swissmedic

Swissmedic IDMP Advisory Group Meeting

13.03.2024

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern
www.swissmedic.ch

Agenda Items

Topic	Lead	Duration	Starting Time
Welcome coffee			13:30
Introduction	S. Järmann	15’	14:00
IDMP initiatives in Switzerland • SAI IDMP User Group • Project ePL (FOPH) • TSP (Swissmedic)	 M. Müller F. Sendfeld R. Rüegg	20’	14:15
Swissmedic’s approach • First implementation packages • KPA notification procedure (IDMP basic features) • Connections to eCTD 4.0, ePI, Accumulus, CTIS	 R. Rüegg M. Ziak S. Järmann	20’	14:35
Swissmedic IDMP implementation: current status • Update IDMP data model Swissmedic • Data model FOPH • Update data exchange pilot	 R. Güttinger C. Kravogel U. Eugster	45’	14:55
Break		*20’*	*15:40*
Discussion • Stakeholder involvement and further exchanges • Open questions	all	45’	16:00
Next steps	S. Järmann	15’	16:45

Agenda

Introduction

IDMP Initiatives in Switzerland

Swissmedic’s Approach

Swissmedic IDMP Implementation: Current Status

Discussion

Next Steps

Welcome!

Stakeholder representatives

Markus Müller, Astellas

Jean-Michel Cahen, Novartis

Quentin Darrasse, Roche

Deborah Cooper, MSD

Jean-Gonzague Fontaine, GSK

Enea Rosselli, Zambon Group

Frits Stulp, Deloitte

Nicolas Florin, RefData

Christian Kravogel, SeicoDyne

Franziska Sendfeld, BAG

Mirco Cassina, BAG

Swissmedic representatives

Roger Rüegg, Program Lead TSP

Martin Ziak, Business Owner TSP

Urs Niggli, Business Owner TSP

Philipp Weyermann, Business Owner TSP

Simon Dalla Torre, Business Owner TSP

Urs Eugster, IDMP Expert TSP

Robin Güttinger, IDMP Expert TSP

Maren Eschermann, EA / Data Architect TSP

Stephan Järmann, Int. Standards Expert TSP (Moderation)

Excused

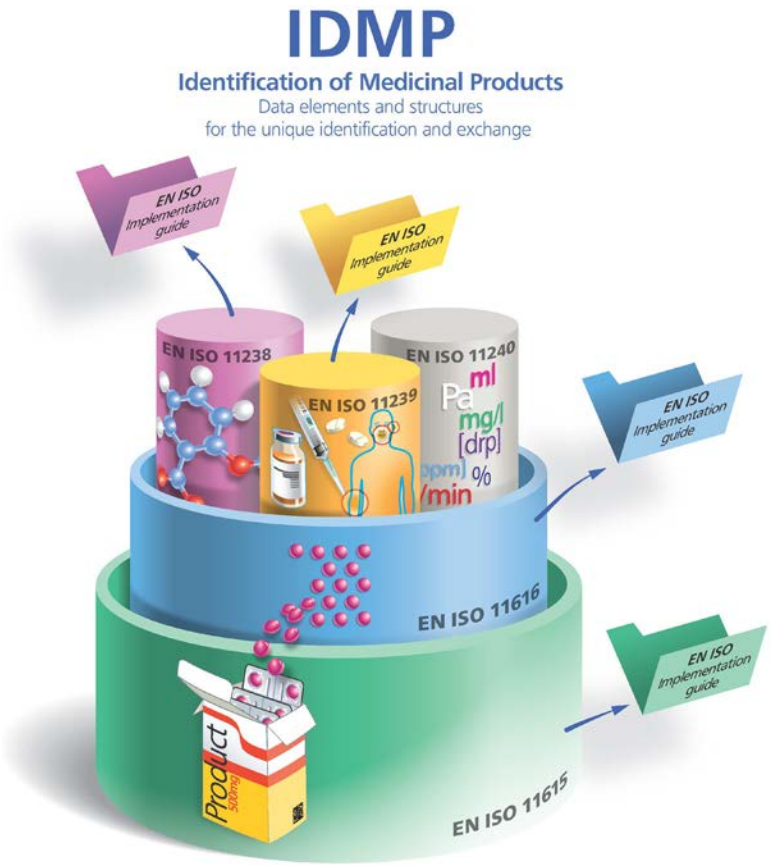
Marcel Burger, Novartis

Omar Tizgui, MSD

Introduction

Please introduce yourself briefly
(name, organization, role)

What do you expect to gain from the workshop?



