Ms. Cecilia Malmström
Commissioner for Trade

Brussels, October 2014

Dear Commissioner,

On behalf of the European generic and biosimilar medicines industries (EGA) we would like to congratulate you on your appointment as Commissioner for Trade. Your mandate commences at a crucial time for the development of the EU international trade policy agenda. The EU has just concluded negotiations for an EU-Canada Comprehensive Economic and Trade Agreement (CETA) and is currently negotiating preferential trade agreements with the United States and Japan.

We support the CETA and notably the full implementation of the export provision under the Supplementary Protection Certificate[1] (SPC) into EU internal law. The export provision is essential to enable the European generic and biosimilar medicines industry to compete on a level playing field with Canadian and other pharmaceutical producers like India, China, and Brazil. As generic and biosimilar medicines are expected to represent 80% of the volume of medicines by 2020, the EU needs this measure to give our industry the opportunity to manufacture these important medicines in Europe.

The EU-US Transatlantic Trade and Investment Partnership (TTIP) is a unique opportunity for the EU and the US to strengthen regulatory convergence to improve regulatory science while reducing costs for both industry and regulators. We appreciate and strongly support the efforts of the European Commission and the European Medicines Agency to foster cooperation with their respective American counterparts for the single development of biosimilar and generic medicines and for the mutual recognition of good manufacturing practice (GMP) inspections. This policy will deliver benefits to healthcare by lowering the development and production costs of pharmaceuticals while also promoting high (EU-like) global standards for medicines approvals and manufacturing. In addition, this will allow EU companies to benefit from the enormous opportunities opening up in the US, where the sales value of medicines losing exclusivity by 2016 amounts to €73,6 billion.

Removing non-tariff barriers and improving convergence in the regulatory field would definitely contribute to growth and creating job opportunities in Europe, while increasing export opportunities for pharmaceutical companies, including small and medium enterprises. The EU generic and biosimilar

[1] Council Regulation (EEC) No 1768/92

EUROPEAN GENERIC MEDICINES ASSOCIATION
Rue d'Arlon 50, B-1000 Brussels Belgium
T: +32 (0)2 736 84 11 F: +32 (0) 736 74 38
E: info@egagenerics.com www.egagenerics.com
VAT: BE 0449 332 209

medicines industries are among the most valuable assets of the European economy and will therefore play a pivotal role in contributing to the achievement of these objectives.

Similar objectives can be achieved in the EU-Japan FTA negotiations, which represent a crucial opportunity for the sector, especially in light of the Japanese Government's established target for generic medicines to reach 60% by volume of Japan's off-patent market by March 2018 and the Japanese policy of promoting biosimilar medicines. In order for the European industry to take proper advantage of the future expansion of the generic and biosimilar medicines market, it is crucial that the EU and Japan negotiate an agreement that will contribute to the improvement of conditions for the uptake of generic and biosimilar medicines use.

I would like once again to assure you that the EGA is committed to supporting the EU trade policy agenda and is ready to further engage in the positive collaboration with the European Commission.

Yours faithfully,

Nick Haggar, President
European Generic medicines Association
+32 (0)2 736 84 11 | info@egagenerics.com

Adrian van den Hoven, Director General
European Generic medicines Association
+32 (0)2 736 84 11 | info@egagenerics.com

The EGA represents the European generic and biosimilar pharmaceutical industries, which provide high-quality cost-competitive medicines to millions of Europeans. Companies represented within the EGA provide over 150,000 jobs in Europe. Generic medicines save EU patients and healthcare systems over €40 billion each year and account for 54% of all dispensed medicines but for only 21% of the pharmaceutical expenditure in Europe.