EUROPEAN GENERIC MEDICINES ASSOCIATION

RESPONSE TO EC PUBLIC CONSULTATION

EU-US HIGH LEVEL WORKING GROUP ON JOBS AND GROWTH

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The EGA is the official representative body of the European generic and biosimilar pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.

The European Generic medicines Association (EGA) highly supports the European Commission's trade policy aimed at creating opportunities for the European industry in a globalised economy. We are in favour of measures that seek to increase EU-US trade and investment, to support mutually beneficial job creation, economic growth and international competitiveness.

In this context, the EGA would like to put forward three practical priority measures for our industry that we trust will improve the regulatory environment for generic and biosimilar medicines in Europe and the US and facilitate business on both sides of the Atlantic.

These are 1) global development and international harmonisation of data requirements for approval of biosimilar medicinal products, 2) a single development programme and international harmonisation of data requirements for approval of generic medicinal products and 3) mutual recognition of compliance inspections.

1. Global Development and International Harmonisation of Data Requirements for Approval of Biosimilar Medicinal Products

The EGA calls on the newly established High-Level Working Group on Jobs and Growth to support a regulatory framework which allows a single development programme for biosimilar medicinal products for the European Union (EU) and the USA. Such a programme would substantially reduce the development costs of biosimilar medicines and therefore enable the European as well as the American biosimilars' industry to substantially increase patient access to high quality biopharmaceuticals, while at the same time boost their competitiveness and support the sustainability of the respective healthcare systems.

The EU was the first worldwide to put in place a legal and regulatory framework for the registration of biosimilar medicines and is consistently developing general and product-specific scientific guidelines. But the cost of development of a biosimilar for one region ranges between EUR 100 and 220 million depending on the molecule. Duplication of trials involving the biosimilar and the same reference product would be unethical, unnecessary and definitely uneconomical. The moment has come for this young industry to capitalise now on its very high investments. The three draft guidance documents on biosimilar medicines issued by the US Food and Drug Administration (FDA) on 15 February 2012 as part of the implementation by the FDA of the new abbreviated biosimilar pathway created in the US Biologics Price Competition and Innovation Act of 2009 provide now an excellent opportunity to work together on avoiding the unethical conduct of duplicative trials. The EU (EC/EMA) and the US FDA have recognised this issue and have started talks.

The EGA therefore calls hereby for continued support for these very important regulatory developments between the EU and the US. Further regulatory harmonisation with respect to the development of this new category of medicines could follow and lay down the basis for a true global biosimilar development. Biologicals represent indeed the fastest growing pharmaceutical market worldwide and patents have or are about to expire. Creating together a competitive regulatory framework for biosimilar medicines, based on sound science, will enhance growth, jobs and health in the EU, the US and worldwide.

2. A Single Development Programme and International Harmonisation of Data Requirements for Approval of Generic Medicinal Products

With the globalisation of markets, an increasing number of generic medicines manufacturers are keen to introduce their products on both the EU and the US markets. In view of this trend, and given the pressing need to boost competitiveness in both the European and the USA regions, the EGA calls on the EU-US High Level Working Group on Jobs and Growth to consider among its priorities and deliverables with substantial impact the need for simplification and stimulation of the recognition of assessments of generic medicinal products between the EU and the US in order to avoid duplications and to ensure faster access to both markets.

A Single Development Programme for Generic Medicines versus Reference Medicinal Products instead of duplication of studies (coherent with the idea of a Global Development Programme for Biosimilars outlined above) is an area where the EGA sees potential for cutting inefficiencies, responding to the needs of the patients and gaining from larger markets. A Single Development Programme for Generic Medicines would entail three key elements:

- Harmonised approach with regard to which studies are requested for generic and hybrid applications
- Harmonised criteria that have to be met for an application to be successful
- Common reference product mutually accepted by the EU and the US

Accelerating Harmonisation of Pharmacopoeia (USP-NF versus Pharm Eur) for further achieving the aforementioned point is another concrete element which would contribute to the simplification and harmonisation of the two systems.

