REGULATORY SYSTEMS STRENGTHENING

Policy, Process and Tool to Strengthen Regulatory Capacity for Medical Products

HIS/EMP/RHT/RSS

World Health Organization
Outline

1. Who we are?
2. What work we do?
3. Why we do our work?
4. How we do work?
5. Impact of our work
1. Who we are?

2. What work we do?

3. Why we do our work?

4. How we do work?

5. Impact of our work
RSS in the WHO hierarchy

HIS: Health systems and Innovation
EMP: Essential Medicines and Health Products
RHT: Regulation of Medicines and other Health Technologies
PAU: Policy, Access and Use
PHI: Public Health, Innovation and Intellectual Property
SAV: Safety and Vigilance
RSS: Regulatory Systems Strengthening
TSN: Technologies Standards and Norms
PQT: Prequalification

Director General
(M. Chan)

HIS Cluster
(M.P. Kieny)

EMP Department
(C. De Joncheere)

RHT
(L. Rago)

PAU
(G. Forte)

PHI
(Z. Mirza)

SAV
(C. Ondari)

RSS
(M. Ward)

TSN
(D. Wood)

PQT
(M. McDonald)
RSS Team

NRA assessment Group lead
(L. Belgharbi)

RSS Coordinator
(M. Ward)

Capacity building Group lead
(S. Azatyan)

S. Jones
A. Bellah
U. Kartoglu

A. Khadem
S. Wahab
L. Brown
M. Yap

M. Refaat
A. Samy

E. Uramis
D. Decina
P. Guillot
C. Alfonso
D. Vasile

R. Ostadali
S. Ramirez
Outline

1. Who we are?
2. What work we do?
3. Why we do our work?
4. How we do work?
5. Impact of our work
Gap analysis
• Assessment

IDP
• A plan for addressing the identified gaps

Addressing the gaps
• Providing technical support
• Training

Monitoring progress and impact
• IDP follow-up
• Re-assessment

Global Learning Opportunities (GLO)
In-county workshop
Technical Support and on site consultants
Placement, joint review, twining, etc

Regulatory functions targeted:
1. National Regulatory System (NRS)
2. Registration and Marketing Authorization (RMA)
3. Vigilance (VGL)
4. Market Surveillance and Control (MSC)
5. Licensing Premises (LIC)
6. Inspection and Enforcement (INE)
7. Laboratory Access and Testing (LAT)
8. Clinical Trials Oversight (CTO)
WHO NRA 5 step capacity building

1. Benchmarking
   Development of NRA assessment tool

2. Assessment of NRA

3. Development of Institutional Development Plan (IDP)

4. Providing technical support, Training/Learning, networking,
   Monitoring progress and impact

5. Functional NRA
Outline

1. Who we are?
2. What work we do?
3. Why we do our work?
4. How we do work?
5. Impact of our work
Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

In order to achieve its objective, the functions of the Organization shall be: .... (c) to assist Governments, upon request, in strengthening health services
Essential medicines should be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.
Effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products.
Our Strategic Priorities

1. **Functional national regulatory systems** developed and sustained

2. **Regional regulatory networks** developed and sustained

3. Seek *convergence and alignment* of regulatory requirements
1. to continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:

   - (a) evaluate national regulatory systems;
   - (b) apply WHO evaluation tools;
   - (c) generate and analyse evidence of regulatory system performance;
   - (d) facilitate the formulation and implementation of institutional development plans; and
   - (e) provide technical support to national regulatory authorities and governments;
WHA Resolution 67.20: What WHO should do: Part II

2. to continue to develop appropriate norms, standards and guidelines, including taking into account national, regional and international needs and initiatives, in accordance with WHO principles;

3. to ensure that all relevant parts of the Organization, at all levels, are actively engaged and coordinated in the carrying out of WHO’s mandate pertaining to regulatory system strengthening as an integrated part of health system development, recognizing that WHO’s support in this critical area, particularly for developing countries, may be required, as appropriate, well into the future;

4. to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;

5. to promote the greater participation of Member States in existing international and regional initiatives for collaboration and cooperation in accordance with WHO principles and guidelines;

6. to strengthen WHO’s prequalification programme, including its integration and coherence, taking into account the needs and capacities of national and regional regulatory systems to assist in ensuring a supply of quality, safe, efficacious and affordable medical products;
WHA Resolution 67.20: What WHO should do: Part III

6. to support the building-up of effective national and regional regulatory bodies and networks;

7. to increase support for and recognition of the significant role of the International Conference of Drug Regulatory Authorities in promoting the exchange of information and collaborative approaches among drug regulatory authorities, and as a resource to facilitate further development of regulatory cooperation and coherence;

8. to raise awareness of the importance of effective regulatory systems within the health system context;

