WHO Pharmacovigilance Update – Sub-Saharan Africa

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AFRICA PHARMACOVIGILANCE MEETING 2012
Ensuring Quality and Safety of Medicines in Sub-Saharan Africa

Dokumentarfilm
Contergan: Die Eltern
Montag, 19. Januar 2004
um 22.45 Uhr
World Health Assembly Resolution 16.36 - Clinical and Pharmacological Evaluation of Drugs

INVITES Member States to arrange for a systematic collection of information on serious adverse drug reactions observed during the development of a drug and, in particular, after its release for general use.
Growth of WHO PV programme
African member countries: From around 6 in 2001, to nearly 50 in 2012
How did this come about?

1. Focus on norms and standards for PV: WHO mandate
2. Capacity building: training courses, consultations, exchange visits
3. Technical assistance: tools, data management
5. Focused support: francophone Africa (Morocco/WHO/USAID since 2007)
6. Working with public health programmes: EC, BMGF
## Africa Pharmacovigilance Meeting 2012

**Ensuring Quality and Safety of Medicines in Sub-Saharan Africa**

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### Reports in WHO PV database

<table>
<thead>
<tr>
<th>Country</th>
<th>Count ICSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>45</td>
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<tr>
<td>Burkina Faso</td>
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<tr>
<td>Cameroon</td>
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<tr>
<td>Congo, the Democratic Republic of the</td>
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<td>Cote d’Ivoire</td>
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<td>Sierra Leone</td>
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<td>South Africa</td>
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<td>Tanzania, United Republic of</td>
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<td>Togo</td>
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<td>Uganda</td>
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<td>Zambia</td>
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<td>Zimbabwe</td>
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<tr>
<td>All other countries</td>
<td>7,129,277</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>7,160,190</strong></td>
</tr>
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</table>
Active ICSRs in the WHO global ICSR database per million inhabitants and year
Period covers 2007-03-14 and 2012-03-14
The SPS assessment: broad summary

- Reinforces previous findings
- And an objective way of scoring
  - Useful in focusing our attention
- Proposes recommendations
But would be useful to 'interpret' the reasons

• Why the lack of active surveillance
• Why the lack of collaborations with relevant stakeholders
• Why products quality, medication errors have not pursued as part of PV
• Understanding the reasons will help develop better solutions
• Needs to link with previous works and analysis
  • National PV Systems, 1997 (S Olsson)
  • WHO/UMC/ UW PV assessment of 2008
  • Various PV assessments by PAHO assessments
  • UMC- A PV assessments

• How
  • To implement the proposed recommendations
  • And sustain
The proposed recommendations would benefit by

- Highlighting the
  - 'how'
  - 'who' and the
  - 'when'
Roles and responsibilities…
Annex B: mapping of institutions working towards strengthening PV in SSA

• Different players than 10 years ago
• Some overlaps are good (training and capacity building)
• But norms and standards?
  • Multiple standards: can they help?
  • Can we learn from ICH?
The way forward

• Assessment(s): what we need to do
• How: identified in Global PV strategy (WHO GF stakeholders meeting, 2010, Ghana)
  • Identifies partners
  • Defines roles and responsibilities
  • Proposes resources and
  • Coordination mechanism: WHO
  • Implement solutions: gradual, phased
• Present assessment should consider the above implementation model