

## Statement by the International Generic and Biosimilar Medicines Association on the Signing of the Trans-Pacific Partnership Agreement

February 4, 2016 - Geneva, Switzerland - The International Generic and Biosimilar Medicines Association (IGBA) represents companies that are actively engaged in the global manufacturing and trading systems for medicines. We support enhanced cooperation between regulators to foster the global trade in medicines, as well as measures aimed at the elimination of barriers to trade in medicines in order to increase access for patients.

The Asia-Pacific Region is of key importance to the generic and biosmilar medicines industries. It is the location of hundreds of manufacturing facilities and strategic export opportunities. It is also an important source of medicinal ingredients and other raw material inputs for our high quality, cost-competitive medicines.

IGBA members were active stakeholders throughout the Trans-Pacific Partnership (TPP) negotiations, and communicated the potential impact of various proposals to negotiators from all countries. IGBA recognizes and welcomes the significant efforts made by TPP countries to develop a final intellectual property text with a balanced outcome.

From a global perspective, the IGBA remains concerned regarding the scope and wording of intellectual property provisions included in the final TPP text, which goes beyond the international standard established by the World Trade Organization Agreement on the Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement).

Some countries, including developing countries, will need to implement new intellectual property measures or legislation if they ratify the TPP. This risks to delay access to lifesaving generic and biosimilar medicines in these countries, and to create disruptions in the global trading system for generic and biosimilar medicines.

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IGBA supports fair and reasonable lengths and coverage of intellectual property protection. However, such a system must be balanced with the need for governments to manage escalating health care costs and for patients to obtain access as early as possible to safe, effective and affordable generic alternatives. A properly functioning patent and intellectual property system is crucial for the generic pharmaceutical industry to develop and bring its equivalent products to market with business certainty. To this end, IGBA supports the WTO TRIPS Agreement as the basis for IP provisions in trade agreements, which was intended to establish global standards that balanced these needs. Many of the intellectual property measures included in TPP go far beyond TRIPS and will have the consequence of significantly delaying patients' access to life-saving affordable medicines.

As countries consider whether to move forward with TPP ratification, IGBA member Associations will continue to work closely with their domestic governments to advance the interests of wider access to medicines and the industrial and export interests of generic and biosimilar medicines companies.

## About IGBA

The International Generic and Biosimilar Medicines Association (IGBA) was founded as IGPA (International Generic Pharmaceutical Alliance) in March 1997 to strengthen cooperation between associations representing manufacturers of generic medicines. Its membership includes the EGA (Europe), the CGPA (Canada), the GPhA (USA), the JAPM (Jordan), the NAPM (South Africa), the TGPA (Taiwan) and the JGA (Japan) while the associations from Australia (GBMA), Brazil (ProGenericos) and Mexico (AMEGI) are Associate Members. The IGBA is at the forefront of stimulating competitiveness and innovation in the pharmaceutical sector by providing high quality pro-competitive medicines to millions of patients around the world. Through its constituent member associations, the IGBA maintains constant dialogue with government authorities (including the European Commission for Europe) as well as with international institutions such as WTO, WIPO and WHO. More information: www.igbamedicines.com.

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