COMMENTS TO THE CONSEPT 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 NORWEGIAN MEDICINES AGENCY (NOMA)

CONSULTATION ITEMS

Consultation item n°1: please comment on this abovementioned possibility for checks and verifications (paragraphs 15, 16, 17):

Verifications of the potential falsified character of a medicinal product related to its identity, source and history:

Check of identity

Analytical testing of the composition of the medicinal product will only reveal if the product contains the specified API or not and in what amounts. It is by analysis possible to check for discrepancies between the actual content and the declared content on the packaging, and such discrepancies will strongly indicate that the product is falsified. Such verification, as also stated in paragraph 15, will be particularly challenging due to lack of relevant reference samples, analytical methods and standards. If the content of API is according to the declared amount, the product may still be falsified with regard to identity since there will be no way to know the specification of the original product including the original packaging. Analytical testing is time consuming and costly. It should to our opinion be the last resort and only be performed if there is good reason to suspect that the product is falsified (high risk).

Check of source

Products, included medicinal products, transported from third countries to the EEA are required to be pre announced to customs in the Member State which are to receive the goods (a pre-arrival declaration). The sender must register product information either by describing the nature of the goods or use customs tariff code. In addition company information of both sender and receiver is registered. This system should be explored for possibilities to recognize medicinal products coming in from third countries and for it to give an alert to the authorities when medicines are registered (system alerts are implemented for other types of goods). The information logged may further on be used by the competent authorities to perform a risk analysis of the goods in regard to falsification.

Generally the checks should be based on risk assessment in view of the number of consignments sent through EEA each year and the human resources available in Member States.

Medicinal products may be stored in transit just for a few hours. Automatic computerized first checks will be preferable.

The pre-arrival declaration system is entirely based on trust and it is not difficult for criminals to be unspecific in the product description or declare the product as something else entirely. This check may though be supported by additional requirements.

Companies offering to store products in transit (undeclared goods) must hold an authorization issued by customs. In the near future companies offering in transit storage of medicinal products will also need to hold a Wholesale Dealers License issued by the competent health authorities. Additional requirements may be laid on these wholesalers. This could include an obligation to give the competent authorities alerts if wrong pre-arrival declaration is suspected.

A risk assessment may be based on trust, that is, with the competent authorities knowledge of the companies involved in the trade. (Do they hold a Manufacturing License or a Wholesale Dealers License?). This information will usually be available for companies based in third countries which we already cooperate with (through PIS/C, MRA…).

E.g. medicinal products sent from a well known pharmaceutical source in one third country headed for a known pharmaceutical source in another third country might be regarded as low risk. While unknown companies in third countries, may be regarded as high risk and trigger additional checks.

Check of history

Checking documents concerning the distribution channels will be time consuming and may disrupt the trade of flow for a long period of time. Distribution channels may be complex and companies in third countries may be reluctant to give out documents. This will be a difficult task for Member States to perform on regular basis and this kind of check will be demanding on our human resources.

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?

Checking documents concerning the distribution channels (check of history) should only be performed if there is good reason to suspect that the goods are counterfeit medicines (high risk) or in cases were the goods are likely to have been transported under wrong conditions. If there is a suspicion that the medicines have been subjected to wrong transport conditions, the documentation checks of the distribution chain should be done by the wholesaler.

Consultation item n°3: who performs the verifications?

Both NOMA and Norwegian Customs needs to be involved in Norway, and there is need for cooperation.

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.

It is important to also include customs terminology since their systems needs to be used. We will not be able to know when medicines are arriving at the boarder unless customs is involved.