PMDA International Forum, 8 February 2014

Swissmedic, Swiss Agency for Therapeutic Products

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Grüezi. Bonjour. Buongiorno. Allegra.

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Overview

- Swissmedic Introduction
- Strategic Approach to International Cooperation
- The International Pharmaceutical Regulators Forum
- Cooperation with MHLW/PMDA
- Current Challenges and Future Directions

Swissmedic Introduction

Mission

- We are the central Swiss authority for the authorisation and supervision of therapeutic products
- We endeavour to ensure that authorised therapeutic products are of high quality, effective and safe
- We thereby contribute towards protecting the health of humans and animals
- We fulfil our legal mandate and work with partner authorities on a national and international basis

Swissmedic Introduction

- Swissmedic was established in January 2002 as the first Federal authority on therapeutic products along with the coming into force of the Therapeutic Products Act (TPA)
- Scope of products:
  - Medicinal products for human and veterinary use (Chemical, biotechnology, biologic, stable blood products, transplant products, traditional and herbal medicines, …)
  - Medical devices (based on EU system, Notified Bodies and CE-marking)

Swissmedic Introduction

Core responsibilities

- Granting marketing authorizations for medicinal products
- Inspections & granting of authorisations to manufacturing facilities and distributors
- Market surveillance of medicinal products and medical devices
- Controlling the traffic of narcotics
- Laboratory testing and medicine quality
- Provision of information on therapeutic products
- Drafting laws, norms and standards

