How Swissmedic uses concepts of reliance – experiences

Dr. Petra Doerr

Director, Petra Doerr Consulting GmbH

Former Deputy Executive Director, Swissmedic

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Outline

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Outline

Introduction

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Definition of reliance

Reliance: the act whereby the regulatory authority in one jurisdiction may **take into account and give significant weight to** – i.e., totally or partially rely upon – **evaluations performed by another regulatory authority** or trusted institution **in reaching its own decision**. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

Definitions are taken from the WHO draft GRP Guideline: http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodRegulatory_PracticesPublicConsult.pdf?ua=1

Introduction

Definition of work-sharing

Work-sharing: a process by which regulatory authorities of a number of jurisdictions share activities. Work-sharing entails exchange of information consistent with the provisions of existing agreements and compliant with each agency's or institution's legislative framework for sharing such information with other regulatory authorities. Other opportunities for work-sharing include **jointly assessing applications for marketing authorizations or therapeutic product manufacturing sites, joint work in the post-marketing surveillance** of therapeutic product safety, **joint development of technical guidelines or regulatory standards**, and collaboration on information technology.

Introduction

- Pre-requisites for reliance
- Equivalence of requirements based on international standards
- Application of good regulatory and/or good review practices
- Availability of assessment or inspection reports
- Confidence building → trust

Introduction

IPRP survey on reliance

- A survey was developed by the World Health Organization (WHO) and conducted among IPRP parties on their experiences, challenges, perceived benefits and opportunities of reliance.
- Respondents: ANVISA, US FDA, Health Canada, HSA, MHLW/PMDA, Swissmedic, TFDA (CT), TGA, EU (EC/EMA), CECMED, COFEPRIS, MEDSAFE, Roszdravnadzor, TITCK
- The IPRP Management Committee discussed the outcome of the survey in June 2019 and agreed to continue discussion at its next meeting in November 2019 with a focus on key considerations for reliance.

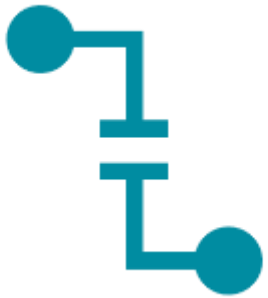
http://www.iprp.global/news/outcome-who-survey-reliance

Introduction

- IPRP survey on reliance

1. Does your agency practice reliance?
2. The WHO has developed definitions for reliance and recognition. Should other terms also be defined?
3. Please provide examples of reliance undertaken by your agency or by other agencies to your agency. Describe impact and outcomes.
4. Which authorities and institutions serve as a reference for reliance for your agency? Why were they chosen?
5. What are the key lessons learned to date in the use of regulatory reliance?
6. Why do you practice reliance? Has the use of reliance by your agency had the desired outcome?
7. What have been the main challenges and areas for improvement?
8. What do you see as the greatest future opportunities for reliance?
9. Do you have any further suggestions or comments on the subject of reliance?

Outline



The Swissmedic approach to reliance

The Swissmedic approach to reliance

- Swissmedic in the national context
  - Swissmedic: a “small and medium sized agency” (360 FTE; budget: 95 Mio. CHF)
  - Mature system for the regulation of therapeutic products, applying international standards
  - Well-established international network and active involvement in international initiatives
  - Switzerland is a major location for research-based pharmaceutical and medical device industry; exports in pharmaceuticals: 88.3 Bio. CHF (2018, 38% of all Swiss exports)

The Swissmedic approach to reliance

- Legal basis for reliance
  - Political/strategic approach: Article 13 Therapeutic Products Act
  - “If a medicinal product or procedure is already **authorised in a country having equivalent medicinal product control**, the **results of tests (= assessments)** carried out for this purpose **shall be taken into account**.”

The Swissmedic approach to reliance

- Marketing Authorisation
  - Applications for **innovative medicinal products**
  - For applications for approval of a drug with a new active substance or its line extensions (e.g. new indications) Swissmedic **conducts a comprehensive scientific assessment**.

