Radiopharmaceuticals

Presentation
Challenges in regulating radiopharmaceuticals: view of the International Consultancy Group affiliated to IAE. Kadariah Mohamed Ali, Malaysia.

Recommendations

1. Encourage better regulatory oversight.

2. Establish a prequalification system for radiopharmaceuticals.

3. Establish an international common platform (website and electronic database) for harmonized dossiers to prequalify radiopharmaceuticals.

4. Establish detailed mechanisms.

Involvement of consumers in medicines surveillance reporting

Presentation
Involving consumers in medicines surveillance reporting. Tan Lie Sie, Malaysia, and Cynthia Lim, Philippines.

Recommendation

1. Increase efforts to include consumers in medicines surveillance reporting by fostering consumer awareness, informing and educating the public and by promoting the programme to consumers.

WHO Stability Testing Guideline

Presentation
Revision of WHO stability testing guidelines. Tamás Paál, Hungary.

Recommendations

1. Finalize the revision of the guideline and apply it in Member States.

2. Provide information about the national long-term conditions to WHO.

3. WHO to make the data available on its web site.

WHO Certification Scheme

Presentation
WHO Certification Scheme for finished pharmaceutical products, where are we today? Margareth Sigonda, Tanzania.

Recommendations

1. Review reports of recent meetings held at WHO.

2. Give feedback to WHO for further discussion.

Adverse reactions

Presentation
Adverse reactions related to change of formulation: thyroxine case. Stewart Jessamine, New Zealand.

Regulatory aspects of paediatric medicines

This session was linked to the two day pre-ICDRA meeting “Better Medicines for Children: the way forward”. The meeting was unique in inviting, for the first time, regulators, industry, clinicians, civil society and academics to meet and identify challenges and seek solutions to ensuring better access to medicines for children. The pre-ICDRA meeting was attended by more than 240 participants from 75 countries. [A summary of the main themes to emerge from the meeting is presented on page 282.]

Moderator
European Union: Agnès Saint-Raymond

Presentations
Recent legislative changes regarding paediatric medicines in the European Union. Agnès Saint-Raymond, European Union.

Clinical trials in neonates – challenges for all stakeholders? Irja Lutsar, Estonia.

Paediatric medicines: a viewpoint from an African regulator. Richard Rukwata, Zimbabwe.

Report from the pre-ICDRA meeting "Better medicines for children – the way forward". Agnès Saint-Raymond, European Union.

Recommendations from pre-conference vaccines and biologicals track. David Wood, WHO.

Recommendations

Member States should:

Assist WHO to form an ICDRA paediatric working group to:

1. Ensure global collaboration.

• Agree on global regulatory standards.

• Streamlining paediatric clinical trials.

2. Implement efficient registration of children's medicines.

• Put children medicines as top priority.

• Fast track strategies: e.g., hybrid applications, mutual recognition, cooperative review, waivers, etc.

3. Develop consolidated views/advice on dosage forms and delivery devices.

• Guideline on dosage forms.

• Manipulations, extemporaneous formulations.

• Increase knowledge on paediatric excipients.

4. Devise mechanisms for ensuring transparency and exchange of information on trials, licensing, and children's medicines (dose, adverse effects).

5. Improve information on safety of medicines used in children and building infrastructure for pharmacovigilance.

Other parties

For industry: continue integrating paediatric dosage forms and delivery devices early in development of new medicines.

For industry: continue integrating paediatric needs, including developing countries needs in the development of new vaccines.

For the generic industry: develop missing dosage forms of off-patent medicines (including necessary fixed-dose combinations).

To health professionals: engage actively in sound, ethical research with children, with the aim of avoiding duplication of research.

WHO should:

1. Convene a global paediatric working group of regulators.

2. Work with civil society to mobilize and empower consumers, parents, patients' groups and health professionals to advocate for better medicines for children.

3. Develop strategies for addressing high priority needs with achievable results including: zinc for diarrhoea, *Pneumoniae* treatment, neonatal sepsis, HIV, TB, malaria treatments, and analgesics.

4. Establish a drug development helpline to support new essential medicines for children.

Vaccines and biologicals:

1. National regulatory authorities (NRAs) should prioritize evaluation of vaccines for diseases of most importance to child survival.

Member States and WHO:

1. Networking among NRAs for the joint evaluation and oversight of clinical trials of new vaccines is proving an effective process in Africa. NRAs are requested to continue to develop this type of collaboration and WHO is requested to facilitate the long-term sustainability of this and other vaccine regulatory networking initiatives.

2. Post-marketing effectiveness data is an important aspect of vaccine evaluation. WHO is requested to support capacity building and NRAs are requested to strengthen collaboration with public health agencies in this area.

3. Vaccine pharmacovigilance is a regulatory function that needs to be strengthened. NRAs are requested to prioritize capacity building for this function and WHO is requested to support this activity through setting standard definitions, development of guidelines, training, and development of networks.

4. NRAs are requested to expedite national-level approval of WHO prequalified vaccines. To facilitate this, WHO is requested to provide more detailed information about the quality, safety and efficacy of prequalified vaccines.

5. Forty per cent of venomous snake bite victims are children. There is a shortage of appropriate antivenoms globally. Improving the quality, quantity and distribution of antivenoms is essential. NRAs are requested to implement new WHO guidance on the quality, safety and efficacy of antivenoms and WHO is requested to develop a prequalification programme for antivenoms

Development of regulation for herbal medicines

Currently, around 110 countries regulate herbal medicines in response to a dramatically increased use globally and demand for more vigorous requirements to ensure quality, safety and efficacy. A number of countries also review and strengthen existing regulations for herbal medicines in a continued effort to improve their use and efficacy. Regulation of herbal medicines varies from country to country, reflecting national circumstances and legislative frameworks. A global network of regulatory agencies responsible for regulation of herbal medicines, the "International regulatory cooperation for herbal medicines (IRCH)" was established in 2006 under the coordination of WHO and currently has 19 members.

Moderators
Singapore: Shen Kuan Yee

Lao PDR: Somthavy Changvisommid

Presentations
Regulatory Framework: overview of the regulation of herbal medicines in Switzerland. Karoline Mathys, Swissmedic, Switzerland.

Regulatory Framework: overview of the regulation of herbal medicines in Brazil Bruno Rios, ANVISA, Brazil.

Overview of the regulation of herbal medicines in Benin in supporting primary health care needs. Regina Badet, Department of Traditional Medicine and pharmacopoeia, Ministry of Health, Benin.

Overview: revising the regulatory framework of herbal medicines in China. Zhang Wei, State Food and Drug Administration, China.

Promotion of regulatory cooperation: perspectives from IRCH. Shen Kuan Yee, Deputy Director, Centre for Drug Adminis-