AIM
ASSOCIATION INTERNATIONALE DE LA MUTUALITE

AIM Response to Public Consultation in preparation of a legal proposal to combat counterfeit medicines for human use

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AIM welcomes the Commission's public consultation in preparation of a legal proposal to combat counterfeit medicines for human use.

According to recent studies, counterfeit medicines have become an increasing threat to public health. These **studies unfortunately often do not focus on and explain the origin and main sources of counterfeit products**. However such data are extremely important in tackling and remedying these problems.

We draw attention also to the likely costs of the administrative burdens arising from some of these proposals, and to the potential inhibition of cost-effective parallel imports which would otherwise be safe and justified.

1. Control in the distribution chain and inspections

AIM fully supports the proposals:

- to subject all parties in the distribution chain (brokers, traders, agents) to the application of the obligations for wholesalers;
- to strengthen provisions on inspections and supervision, in particular regarding inspections in third countries, by making them compulsory.

2. Product integrity and traceability

2.1 Ban on repackaging

The Commission proposes to improve product integrity through a unique seal from the manufacturer, supported by a ban on repackaging of products identified by using a risk-based approach. The right to open the seal would be restricted to the market authorisation holder and the end user (hospital, health care professional or patient).

In footnote 20, the Commission outlines that this may affect the possibility of exchanging package leaflets and inner packaging by actors in the distribution chain. However the Commission postpones the analyses of the consequences until the impact assessment study. At this stage we would like to highlight that **the ultimate proposal must not incur disproportionate costs compared with expected benefits,** and that it should favour patient advantage as sincerely as it does patent-holder protection.

Considering the wording used by the Commission, AIM would like to highlight that the main consequence of this proposal would be to **limit parallel trade of pharmaceuticals**. However, so far, parallel trade is legal according to the European Treaty.

AIM therefore calls on the Commission to be much clearer about its real intentions underlying these proposals. If it is intended that parallel trade should continue to be allowed, it would therefore be necessary to consider activities of wholesalers when organising parallel trade in the chain of pharmaceutical distribution. Safe repackaging should continue to be allowed, to guarantee correct utilisation of medicines - in particular through appropriate packaging and leaflets available in the langue of the country of distribution.

We would like to invite the Commission to consider following proposals:

- A possibility for the parallel trader to put a label on the outer packaging containing all legal particulars in the language of the country of product sale. In this case, the seal would remain untouched.
- A possibility for the parallel trader to open the seal to provide new packaging containing all legal information in the language of the country. In this case, the parallel trader should be allowed to reseal the package.

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2.2 Traceability

The traceability of a product can also be improved through a reference on the outer packaging for each product in a batch (each product in a batch thus having a reference), included in a central register (pedigree) - from manufacturer to the salesperson, including the different parties in the distribution chain. This would enable better identification of the product and would secure the distribution chain:

- If the parallel trader respects this circle when repackaging, and reuses the number of the reference/batch of the product, traceability is respected.
- This reference could also be included on the blister pack in order to guarantee a high level of security.

Current legislation should also be amended (art. 55.2 Dir. 2001/83/EC) by stipulating that each product should be identified through its INN name. This would also contribute to strengthening the security of the product user.

Some Member States have already put in place a strategy for authenticity checks. Belgium for instance has already had for two years a system of "unique barcode" that identifies each package separately.

2.3. AIM supports the Commission's proposals for increasing transparency concerning authorised wholesale transactions, through a Community database.

2.4. In addition to Commission proposals, the role of the pharmacist should also be emphasised, e.g. by opening the outer and inner package in front of the patient and doing proper visual inspection (pharmaceutical care).

3. Strengthened requirements for the import/export/ transit of medicinal products

AIM agrees with the necessity of amending Dir. 2001/83/EC to make clear that it applies also for imported products intended for export.

4. Strengthened control on active substances

AIM supports following proposals:

- to submit the manufacturing/import of active ingredients to a mandatory notification procedure
- to control active substances
- to make the respect of GMP guidelines legally binding
- to make regular audits of active substance suppliers' GMP compliance (by manufacturers and importers of medicinal products) mandatory

5. Further to the Commission's proposals, AIM calls on the Commission to consider following **additional measures:**

- to enlarge the initiative also to cover nutriments, vitamins, etc.;
- to sensitize patients themselves to the problem of 'counterfeiting', for instance through initiatives facilitating direct reporting by patients of irregularities; cf. the direct reporting of side effects by patients;
- to foresee sanctions for non respect of rules/legislation.

About AIM

The *'Association Internationale de la Mutualité'* (International Association of Mutual benefit societies) (AIM), created in 1950, brings together 45 national federations of autonomous health insurance and social protection bodies in 28 countries, all operating according to the principles of solidarity and not-for-profit orientation. They provide coverage against sickness and other social welfare risks to more than 170 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

AIM's goal is to defend and promote, at international and European level, the social values and basic principles shared by its members: access to health care as a fundamental right, solidarity and non-exclusion as essential means to ensure this access to quality health care for all, irrespective of health status or financial capacity to pay; finally, autonomous management and non profit orientation as guiding principles for health insurance based upon the needs of citizens.

AIM endeavours to voice concerns and ideas raised within the sphere of non-profit health insurance institutions in the EU. AIM positions, requiring validation through its own statutory decision-making process, do not commit its individual member organisations. Therefore, AIM involvement does not detract from its member organisations taking dissentient views.