

Role of Customs / Interaction with Customs

Customs

Generally, the role of customs is to control the movement of goods across borders. They enforce duties, tariffs, and regulations to ensure compliance with the national regulations. In the context of medicinal products customs enforce national law preventing illegal medicinal products from entering a country.

Customs play therefore a crucial role in applying the rules and regulations on the classification of borderline products when these products cross borders.

Health authority

The health authority provides general information about the classification of borderline products and takes the decisions in particular cases on whether a product is a medical product or not. In order to have products efficiently classified by customs when crossing the border, the health authority has different options to support customs.

Process and tools

Customs have to handle a broad spectrum of products and items, requiring a very broad knowledge for the categorisation and classification of these products and items. In consequence, it is important to have a good routine in place at customs on how to handle a product in the borderline to medicinal products. .

1. Customs needs to systematically control product to identify possible borderline products that might be medicinal products (see Detection). To save resources it is important that the control is done risk based (see below).
2. It needs to be clear who makes the classification; customs or the health authority.
3. In the case that the health authority makes the classifications there needs to be a specific routine and collaboration for this, e.g. that officers for the health authority visit customs.
4. In the case that customs makes the classifications there are several tools that the health authority could use to support this work (see table). To further support customs it is of advantage if the health authority is available for questions on specific cases (see Table on interactions below).

Tools for health authorities to support customs

Training	As a basis with the main goal of awareness raising for the topic of borderline products, general training of customs officers by the HA is an option. Examples for such trainings: <ul style="list-style-type: none">– general basic training– regular training
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	<ul style="list-style-type: none"> - follow-up trainings - ad hoc training - e.g....
Decision trees	Decision trees leading to a classification by specific questions on certain product characteristics are an option in case a personal or formal interaction is not possible or for clear cases/situations.
Decision lists	Decisions lists (eventually provided in a database format) can be used in order to take decisions. Decision lists can prevent repeated requests for the same product in the future. Continuous updating and reviewing is key in order to keep these lists up to date with respect to scientific knowledge and jurisdiction.
Non-binding guidance lists	Non-binding guidance lists (eventually provided in a database format) can also be used to support the decision-making process. continuous updating and reviewing are also key here to reflect current knowledge and jurisdiction. .

—> add examples for each of these for illustration

Interaction

Interaction options with the respective responsible authorities for the classification of borderline products for timely decisions should be built. Below listed options could be implemented. The information about the dedicated contact point at the HA and the process on how to interact based on the situation (travel or post traffic) has to be transparent and easily available at customs.

“Hotline” by phone	For immediate (if possible) decisions a standing “hotline” could be implemented. Dedicated persons at the HA could decide on the classification of borderline products ad hoc (in case a decision is possible based on the information available) and communicate directly to the respective customs officer asking.
Email contact	For decisions that are not needed immediately (e.g. for postal parcels), a designated email-contact at the HA could be established to be contacted by customs.
Checklist (for customs officers)/specific form	A checklist collecting all relevant information on the product available in order to decide on the classification of the product can be implemented. This checklist can the be used by the customs officer requesting a classification at the HA.
Regular meetings	In regular meeting between customs and HA, specific products or general aspects can be discussed and decisions can be made and documented.
Physical presence	Physical presence (permanent or sporadic/regular) of a dedicated customs officer at the HA or vice versa (a dedicated person of the HA at customs) can be established in order to facilitate classification questions as a permanent routine process at the respective location.

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Information from customs to the health authority

Trends	Customs are the first to see trends for new borderline products crossing the border and can therefore provide this information to the HA.
Data lists	Customs can provide data lists on specific shipments (tariff codes), on specific recipients, on specific senders in order for the HA to do evaluation and decide on measures to be taken.
Data analysis	Customs can do data analysis of shipments on any specific parameter, such as products, senders, recipients, in accordance with national law on data protection and regulations.
Monitoring	Customs can do monitoring of specific products or any other parameter (persons, senders e.g.), in accordance with national law on data protection and regulations.

Generally, customs controls are mostly done on a risk based approach.

Health authority has to be aware that customs have their own classification system. This classification is used by customs to determine not only tax tariffs, but the system is also used to attach certain conditions (e.g. special import requirements or administrative decisions for particular goods or imports, respectively) for certain specific classification numbers. It is important to raise awareness in communication with customs that the classification of products in the sense whether a product is a medicinal product or not (classification of borderline products) is done irrespective of the customs classification of goods.

More specific information on the international harmonised system of the customs classification system can be found under the following links:

- <https://www.wcotradetools.org/en/harmonized-system>
- <https://www.wcoomd.org/en/topics/nomenclature.aspx>

Many countries might have national links to the national customs classification system. Based on the classification numbers, data extracts (e.g. lists of importations matching certain criteria) from the customs database can be requested.

Appendix customs interaction

Examples and contacts for the tools explained

We may not need the situation for all countries, but keep list of tools and provides examples for illustration.

Decision trees

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Decision lists

EE	Not officially published, list regularly sent to customs.

Non-binding guidance lists

SW	List for herbal drugs provided

Hotline

CH	Hotline for customs to the medicrime SPOC at the HA established (phone number included in customs handbook) in order to provide immediate guidance to customs in case of classification questions at the border.

Email contact

Checklist/specific form for customs to request a classification at the HA

BE	Specific form/checklist established for the interaction btw. customs and the HA

Regular meetings

DK	

Physical presence

UK	permanent custom officer at the MHRA that allows a close collaboration
ES	regular physical presence of HA at customs
DK	regular physical presence of HA at customs