

PANEL F: Emergency Preparedness

International mobilization: public health emergencies of international importance

Regulators` Role

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Patricia Oliveira Pereira Tagliari
Head of International Affairs Office
Brazilian Health Regulatory Agency - ANVISA

VIII Conference of the Pan American Network on Drugs Regulatory Harmonization | Mexico City | 19 to 21 October



Crisis Management - On going initiatives

International Coalition on Medicines Regulatory Authorities

ICMRA

Context:

On an International Crisis:

Need of actions from Regulatory Authorities.

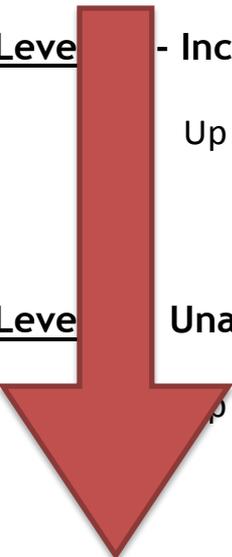
Lack of coordinated/cooperative response.

Framework for the involvement of Health Regulatory Authority in the management of Global Health Crisis

For regulatory action purpose: Categorization of Crisis on 3 Levels.

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or the involvement of Health Regulatory Authority in the management of Global Health C

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- Level 1** - Incidents of quality or safety issues for products on the market, where such quality or safety issue
Up to each involved HRA to assess if it would benefit from an international involvement.
- Level 2** - Unavailability of products due to a crisis, where already registered products are in short supply or
Up to each involved HRA to assess if it would benefit from an international involvement.
- Level 3** - Urgent need for new medical treatments or vaccines in the face of an emerging health treats (e.g.
An incident will be categorized as at level 3 whenever WHO declares it a Public Health Emergency

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outbreak). Public Health Emergency of International Concern (PHEIC)

1. Case Study: Actions taken by ANVISA/Brazil dealing with the Zika Crisis;

2. Standard Operational Procedure for dealing with international crisis;

NRA Network

3. Non-NRA Stakeholder Communication List;

4. Zika Network established:

outbreak). Public Health Emergency of International Concern (PHEIC)

Need for better alignment with WHO, on ongoing initiatives of Emergencies and Crisis Situations:

- . WHO International Health Regulations (WHO – IHR)
- . Global Outbreak Alert & Response Network (GOARN Steering committee)
- . WHO Programme on Health Emergencies

*A Panel on Crisis Management and the Role of Regulators is being planned at the margins of the next
WHA (May, 2017).*

Workshop with WHO to discuss these topics and to plan for better coordination with Regulatory

Lessons already Learned

with other National Stakeholders with responsibilities in crisis management

with International Partners

1. Fast Communication is key: within Regulatory Authorities

2. Action Protocols: predictable and unpredictable events

3. Learn from the Past:

Previous events are of great value preparing for future ones.

Failures and Successful experiences contribute to the preparedness process.

4. Multiple Networks are beneficial, but there is a need to better coordinate them.

5. Emergencies and Crisis require prioritization, flexibility and risk analysis approach.

Thank you!

Patrícia O. Pereira Tagliari

Head of International Affairs Office

patricia.pereira@anvisa.gov.br

+55 61 3462-5404/5402

www.anvisa.gov.br

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