Swissmedic Introduction

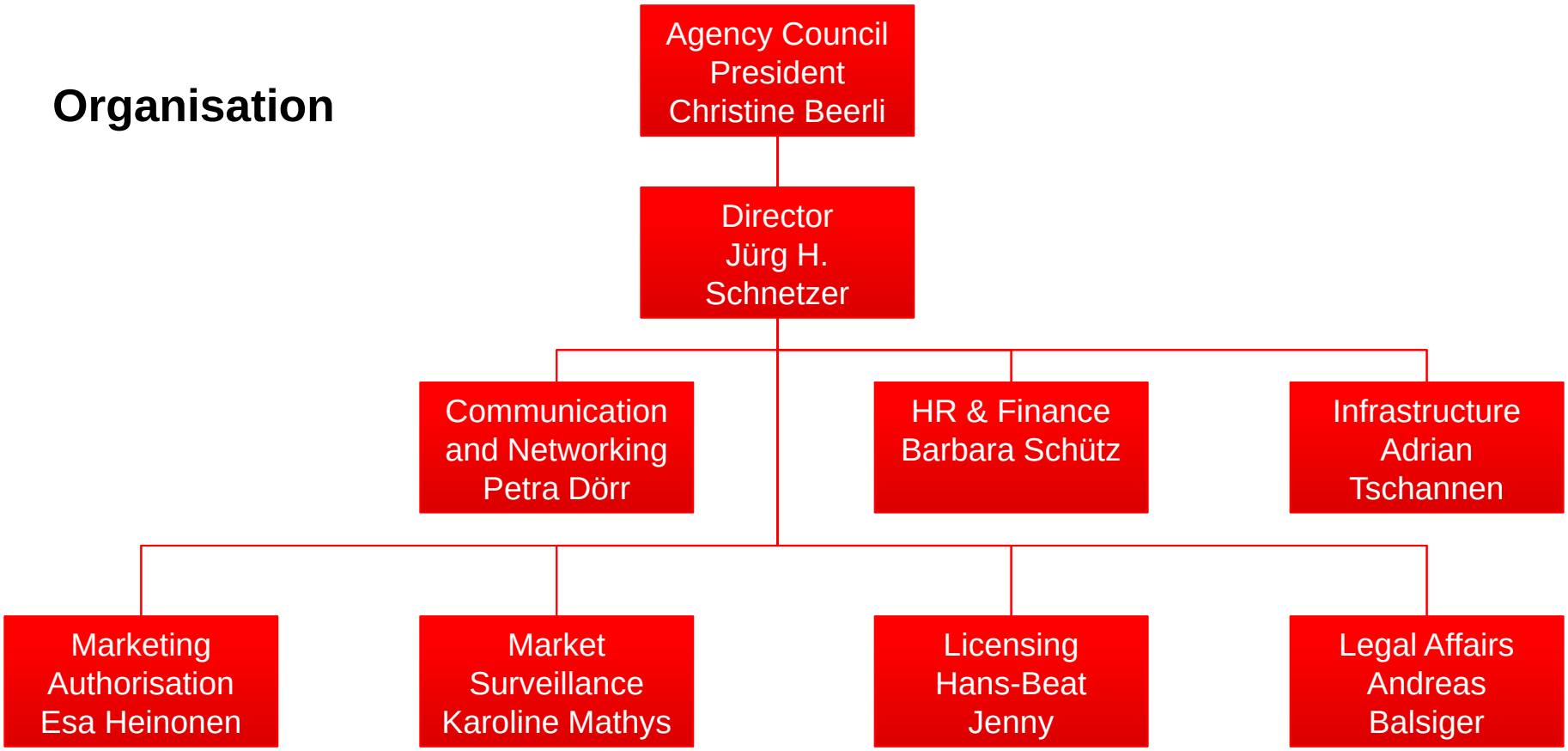
Key figures

Staff: 360 FTE
(440 employees)

Budget 2014:	**~ 90 Mio. CHF**
Federal contribution:	< 20%
Fees:	> 80%

Swissmedic Introduction

Organisation



Swissmedic Introduction

Change Process 2006-2012

Swissmedic Introduction

Risk-based evaluation of resource allocation

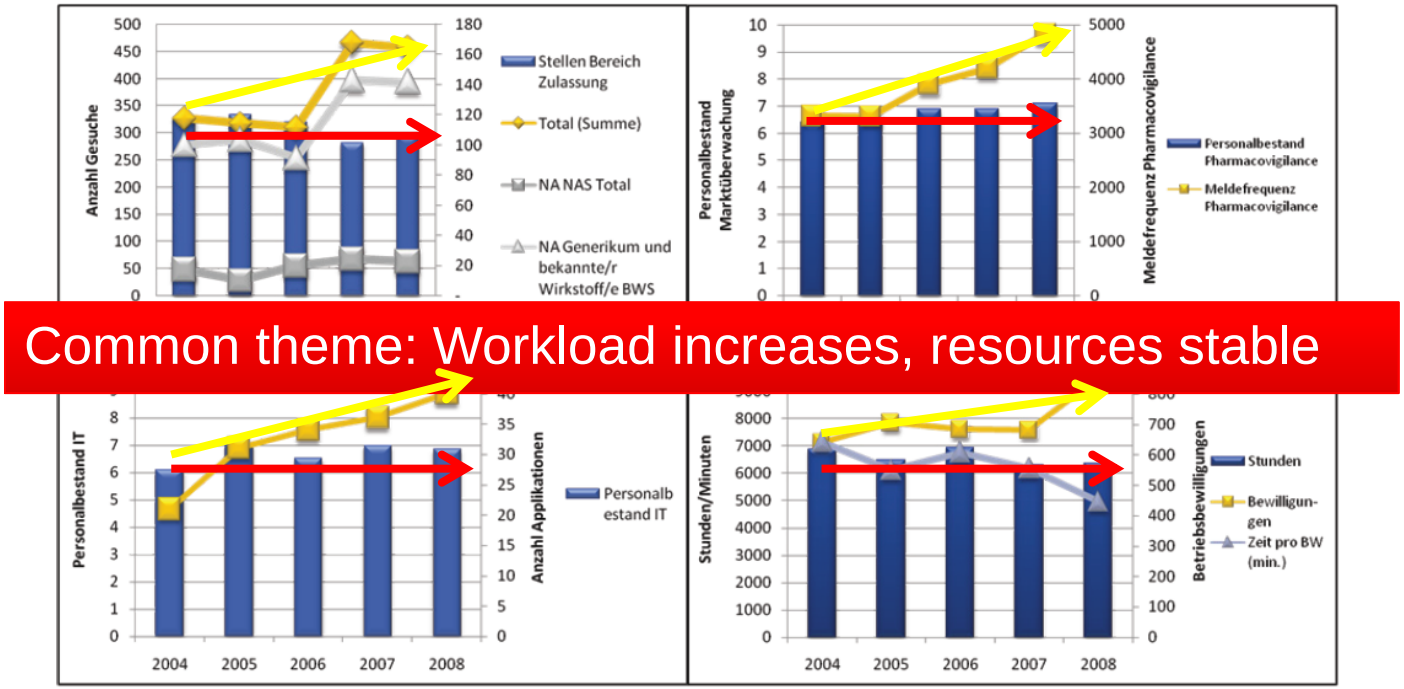
Risk-based evaluation of resource allocation

