BEUC The European Consumer Organisation

The Consumer Voice in Europe

Implementation of EU legislation to combat falsified medicines

BEUC response to the public consultation

Contact: **Ilaria Passarani – health@beuc.eu**

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BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • Fax +32 (0)2 740 28 02 • consumers@beuc.eu • www.beuc.eu
EC register for interest representatives: identification number 9505781573-45

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Summary

The European Consumer Organisation (BEUC) welcomes the adoption of the EU legislation to combat falsified medicines (Directive 2011/62/EU) as a contribution to increase patient safety. Our main concern is that the implementing measures are supported by a thorough impact assessment, that they are proportionate and cost-efficient.

We hope that the results of the consultation and the impact assessment will help to clarify the costs associated with the introduction of the complex authentication and verification system required by the legislation. We also wish that in order to enhance patient safety and optimize the use of resources the system will be used also for pharmacovigilance and for reimbursement purposes.

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1. General remarks[1]

BEUC welcomes the adoption of the EU legislation to combat falsified medicines (Directive 2011/62/EU) as a contribution to increase patient safety. The Directive strengthens the controls all along the supply chain, clarifies roles and responsibilities of the actors involved and increases transparency. We particularly welcome the provisions clarifying the distinction between falsified medicines and problems associated with intellectual property rights, the increased cooperation among the national competent authorities and the improved inspections. The proposal addresses of course only the legal supply chain but we know the main source of counterfeit remains the illegal supply chain especially via the internet[2]. In this respect we welcome the measures aimed at increasing consumers awareness about the risks of buying medicines from illegal sources and in particular from unauthorized on-line pharmacies[3].

Unfortunately the increased safety comes with a price and since the beginning of the debate on this topic we always highlighted the importance of conducting a thorough impact assessment and of ensuring that the measures are proportionate and cost-efficient and that they do not have a negative impact on access to treatments and on health care budgets.

We hope that the results of the consultation and the impact assessment will help to clarify the costs associated with the introduction of the complex authentication and verification system required by the legislation. We also wish that in order to enhance patient safety and optimize resources the system will be used also for pharmacovigilance and for reimbursement purposes.

2. The unique identifier

BEUC agrees that the unique identifier should be a randomized serialization number put on each pack. With regard to the carrier, on the basis of the information provided in the concept paper, the two dimensional bar code seems to offer more advantages compared to the other carriers taking into account that RFID is still relatively more expensive than the others and that it is still not known to what extent it can interfere with the quality of certain medicines. In addition the two dimensional bar code can contain more information than the linear code. In any case, without a good understanding of the costs associated for example with the reading devices needed to read the code, it is not possible to make a proper cost-benefit analysis. We support the composition of the serialisation number proposed by the Commission (product code and pack number) as well as the

[1] This is a consolidated version of the BEUC response to the three concept papers submitted for public consultation in relation to the implementation of the Directive 2011/62/EU.
[2] Test Salute n.95, Altroconsumo, December 2011.
[3] BEUC position on counterfeit medicines (X/2009/81).

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inclusion of the batch number in order to facilitate recalls and information on the expiry date. In order to optimize resources it would be useful to use the investments made to build up the authenticity and verification system also for reimbursement purposes – including the prevention of frauds to the national health care systems - thus we support the inclusion of the national reimbursement number in the serialization number. In relation to the policy options indicated in the concept paper, we support the option of harmonizing at EU level the details concerning the serialization number including them in the delegated acts. Leaving the choice of the technical specifications to the individual manufacturer would undermine the verification system and prevent the free movement of medicines across national borders.

3. Verification

The unique identifier is useful only if systematically checked against a well-functioning and constantly updated verification system. We support the check-out of the serialization number at the dispensing point (retailer, pharmacy or hospital pharmacy). The check should be done as close as possible to the moment when the product is handed to the final user but, in order to avoid counterfeit products to circulate for long time in the distribution chain without control, it is useful to make random checks at the level of wholesale distributors (option 2/2).

4. Repository system

The establishment and the management of the repository system are the crucial aspects of the implementation of the legislation. Our major concerns in relation to the repository system is that it should not contain any consumer personal data, that the system is efficient and cost effective and that the information collected is not used inappropriately, for example to profile patients or to unduly influence prescribing behaviors. At present some pharmacies sell sales information to private companies for market studies that are then purchased by pharmaceutical companies. Consumers should be reassured that none of their personal data is given to third parties other than the reimbursement authorities and in all cases they should be informed by the pharmacists about how their personal data will be processed.

With regard to the proposed policy options we support the national governance model (option 3/3) with interconnected national database. We consider this less complex than a centralized system governed by an EU body (option 3/2) and more appropriate that than the proposal to have a system governed by stakeholders (option 3/1). We have reservations on the stakeholder model as it would be equally complex from a technical point of view and because of the legal issues (scope, liability etc.) linked to the status of a non-profit organization jointly managed by various stakeholders, themselves non for profit organizations with

different legal basis, status, liabilities, funding, etc. The concept paper states that the stakeholder governance option "*may be the most cost efficient as it may create a market that provides the best value for money*". Indeed, the repository system generates data of high commercial value. Before establishing such system it is necessary to well understand how much the information is worth, how it will be managed and most of all who will be the owner of it.
The Directive indicates that the serialization as well as databases will be paid by the manufacturers and presumably wholesalers and pharmacists will also bear some costs associated with the software and the scanners. The additional costs should be considered as compensated by the gain in terms of market data and in terms of logistics information from the repository system and should not be claimed to justify higher prices for medicines. Nor the compliance with the legislation and the safety of the chain should be used by commercial actors to promote their image among consumers who consider the safety and integrity of the medicines they buy as a given.

5. Scope of the safety features

We always supported a risk based approach for the definition of the scope of the application of the safety features and we agree with the proposed identification criteria. We only recommend clarifying if the indication of two euros as "high price" refers to the manufacturer gross price per pill or per box or any other element. We support that the " black" and the "white " list will be made at EU level so to avoid discrepancy at national level but it is necessary to take into account that in some countries some products are classified as prescription medicines and in others as over the counter. In these cases it is important to ensure consistency in order to avoid confusion for consumers.

6. Active pharmaceuticals ingredients (API)

With regard to the measures affecting the import of active pharmaceutical ingredients it is important to safeguard the continuity of safe supply and to avoid that administrative hurdles block access to API and ultimately to some medicines used by European consumers. In this respect we encourage the European Commission to undertake all efforts and to work not only with the trade and custom authorities but also with the health authorities of third exporting countries in order to ensure they are in the position to meet the safety and quality standards set in the Directive as soon as possible.

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