GlaxoSmithKline

Global Manufacturing & Supply
980 Great West Road
Brentford
Middlesex
TW8 9GS

Tel. +44 (0)20 8047 5000
www.gsk.com

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GlaxoSmithKline response to the European Commission Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use: Key Ideas for Better Protection of Patients Against the Risk of Counterfeit Medicines.

GlaxoSmithKline (GSK) welcomes the opportunity to comment on the European Commission's proposal to better protect European patients from counterfeit medicines. We fully support the objectives behind the proposal and the principles contained in it.

GSK is a diverse organisation with a number of divisions, including vaccines and consumer healthcare products. For the purposes of this response, our focus is on prescription medicines handled at pharmacy level (including vaccines), as this is currently the business area most vulnerable to the risk of counterfeits in the European Union. However, it is recognised that a tightening of supply chain security for prescription products may, over time, shift counterfeiting activity to other healthcare products e.g. over-the-counter products.

GSK has contributed to, and is fully supportive of, the comments submitted by EFPIA. In addition, we have a number of general points which we would ask to be taken into account by the European Commission.

Definition of repackaging:

Repackaging for the purposes of this response has been taken to mean:

1. re-boxing the original product into a new outer carton undertaken by someone other than the original manufacturer, the MA holder of the original product or a third party contracted to repack by the original manufacturer or MA holder of the original product;
2. affixing labelling to the original outer carton and opening the original outer carton to insert a new patient information leaflet and/or to affix labelling to the contents of the original outer carton;
3. over-boxing whereby the whole of the original product (e.g. blister strips and outer carton) is placed into a new, second box along with a new patient information leaflet. This practice undermines the informative value of the original seal, which would be covered by an additional outside packaging.

Repackaging should be prohibited:

GSK fully supports a ban on repackaging by anyone other than the original Marketing Authorisation Holder, the original manufacturer or any party approved by either of them.

Authenticity & traceability of products:

Product verification by mass serialisation will provide an appropriate level of supply security alongside enhanced patient safety at pharmacy level. This can be achieved without moving immediately to a full e-pedigree system. We consider that a standardised

European coding system is essential for the successful implementation of this proposed legislation.

Enforcement and criminal sanctions:

In order to have a fully effective framework to combat counterfeit medicines, there is a need to put in place appropriate enforcement and sanctions to act as a deterrent for criminal activity. Internet trading is one key area which needs to be addressed, as is the area of international enforcement and how Europe can influence anti-counterfeiting measures on a global level.

Definition of audit and inspection:

The terms audit and inspection are used widely throughout the document. It is assumed that the terms inspection and audit are conducted by regulators, and originator pharmaceutical companies, respectively. It is recommended that the wording in the proposal is amended to make the distinction clear between the two types of activity.

Additionally, the use of the term 'safety audit' in section 4.1.1 has the potential to be confused with other types of audit, and we propose that the term is replaced by 'supply chain security audits' to fully elaborate the purpose of this particular type of audit.

Classification of logistics and transport providers:

There are various players in the supply chain, who carry out a purely logistics or transport activity e.g. logistics providers, train operators, airlines, etc. all of whom are involved in the shipment of medicines. These service providers are not wholesalers, and differentiation is required to separate their activities from wholesaling activity.

GSK recognises that this consultation proposal is the beginning of a process to effectively combat anti-counterfeiting measures, and that success will in part be determined by finding robust practical technical solutions. In view of the significant technical expertise held by GSK, we would be happy to work with the Commission on developing these solutions.

Contact details:

Yvonne M Stewart

GlaxoSmithKline

Tel. +44 (0) 208 047 4376

Email: yvonne.m.stewart@gsk.com