- Elements
  - Analysis of current situation; developments/trends
  - Show potential for process-optimisation
  - International benchmark
  - Involvement of external stakeholders

Swissmedic Introduction

Risk-based evaluation of resource allocation

Risk-based evaluation of resource allocation



Common theme: Workload increases, resources stable

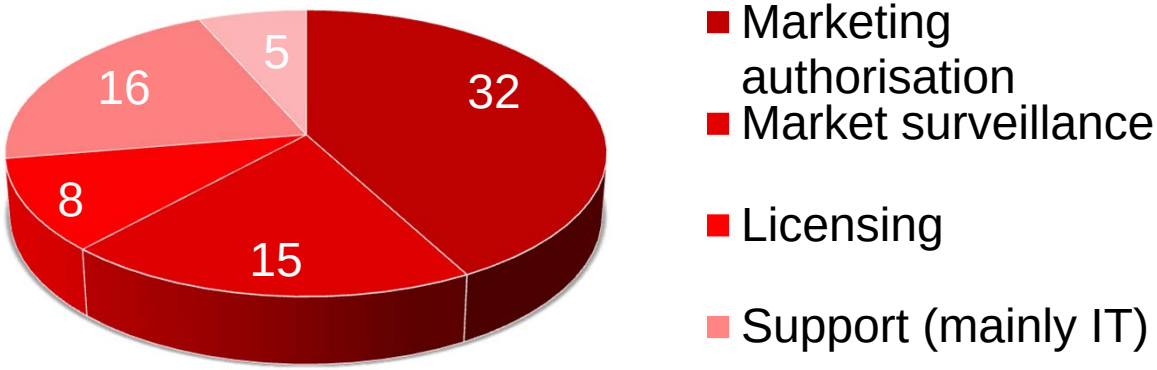
Swissmedic Introduction

Risk-based evaluation of resource allocation

Risk-based evaluation of resource allocation

Additional resources approved based on analysis results:

Headcount increase by 76 FTE (from 284 to 360 FTE) over three years



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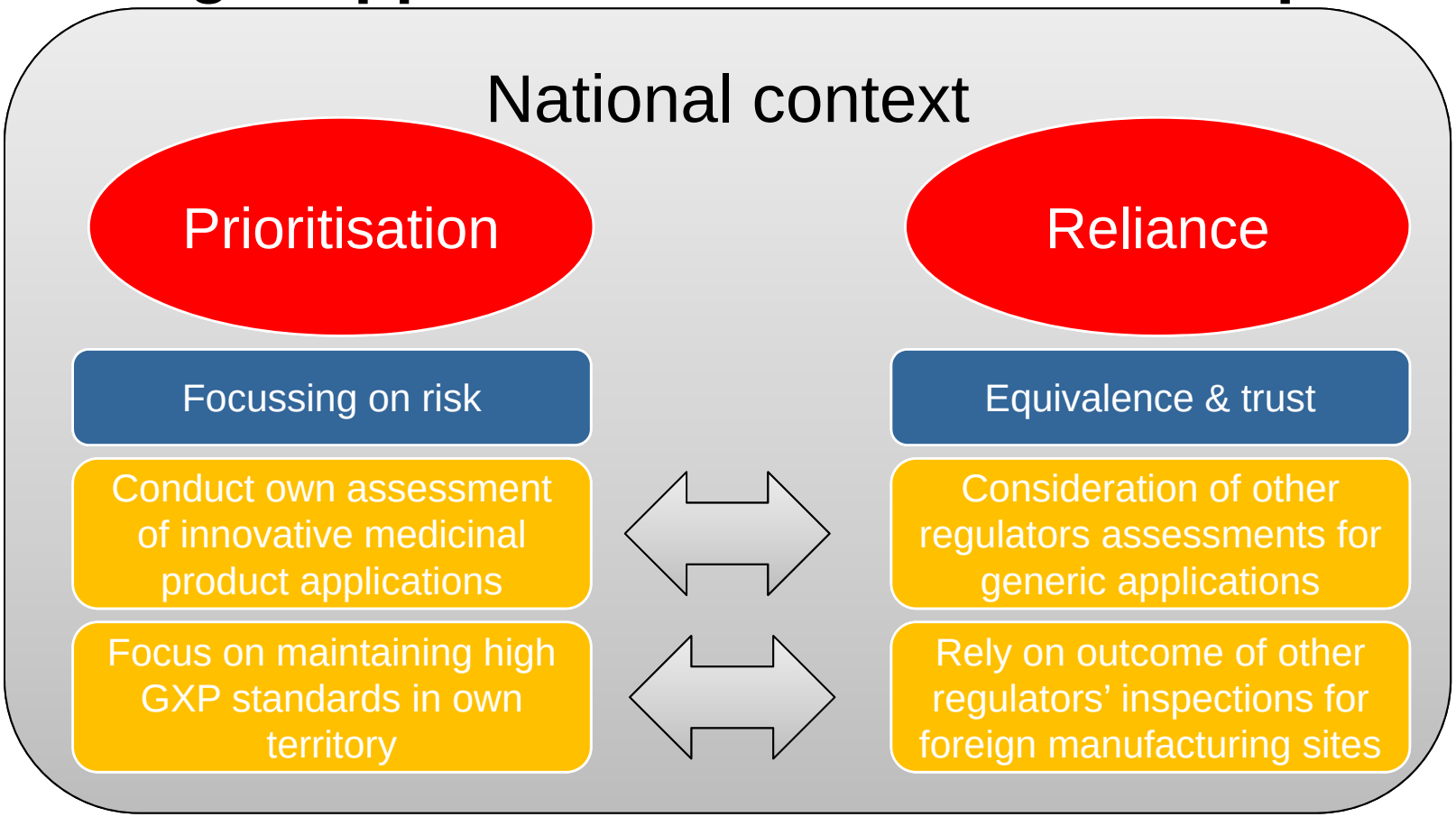
Strategic Approach to International Cooperation