Reaching a true Common Technical Document dossier between the EU and the US would largely benefit both systems by contributing to the improvement of transparency and reducing bureaucracy in the two markets.

It is important that the EU and the US further enhance mutual trust and confidence building through initiatives such as the pilot parallel assessment of Quality by design applications[1]).

Such collaborative efforts will help identify and resolve potential gaps (e.g. interpretation, approach) even in situations where in theory, regulatory concepts are harmonised (e.g. ICH).

[1] EMA-FDA pilot program for parallel assessment of Quality by Design applications - http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500103621.pdf

3. Mutual Recognition of Compliance Inspections between Europe and the USA

To establish a true level playing field, particularly in the area of pharmaceutical Good Practice (GxP) inspections, supporting fair global competition while overcoming the issue of limited resources in both the EU and the USA, there is a need for the extension of the scope of Mutual Recognition Agreements (MRAs), the development of alternative, less formal collaborative schemes and a more centralised coordination of inspection activities.

The EGA recognises the efforts put into initiatives such as the pilot international collaboration programme on good manufacturing practice inspections for active substances between the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and Australia's Therapeutic Goods Administration (TGA) that was carried out in 2010. The scheme has fostered greater collaboration and trust between regulators from the participating regions. This project has allowed a better prioritisation of inspections through information sharing on inspections, including planning, policy and reports, for manufacturers of active pharmaceutical ingredients that are located outside the participating countries. The EGA welcomes the fact that the scheme has now been extended beyond its pilot phase to become permanent and that it is open to new participating regions/countries. The EGA commends the boost of cross-border collaboration and the increased number of joint inspections or alternatively, reliance on partner regulator reports. We believe that regulators as well as pharmaceutical and API manufacturers would benefit from reduced redundant inspections and increased partnerships in the field (e.g. mutualisation of database, intelligence, IT and human resources). As the EMA noted, the cooperation has shown that "there is a need for an improved shared inventory of sites of common interest and supporting software applications and a need for longer planning lead times to arrange joint inspections"[2].

In this regard, the European Generic medicines Association (EGA) welcomes the joint initiative of the EMA and the FDA from 7 December 2011 for enhancing GMP inspection collaboration, not only focusing on information sharing, but also ultimately relying upon that information to meet inspectional obligations, including confidentiality arrangements, participation in joint inspection and information-sharing projects. The EGA sees major opportunities for gaining inspection resource efficiencies from moving on beyond existing collaborative projects towards reliance on each other's inspection outcomes. The joint efforts towards applying a mutual recognition approach is of high importance given the large number of inspections carried out by the FDA in the EU and vice versa, and especially in view of the shift of manufacturing base away from Europe and the USA and towards other regions.

Mutualisation of inspection efforts will also contribute to bringing a level playing field among all pharmaceutical supply chain operators through the headroom provided for more manufacturing sites to be visited in countries / regions outside the EU and USA. This will help the competitiveness of all US and EU operators with these of third countries where operators are, today, less subject to such inspections.

[2] "Joint API inspection pilot a success, says EMA", by Gareth Macdonald, In Pharma Technologist, 8 November 2010

Finally, the proposed mutual recognition initiative will bring relief to manufacturers who also put substantial resources into hosting inspections, sometimes with intervals of only weeks.

4. Conclusion

In conclusion, the EGA is confident that if implemented the three proposed measures: 1) global development and international harmonisation of data requirements for approval of biosimilar medicinal products, 2) a single development programme and international harmonisation of data requirements for approval of generic medicinal products between the EU and the US and 3) mutual recognition of compliance inspections, would bring a substantial improvement to the regulatory environments in both the EU and the US, which in turn would stimulate competitiveness and foster growth and jobs in both regions during these critical times of austerity.