



Making Medicines Affordable



Mr. Karel De Gucht
Commissioner for Trade
European Commission
B-1049 Brussels

The Honorable Michael Froman
United States Trade Representative
600 17th Street NW
Washington, DC 20508

Brussels, 3 April 2014

Dear Commissioner De Gucht and Ambassador Froman,

The European Generic medicines Association (EGA) and the US Generic Pharmaceutical Association (GPhA) would like to thank you for your invitation to present our views during the fourth round of the Transatlantic Trade and Investment Partnership (TTIP) negotiations. We found this to be a very useful event and greatly appreciated the negotiators' kind attention and thoughtful questions during our presentations.

EGA and GPhA would like to take this opportunity to put our views in writing and, also, to answer some of the questions posed during the presentation.

Recommendations

EGA and GPhA strongly support regulatory convergence for pharmaceuticals between the EU and US. The increasing utilization of generic medicines delivers greater access to safe and effective medications and contributes to significant cost savings for governments and consumers worldwide.¹ An additional, but important, benefit to both the EU and US is the value to our national economies of manufacturing jobs and revenues provided by domestic consumption, as well as exports, of generic and bio similar medicines.

Regulatory convergence between the EU and US will significantly reduce unnecessary costs and delays, as well as unethical duplication of scientific studies associated with the approval of generic and biosimilar pharmaceuticals. Specifically, EGA and GPhA recommend that TTIP pursue convergence in the following areas:

¹ Generics represent 84% of all prescriptions dispensed in the US, but only 27% of drug expenditures. Over the 10-year period 2003 through 2012, generic drug use has generated more than \$1.2 trillion in savings to the US healthcare system. In 2012 alone, generics saved the US healthcare system \$217 billion, up from \$188 billion in 2011. Globally, generics account for nearly 30% of the \$1 trillion pharmaceuticals market and up to 48% of prescriptions dispensed.

1. Advance the biosimilar cluster work between EMA and FDA by adopting the guidelines/Guidance for single development.

Biotechnology products are the most expensive in the market, with prices that range from \$20,000 to \$300,000 per year per patient, and their market share is growing. By 2015, over 50% of all newly approved prescription drug products in the US will be biologics. With regard to the EU, biologics are forecast to represent 50% of all medicinal expenditure by 2018, and cumulative savings from biosimilars for eight EU countries, between 2007 and 2020, could reach 33.4 billion Euros. The global biopharmaceuticals market, estimated at \$199.7 billion in 2013, is projected to reach \$497.9 billion by 2020, growing at 13.5% CAGR between 2010 and 2020.

To reduce development costs of up to \$200-300 million per product, and to avoid unnecessary and unethical duplication of clinical tests in humans, the EU and US should enable the single development of biosimilar medicines to boost existing cooperation between the EMA and the FDA on the convergence of development pathways. By adopting the EU guidelines and US Guidance on this matter, the biosimilar medicines industries of the EU and US would be able to substantially increase patients' access to high quality biopharmaceuticals, boost industrial competitiveness and support the sustainability of healthcare systems, while promoting the global use of the highest approval standards for such medicines in relation to comparability and clinical effectiveness.

2. Support the implementation of a single development and approval pathway for generic medicines.

Similarly, EGA and GPhA recommend setting up a generic medicines cluster, like the biosimilar medicines cluster, between EMA or national medicines agencies of EU Member States (HMA) and the FDA to adopt guidelines/Guidance for the single development of generic medicines. This would avoid unnecessary and costly redundancy, ensure faster patient access to pharmaceuticals in both markets and help to avoid the unethical duplication of clinical studies.

The cost savings alone justifies this recommendation. In the US, where some 1000 new generic applications are filed with the FDA per year, development costs are \$1.5-10 million for each product, yielding \$1.5 to \$10 billion in total development costs annually. If half of these drugs are also approved in the EU (a conservative estimate), a single pathway could result in \$750 million to \$5 billion in reduced expenditures.