= **Prioritization**

The Swissmedic approach to reliance

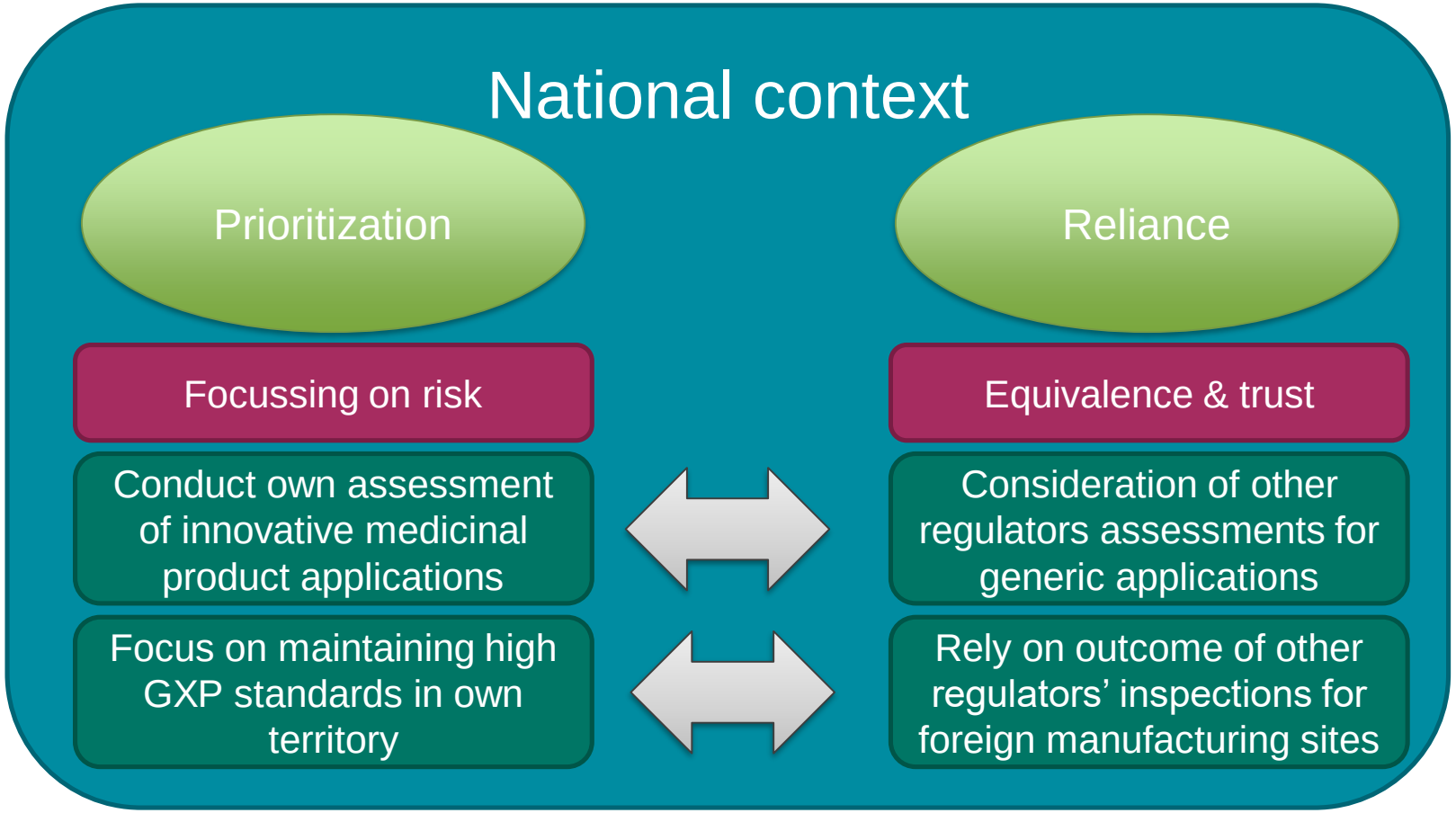
- Marketing Authorisation
  - Applications for **non-innovative medicinal products**
  - Swissmedic **should consider assessments of regulatory authorities with an equivalent control system**, such as e.g. the European Medicines Agency (EMA), the US-Food and Drug Administration (US-FDA), etc.

