TERMS OF REFERENCE
ANNUAL SUMMIT OF
THE HEADS OF MEDICINES REGULATORY AGENCIES

Purpose: The Annual Summit of the Heads of Medicines Regulatory Agencies ("annual summit") was inaugurated in 2006 to provide a confidential forum for (i.e., without press or formal minutes) and an informal atmosphere in which the chief executives of the major and upcoming science-based, like-minded medicines regulatory agencies could meet annually to:

- discuss common executive and scientific challenges (including regulatory policies and regulatory approaches) at a strategic level,
- share experiences dealing with significant and/or breaking public health or regulatory issues, and
- have the opportunity to plan any further activities in which they would like to engage as a group or to which they chose to commit their agencies.

Meeting: The annual summit shall occur generally in the fourth quarter of each calendar year for approximately two to three days. The host agency will choose the specific dates and location of the annual summit. The Steering Committee will choose the host agency from those agencies that have expressed in writing to the Steering Committee an interest in hosting the annual summit. Generally, the host agency is chosen on a rotating basis from three major geographic regions: (1) The Americas, (2) Europe-Africa, and (3) Asia-Australasia.

To date the host agencies and locations of the annual summit have been:

Year	Agency	Site
2006	The U.S. FDA	Washington
2007	The Irish Medicines Board	Dublin
2008	Singapore's HSA	Singapore
2009	The HPFB of Health Canada	Ottawa
2010	The UK's MHRA	London
2011	Australia's TGA	Sydney
2012	Brazil's ANVISA	Manaus

Agreed future host agencies at present include:

2013	The Netherlands' MEB	Amsterdam

2014 China's CFDA To be determined

Attendance: In order to maintain a chief executive level, informal atmosphere conducive to productive, strategic discussions, and to help defray costs of the host agency, attendance at the annual summit is limited to the chief executive ("head") of the agency and one other person of his/her choosing (the so-called "plus one" attendee per agency.) In addition to the "plus one" attendee, if a head of agency requires translation in order to participate, that/those translator(s) may also be an additional part of that agency's delegation. If the head of the agency cannot attend, an institutional deputy head of agency (or equivalent) may attend, but, otherwise, no substitute is allowed, as this is a chief executive focused agenda and meeting. However, on application from a head of agency, the Steering Committee can agree - on a case-by-case basis - to allow a substitute for that head of agency or deputy head of agency in truly extraordinary circumstances. In addition, on application of a head of agency, the Steering Committee, with the concurrence of the host agency, can agree to a delegation larger than the head of agency plus one, again, in truly extraordinary circumstances.

Understanding that media coverage of the deliberations is not consistent with the informal atmosphere requisite for the success of this meeting, no press will be allowed in the room, and press coverage, in general, will be strongly discouraged.

Membership: Permanent membership is, in general, offered to: (1) well-established medicines regulatory agencies with a demonstrable track record of contributing to the advancement of regulatory science and global regulatory harmonisation, or (2) medicines regulatory agencies in countries that are major global medicines supplier countries for which there is a shared public interest in reaching common international perspectives and standards of regulation as quickly as possible.

The heads of the following agencies are current permanent members of the annual summit and will receive an invitation, along with their "plus one" attendee, to attend each year.

Australia's TGA
Brazil's ANVISA
Canada's HPFB of Health Canada
China's CFDA
The European Union's Directorate General SANÇO
The European Medicines Agency
The European Heads of Medicine Agencies' chair (if not already attending)
France's ANSM
Germany's BfArM

Germany's PEI
India's CDSCO
Ireland's IMB
Japan's PMDA
Japan's MHLW
Mexico's COFEPRIS
The Netherlands' MEB
New Zealand's Medsafe
Nigeria's NAFDAC
Singapore's HSA
South Africa's MCC
Sweden's MPA
Switzerland's Swissmedic
The United Kingdom's MHRA
The United States' FDA

The World Health Organization will also be invited each year to send a representative and a "plus one" attendee.

In addition, it is recognised that the host agency may, for its own regional needs, invite - on a one-time basis - other regional regulatory authorities to attend the meeting they are hosting. However, it needs to be made clear to these authorities that such attendance is on a one-time basis only.

New permanent members may be added to this list at the discretion of the Steering Committee through a process it chooses to use. Likewise, the Steering Committee shall recognise changes in agency titles, missions, and organisations to assure continued appropriate representation to accomplish the purpose of the annual summit.

Steering Committee:

All previous host agencies and the EMA are invited to participate in the work of the steering committee., It is expected that the previous four host agencies and the agreed host for the present year will form the "core" of the steering committee group for that year. The Steering Committee "core" group shall be co-chaired by the host of the summit for that year and the head of the agency that hosted four years previously (provided that head of agency or agency representative attended the meeting four years previously). If that head of agency or representative did not actually attend him-/herself, then the co-chair will devolve to the next head of agency who actually attended/hosted him-/herself in the most distant past. The Steering Committee shall try to make decisions by consensus; however, if a vote needs to be taken, a simple majority of those voting will be decisive.

Agenda: The agenda for the Annual Summit shall be drafted and agreed by the head of the host agency and the "core" group of the Steering Committee. The head of the host agency is encouraged to convene several teleconferences of the "core" group of the Steering Committee throughout the year to discuss the agenda. Any other Steering Committee members who wish to participate in these teleconferences are welcome to do so.

Generally the agenda shall consist of both didactic presentations by heads of agencies and smaller group discussions that provide feedback to the larger group. There shall be adequate built-in time in the agenda for discussion among the heads of agencies on the various topics selected. In addition, there shall be a section of the agenda reserved for any late-breaking or significant issue(s) not otherwise covered in the agenda.

Changes: Suggested changes to these Terms of Reference can be made in writing to the Steering Committee by any member of the annual summit. Upon receipt of such suggested changes, the entire Steering Committee shall make the final decision on any changes in these terms of reference.

Agreed in Principle by the Steering Committee of the Annual Summit of the Heads of Medicines Regulatory Agencies at its meeting in Manaus, Brazil on 29 November 2012,

John Skerritt — Australian TGA

Dirceu Barbano — Brazilian ANVISA

Paul Glover — Canadian HPFB of Health Canada

Andrzej Rys — European Commission – DG SANCO

Guido Rasi — European Medicines Agency

Rita Purcell (for Pat O'Mahony)	Irish Medicines Board
John Lim	Singaporean H.S.A.
Alasdair Breckenridge	United Kingdom's MHRA
Kent Woods	United Kingdom's MHRA
Murray Lumpkin (for Peggy Hamburg)	United States' FDA