Swissmedic in the national context

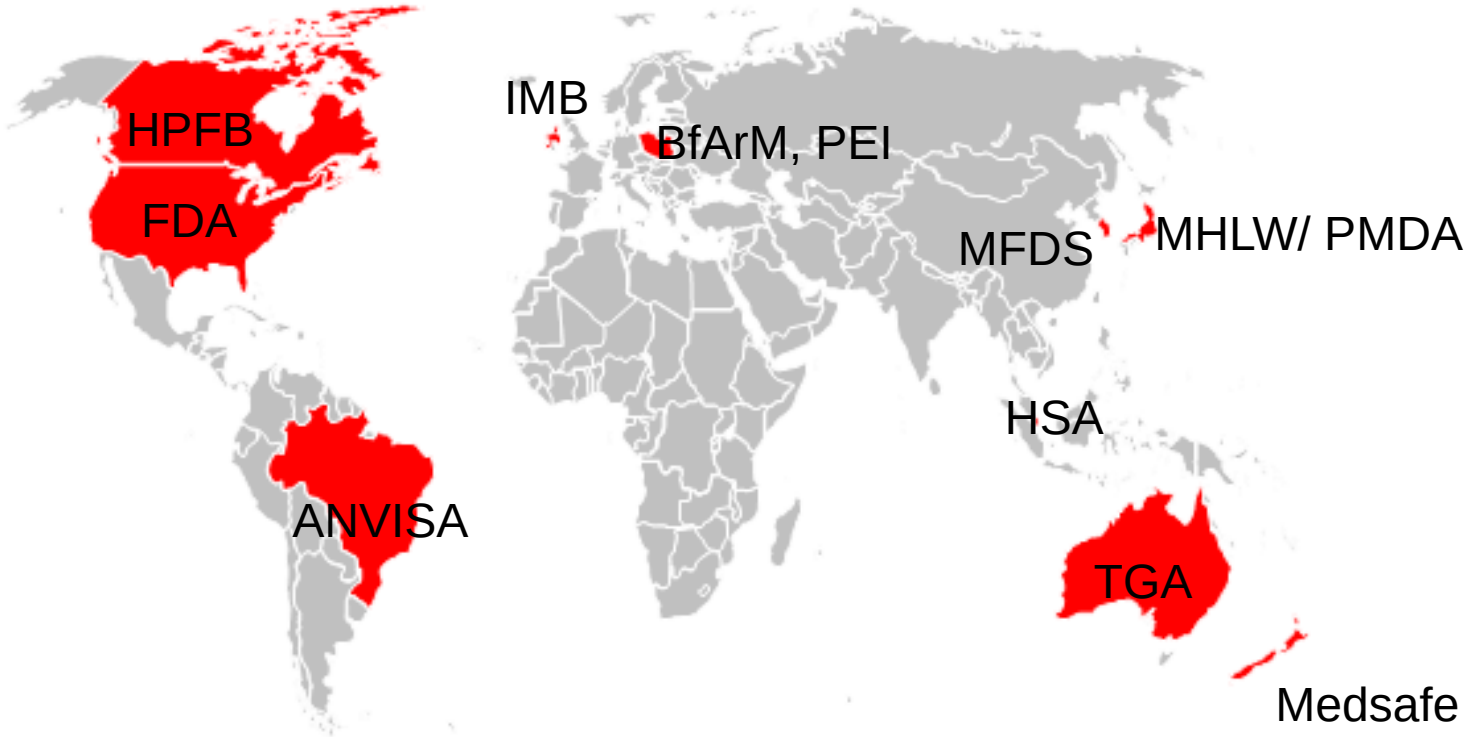
- Mature system for the regulation of therapeutic products
- Swissmedic: a “small and medium sized agency”
- Major location for research-based pharmaceutical and medical device industry
- Exports in pharmaceuticals: 64 Bio. CHF (2012, 30% of all Swiss exports)