Goals of the meeting

1. Provide an overview of current IDMP initiatives in Switzerland
2. Update on Swissmedic's progress and answer questions
3. Discuss stakeholder collaboration and engagement
4. Define next steps for future exchange and communication

Agenda

Introduction

IDMP Initiatives in Switzerland

Swissmedic’s Approach

Swissmedic IDMP Implementation: Current Status

Discussion

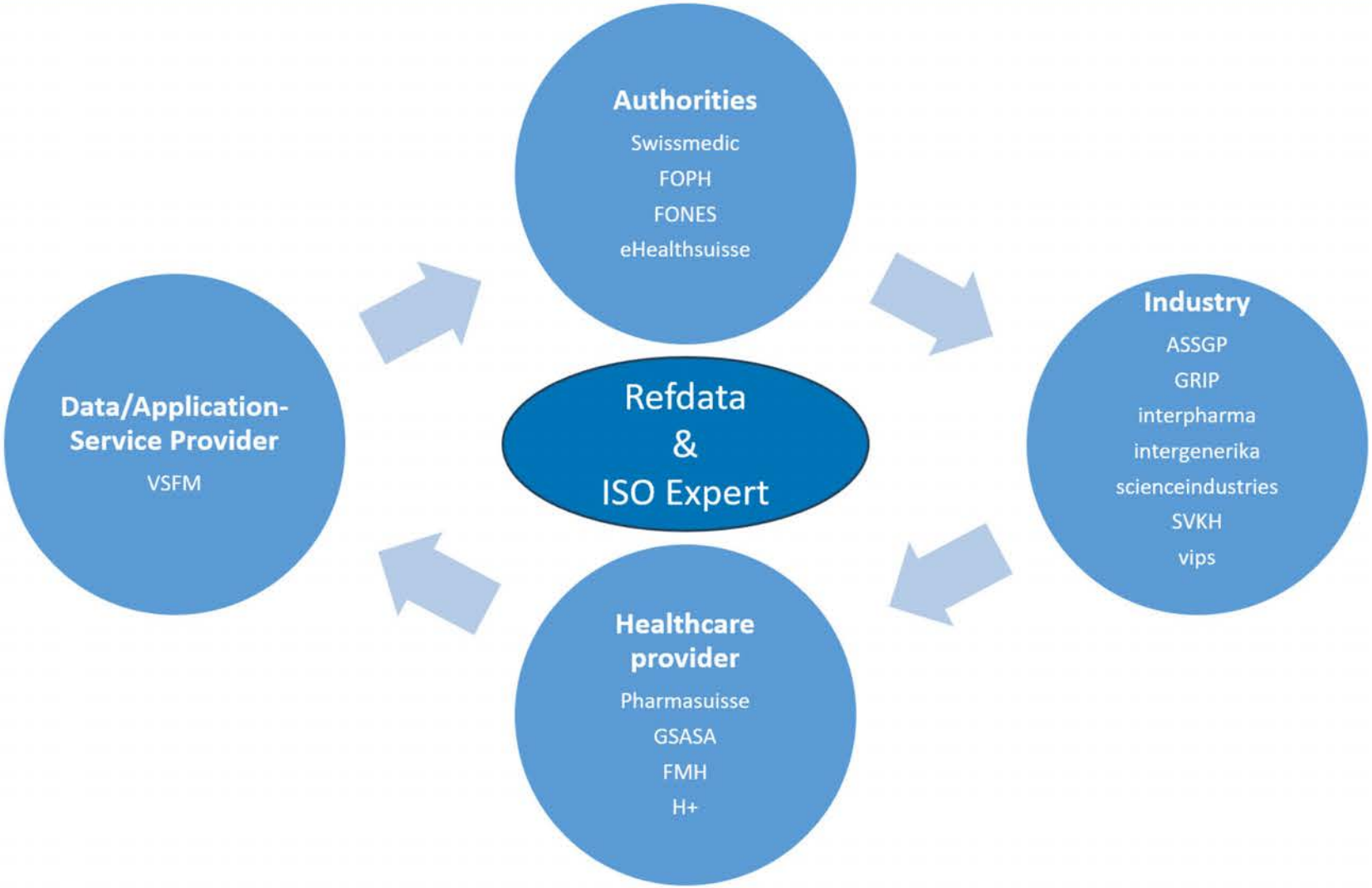
Next Steps

SAI-IDMP User Group

Swissmedic Advisory Group Meeting

March 13th, 2024

25 Stakeholders and Experts at one table

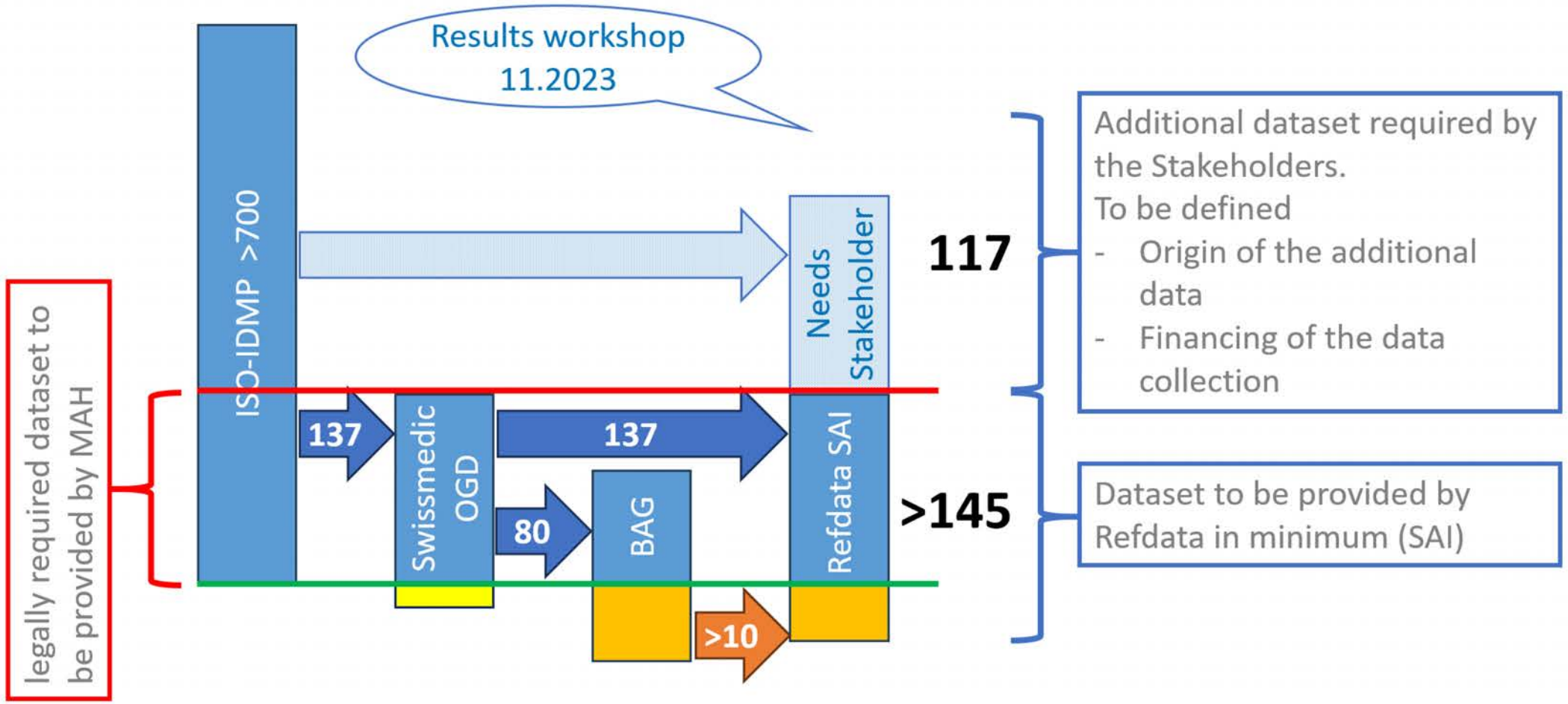


Goals of the SAI/IDMP User Group

- Bring all those affected up to date with the latest information.
- Contribute information from domestic and foreign experts.
- Clarification and discussion of specific questions from practice, such as
  - Development of legal requirements in Switzerland and the EU
  - Useful tools such as DMS/CMS, RMS, eCTD, data sources, etc.
  - Use of FHIR (HL7) as IDMP transmission standard
- Exchange of experiences between the participants, e.g.
  - Project planning and prerequisites for the introduction of IDMP
  - Information on current projects of the participating companies
- continuously meet the expectations of those affected.
- Development needs of the SAI platform.

