ICDRA

International Conference of Drug Regulatory Authorities (ICDRA) comes to Africa

Established in 1980 as a platform to develop international consensus, the WHO-convened ICDRA conference has become the place of choice for regulators from WHO Member States to meet and discuss strategies to harmonize regulation and improve the safety, efficacy and quality of medicines. The 17th ICDRA, to be held in November 2016, will be the first to take place in sub-Saharan Africa.

ICDRA – a forum for regulatory authorities

The International Conference of Drug Regulatory Authorities (ICDRA) provides medical products regulators of WHO Member States with a forum to meet and discuss ways to strengthen collaboration. It is co-organized every two years by WHO and the regulatory authority of the host country.

The ICDRA conferences have been guiding regulatory authorities, WHO and interested stakeholders in determining priorities for action in national and international regulation of medicines, vaccines, biomedicines and herbal products. The ICDRA programme is developed by a planning committee of representatives from medicines regulatory authorities. While the pre-ICDRA event is open to all interested stakeholders, participation at the actual conference is restricted to representatives of medicines regulatory authorities. Recommendations are agreed at each ICDRA for action among agencies, WHO and related institutions and are documented on the WHO web site (1).

International Conference of Drug Regulatory Authorities (ICDRA)

The 17th ICDRA will take place in Cape Town, South Africa on 27 November – 2 December 2016

Register now:
www.icdra.co.za
Closing date for registrations: 31 August 2016
Bringing regulators together
From their inception, the ICDRA conferences have been instrumental in bringing regulators together to move towards international harmonization (Box 1). Regulatory harmonization was pioneered in Europe some forty years ago, eventually leading to the establishment of the International Conference for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH, recently renamed International Council on Harmonization)\(^1\). Regulatory harmonization then took hold in other parts of the world, with active initiatives ongoing within the Pan American Network for Drug Regulatory Harmonization (PANDRH), the Asia-Pacific Economic Cooperation (APEC), the Association of the Southeast Asian Nations (ASEAN), the Gulf Cooperation Council (GCC) and more recently also in Africa.

Focus on Africa
The potential benefits of harmonizing medicines registration in Africa were recognized at the 13\(^{th}\) ICDRA in 2008. A WHO concept paper was then developed to describe a proposed approach to supporting harmonization of medicines registration within and across African regional economic communities (2). Further discussions and a call for proposals followed in 2009. The first project started in the East African Community (EAC) in 2011; active projects are meanwhile ongoing in several regions.

One aim of the African Medicines Regulatory Harmonisation Programme (AMRH) is to establish – in partnership with the African Union Commission and WHO – the African Medicines Agency, which will operate under the authority of AMRH. During a meeting in Luanda in 2014, African Health Ministers endorsed this proposal (3).

Given this impressive momentum, it is fitting that in 2016 the ICDRA conference should come to Africa. The 17\(^{th}\) ICDRA will be hosted by the South African medicines regulatory authority in Cape Town on 29 November – 2 December 2016. The theme of the event is “Patients are waiting: How regulators collectively make a difference”. In keeping with

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\(^1\) www.ich.org

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**Box 1: ICDRAs around the world**

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<tr>
<th>1(^{st}) ICDRA</th>
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<th>17(^{th}) ICDRA</th>
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</thead>
<tbody>
<tr>
<td>Anna- polis (United States of America)</td>
<td>Rome (Italy)</td>
<td>Saltsjöbaden (Sweden)</td>
<td>Tokyo (Japan) – first in Asia</td>
<td>Paris (France)</td>
<td>Ottawa (Canada)</td>
<td>Noordwijk (Netherlands)</td>
<td>Manama (Bahrain) – first in an Arabic country</td>
<td>Berlin (Germany)</td>
<td>Hong Kong (China)</td>
<td>Madrid (Spain)</td>
<td>Seoul (Republic of Korea)</td>
<td>Berne (Switzerland)</td>
<td>Singapore (Singapore)</td>
<td>Tallinn (Estonia)</td>
<td>Rio de Janeiro (Brazil) – first in South America</td>
<td>Cape Town (South Africa) – first in Africa</td>
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the motto of “Strengthening regulatory systems through convergence, reliance and networks” the 17th ICDRA offers a rich programme of topics for discussion (Box 2).

More than ever, regulatory convergence and cooperation are needed to ensure that patients around the world, including those in the resource-constrained environments of many African countries, have access to quality medical products at affordable prices. By facilitating discussions among regulators in an atmosphere of trust and professional commitment, the 17th ICDRA will be instrumental in bringing about progress in this ambitious agenda. It is an opportunity not to be missed by any regulatory authority wishing to contribute to global regulatory convergence, effective collaboration and good regulatory practices in the interest of public health.

References

(See page 229 under “Upcoming events” for practical information)