Strategic Approach to International Cooperation



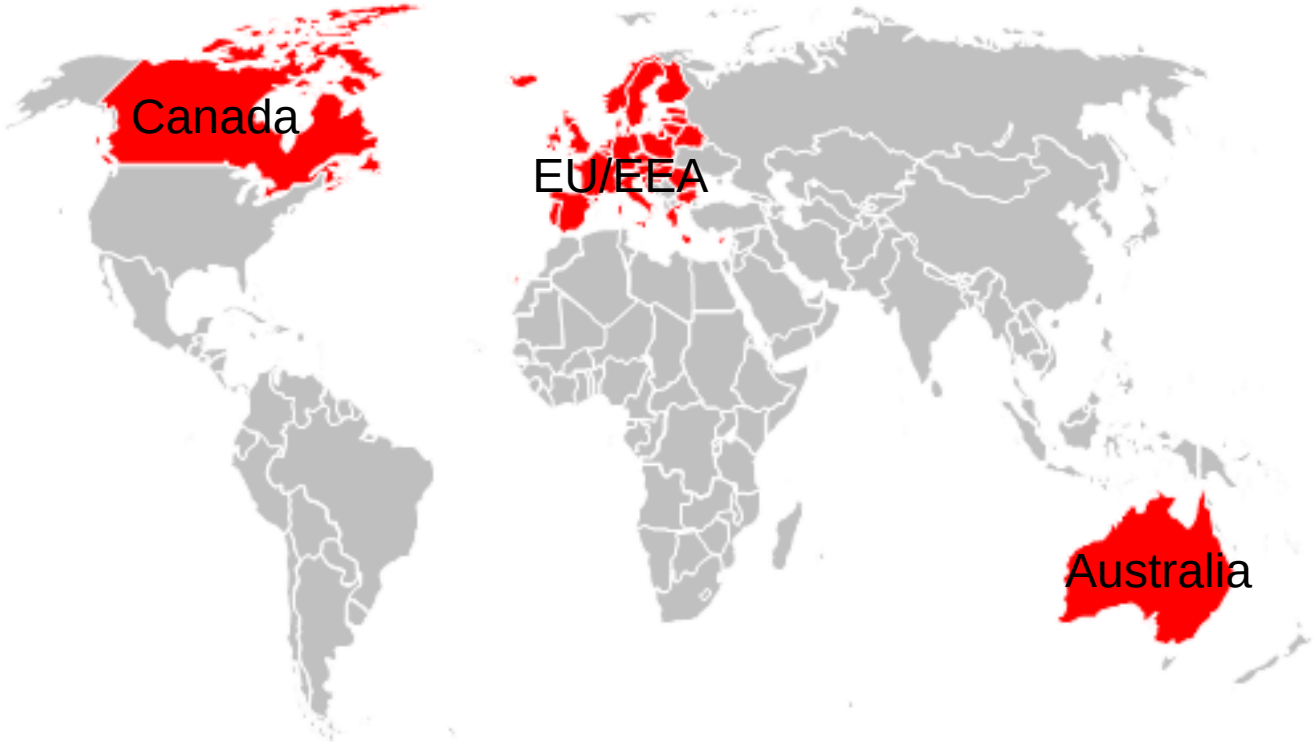
Strategic Approach to International Cooperation

