# GIRP response to the public consultation on the revision of Annex 16: Certification by a Qualified Person and Batch Release

## General remarks

GIRP is the umbrella organization of pharmaceutical full-line wholesalers in Europe. It represents the national associations of over 750 pharmaceutical full-line wholesalers serving 31 European countries, including major pan-European pharmaceutical full-line wholesaling companies.

Through their distribution infrastructure, GIRP members employ about 140,000 people and serve over 170,000 pharmacies and other healthcare professionals dispensing medicinal products to the public. In the performance of their public service role, they absolutely guarantee the highest level of quality, integrity and excellence. They operate according to the highest supply chain quality standards.

The wholesale distribution of medicinal products is an important activity in the integrated supply chain management. To this end, the European Commission published its first guidelines on Good Distribution Practice of Medicinal Products for Human Use in form of a Commission guideline 94/C 63/03. It is in compliance with the standard as set down in this guideline that GIRP members have been operating.

On 8th March 2013 the European Commission published the revised guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 68/01). The revised guideline has come into effect as of 8th September 2013.

## Specific remarks

GIRP would like to point to chapter 5 section 5.4 of the new GDP-Guidelines which deals with requirement that must be met for a wholesale distributors' receipt of medicinal products:

> *"The purpose of the receiving function is to ensure that the arriving consignment is correct, that the medicinal products originate from approved suppliers and that they have not been visibly damaged during transport.*
>
> *Medicinal products requiring special storage or security measures should be prioritised and once appropriate checks have been conducted they should be immediately transferred to appropriate storage facilities.*
>
> *Batches of medicinal products intended for the EU and EEA countries should not be transferred to saleable stock before assurance has been obtained in accordance with written procedures, **that they are authorised for sale**. For batches coming from another Member State, prior to their transfer to saleable stock, the control report referred to in Article 51(1) of Directive 2001/83/EC or another proof of release to the market in question based on an equivalent system should be carefully checked by appropriately trained personnel." [underlining added]*

1. Provision like Article 51 (1) of the Directive 2001/83/EC are intended to pharmaceutical manufacturers and are Good Manufacturing Practice (GMP) orientated standards. The authorization for sale by a pharmaceutical manufacturer is a precondition for any medicinal product, sold by a pharmaceutical manufacturer and is therefore not attributable to the pharmaceutical wholesaler.

2. GIRP is of the opinion that principles and responsibilities of GDP should not include GMP requirements, especially when wholesale distribution authorisation holders are not permitted to interfere in any way with the actual medicinal product. Wholesalers are only handling, storing and delivering medicinal products in their secondary packaging. A distinction has to

be made between provisions applicable to manufacturers, as the release for sale by the QP of the manufacturer, and wholesale distributors.

3. Any sold or supplied batch of licensed medicinal products from the manufacturer to the wholesaler must be considered to be released for sale or supply to the market. The obtaining of any assurance about a batch release by the QP of the pharmaceutical manufacturer by a pharmaceutical wholesaler goes far beyond what is necessary to ensure the safe handling, storage and transportation of authorized and marketable medicines.

4. Furthermore, the proposal to obtain the batch releases of the pharmaceutical manufacturers would lead to additional costs unacceptable administrative burden for wholesale distributors that cannot be covered by current margins, which have significantly declined throughout the years and lately have been cut severely in several EU countries as part of general austerity measures.

GIRP therefore takes the current opportunity to respond to the European Commissions' public consultation on the revision of "Annex 16: Certification by a Qualified Person and Batch Release" in order to suggest the inclusion of a reference in Chapter 6 of Annex 16 to the appropriate assurances of batches of medicinal products intended for the EU and EEA countries as authorised for sale in respect of chapter 5 section 5.4 of the new GDP-Guidelines. GIRP suggests the following addition of a final paragraph to section 6:

**'Any sold or supplied batches of licensed medicinal products to the market, after a notified certification by a QP as described above, are considered to be released for sale or supply to the market.'**