

29 May 2008

13th International Conference of Drug Regulatory Authorities (ICDRA)

16-19 September 2008, Berne, Switzerland

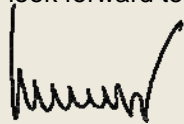
Ladies and Gentlemen, dear Colleagues

The opening of the 13th International Conference for Drug Regulatory Authorities, which will take place in the Swiss capital city of Berne in mid-September, is now just four months away. For the Swiss Agency for Therapeutic Products, Swissmedic – and for me personally – it is a tremendous mark of confidence that the WHO has entrusted us with the organisation of this 13th edition of ICDRA.

ICDRA provides an opportunity that is unique in the world for exchange among experts and for an update on the latest experiences and findings. It is moreover an important forum regarding worldwide harmonisation within the regulation of medicines.

Swissmedic and the ICDRA 2008 Organising Office are making every effort to provide a setting that will permit this 13th edition of ICDRA to be a successful one. As of today and until ICDRA starts, we will be sending you a newsletter every four to six weeks. It will contain information about how the conference programme is developing, introduce speakers, and provide organisational details. Above all, however, our aim is to make you look forward to the 13th ICDRA in Switzerland.

I look forward to welcoming you this September.



Jürg H. Schnetzer
Director of Swissmedic

The ICDRA 2008 Organising Office

Petra Doerr, Head of Management Services and Networking as well as a Member of the Management Board, is responsible for organising the ICDRA, and for coordinating the activities with the WHO. Cordula Landgraf is Head of Networking at Swissmedic. Her main responsibilities for the ICDRA are supporting the conference management and co-ordinating work on establishing the programme. Nicole Luethi, Public Relations officer at Swissmedic, will be handling the logistic and administrative support of ICDRA.

If you would like to contact us: icdra@swissmedic.ch

Register now!

If you haven't registered for the 13th ICDRA, you can do it right now on the dedicated website: www.icdra.ch. Deadline for registration as well as for the hotel booking is 30 July 2008.

Please pass this Newsletter on to anyone who would be interested. You can find more information about ICDRA at: www.icdra.ch



Cordula Landgraf, Petra Doerr and Nicole Luethi (from left to right)

Update on the Programme

The 13th ICDRA will be opened by Christine Beerli, Chairwoman of the Institute Council, Swissmedic, and Carissa F. Etienne, Assistant Director-General, World Health Organization.

We are pleased to announce that the conference programme is in the finalization stages and we are particularly glad to note the number of speakers who have confirmed their participation at either a plenary session or workshop. Among these are regulators from the major agencies such as Thomas Lönngren, European Medicines Agency (EMA), and Justina Molzon, US Food and Drug Administration. Regulators from national authorities include Tamás Paál, Institute of Pharmacy, Hungary, Margareth Sigonda, Tanzania Food and Drug Administration, and Lucky Slamet, National Agency of Drug and Food Control, Indonesia.

With the next issue of the ICDRA Newsletter we will provide a detailed overview of session topics. Meanwhile, we offer here a selection of presentations that have been confirmed:

- Overview on revising the regulatory framework of herbal medicines in China
- PaniFlow tool for monitoring drug/vaccine adverse events during a pandemic
- Blood supply and blood products: regulatory issues in the pandemic context
- WHO biowaiver guideline in regulatory practice
- Changing environments and small regulatory authorities
- Status of counterfeit medicines in Iran
- Regulation of subsequent entry biological medicinal products: WHO guidelines
- Assessment criteria for blood regulatory systems: effectiveness in risk management
- Plasma Quality: why does it matter?
- Interactions between manufacturing and trial host country regulators
- Coping with increasing need for inspections: ASEAN initiatives
- What is EMA's approach in GMP inspections?
- New proposal for the EU Variation Regulation - point of view of an EU National Competent Authority
- Challenges in regulating radiopharmaceuticals

The main programme can be viewed at www.icdra.ch

Better medicines for children: the way forward is a two-day meeting which will take place from 14-15 September 2008 and is open to regulators and other interested parties. Registration can be made through the main ICDRA website at www.icdra.ch



The Venue

This year's ICDRA will take place in Berne, the capital of Switzerland. The city lies in the heart of Switzerland between the country's German- and French-speaking regions. The city's charm is partly due to its extraordinary location; the River Aare winds its way around the old town like a ribbon around a gift. And when it's sunny, the famous Bernese Alps can be seen in all their splendour. We hope that you'll have a chance to see this stunning sight during ICDRA. The well-preserved old town of Berne has even been classified as a UNESCO World Cultural Heritage site. The town and its citizens are known for being calm and easy going.

We have chosen the venue for the conference with the aim of making you feel the charme of "our home". The hotel Allegro Kursaal Berne stands out thanks to its central location at the edge of Berne's old town but also because of its modern design and great atmosphere. We believe it will be an ideal setting for our discussions.

Poster Session

The ICDRA will provide the opportunity for participants to present country related regulatory news or topics by means of a poster (max. size 1,15 X 1,45 m). The poster could convey a message relating to a specific topic from a country or to raise awareness of a common problem encountered by other countries. The poster could also be supported by brochures or leaflets on the same topic.

Those who wish to present a poster are kindly invited to send an e-mail to the ICDRA 2008 Organising Office at icdra@swissmedic.ch submitting the following information before 30 June 2008:

- Name
- Address
- Title of poster
- Short abstract (not more than 300 words)

As the number of posters is limited, topics will be selected by a programme committee comprised of WHO representatives as well as representatives of the ICDRA 2008 Organising Office.

We are looking forward to receiving your suggestions!