



Brussels,
15 December 2011

Subject: Revision of the guidelines on GDP of medicinal products for human use

Dear Sir/Madam,

I write to you on behalf of the Pharmaceutical Group of the European Union (PGEU) responding to the public consultation the guidelines on GDP of medicinal products for human use. PGEU's members are the national associations and professional bodies of community pharmacists in 31 European countries, including EU Member States, EU candidate countries and EEA members. Through its members, PGEU represents around 400,000 community pharmacists.

Firstly, we would like to express our support for the revision of the Guidelines on Good Distribution Practice. The Guidelines need to take into account changes and advances in practice in connection with the appropriate storage and distribution of medicinal products. They also need to reflect the recently adopted Directive on Falsified Medicines.

However, we believe that the current distribution system of medicines in Europe is highly efficient, and consistent with the rights and needs of European patients. In the majority of EU member states, pharmacies receive multiple daily deliveries from wholesalers, and thus can effectively meet the needs of the population they serve without delays. We therefore believe it is essential that any changes to the Guidelines are proportionate, and do not place excessive burdens on wholesale distributors which may necessitate the lowering of current high service standards.

We are concerned that some of the proposed changes may in fact be excessively burdensome. For example, in some countries, wholesale distributors operate out of hours and undertake night deliveries, and thus frequently do not hand the deliveries directly into the care of the consignee, but make special arrangements to leave the medicinal products in the premises of the pharmacy. If wholesale distributors are required to hand the delivery into the care of the consignee, the efficiency of deliveries to the pharmacy may be compromised as it will be impossible to deliver outside pharmacy opening hours.

With regard to returns from pharmacies of medicines as described under heading **6.9 Returned Medicinal Products** of the consultation, we would like to bring your attention to the fact that European community pharmacies have to comply with storage conditions of medicines set by National Authorities, in many cases equal to those in the wholesaler warehouse. The registration of environmental parameters such as temperatures and humidity in the pharmacy at regular intervals for quality assurance purposes is normally a requirement. Consequently, we believe that pharmacies are in a position to ensure the appropriate storage conditions for products as they are described by the manufacturer. Therefore, we believe that the proposed requirement that pharmacy returns should take place within 5 days of receiving goods is not justified.

Moreover such a condition will impact price of medicines and existing delivery rules for example in Denmark, where pharmacies operate with a price period of 2 weeks and where the pharmacies are obliged to supply the cheapest alternative medicine during that period (these

types of arrangement are indeed becoming more common in the EU). Restrictions on the possibility of return may mean that the pharmacies will be reluctant to hold high stock levels. This may impact on availability of medicines where there are unpredicted changes in demand, and increase the burden on the distribution system, to the detriment of patients. Therefore, we strongly suggest that existing national return rules of medicines from pharmacies should be maintained.

Finally, we would like to take this opportunity to express our support to comments submitted by European Association of Full Line Wholesalers (GIRP), subject to our view that returns from pharmacies (including the cold chain products) should be allowed on the terms and within the time periods that are usually set at national level or by contract between wholesaler and pharmacy.

Should you require any further information on this matter, please do not hesitate to contact me.

Yours sincerely,

A handwritten signature in blue ink that reads "John Chave". The signature is written in a cursive style.

John Chave
PGEU Secretary General