= **Reliance**

The Swissmedic approach to reliance

- GXP Inspections
  - Prioritization of inspections of facilities in Switzerland:
    - Ensure a high standard of GXP in the territory.
    - Inspection frequency is based on previous performance of facility and on “complexity” (risk) of manufacturing processes performed at the site. = Risk-based approach
  - Reliance on inspections of foreign regulatory authorities (MRA partners, PIC/S members)

Swissmedic approach



Outline

Work-sharing in the ACSS Consortium

Work-sharing in the ACSS Consortium

- The Australia, Canada, Singapore, Switzerland (ACSS) Consortium
  - Members:
    - Therapeutic Goods Administration, **A**ustralia
    - Health **C**anada
    - Health Sciences Authority, **S**ingapore
    - Swissmedic, **S**witzerland
  - Established in 2007
  - Focused on work-sharing from the beginning

[Swissmedic - ACSS Consortium]

Work-sharing in the ACSS Consortium

- Purpose
  - Build synergies and result in improved health and safety benefits as a consequence of enhanced effectiveness and efficiency of domestic regulatory systems and the interface between each.
  - Capitalize on each country's area of strength, address gaps in science, knowledge, and expertise and leverage resources to help expedite risk assessment processes while maintaining or raising quality and safety standards.

Work-sharing in the ACSS Consortium

Objectives

- To provide an **effective and efficient** alternative to participating regulators working independently on similar scientific and regulatory work.
- To enable participating regulators to **draw on the very best scientific and technical data, information, expertise and resources** from around the world to better inform regulatory decisions including risk assessments, along the product lifecycle.
- To improve each participant's **effectiveness and efficiency** as a regulator by providing a framework for identifying work-sharing opportunities, facilitating action and achieving tangible results.
- To provide participating regulators with a mechanism to **share** with other regulatory authorities their **unique knowledge in specific scientific areas**, i.e., compliance and enforcement and post-market surveillance, as well as best practices thereby making a significant contribution to addressing global health and safety issues.
- To create or complement existing communication networks and an **increased dialogue and understanding** of the basis of scientific advice between regulators and decision makers throughout the lifecycle of products.
- To **explore new initiatives and concepts**.

Work-sharing in the ACSS Consortium

- Ongoing work/projects
  - Work-sharing in the assessment of generic medicines
  - Work-sharing/reliance in the assessment of biosimilars (exploration/confidence building)
  - Work-sharing in the assessment of new chemical entities
  - Work-sharing in the assessment of safety and efficacy of complementary health products
  - Exchange on current challenges and projects in the area of information technology

Work-sharing in the ACSS Consortium

- Achievements
  - Confidence and trust built over the years.
  - Processes aligned and tools developed to facilitate work-sharing.
  - Successful completion of Generic Medicines Work-Sharing Trial (GMWST)
  - First approval of a New Chemical Entity (apalutamide; ERLYAND in Australia and ERLEADA in Canada)

https://www.tga.gov.au/media-release/international-work-sharing-pilot-apalutamide-erlyand

https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices/notice-erleada.html

Outline

Summary & Conclusion

Summary & Conclusion

- Reliance and work-sharing approaches at Swissmedic are based on legislative provisions and a strategic approach.
- Reliance and work-sharing require equivalence of requirements, based on international standards - and trust.
- Building of confidence to establish trust takes time as it requires a change in the approach of reviewers or inspectors (“cultural change”).
- Reliance and work-sharing allow focusing of resources on prioritized activities (maximization of public health impact).
- “Reliance is not a sign of weakness – reliance is smart!”

List of abbreviations (in alphabetical order)

ACSS	Australia-Canada-Singapore-Switzerland Consortium
ANVISA	Brazilian Health Surveillance Agency
CECMED	Regulatory Authority for Medicines and Medical Devices, Cuba
CHF	Swiss Frank (Swiss currency)
COFEPRIS	Federal Commission for the Protection against Sanitary Risk, Mexico
CT	Chinese Taipei
EC	European Commission
EMA	European Medicines Agency
EU	European Union
FTE	Full-time Equivalent
GRP	Good Regulatory Practices
GXP	Good Practices in the (includes e.g. GDC, GLP, GMP)
HSA	Health Sciences Authority, Singapore
IPRP	International Pharmaceutical Regulators Programme
Medsafe	New Zealand Medicines and Medical Devices Safety Agency
MHLW	Ministry of Health, Labour and Welfare, Japan
MRA	Mutual Recognition Agreement
PAHO	Pan-American Health Organisation
PANDRH	Pan-American Network for Regulatory Harmonisation
PIC/S	Pharmaceutical Inspections Cooperation Scheme
Roszdravnadzor	Federal Service on Surveillance in Healthcare, Russia
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration, Australia
TİTCK	Turkish Medicines and Medical Devices Agency
US-FDA	United States Food and Drug Administration
WHO	World Health Organisation