

Generic Pharmaceutical Association
1620 I St., N.W., Suite 800
Washington, DC 20006

July 7, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: The Future of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) [Docket No. 00N-1220]

Dear Madam/Sir:

On behalf of the International Generic Pharmaceutical Association (IGPA), I would like to submit belated comments on the future of ICH for consideration at the upcoming ICH Steering Committee meeting in Brussels, Belgium.

IGPA is an alliance of associations representing the generic industry in Canada, Europe and the United States. The members of IGPA appreciate the opportunity they have had during the last few years to actively participate in the ICH Expert Working Groups (EWGs) whose work products have the potential to significantly impact the generic industry. They also appreciate the opportunity to have had a representative present at "open" portions of the regularly scheduled ICH Steering Committee meetings. The following comments are concerned primarily with the continued participation of IGPA in ICH. However, in most if not all instances, these comments may be relevant to WSMI representation, as well.

Expert Working Groups (EWGs):

Adequate representation for IGPA on *all* EWGs whose work products have the potential to either directly or indirectly affect the generic industry is very important. Currently, a single IGPA representative is permitted participation on each of several key quality topics. This single individual has the daunting responsibility of appropriately representing three potentially different "generic" perspectives on an issue (perhaps because of regional differences in current regulatory environments, for example) – those of Canada, Europe and the United States. Furthermore, if this single individual has a health problem, travel difficulties, or a work or family conflict that precludes attendance at an EWG meeting, the meeting must proceed without generic representation. Limitation of participation to select quality EWGs, only, presupposes that documents developed in the areas of safety, efficacy, adverse event reporting, medical terminology, etc. will never be applicable to the development, submission, and approval of generic drug product applications. This is not a valid supposition.

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Recommendations:

- *All EWGs should be open to generic representation. Whether or not the generic industry takes advantage of the opportunity to participate on an EWG should be an IGPA decision.*
- *In order to provide for appropriate and sufficient representation of the worldwide generic industry, at least three participants from the industry should be permitted on each EWG. This will allow for appropriate representation of global perspectives and provide continued generic coverage and continuity in the work of an EWG in the event that any one IGPA representative on an EWG is unable to attend a meeting.*
- *To the extent that future topics may be of greater, or even of equal, importance to generics than to new chemical entities (e.g., bioequivalence issues or GMPs for excipients, post-marketing development, pharmacopeial harmonization issues, etc., respectively), consideration should be given to re-balancing generic and brand representation, accordingly, on the EWGs in question.*

Steering Committee (SC):

Currently, a single IGPA representative is permitted attendance at the ICH Steering Committee meetings for designated "open" agenda items. These "open" items are generally restricted to discussions on the work of quality EWGs and pharmacopeial issues.

Recommendations:

- *In order to ensure generic representation at all Steering Committee meetings as appropriate, it is recommended that the designated IGPA representative be permitted to name an alternate in advance of the meeting should the presence of the designated representative at the meeting be precluded for any reason.*
- *It is recommended that the presence of an IGPA representative at the meeting not be restricted to EWG or pharmacopeial harmonization discussions only. Broader Steering Committee issues such as consideration of future topics, implementation and maintenance of ICH guidelines, etc. should also be transparent to non-founder parties such as the generic industry. An IGPA presence during discussions of these issues would facilitate this.*

Other Comments

Pharmacopeias: In the interest of more effective harmonization of the three pharmacopeias and appropriate integration of these harmonization efforts into relevant ICH guidelines, a more active role of pharmacopeial representatives at both the EWG and Steering Committee levels is encouraged.

Guideline Implementation: Appropriate monitoring to assure consistent implementation of final ICH guidelines is critical to the continued value of harmonization. For those guidelines that are focused on new chemical entities and in which generic or other second-entry drug

substances/products are not specifically addressed, application to generic or other second entry drug substances/products should be optional in all regions.

Guideline Maintenance/Revision: During the maintenance or revision of ICH guidelines which may directly or indirectly impact generic or other second-entry drug substances/products, priority should be given to specifically address these applications.

Future topics: Consideration should be given to harmonization of post-approval change requirements or post-marketing development requirements.

Expansion of Participants: Consideration should be given to an expanded or more global participation, beyond the U.S., Japan and the EU, in the ICH process.

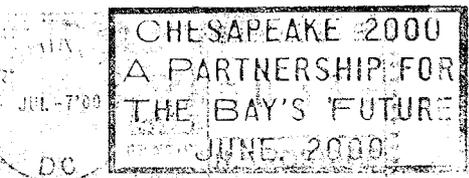
Sincerely,



Alice E. Till, Ph.D.
IGPA ICH Coordinator and
Representative to the ICH SC

CC J. Molzon, FDA
J. Showalter, FDA
H. Cranz, WSMI

Generic Pharmaceutical Assoc.
1620 I St., NW
Suite 800
Washington, DC 20006



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Rockville, MD 20852

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