pre-printed cartons.

Objective 2: To introduce proportionate verification of the safety features in order to combat falsified medicines

Social impact: Risk-based checks by wholesale distributors provide a higher level of protection of patients' health against falsified medicines.

Economic impact/costs: Both options require an annualised investment cost of €530 per pharmacy and general practitioner and up to €750 for hospital pharmacy.

Option 2/2 also generates costs for wholesale distributors (about €33 million for the first year) due to the need to modify software, buy scanners, the increased scanning time and warehouse space. Some of those investments will anyway stem from the new obligation for wholesale distributors to record batch numbers (Article 80 of Directive 2001/83/EC).

Benefits: Risk-based checks allow for detecting falsified medicines earlier in the supply chain in a cost-effective way. Moreover, they will also increase the traceability of medicines and facilitate stock management in case of shortages.

Objective 3: To ensure interoperability of the repository system, free movement of medicines and supervision by the competent authorities

Social impact: Experience shows that a stakeholder model (option 3/1) ensures an effective verification of medicines and detection of falsified, expired and recalled products and ensures a high level of protection of patients' health.

Economic impact/costs: The manufacturers' costs for the stakeholder-led model could reach €205 million annually, i.e. up to €0.022 per pack of medicinal product. The EU-led repository (option 3/2) would require significant resources from the EU budget to hire staff and set up the system from scratch. Option 3/3 would entail high costs for national authorities to set up the national systems and for manufacturers for connecting to and paying fees for multiple systems.

Benefits: Scaling up existing pilot systems (option 3/1) would save time and be more cost-effective than creating a brand new system. The supervision by the national competent authorities would guarantee the necessary controls. The benefits of an EU system are a single entry point and supervision by an official body. The latter also applies to the national model.

6. COMPARISON OF THE OPTIONS

The effectiveness (i.e. to what extent they fulfil the objective) and efficiency (i.e. at what cost they do so) of the policy options for the three problem areas are compared below:

Comparison of the options for objective 1: To ensure efficient and effective characteristics and technical specifications of the unique identifier		
OPTIONS	EFFECTIVENESS	EFFICIENCY
Policy option 1/1: Harmonisation of the composition of the number and the data carrier to fight against falsified, recalled and expired medicines	HIGH in harmonising the unique identifier. HIGH in protecting patients against the entry of falsified medicines and recalled and expired products. HIGH in ensuring the free movement of medicines in the internal market.	HIGH as the fixed costs for the introduction of the unique identifier are mitigated by the reduced costs of verification equipment and reduced need for country-specific manufacturing lines.
Policy option 1/2: Partial harmonisation of the composition of the number and the data carrier to fight against falsified medicines	MEDIUM in protecting public health, ensuring harmonisation and protecting against falsified medicines due to the non-uniformity of the features and the data carrier.	LOW as the fixed costs for the introduction of the unique identifier are aggravated by the necessity of buying multiple pieces of equipment to verify divergent number formats, and the need for country-specific manufacturing lines.

Consequently, option 1/1 prevails in terms of both effectiveness and efficiency.

Comparison of the options for objective 2: To introduce proportionate verification of the safety features in order to combat falsified medicines		
OPTIONS	EFFECTIVENESS	EFFICIENCY
Policy option 2/1: Systematic verification of the safety features at the dispensing point — end-to-end verification	LOW as this is the minimum verification to be performed in the supply chain to ensure the prevention of falsified medicines. Fake medicines may still circulate in the EU for months or years before being detected.	HIGH as only pharmacies/retailers would be affected by the costs.
Policy option 2/2: Systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors	HIGH in ensuring proportionate verification of the safety features. Additional verifications are performed only when there is an increased risk of falsification.	MEDIUM as wholesale distributors, in addition to pharmacies/retailers, would also be affected by the costs

Consequently, option 2/2 prevails in terms of both effectiveness and efficiency.

Comparison of the options for objective 3: To ensure interoperability of the repository system, free movement of medicines and supervision by the competent authorities		
OPTIONS	EFFECTIVENESS	EFFICIENCY
Policy option 3/1: Establishment and management by stakeholders with supervision by the relevant competent authorities	HIGH in ensuring interoperability of the databases and interfaces. HIGH in ensuring coordination of the various stakeholders. HIGH in ensuring the free movement of medicines. HIGH in ensuring supervision by competent authorities.	HIGH due to the low coordination costs and the possibility to rapidly roll out existing pilot projects.
Policy option 3/2: Establishment and management by a public authority at	HIGH in ensuring interoperability as there would be a single database and limited interfaces.	LOW due to additional costs to set up a pilot project and the coordination costs necessary to align the

EU level	MEDIUM in ensuring coordination of the various stakeholders. HIGH in ensuring the free movement of medicines. HIGH in ensuring supervision by an official body.	interests of all stakeholders.
Policy option 3/3: Establishment and management by public authorities at national level	LOW in ensuring interoperability of the systems in the EU. MEDIUM in ensuring coordination of the various stakeholders. HIGH in ensuring the free movement of medicines. HIGH in ensuring supervision by competent authorities.	LOW due to the extra costs of 28 national systems

Consequently, option 3/1 prevails in terms of both effectiveness and efficiency.

The total annual cost estimates for introducing the unique identifier for the entire sector range from €200 million to €800 million. However, looking at the production value (ex-factory) of the sector, the additional cost for the pharmaceutical sector and the impact on the costs of medicines is expected to remain limited.

	Total costs sector	*Costs per company*
Manufacturers	*(in € million)*	*(in € 1,000)*
Originator manufacturers	20 – 110	7 – 39
Generics manufacturers	30 – 210	30 – 210[2]
Repackagers / parallel importers	1 – 5	1 – 5
Total costs manufacturers	**51 – 325**	-
Wholesalers	*(in € million)*	*(in € 1,000)*
Full-line wholesalers	33	43
Short-line wholesalers	Not available	Not available
Other	0	0
Total costs wholesalers	> **33**	-
Retailers	*(in € million)*	*(in €)*
Community pharmacies	17 – 69	270 – 530
Dispensing doctors	2	270 – 530
Hospital pharmacies	2 – 4	390 – 750
Other retailers	Not available	Not available
Total costs retailers	**21 – 75**	-
Repositories system	(in € million)	
Stakeholder governance	100 – 400	
EU governance	100 – 400	
National governance	> 100 – 400	
Total costs repositories system	**100 – 400**	-
Total costs pharmaceutical sector	**205 – 833**	-

The implementation of the unique identifier will protect patients from falsified medicines in the legal supply chain, although it will generate costs for the pharmaceutical sector. The most cost-effective options to mitigate these costs are:

- harmonising the composition of the number and the data carrier;
- verifying the unique identifier at the level of the pharmacy and, for medicines at higher risk of falsification, at the level of wholesale distributors;
- using a repository established and managed by stakeholders, under the supervision of the relevant competent authorities.

[2] The number of generic companies is estimated to be around 1,000 companies