9. to increase support and guidance for strengthening the capacity to regulate increasingly complex biological products with the focus on biotherapeutic products, blood products and associated in vitro diagnostics, and, where appropriate, on new medicines for human use based on gene therapy, somatic-cell therapy and tissue engineering;

10. to ensure that any activity carried out under this resolution does not duplicate or circumvent the work plan and mandate of the Member States mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products;

11. to report to the Seventieth and Seventy-second World Health Assemblies on progress in the implementation of this resolution.
Outline

1. Who we are?
2. What work we do?
3. Why we do our work?
4. How we do work?
5. Impact of our work
WHO NRA 5 step capacity building

1. **Bench Marking**
   - Development of NRA assessment tool

2. **Assessment of NRA**
   - Re-assessment
   - Every 2-5 years
   - Self assessment for planning formal assessment

3. **Development of Institutional Development Plan (IDP)**
   - With or without a road map for prequalification of products

4. **Providing technical support, Training/Learning, networking,**
   - WHO support through:
     - Global Learning Opportunities (GLO)
     - Technical Support
     - In-country training

5. **Monitoring progress and impact**
   - WHO electronic platform to monitor NRAs information and assessment reports, IDP, training, etc.

- Revision of indicators & assessment process (Every 2-3 years)
- Harmonization of tools
WHO NRA assessment process and timeline

Validation:

- Pre visit
- Self assessment
- Assessment
- Follow up and monitoring

- Observed audit
- Pharmacovigilance field visits
- IDP implementation

Timeline:
- 4 to 8 Months
- 6 to 18 Months
- 12 to 36 Months
China: The Success Story

NRA Assessment

Functional NRA, after assessment in Dec 2010

1st PQ vaccine

NRA Re-Assessment

IDP


NRA Assessment

Functional NRA, after assessment in Dec 2010

1st PQ vaccine

NRA Re-Assessment

IDP

Development of the Global Tool

Vaccine 2011

Medicine 2007

PAHO 2012

Harmonized tool Prototype I

Harmonized tool Prototype I Discussion

Refining the tool and develop prototype II Rev.2

1st IC

Global tool Prototype II

Filed test in 3 countries

2nd IC

Jun 2013

May 2014

Dec 2014

Jul 2015

Nov 2015

Informal consultation meeting, Geneva, June 2013

As part of preparatory work for IC

Istanbul workshop to implement IC recommendation

1st IC

2nd IC
WHO Global Assessment Tool 2015
Computer Based User Friendly Assessment Tool
Outline

1. Who we are?
2. What work we do?
3. Why we do our work?
4. How we do work?
5. Impact of our work
WHO NRA Assessment visits 1997

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.


Map Production: Public Health Information and Geographic Information Systems (GIS) World Health Organization in collaboration with P&B Consulting

WHO 2008: All Rights Reserved
WHO NRA Assessment visits 2014

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city, or area of its authorities, or concerning the delimitation of its frontiers or boundaries.

Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization, Immunization, Vaccines and Biologicals (IVB). Updated as of 5 June 2013

Map Production: Public Health Information and Geographic Information Systems (GIS)

World Health Organization in collaboration with P&B CONSULTING

WHO 2011. All Rights Reserved.
### Status of National Regulatory Authority functions in the area of vaccine regulation, 2014.

As of June 2014, Source WHO/HQ, Geneva

<table>
<thead>
<tr>
<th>Main source of vaccines</th>
<th>Number of countries that have Functional/Non Functional NRAs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Functional (Number/%)</td>
</tr>
<tr>
<td>1. Producing</td>
<td>36 (83%)</td>
</tr>
<tr>
<td>2. Procuring</td>
<td>20 (41%)</td>
</tr>
<tr>
<td>3. UN agency</td>
<td>9 (9%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>65 (33%)</strong></td>
</tr>
</tbody>
</table>
WHO: Number and percent of Members States (vaccine producing and non-producing) by the functionality of their NRAs as of July 2014

- 43 out 194 countries are producing human vaccines out of which 36 had functional NRAs (as assessed by WHO) as shown in 24 countries were producing one or more WHO prequalified vaccines.
- China being the new country that had been able to prequalified JE vaccines in late 2013.
About 69.71% (4.831 billion people) live in the 65 countries, both vaccine-producing and non-producing, where there is direct oversight by a functional NRA.

However, even in the remaining countries without functional NRAs where 30.3% of the world’s population lives, they have access to WHO prequalified vaccines through their national immunization programs.
Since 2009, India and China – two Member States with large populations and large capacity to produce different types of vaccines – have accelerated their efforts to strengthen their regulatory oversight for vaccines.

India – one of the world’s major suppliers of prequalified vaccines – already had a functional NRA by this time.

China’s NRA became functional in early 2011 and recently Mexico early 2014 however Mexico current vaccine production is currently not having a significant impact on the doses of assured quality vaccines.

Both China (all types of vaccines) and Mexico (Hepatitis B, Polio and Influenza and Quadrivalent or Pentavalent vaccines) may contribute to increase availability of prequalified vaccines.

