The place of the Certification Procedure in the global regulatory environment
19/20 September 2017, Prague, Czech Republic

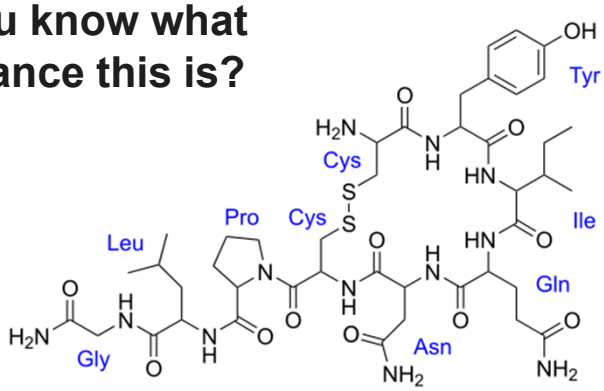
An overview of international initiatives in the regulatory sphere

swissmedic

Cordula Landgraf
Head of Networking, Swissmedic

swissmedic

Do you know what substance this is?



swissmedic

Oxytocin – an elixir to support cooperation?

What recent studies suggest …

- Increase of attention to social stimuli
- Reduction of natural fear of the other
- Promotion of getting closer to others and let us enjoy this "closeness"
- Cortisol ↓
- Last but not least: promotion of building **trust** and establishing **confidence**

Research by Markus Heinrichs and Ernst Fehr, University of Zurich

swissmedic

Nobody can do everything alone:

An overview of international initiatives in the regulatory sphere

swissmedic

Outline

1. Background
2. Examples of initiatives
3. Latest developments and achievements
   - ☞ Focus on IPRF and ICH
4. Summary & Outlook

swissmedic

Harmonisation versus **Convergence**

- Harmonisation of technical requirements for medicines regulation, i.e. legislation, guidelines, procedures, etc. (WHO)
- The process by which the interpretation and/or application of technical guidelines can be made uniform or mutually compatible. (FDA/CBER)

- Regulatory requirements become more similar or aligned over time as a result of gradual adoption of internationally recognised technical guidance documents and standards
- Does not represent harmonization of laws and regulations (APEC)

swissmedic

Reliance

- State of being dependent upon or confident in something or someone
- Having trust

(The Business Dictionary)

and

Work Sharing

- Making use of work products and leveraging resources and expertise of as well as sharing workload between agencies.

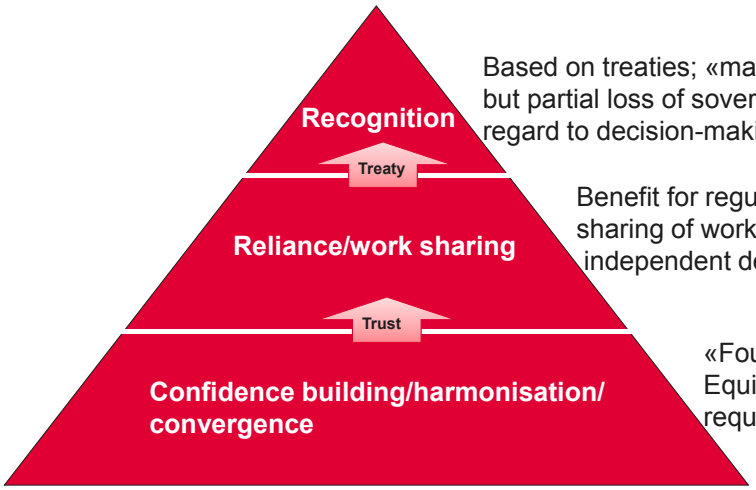
This includes:

- Reliance on or consideration of work already performed by other agencies
- "Real-time" work sharing for simultaneous activities ("joint assessments").

(ACSS Consortium)

swissmedic

Levels of regulatory cooperation



Based on treaties; «maximal benefit» but partial loss of sovereignty with regard to decision-making

Benefit for regulators; sharing of workload, but independent decisions

«Foundation», Equivalence of requirements

swissmedic

Levels of regulatory cooperation

Recognition
Examples: Mutual Recognition Agreements (EU, ASEAN); marketing authorisation procedures (EU, GCC); unilateral recognition of marketing authorisations (Mexico);…

Reliance/Work-sharing
Examples: Abridged application routes/reference country model; WHO Pre-Qualification; EAC/MRH joint assessment procedure; ZAZIBONA(S), IGDRP; ACSS Consortium (HSA, TGA, HPFB, Swissmedic); …

Confidence building/harmonisation/convergence
Examples: AMRH; EAC/MRH; PIC/S; ICH; IPRF; IGDRP; IMDRF; RHIs/RECs; WHO trainings and networks, ICDRA; GRPs; Bilateral agreements; …

swissmedic

Outline

1. Background
2. Examples of initiatives
3. Latest developments and achievements
4. Summary

swissmedic

Examples of global initiatives involved in convergence/harmonisation (1)

