

IGPA CALLS FOR EQUAL STATUS FOR GENERICS INDUSTRY AT GLOBAL PHARMACEUTICAL STANDARDS ORGANIZATION MEETING

Generics are more than 50% of global prescriptions, equal participation in all aspects of management and standards-setting in International Conference on Harmonization best serves public health.

LISBON, PORTUGAL (November 10, 2014) —

Statement by David Gaugh, International Generic Pharmaceutical Alliance (IGPA) Management Committee Representative:

"The International Generic Pharmaceutical Alliance (IGPA) met yesterday with the Steering Committee of the International Conference on Harmonization (ICH) to present details on the IGPA IGPA member associations represent request to gain ICH Executive Board membership. companies making more than half of prescriptions worldwide. IGPA also represents companies that have moved into developing and manufacturing biosimilar medicines.

Having participated in ICH since 1997, we have the utmost respect for ICH and what it has accomplished. What we seek now is a seat on the ICH Executive Board (formerly the Steering Committee). The Executive Board will perform the executive function for ICH. The ICH executive function has historically been performed by global regulators and brand pharmaceutical industry representatives, without the beneficial input that the generic industry can provide. Even administrative decisions can significantly impact the outcome of a proceeding. We believe the generic industry should be a full part of those discussions and decisions.

If IGPA is permitted to join the ICH Executive Board, it would fully participate in all decisions relating to ICH management and harmonization of global drug quality, safety, and efficacy standards. We would like to be full participants so that we can help ICH to represent public health in the 21st century.

We were grateful for the opportunity to address the Steering Committee. We are optimistic about what we heard at today's meeting, and we look forward to contributing our scientific expertise to all important ICH discussions as a member of the ICH Executive Board."



Canadian Generic **Pharmaceutical** Association 4120 Yonge Street Suite 409

Toronto, Ontario M2P 2B8, Canada T: + 1 416 223 2333 www.canadiangenerics.ca



European Generic Medicines Association Rue d'Arlon 50 B-1000 Brussels, Belgium T: +32 2 736 84 11

www.egagenerics.com



Generic Pharmaceutical Association 777 6th Street, NW Suite 510 Washington, DC 20001

T: +1 202 249 7100 www.gphaonline.org



The Jordanian Association of Pharmaceutical Manufacturers Khalda, Villa No. 1

Yazan Aranki Street P.O. Box 5382 Amman, 11953 Jordan T: +962 6 5413114 www.japm.com



Japan Generic **Medicines Association**

3-3-4 Nihonbashi-honcho Chuo-ku, Tokyo 103-0023 Japan T: +81 3 3279 1890 www.jga.gr.jp



National Association of **Pharmaceutical** Manufacturers

Ground Floor 1342 Howick Mews Waterfall Park. Bekker RD, Midrand P.O. Box 32361, 1684 Kyalami, South Africa T: +27 11 312 6966 www.napm.co.za



For a link to IGPA's slide presentation, please see http://www.igpagenerics.com/doc/ICH Steering Committee Lisbon 09 11 2014.pdf

For any questions please contact www.igpagenerics.com

##

About IGPA: The International Generic Pharmaceutical Alliance was born as an international network of generic medicines associations, committed to promoting generic medicines and exchanging information worldwide. The IGPA was founded in March 1997 and consists of the following associations:

- Canadian Generic Pharmaceutical Association (CGPA-Canada)
- European Generic medicines Association (EGA-Europe)
- US Generic Pharmaceutical Association (GPhA-USA)
- Jordanian Association of Pharmaceutical Manufacturers (JAPM-Jordanian)
- Japan Generic Medicines Association (JGA-Japan)
- National Association of Pharmaceutical Manufacturers (NAPM-South Africa)
- In addition, generic medicines associations from Australia, Brazil, Mexico and Taiwan are associate members