Continuous efforts by these two Member States to meet the highest quality standards have been documented through reassessment conducted in China (April 2014) and Mexico (March 2014) and reflect major commitments by their respective governments and NRAs.
STRENGTHENING NATIONAL REGULATORY AUTHORITIES (NRA) TRAINING CONDUCTED, 1996-2014

5324 PARTICIPANTS FROM NRA*s, NCL*s*, EPI** AND/OR VM*s

5,324 head counts have been trained by WHO between 1996 till July 2014 in the area of vaccine regulation

- **Meeting, 914**
- **InCountry, 2459**
- **GTN, 1873**
- **Placement, 59**
- **Other, 19**

*National Control Laboratory, **Expanded Programme on Immunization

***TOT : Training of trainers,

Source: WHO/EMP/RSS as of October 2014
STRENGTHENING NATIONAL REGULATORY AUTHORITIES (NRA)
TRAINING CONDUCTED, 1996-2014

5324 PARTICIPANTS FROM NRA, NCL*, EPI** AND/OR VM***

- AFR, 1064, 20%
- WPR, 1523, 29%
- SEAR, 1086, 20%
- EUR, 459, 9%
- AMR, 378, 7%
- EMR, 720, 13%
- Unknown, 94, 2%

*National Control Laboratory
**Expanded Programme on Immunization
***TOT : Training of trainers,
Source: WHO/EMP/RSS as of October 2014
STRENGTHENING NATIONAL REGULATORY AUTHORITIES (NRA) TRAINING CONDUCTED, 1996-2014

5324 PARTICIPANTS FROM NRA\textsubscript{s}, NCL\textsubscript{s}\textasteriskaddition{*, EPI** AND/OR VM\textsubscript{s}}

**National Control Laboratory, **Expanded Programme on Immunization

Source: WHO/EMP/RSS as of October 2014
Keep yourself updated: **WHO HIS/RSS** Mobile Application

**WHO RSS Events**
Mobile Application
References


- Sixty-seventh World Health Assembly (WHA) Resolution 67.20, 24 May 2014.

If you need our help or advice…

**Lahouari Belgharbi**, Group lead, NRA assessment, Regulatory Systems Strengthening (RSS), RHT/EMP/HIS. Email: belgharbi@who.int,

**Alireza Khadem**, Scientist, NRA assessment group, Regulatory Systems Strengthening (RSS), RHT/EMP/HIS. Email: khadembroojerdia@who.int,

**Laura brown**, Budget and Administrative, Project assistant, NRA assessment, Regulatory Systems Strengthening (RSS), RHT/EMP/HIS. Email: brownl@who.int,

**Madette Yap**, Administrative support Secretary, NRA assessment, Regulatory Systems Strengthening (RSS), RHT/EMP/HIS. Email: Yapm@who.int,

**Samir El Hemsy**, IT support and programming, data management, and monitoring IT/EMR and NRA assessment, Regulatory Systems Strengthening (RSS), RHT/EMP/HIS. Email:awahabs@who.int

**Mohamed Refaat**, Consultant, NRA assessment, Regulatory Systems Strengthening (RSS), RHT/EMP/HIS. Email: refaatm@who.int
Thank you

Strengthening National Regulatory Authorities (NRAs) - Vaccines

View All Site Content

- China Quality Management System Strengthening
- Quality Management System (QMS)
- NMS Vision Project
- NMS from 2011
- International Consultative Meeting on Regulatory System Strengthening Strategic Directions, Assessment Process
- Self-Assessment
- Regional alliance for the Western Pacific Region
- WHO workshop on NMS strengthening national regulatory capacities
- Global Supported Activities
- 2013 cost assessment for National Regulatory Authorities by vaccine regulatory region
- Global workshop on NMS strengthening national regulatory capacities
- Global workshop on NMS strengthening national regulatory capacities using the WHO NMS Management Approach (Advanced), Beijing 28-29 October 2013

Documents
- NMS and NMS contact
- NMS Local Reports
- Public Domain Scientific Papers
- NMS Work plan 2013

WHO Polity for NRA Assessment, including manuals and tools
- Policy documents concerning NMS, including assessment manuals and tools

WHO Polity for NRA Assessment, including manuals and tools
- Policy documents concerning NMS, including assessment manuals and tools

Announcements
- APA - MEXICO - OUTCOME OF WHO NRA ASSESSMENT - COMPETENCIES AND RELATED INSTITUTIONS FOUND FUNCTIONAL IN THE AREA OF VACCINE QUALIFICATION
- 13/04/2014 11:15
- Details
- Add new link

Other activities
- NMS in 2014
- Add new link

- www.who.int
- https://workspace.who.int/sites/att/default.aspx
- https://extranet.who.int/gavi/NRAPlanning/Login.aspx