INTERNATIONAL GENERIC
PHARMACEUTICAL ALLIANCE

8 August, 2014

ICH Steering Committee Members
C/o ICH Secretariat

Dear ICH Steering Committee Members:

We are writing you on behalf of the International Generic Pharmaceutical Alliance (IGPA) and to follow-up on our previous communications to you. It has come to our attention that the ICH Steering Committee, during your meeting in Minneapolis on May 31 – June 05, 2014, has made the recommendation to NOT allow the generic pharmaceutical industry a position on the ICH Steering Committee (as noted in slide 3 – ***ICH Membership/Structure*** – of the attached presentation which is titled "***Proposed ICH Membership & Governance***").

Under the proposed potential structure, the ICH Steering Committee would consist only of regulators and originator industry representatives. This is the case even though the originator industry represents only a minority of global pharmaceutical production. The generic pharmaceutical industry has undergone immense changes since the inception of ICH in the early 1990s. The generic industry is now largely a global industry, with generic pharmaceuticals accounting for, on average, over 50% of the prescriptions filled globally. In fact, in 2013, generic pharmaceuticals accounted for over 84% of the prescriptions filled in the U.S.

As noted by ICH, it is entering its third decade of activity. As ICH currently stands, it will enter the decade with only limited involvement from the generic pharmaceutical industry – as an ICH Party (as noted in slide 3) but not as an ICH Steering Committee Party. The generic industry will remain completely barred from the formal ICH decision making process even though the vast majority of ICH guidelines become regulatory requirements and guidances that are directly applicable to generic pharmaceutical manufacturers.

IGPA believes that much of ICH's original vision and mission transcends particular business models, and that ICH should instead focus on how it can positively impact public health. The ICH Mission Statement describes the process of regulatory harmonization as offering many "direct benefits to both regulatory authorities and the pharmaceutical industry with beneficial impact for protection of public health." The Mission Statement also states that "The Guidelines are developed through a process of scientific consensus with regulatory and industry experts working side-by-side." These tenets are applicable to both the originator and generic pharmaceutical industries. As such, **the generic pharmaceutical industry, represented by IGPA, seeks to join ICH as a full Steering Committee member.** This will enable the generic pharmaceutical industry to work side by side with regulators and with our colleagues across the pharmaceutical industry – originator and generic – to improve pharmaceutical quality, safety, and efficacy. IGPA recognizes that we can have some impact as an ICH Party. But, if we are not a Steering Committee Party, our input can be rendered null and void by the ICH Steering Committee's executive authority.

As noted above, over the years that ICH has been in existence, the availability and utilization of generic medicines has expanded dramatically globally. This notable shift in the global presence of generic drugs has not yet propelled ICH to change its structure to embrace the component of the pharmaceutical industry that plays so prominently in the role of global public health. IGPA believes that ICH should shift together with the industry it covers and that regulators, industry, and the public health would benefit from the generic industry serving as equal partners in relevant ICH steering committee activities and actions, as has the originator industry for over 20 years.

Clearly ICH guidelines impact the generic pharmaceutical and biosimilar medicines industries. For example, each of the quality guidelines has direct impact on the generic pharmaceutical industry. In fact, global agencies have cited ICH guidelines as specific reasons for changing longstanding quality related agency guidelines/guidances to conform to those requirements developed by and for the originator industry. Agencies have also affirmed that the same quality expectations are applicable for all marketed drugs. As such, the entire spectrum of ICH quality guidelines has direct application to the generic pharmaceutical and biosimilar medicines industries. Fully including our prominent sector of the industry in developing and revising pertinent quality standards, among others, would further quality goals.

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Particularly notable is ICH Q5 (Quality of Biotechnological Products), which applies to our generic pharmaceutical industry as it actively develops biosimilar products. A smaller number, but several ICH safety guidelines are relevant to generic pharmaceutical and biosimilar products as well as the multidisciplinary guidelines that related to electronic submissions. See Attachment 1.

IGPA and many of its members operate in a global environment and recognize the value and benefit of regional harmonization. Just as the originator industry perceives the need for harmonization and its inherent advantages for patients, regulators, and industry, the generic industry holds this same vision. Because of the substantial impact of many ICH guidelines on the generic industry, **the generic industry firmly believes it should become equal industry partners in future ICH activities, beginning with the appointment of IGPA to the ICH Steering Committee**. It is important to note that we do not seek to obstruct ICH's activities in any way. IGPA recognizes the great value that ICH has contributed throughout the years. IGPA's goal is to become a full part of that process, just as we are a full part of the pharmaceutical industry. We wish to fully collaborate in ICH's continued success, and as such IGPA is committed to dedicating the necessary experts and resource support for engagement in ICH activities.

We would also like to inform the ICH Steering Committee that if IGPA is not included as a Steering Committee member, then we will be required to evaluate our continued relationship with and involvement in ICH.

Thank you for your serious consideration of this matter and we look forward to receiving your response.

Sincerely,

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