

Ms Elizabeth Evans  
Medicines and Healthcare products Regulatory Agency  
Room 16-161 Market Towers  
1 Nine Elms Lane  
London SW8 5NQ



Brussels, 13 March 2009

### **EAEPC comments to MHRA Review of UK Supply Chain**

Dear Ms Evans:

Thankful for the opportunity to take part in earlier stakeholder consultations, I should like to submit, on behalf of the EAEPC, the representative European trade association for Parallel Distribution of Medicines in Europe, a number of comments to the questions raised in the review document. I will focus on issues which may have a pan-European dimension.

#### **Wholesale dealers**

Issuing licences to „fit and proper persons“ seems a minimum requirement. Together with the idea to charge fees upfront, including for an initial inspection, this sets standards already higher.

Under a risk based approach one could even think of going a step further and invite an applicant to submit his business plan (types, volumes and sources of medicines intended to trade) together with the application or ahead of the initial inspection, and to request an evaluation by a qualified insurance assessor of the risks implied in such a business and set a corresponding risk premium. This would i.a. allow to ask for a capitalization of the business in line with its potential risks, thus complementing the aspect of „fit and proper person“. While this may sound far fetched at this stage, it is submitted nonetheless as an idea for further consideration.

Due diligence: the Commission proposal (referenced in Annex B) suggests that wholesalers who source product from other wholesalers shall carry out an audit on their supplier before engaging in transactions. There are standards for such GDP audits developed by quality assurance bodies; in the EAEPC we have initiated a programme to audit those among our membership who, as licensed wholesalers, are suppliers to parallel importers/distributors. Audit reports are shared among the members. This is a programme driven, and fully supported, by our members, and we believe this is an important way forward to enhance the high level of behavioural standard that is commensurate to handling medicines along their supply chain.

In case a WS dealer's licence were revoked, it is suggested that this be made public, so as to enhance transparency for other operators, notably also operators from outside the UK.

#### **Responsible Person**

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I shall not comment on the requirements envisaged for the RP. However, while it makes sense to oblige an RP „to report suspicious incidents“, there should also be a provision that RP’s can obtain information, eg. from the regulator, or the marketing authorisation holder, in case that there may be suspicious material on the market; information channels on safety related issues should be both ways. Watchlists, as an example, should be communicated to the persons responsible for quality assurance along the supply chain, without however scaring the public.

### **Import for export**

Conceptually, if the MHRA has identified this sector as a weak link in the supply chain, it makes sense to raise the stakes and to introduce proportionate steps. A licensing requirement for such businesses, and GDP type of record keeping, could be combined with an obligation, known also in the parallel distribution sector, to keep batch retention samples of all products handled during a reasonable period and make these available for inspectors when needed.

It could further be envisaged to make provisions for enhanced cooperation between customs and MHRA in respect of such activities.

### **Storage and Transit**

Para 47 of the consultation paper addresses trade of medicines across EU internal borders. All of that does, however, not fall under the strict term of „parallel trade“. Wholesalers are free to engage in such intra-EU trade so long as they do not place the products on another market than the one for which these were destined.

As the threat of counterfeits entering the legitimate supply chain is perceived to be on the rise, the EAEPC would encourage the MHRA to examine the option of restricting intra-EU trade in medicines to licensed operators. In the parallel trade context, this would mean that only holders of parallel import product-related marketing authorisations would be allowed to operate in the EU national markets where ‘parallel imports’ exist. Licensed importers are subject to GMP obligations and are thus held to a more stringent set of quality and safety requirements than operators only regulated by GDP. We also believe that this recommendation has the advantage of not requiring a change in legislation, merely a more stringent interpretation and practice of existing law.

In this way, stricter standards like the ones suggested for transport, and for establishing an audit trail, can be easier set and enforced.

### **Pharmacies**

The MHRA alludes to recent trends in trade by pharmacies. It will be no secret that these are developments resulting from the increasing circumvention of licensed wholesalers by the big pharmaceutical manufactures through DTP distribution schemes. While price differentials between European markets seem to persist, and DTP models aim at closing trade initiated by wholesalers, it is economically obvious that the incentive to trade moves downstream to a level where the freedom of trade is not hampered by anti-competitive practices of pharmaceutical manufacturers. Under certain DTP schemes, quota systems are said to be applied even towards pharmacies.

The right thing to do from a clean regulatory perspective is to enable the wholesale sector to fully play its role of purchasing from manufacturers and selling medicines to pharmacies and liberate this profession from the ever stricter restrictions imposed by the manufacturers, in the absence of determined and rapid action by competition authorities. This will take the pressure away from pharmacies, which, under good distribution practice considerations will be more than welcome. But one should not confuse the causality in this respect.

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Pharmacies/pharmacists who intend to engage in wholesale activities can rightly apply for a wholesale dealer's licence.

**Sanctions**

Respecting that sanctions remain a national prerogative, I should only like to refer to ongoing work in the Council of Europe to establish a coordinated legal framework, in the form of a Convention, for penalising pharmaceutical crime.

Thank you for the opportunity to participate in this consultation.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Heinz Kobelt". The signature is written in a cursive style with some loops and flourishes.

Heinz Kobelt  
Secretary General EAEP