MINISTERIO
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agencia española de
medicamentos y
productos sanitarios

DIRECCIÓN DE LA
AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y
PRODUCTOS SANITARIOS

COMMENTS TO THE CONCEPT PAPER ON THE DELEGATED ACT ON THE CRITERIA TO BE CONSIDERED AND THE VERIFICATIONS TO BE MADE WHEN ASSESSING THE POTENTIAL FALSIFIED CHARACTER OF MEDICINAL PRODUCTS INTRODUCED IN THE UNION BUT NOT INTENDED TO BE PLACED ON THE MARKET.

SUBMITTED BY THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS), SPAIN.

As an introductory remark, AEMPS appraises the initiative from the Commission to elaborate this concept paper on the delegated act setting out the criteria to be considered and the verifications to be made when assessing products introduced in the Union but not intended to be placed on the market. Cross-border trade commonly involves several Member States and measures contributing to an harmonized application across the Union are welcome.

CONSULTATION TOPICS

Consultation item n°1: please comment on this abovementioned possibility for checks and verifications.

A first verification should be based on a documentary check, based on the information provided by the economical operators. Processes flows at customs and customs code should be thoroughly revised to identify opportunities for setting the necessary controls.

Ideally, it could be based on the pre-arrival declaration on goods entering the EU (Entry of Summary Declaration, ENS filed by the economical operators), presented in the first point of entry into the EU, measures designed to meet the need for safety and security in relation to goods crossing international borders. However, the information provided in the ENS e.g. concerning the content of the shipment is incomplete and not reliable enough (i.e. does not include validated information about the content, too vague goods description) to allow for appropriate risk identification.

When the goods are to be unloaded in the Union territory, a Summary Declaration for Temporary Storage is lodged at customs and placed under customs supervision in temporary storage (maintained by customs authorities, operated by the importer or by a storage keeper). However, again, it is not a requirement to declare the type of goods, which does not facilitates control. Nevertheless, when these warehouses receipt and storage medicinal products, they should hold a license as wholesalers and be subject to periodic GDP inspections..

The Single Administrative Document (customs declaration) is lodged when the goods are placed under any customs procedure (export, import, transit , warehouses, temporary import, inward and outward processing, etc.).

Based on these declarations, risk-based filters could be established and higher risk goods could be set for further verifications. Such second tier of verifications could include physical examination of the goods, its package and other characteristics. To perform these controls cooperation of third country authorities might be needed. Controls beyond those (i.e. sampling and testing) would in our opinion be excessive and very resource demanding.

CORREO ELECTRÓNICO
sdaem@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 50 28
FAX: 91 822 50 10

Nevertheless, the information about the products in transit is very limited because no original sample for comparison or the authorized specifications for testing would be available.

Consultation item n°2: do you consider that all the verifications mentioned in paragraphs 15, 16 and 17 should be carried out ? If not, in which cases it would not be necessary to check all these verifications?

We don't have currently any data about the number of these operations but, most likely, systematic controls will not be possible.
The checks and verifications should be tiered in different levels of depth and resources invested, following a risk-based approach. Besides they should not hinder or delay unnecessarily the cross-border movement of goods.
Besides controls on each importation, other alternative approaches to diminish the risk of import for export falsified medicines could be used. Firstly, economic operators performing wholesaling activities, as defined in the Directive 2001/83/EC, should be subject to authorization and periodic inspections to verify GDP compliance. In these inspections, it could be checked whether the operator has fulfilled the obligations provided for in the Article 85c concerning the legality of suppliers/customers. Secondly, economic operators who are considered as reliable partners are usually identified or qualified by customs authorities, and transactions of these operators could be considered as lower risk.

Consultation item n°3: who performs the verifications ?

We agree it is important that the delegated act allow for organizational flexibility, as systems may differ between Member States. Nevertheless, the delegated act should foster cooperation between medicinal product competent authorities and customs.

Consultation item n°4: please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

During the Directive 2011/62/EU discussions at the Council, it could be noted that the terminology used by national competent authorities and experts in the field of public health differs significantly from the terminology used by customs officers. Any delegate act resulting from this work should use a terminology understandable for both parties, both of who will share the responsibility for enforcement in this area.
A list of contact points of third country authorities in order to contact them, if needed, when performing these verifications would be helpful
As these operations of 'import for export' may involve several MMSS it should be clarified in the delegated acts who should perform these controls in order to avoid duplication of efforts. In our opinion the controls should be made at the first point of entry into the EU.
The scope of the delegated act should clarify that these verifications will take place only when the medicinal products are introduced in the EU and declared as such on ENS. The illegal introduction of medicinal products should be outside the scope of this delegated act.

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