

DIVIZJONI TAS-SAHHA
“Palazzo Castellania”
15, Triq il-Merkanti,
il-Belt



HEALTH DIVISION
“Palazzo Castellania”,
15, Merchants Street,
Valletta

Telephone + 356 224071
Telefax + 356 242884

D.H.Circular No: 101/06

13th March 2006

To: Wholesale Dealers
Importers
Qualified Persons

RE. IMPORTATION OF MEDICINES FOR THE PURPOSE OF RE-EXPORT ONLY

The EU Commission has recently informed Member States and clarified the position in respect of the requirements that need to be observed when medicinal products are brought from a third country into a member state (importation) for the sole purpose of re-export, and without placing them on the market in a member state. These requirements also apply even though the product remains intact and no manufacturing activities, e.g. re-labelling or re-packaging, are carried out.

In such cases the provisions of article 40 and 51 of Directive 2001/83 EC, as amended, apply. This means that a manufacturing/ import authorisation is required, that GMP standards should be in place and that the QP should perform a full qualitative and quantitative analysis to ensure the quality of the products in accordance with the marketing authorisation of the country of destination. The QP has full responsibility to ensure that products have been manufactured in accordance with GMP in the source country.

The only exclusion in respect of the requirement for a manufacturing authorisation is when the above mentioned operations are effected within a freeport, free trade zone or customs (e.g. bonded warehouse). However, in such instances a wholesale dealer's licence is still required by the company engaging in the process. Good Distribution Practice standards are to be achieved.

In those cases involving a manufacturing activity in relation to imported products that are destined for re-export only, a manufacturing authorisation and GMP standards are required, even if the operations are effected within the freeport or customs. Operations of re-labelling and/or affixing of labels to the outer pack also fall within this category. The QP should ensure that the applicable GMP standards are observed during these operations.

This information is being communicated for your information and compliance. The Medicines Authority will be enforcing the legal requirements in accordance with the provisions of the EU Directives and the Medicines Act 2003.

Your cooperation is being solicited.

R. Busuttil
Director General (Health)