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Accompanying document to 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

Summary of the Impact Assessment

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COMMISSION STAFF WORKING DOCUMENT

Executive summary of impact assessment report on a Commission 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

There is an alarming increase in the EU of medicinal products which are illegal and false representations relating to identity, history or source. These products (which are commonly referred to as "**counterfeit medicinal products**") usually contain sub-standard or false ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients. They are a major threat to European patients and European industry.

To this adds that the risk profile has changed. The number of false representations of innovative and life-saving medicines is increasing. Moreover, in order to increase volume, these products are channelled through the lawful supply chain towards the patient. In this way, in 2007, many thousand packs of false representations of life-saving drugs have reached patients in the EU.

While there is uncertainty as to the precise number of cases today or in the future, there is a clear trend visible which threatens the high level of protection of public health in the EU. Moreover, it can have disastrous consequences for the trust of the public in the industry and in the policy maker – well comparable to the "food-and-feed crisis" of the 1990's.

The underlying causes for false representations of medicinal products remaining undetected in the lawful supply chain are manifold, but can be reduced to four aspects:

- False representations of medicinal products can not always be easily distinguished from originals;
- 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 false representation of the original API.

These aspects relate in particular to the pharmaceutical legislation in the EU which ensures the functioning of the internal market for medicinal products while safeguarding a high level of protection of public health in the EU. To the extent that this legislation establishes exhaustive rules, Member States are not allowed to "add to" these rules. Moreover, the aim to combat counterfeit medicines in the legal supply chain (without hampering the functioning of the internal market for medicinal products) cannot be sufficiently achieved by the Member States and can be better achieved by the Community.

Against this background, the impact assessment discusses a variety of policy options for a set of specific objectives to address the underlying causes. Many of these policy options

strengthen substantial rules which enhance enforcement. Indeed, enforcement is crucial, as counterfeit is by definition an illegal activity.

The impact assessment supports the following policy options:

- A legal basis for the Commission to render obligatory specific safety-features on the packaging for prescription medicines.

- An extension of certain rules for wholesalers to other economic actors in the distribution chain who are involved in the transactions (for example, by auctioning products) without actually handling the products.

- Obligatory audits of distributors and harmonised rules for official inspections. Moreover, compliant wholesalers would be listed in a European database to enhance transparency of reliable traders.

- Clarification of the rules of "import for export", i.e. clear rules as to the requirements for products entering the Community allegedly not made available on the Community market.

- Strengthened requirements for importations of API if it is established that the regulatory framework in the respective third country does not ensure a comparable level of protection of human health for products exported to the EU.

- Audits and notification of economic actors handling API in the EU.

The assessment of the policy options is made against a baseline of "non-action". As a baseline, various scenarios of the future development of counterfeit medicines for the period until 2020 have been developed. While these scenarios (and related costs) are by their very nature estimations based on best use of existing data (which is in itself limited), they reveal that societal direct and indirect costs of non action will reach, depending on the scenario, between 9.5bn EUR and 116bn EUR until 2020.

These costs of non-action compare against the costs of the chosen policy options. These costs are going to be, until 2020, as follows:

- For manufacturers and importers of medicinal products: between 6.8bn EUR and 11bn EUR, depending on the safety technique chosen; Moreover, depending on the chosen approach, pharmacies are going to bear costs of approx. 157m EUR;

- For wholesale distributors of medicinal products: approx. 280m EUR;

- For wholesale distributors who engage only in export activity: approx. 403m EUR;

- For other traders situated in the distribution chain: approx. 5m EUR;

- For manufacturers of API: approx. 320m EUR. The bulk of these costs is going to fall upon 3rd country manufacturers.

Finally, the impact assessment also discusses as policy option a prohibition of manipulations (i.e. removing, tampering with, or over-labelling) of safety features on the packaging by economic actors situated "in-between" the original manufacturer (typically the trademark

holder) and the last actor in the distribution chain (typically the pharmacist) or end user (doctor/patient).

Manipulations of safety features render subsequent detection of counterfeit medicines more difficult/impossible, which increases the risk of counterfeit medicines reaching the patient through the legal supply chain.

This risk is no theoretical construction. There have been cases in the past where counterfeit medicines, once re-packaged, remained subsequently undetected and reached the patient through the legal supply chain.

The impact assessment report assesses the socio-economic consequences if manipulations of safety-features affixed on the medicinal product were in principle prohibited and shows that these impacts would mainly relate to parallel trade of medicinal products. This is due to the fact that parallel traders, as part of their business model, have to re-package medicinal products in view of, in particular, language requirements in the destination state.

The impact assessment shows that, in a first-round effect, the reduction of parallel trade leads to losses of turnover for these businesses (approx. 3.2-4.5bn EUR) and reduces employment (approx. 9 000 jobs in the EU). Moreover, the reduction of parallel trade removes price-competition (between the originator and the parallel distributor) which may arguably reduce savings for public health budgets and/or social security schemes in high-price countries (DK, UK, SV, NL, DE). The exact amount of these savings is highly controversial. Studies conclude a range between 100m to 600m EUR per year in the EU.

The impact assessment also looks at second round effects of this policy option. It shows that the revenue and employment generated so far by parallel traders may be re-distributed to wholesale distributors and to the research-based industry. With regard to the latter, these revenues may be re-invested in R&D thus contributing to the competitiveness of this sector. As regards potential savings for public health budget and social security schemes, the impact assessment sets out various arguments as to the extent of the savings and whether they could also be obtained through national regulation of pricing and re-imbursement in the high-price countries.

In accordance with the Commission guidelines, the impact assessment does not take a final stance on the policy option. Rather, it sets out the arguments and likely impacts of this policy option thus providing the basis for a policy-decision of Commission in its proposal to the co-legislator.