Memoranda of Understanding/Confidentiality Agreements



Strategic Approach to International Cooperation

Mutual Recognition Agreements



Strategic Approach to International Cooperation

Multilateral Activities

- International Regulators Consortium (Australia, Canada, Singapore, Switzerland)
- World Health Organization:
  Pre-Qualification, trainings, Blood Regulators Network, Paediatric medicines Regulators Network, expert committees,…
- PFIPC (Permanent Forum on International Pharmaceutical Crime)
- Council of Europe/European Pharmacopoeia

Strategic Approach to International Cooperation

Multilateral Activities

- International Conference on Harmonisation (ICH)
- International Pharmaceutical Regulators Forum (IPRF)
- International Generic Drug Regulators Pilot (IGDRP)
- Pharmaceutical Inspection Cooperation Scheme (PIC/S)

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International Pharmaceutical Regulators Forum

History

- Established as the Regulators Forum in June 2008 in the margins of the ICH conference in Portland, USA, to provide a regulators-only platform for discussion around ICH topics (and beyond).
- “Re-launch” as the IPRF in June 2013
- First meeting as the IPRF in November 2013 in Osaka, Japan
- 1.5 day meeting in conjunction with ICH conferences
- Chair: Swissmedic
- Co-chair: MHLW/PMDA
- Secretariat: Swissmedic

International Pharmaceutical Regulators Forum

Objectives

- Practical and operational information-sharing on high priority regulatory issues;
- Support implementation of ICH and other internationally harmonized technical guidelines for medicinal products for human use;
- Regulatory cooperation, including work sharing, on identified topics which are not duplicative of existing processes or organizations;
- Open discussion and the sharing of best practices among the members;
- To identify existing synergies and commonalities with a view to develop common approaches.

International Pharmaceutical Regulators Forum

Objectives

- In the context of a particular issue, identification of common need for development of better regulatory strategies, better information on specific issues or better training, e.g., for regulatory staff, to address specific issues;
- Identification of need for harmonization or convergence in specific areas (to improve regulatory operations efficiency and effectiveness);
- Propose identified topics, not falling in the remit of the IPRF, to appropriate existing process or venues (e.g. to ICH, PIC/S, APEC, PANDRH, WHO, etc.).

International Pharmaceutical Regulators Forum

IPRF Activities

- Working group on General Principles for Training/Education of GCP inspectors
- Cell therapy working group
- Gene therapy working group
- Biosimilars working group

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Cooperation with MHLW/PMDA

MHLW and PMDA are strategic partners of Swissmedic

- Agreements of GMP and GLP in place since 1988
- Confidentiality Arrangements signed in 2010
  - Annual bilateral meetings in the margins of the Summit of Heads of Medicines Agencies

Cooperation with MHLW/PMDA

Focus areas for MHLW/PMDA and Swissmedic cooperation

- Staff exchange program (2013)
  - March 2013: visit of PMDA staff member at Swissmedic to identify areas of interest for future cooperation
  - October to December 2013: placement of a first PMDA liaison officer at Swissmedic
  - November 2013: visit of Swissmedic staff member at PMDA

Cooperation with MHLW/PMDA

Focus areas for MHLW/PMDA and Swissmedic cooperation

- Staff exchange program (2014)
  - February 2014-February 2015: placement of PMDA liaison officer at Swissmedic
  - 2014: Swissmedic staff member to visit PMDA (focus on drug safety and medical devices)

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Current Challenges and Future Directions

Current Challenges

- Keeping timelines while maintaining quality of scientific work
- Increasing complexity of the tasks (science, globalized supply chains) needs to handled without additional resources
- Increased efficiency and optimized processes required
- Modernization of infrastructure (IT)
- Recruiting and retaining qualified staff
- Need to consequently apply risk-based approach

Current Challenges and Future Directions

Future Directions

- “Effective resource management”: (Pro-) active approach to resource allocation
- “Horizon scanning”: Issue management and regulatory intelligence for monitoring of new developments and trends
- Definition of future international positioning
- Dealing with increasing expectations with regard to transparency
- Continuing pressure on performance (keeping timelines)
- Maintaining attractiveness as an employer

→ **Elements of strategy 2015-2018 (work-in-progress)**

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Danke. Merci. Grazie. Grazia.