Initiative	Scope	Main objective(s)/areas of work
ICH www.ich.org	Human medicinal products	Harmonisation of requirements for registration for human medicinal products
VICH www.i-p-r-f.org	Veterinary medicinal products	Harmonisation of requirements for registration for veterinary medicinal products
IGDRP www.i-p-r-f.org	Generics	Promote collaboration and convergence in generic drug regulatory programs in order to address the challenges posed by increasing workloads, globalisation and complexity of scientific issues …
IPRF www.i-p-r-f.org	Medicinal products	Support implementation of ICH and other internationally harmonized technical guidelines; identification of need for harmonization or convergence in specific areas; …

swissmedic

Examples of global initiatives involved in convergence/harmonisation (2)

Initiative	Scope	Main objective(s)/areas of work
IMDRF www.imdrf.org	Medical Devices	Accelerate international medical device regulatory harmonization and convergence …
WHO www.who.int	Health Products	Development of international standards for the manufacturing and regulation of health products
PIC/S www.picschem e.org	GMP inspections	Developing and promoting harmonised GMP standards and guidance documents ...
ICMRA http://www.icm ra.info/	Medicinal products	Regulatory convergence, alignment and standards development; regulatory cooperation and work-sharing; capacity and competence building/technical assistance; regulatory systems comparability criteria and assessment criteria; regulatory science.

swissmedic

Examples of global initiatives involved in convergence/harmonisation (3)

Initiative	Scope	Main objective(s)/areas of work
WHO Prequalification http://www.who.int/topics/prequalification/en/	Drugs, vaccines, diagnostics	The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers.
EAC MRH Joint Assessment Procedure, ZAZIBONA, other RECs… http://mrh.eac.int/; http://www.mcaz.co.zw/index.php	Medicinal products	Work-sharing in the marketing authorisation of medicinal products, supported by WHO and stringent regulatory authorities
ACSS Consortium	Medicinal products/ medical devices	Various collaborative projects ranging from marketing authorisation, post-market surveillance to IT.

swissmedic

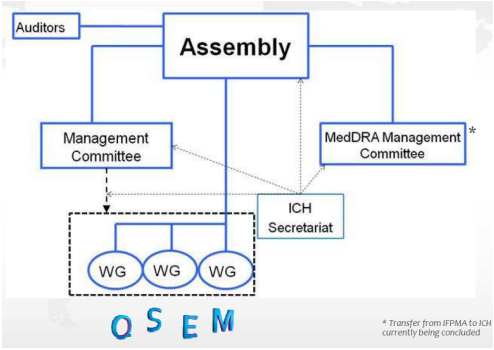
Outline

1. Background
2. Examples of initiatives
3. Latest developments and achievements
   - ☞ Focus on ICH and IPRF
4. Summary

swissmedic

ICH

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- Established as a legal entity (international association based in Geneva, CH)
- Bodies of the association



swissmedic

ICH

Altogether:
- Members 14
- Observers 23

- Opening up to new members and observers
- **New regulatory members**:
  - Agência Nacional de Vigilância Sanitária (ANVISA), Brasil
  - CFDA, China
  - MFDS, South Korea
- **Current observers include**:
  - Southern African Development Community (SADC)
  - Gulf Cooperation Council (GCC)
  - Pan American Network for Drug Regulatory Harmonization (PANDRH)
  - Asia-Pacific Economic Cooperation (APEC)
  - Therapeutic Goods Administration (TGA)
  - …

http://www.ich.org/about/membership.html

swissmedic

ICH

ICH Assembly Meeting, Montréal, Canada, May/June 2017

Adoption of two new ICH topics

- Guideline on **extrapolation of paediatric indications**
- **E8(R1)** General considerations for clinical trials
  ☞ as part of the announced GCP renovation
  (http://www.ich.org/products/gcp-renovation.html)

swissmedic

IPRF

- The IPRF has emerged from the “Regulators Forum” in 2013
- Regulators-only platform, meeting twice a year in the margins of the “ICH week”
- Membership quite extensive
  - Australia (TGA)
  - Brazil (ANVISA)
  - EU (EMA/EU Commission)
  - Canada (Health Canada)
  - Japan (MHLW/PMDA)
  - Korea (MFDS)
  - Mexico (Cofepris)
  - Russia (Roszdravnadzor)
  - Singapore (HSA)
  - Switzerland (Swissmedic)
  - USA (FDA)
  - RHIs
  - WHO (observer)

https://www.i-p-r-f.org/index.php/en/members/

i-p-r-f.org
International Pharmaceutical Regulators Forum

swissmedic

IPRF

The Management Committee (MC) currently oversees the work of five working groups:

