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im Gesundheitswesen

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Austrian response to 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

Ad consultation item number 1:

Freight documents do not have to contain the information necessary to be able to check the identity, the source or the history of the medicinal product.

To be able to check the medicinal product as defined in the paragraphs 15, 16 and 17, the Austrian Federal Office for Safety in Health Care would have to contact the competent authority in the country of origin of the medicinal product. Without their information and especially the reference sample of the original medicinal product it is not possible to check, if the medicinal products are falsified or not.

Besides that, the analytical testing of the composition is cost intensive and time consuming.

Ad consultation item number 2:

The delegated act should enable the competent authority of the Member States to decide, case by case, based on the potential risk, which verifications have to be carried out. Not all verifications mentioned in paragraphs 15, 16 und 17 are always necessary.

Ad consultation item number 3:

We recommend not to include provisions on competence "directly" in the delegated act. It should be up to the Member States to define the competence of the competent authorities involved.
In Austria the relevant competent authorities are customs and the health authority.

For the Austrian Federal Office for Safety in Health Care

Unterkofler Bernd
am 6.12.2012

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