We should underline that these proposals for single development will provide a significant boost to the many small and medium-sized companies that are often product developers in our sector. By reducing the unethical and costly duplication of clinical studies, these companies will be able to engage much more actively in transatlantic medicine development.



3. Foster the mutual recognition of good manufacturing practice (GMP) inspections between Europe and the US.

EGA and GPhA believe that pharmaceutical and active pharmaceutical ingredient (API) manufacturers would benefit from fewer redundant inspections and increased partnerships in the field. This would ensure compliance with quality standards and requirements globally and create a level playing field for all pharmaceutical supply chain operators transatlantically and globally by freeing up resources for European and American inspectors to visit more manufacturing sites in countries outside the EU and US. Additionally, mutual recognition would bring relief to manufacturers, which put substantial resources into hosting inspections, some of which may be redundant.

4. Adopt advanced manufacturing of generic and biosimilar medicines during the Supplementary Protection Certificate (SPC)/patent term extension period.

The EU and the US are among the few regions in the world to extend patent protection for pharmaceutical products to cover delays caused by marketing approval procedures. By applying what should be a market exclusivity as a *de facto* patent extension, the EU and the US unduly harm their generic and biosimilar manufacturers, which cannot produce for export to the rest of the world (where pharmaceutical growth is highest) or for immediate launch at expiry of the SPC/patent term restoration period. Consequently, our companies are left with little choice but to outsource their production or risk being uncompetitive with producers, for example, from Asian countries.

Advanced manufacturing would enable manufacturers to launch their products immediately after patent expiry in markets where an SPC or patent term extension right is not in place or has lapsed. Advanced manufacturing would help EU and US manufacturers hold their own against generic producers from competing markets without patent extension provisions, particularly those from emerging markets, which are enjoying rapidly increasing market share.

An EGA study concludes that exports by five EU countries would create more than 60,000 jobs over an eight-year period. We should underline that advanced manufacturing would have no impact on originator companies because they face off-patent competition from producers located outside of our territories.

5. Avoid harmonization of EU and US intellectual property regimes.

While these recommendations for regulatory convergence and advanced manufacturing will result in quantifiable benefits to the economies of the EU and US, harmonization of the two regions' intellectual property regimes would not. EGA and GPhA urge TTIP negotiators to reject proposals to harmonize the EU's and US's divergent, but equally robust, intellectual property regimes, which



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adequately protect rights-holders in both regions, while allowing access to medicines in lesser developed markets.

In particular, we emphatically reject the mischaracterization of existing law by originators and their representatives in support of their requests to “align” or “level up” regulatory data protection. The US currently has four years (not twelve years) under its law while the EU has eight years (not eleven years) of data exclusivity under its directive.

We hope that, in addition to ensuring that you are relying on facts, you will take into account the economic and societal impact of proposals to extend data exclusivity for biopharmaceuticals for an additional four to eight years which would, in practice, extend the market exclusivity for these products well beyond the current level provided by EU and US law (up to fourteen or fifteen years under patent term restoration or supplementary protection certificate, respectively).

Conclusion

EGA and GPhA believe that adopting these measures in TTIP, while rejecting attempts to harmonize intellectual property regimes, would create jobs, generate revenues and ensure access to medicines where they are needed, while contributing significantly to the sustainability of our health care systems.

Sincerely,

Adrian van den Hoven
Director General
European Generic medicines Association (EGA)

Ralph G. Neas
President and CEO
Generic Pharmaceutical Association (GPhA)

The European Generic medicines Association (EGA) is the official representative body of the European generic and biosimilar pharmaceutical industries, which are 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 pharmaceutical industry directly employs 150,000 people, allocating 7% of its turnover to R&D and bringing savings of more than €35Bn in the EU every year.

The Generic Pharmaceutical Association (GPhA) represents United States-based manufacturers and distributors of generic pharmaceuticals. GPhA's member companies operate in 140 countries and supply more than 90% of generic pharmaceuticals dispensed in the US.
