09 September 2011

Medicines Quality Assurance Programme
Quality Assurance and Safety: Medicines
World Health Organization
1211 Geneva 27
Switzerland

ISPE appreciates the opportunity to provide comments on the above referenced draft document. While ISPE members have no major objections to the proposed wording, they have expressed the concern that any change to the current definition will mean that it will no longer be the same as the definition in ICH Q7, one which is used by many other regions and organisations such as PIC/S. Before any changes are made, we recommend a comprehensive discussion with all stakeholders, especially ICH. The goal should be one definition which is globally acceptable.

Please let me know if you have any questions.

Yours Sincerely,

Robert P. Best
President/CEO
ISPE
Comments on WHO Working Document QAS/11.426/Rev.1

Title of the document: Definition of Active Pharmaceutical Ingredient

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Date: 09 September 2011

Kindly complete the table without modifying the format of the document - thank you.

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<th>General comment(s) if any</th>
<th>Originator of the comments</th>
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Besides exceptions discussed in paper, there are several API’s derived from extraction of natural products that are mixtures of over 100 substances, many which are not identified.

*Please add rows as necessary (with "copy and paste" empty rows)*