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Nick Fahy
European Commission
Health and Consumer Protection Directorate-General
Health services consultation
B232 8/102
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Dear Nick,

I am pleased to send you GlaxoSmithKline's (GSK) response to the consultation on Community Action on Health Services.

GSK welcomes this effort to further clarify the accessibility and availability of healthcare across Europe. Providing citizens and national and local health professionals with a clear framework of Community law or guidance within which to operate will help to create safe, high-quality and efficient health services across the EU. To that end, GSK has identified issues relating to pharmaceuticals for comment.

Whilst GSK has identified a small number of technical issues that it would like to raise, the overall impact of a future Health Services Directive (or non-legislative measure) on the pharmaceutical industry is likely to be limited as long as the ability of a Marketing Authorization Holder (MAH) to comply with its statutory obligations is not compromised.

Patient Safety & Pharmacovigilance

Should cross border healthcare increase, there is a need for improved information exchange between Member States to reinforce pharmacovigilance and the reporting of adverse reactions. In particular, e-health developments should enhance the coherence of safety reporting across Europe. It is already standard practice for MAHs to report all Adverse Events (e.g. side effects) on a periodic basis and to swiftly alert national authorities and the EMEA of serious events. MAHs are also required to conduct periodic signal evaluation.

For many mature products that have been variably approved throughout Europe via the national route, cross border medicine may raise some challenges. For example, if a patient receives treatment outside their country of origin and develops an adverse reaction on their return in which country should this be reported? What if a medical product that is prescribed abroad is not on the market in the patient's country of origin and yet an adverse reaction occurs? How will national rules apply in these circumstances to ensure compliance with regulations but prevent duplicate reporting? The impact on the legal obligations of an MAH needs to be considered and clear guidance given.

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There is also a small possibility that patients may under-report adverse reactions if they do not immediately return to their country of origin, as they may not be sufficiently familiar with the health system in the host country.

There may be some linguistic issues which need to be taken into account. Patient Information Leaflets (PILs) are critical to patient safety. Language problems could be addressed by the availability of information on the internet for example through the EMEA's recently launched EudraPharm website or on manufacturers' websites. A further complication, although not insurmountable, would be differences in Braille language. However, in the event of visually impaired patients receiving treatment in another Member State it is likely that special provisions will already be made on a case by case basis.

Differences in formulation between Member States could complicate safety considerations for the prescriber and the patient, although central registration is reducing such risk. While the availability of all licensed formulations can vary by Member State, dosages or common practice in the way in which a medicine is administered can also vary between Member States.

While Health care professional reporting is not a regulated field, health care professionals practicing outside their country of origin should be sufficiently aware of the national pharmacovigilance regulations and reporting mechanisms. They must be comfortable with local adverse reaction reporting, which may differ from any system they are familiar with.

Although not critical to the industry, we will be following future developments in health services. I would be happy to discuss or clarify any of the points raised in this response.

Chris Strutt
Vice President
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