- Cell Therapy
- Gene Therapy
- Biosimilars
- Nanomedicines
- IDMP

swissmedic

IPRF

Biosimilars Working Group

- Development of a template for “Public Assessment Summary Information for Biosimilar (PASIB)”
- Development of a “Reflection paper on extrapolation of indications for biosimilars”
  ☞ to be published soon on the IPRF website
- The Biosimilars Working Group has held a workshop with WHO to advance work on developing training material to establish biosimilar comparability

IPRF / IGDRP consolidation

- Principle support by both the IPRF Management Committee and the IGDRP Steering Committee
- Establishment of a joint **Implementation Task Group** (ITG) to consider various governance models for the joint initiative and to work out an implementation plan
- Joint initiative expected to be launched in January 2018
- First joint f2f meeting planned for June 2018

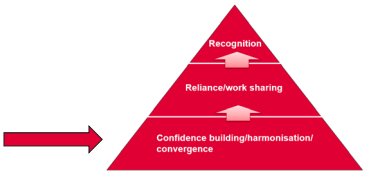
Outline

1. Background
2. Examples of initiatives
3. Latest developments and achievements
4. Summary & Outlook

swissmedic

Summary

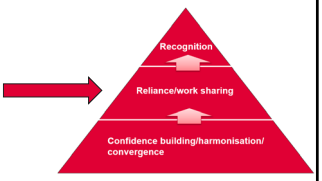
- Initiatives with the focus on harmonisation/convergence are well under way
- Increasing participation from regulators in multilateral/ global initiatives
- Consolidation of initiatives has started to avoid overlap and duplication (IPRF/IGDRP)



swissmedic

Summary

- Increasing number of initiatives focussing on reliance and work sharing *"even the largest agencies cannot do everything themselves"*
- Reliance accepted in the "developed world" (e.g. GMP inspections, sharing of assessment reports)
- WHO increasingly and successfully promotes reliance and work sharing models in developing countries



swissmedic

Interested to read more?

See our article **"Swissmedic emphazises international cooperation"**

https://www.swissmedic.ch/ueber/01398/01401/index.html?lang=en

Forschungsstandort Schweiz braucht unabhängige, kompetente und international anerkannte Heilmittelbehörde

Swissmedic setzt auf internationale Zusammenarbeit

Der Lebenszyklus eines Arzneimittels von der Entwicklung über die Zulassung und Vermarktung bis zur Marktüberwachung ist von nicht zu unterschätzender Komplexität. In der Regel ist dabei heute alles global vernetzt. Will eine kleine Behörde wie Swissmedic mit der rasanten Entwicklung Kopieren halten, ist eine effiziente internationale Zusammenarbeit nötig.

I Peter Balzli und Cordula Landgraf, Swissmedic, Bern, Schweiz

swissmedic

Questions?

Contact Information

Cordula Landgraf
Head of Networking
Swissmedic
Tel.: +41 58 462 0478
E-mail:
networking@swissmedic.ch

swissmedic

List of Abbreviations

- ACSS Australia-Canada-Singapore-Switzerland (“Consortium”)
- AMRH African Medicines Regulatory Harmonisation
- ANVISA Brazilian Health Surveillance Agency
- APEC Asia-Pacific Economic Cooperation
- ASEAN Association of Southeast Asian Nations
- BfArM Federal Institute for Drugs and Medical Devices
- BMGF Bill & Melinda Gates Foundation
- CBER Centre for Biologics Evaluation and Research
- CFDA China Food and Drug Administration
- EAC East African Community
- EAC MRH EAC Medicines Regulatory Harmonisation
- EDQM European Directorate for the Quality of Medicines and Healthcare
- EMA European Medicines Agency
- EU European Union
- GCC Gulf Cooperation Council
- GRP Good Regulatory Practices
- HPFB Health Products and Food Branch
- HPRA Health Products Regulatory Authority
- HSA Health Sciences Authority
- ICH International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
- ICDRA International Conference of Drug Regulatory Authorities
- ICMRA International Coalition of Medicines Regulatory Authorities
- IDMP Identification of a Medicinal Product
- IPRF International Pharmaceutical Regulators Forum
- IGDRP International Generic Drug Regulators Programme
- IMDRF International Medical Device Regulators Forum
- MCC Medicines Control Council, has transitioned into the South African Health Products Regulatory Authority
- MFDS Ministry of Food and Drug Safety
- MHLW Ministry of Health, Labour and Welfare
- MOH Ministry of Health
- MoU Memorandum of Understanding
- OECD Organisation for Economic Co-operation and Development
- PANDRH Pan-American Network for Regulatory Harmonisation
- PEI Paul Ehrlich Institute
- PIC/S Pharmaceutical Inspections Cooperation Scheme
- PMDA Pharmaceuticals and Medical Devices Agency
- REC Regional Economic Community
- RHI Regional Harmonisation Initiative
- TGA Therapeutic Goods Administration
- US-FDA United States Food and Drug Administration
- VICH International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
- WHO World Health Organisation
- ZAZIBONA Zambia-Zimbabwe-Botswana-Namibia (Collaborative medicines registration process)