

Side event application / Formulaire de demande de réunion parallèle

Contact

Name/Nom: Mario Alanís Garza	Date of application: April 2018
Delegation(s)/Délégation(s): Ireland, Mexico, Singapore and the United States of America as confirmed cosponsors and with the active participation and potential cosponsorship of relevant Member States delegations and/or Members of the Steering Committee for WHO Member State Mechanism (ICMRA NRAs are already members of the Member State Mechanism) - See Page 2	
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Concept

Description of proposed side event, including objective, expected results, proposed programme and speakers* /

Description de la réunion parallèle proposée, y compris les objectifs, les résultats attendus, l'ordre du jour et les orateurs* :

An essential component for strong health systems and universal health coverage is high-functioning performing regulatory systems, particularly as the global community works to ensure safe, efficacious and quality medicines for citizens and patients. Within restricted resource environments, national Medicines Regulatory Authorities (MRAs) must manage a diverse and complex regulatory remit to ensure the safety and quality of the medical products they regulate. Adding to that complexity is a diverse and growing supply chain and increasing potential for the introduction of substandard and falsified (S&F) medical products into the marketplace. A panel of MRAs and other stakeholders would discuss the challenges they face and the critical roles they play to better prevent, detect and respond to S&F medical products.

Two WHO reports (11/17) and other relevant data provide a sound framework for discussion:

- “Study on the public health and socioeconomic impact of substandard and falsified medical products,” which presents the first prevalence and cost estimates published by the WHO in the last ten years. The report includes the first estimates from the WHO in almost a decade on the prevalence and costs of SF medical products in low- and middle-income.
- A “Report on the WHO Global Surveillance and Monitoring System for substandard and falsified medical products,” examining the root causes of SF medical products submitted to WHO over the past four years, highlighting risks, weaknesses in health systems, and vulnerabilities in supply chains. The System encompasses 140 countries with over 1,500 medical products reported from over 100 Member States. All therapeutic categories have been recorded - innovator and generic medicines, vaccines and in vitro diagnostics.

The proposed panel would include (panelists TBD):

- XXXXXXXXXXXX, Moderator
- XXXXXXXXXXXX World Health Organization
- XXXXXXXXXXXX, National Regulatory Authority
- XXXXXXXXXXXX, National Regulatory Authority
- XXXXXXXXXXXX, National Regulatory Authority
- XXXXXXXXXXXX, Global Fund to Fight AIDS, TB and Malaria or the World Bank

SPONSORS:

COFEPRIS (co-sponsor)

U.S. FDA (co-sponsor)

Health Sciences Agency/HSA of Singapore (co-sponsor)

Health Canada/HC

The Health Products Regulatory Authority/HPRA, Ireland (co-sponsor)

Italian Medicines Agency/AIFA

Medicines and Healthcare products Regulatory Agency/MHRA, United Kingdom

Mexico Federal Commission for the Protection against Sanitary Risk/COFEPRIS, Mexico

Ministry of Food and Drug Safety/MFDS, South Korea

National Health Surveillance Agency/ANVISA, Brazil

The Paul Ehrlich Institute/PEI, Germany

Tanzania Food and Drugs Authority/TFDA

European Medicines Agency/EMA (non-WHO Member State)

Event details / details de la réunion

Expected number of participants/Nombre de participants attendus : 100 - 200

Exact title of the meeting/Titre exact de la réunion:

Combating the Challenges of Substandard and Falsified Medical Products: the Critical Role of Regulators

Interpretation/Interprétation

Interpretation may be provided in the official languages and the estimated costs are as follows: 2 languages: 2561 CHF; 3 languages: 5123 CHF; 6 languages: 11953 CHF.

L'interprétation peut être assurée dans les langues officielles aux coûts estimés suivants : 2 langues-2561 CHF; 3 langues-5123 CHF; 6 langues-11953 CHF.

Are interpretation services requested? / L'interprétation est-elle requise ? Yes/Oui No/Non

(If yes, which languages)/(Si oui, en quelle langue)

English/Anglais French/Français Russian/Russe Spanish/Espagnol Chinese/Chinois Arabic/Arabe

Other language/autre langue: N/A

Room Layout/Aménagement des salles

Dais and podium placed at front of room. Classroom style for panelists

Due to type of furniture and technical equipment in the room, the layout of the rooms cannot be changed. For information regarding the location and layout of rooms at the Palais des Nations, please see:

[http://www.unog.ch/80256EE60057CB67/\(httpPages\)/BAE3AF717207A5AF80256EF80049C552?OpenDocument](http://www.unog.ch/80256EE60057CB67/(httpPages)/BAE3AF717207A5AF80256EF80049C552?OpenDocument)

Le type de mobilier et les installations techniques dans les salles ne permettent pas de modifier l'aménagement de celles-ci. Pour tout renseignement sur l'emplacement ou la disposition des salles au Palais des Nations voir le lien :

[http://www.unog.ch/80256EE60057CB67/\(httpPages\)/BAE3AF717207A5AF80256EF80049C552?OpenDocument](http://www.unog.ch/80256EE60057CB67/(httpPages)/BAE3AF717207A5AF80256EF80049C552?OpenDocument)

***Badges/ Badges d'accès**

WHA side events are for participants of the WHA and, as such, panellists and participants should be drawn from those participating in the Health Assembly.

Les réunions parallèles sont réservées aux participants de l'Assemblée; Les orateurs de ces réunions doivent donc être choisis parmi ceux-ci.

Please complete the form and send it to / Merci de remplir le formulaire et de l'envoyer à cmpmail@who.int