Ensure that Switzerland does not have isolated solutions, but is in line with the EU and global developments in standards.

Current discussions



Contact

SAI/IDMP User Group

Markus Müller
Chairman
SAI/IDMPU User Group
markus.mueller@astellas.com

Christian Kravogel
ISO-IDMP Expert
SeicoDyne GmbH
christian.kravogel@seicodyne.com

Nicolas Florin
Managing Director
Sitftung Refdata
nicolas.florin@smvo.ch

Stiftung Refdata
Baarerstrasse 2
6300 Zug
office@smvo.ch
www.smvo.ch

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG

Electronic platform for reimbursements (ePL)

Wednesday, 13 March 2024

Electronic platform for reimbursements (ePL) in a Nutshell (1)

Specialities list: list of medicines covered by the compulsory health insurance
Additions to specialities list: application process
Triennial review: review of listing requirements every three years
List of medical devices: list of medical devices covered by the compulsory health insurance

Starting point

- Specialities list: electronic; excel and XML, end of life
- List of medical devices: pdf and excel
- Triennial Review: internet application
- Application for listing: E-Mail, mail, file-transfer
- The FOPH's strategic efforts to digitize processes

Electronic platform for reimbursements (ePL) in a Nutshell (2)

Strategy

- Electronic platform for reimbursements (ePL): current and future lists
- New listings: from receipt of application to publication of the decision
- Triennial review
- Review after patent expiry
- Administrative changes
- voluntary price reductions etc.

-> Control of all speciality list processes via the new platform

Vision functionality

Processes and Userinterface

- Uniform view of the status of products on the specialities list in a central platform
- Standardisation of procedures and data (listing and triennial review)
- The revised web view of the specialities list: modern filters and search functions
- Query of historical data

Data standardisation and reference

- Data security is the foundation
- Data is based on the IDMP standard (IDMP: Identification of Medicinal Products)
- Obtaining standardised data from specialities list via technical interface (API)
- Data is made available via FHIR interface (FHIR: Fast Healthcare Interoperability Resource)

swissmedic

TSP – Transformation of Swissmedic Platforms

Digitalisation Initiative of Swissmedic

Roger Rüegg, Program Lead

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern
www.swissmedic.ch

Strategic Goals of Swissmedic 2023 – 2026

#	Strategische Ziele
GA2	Swissmedic has intensified its supervisory and monitoring activities in the therapeutic products market.
S1	Swissmedic is known to the public as a trustworthy authority.
S2	Swissmedic works together with other authorities and medical experts in a targeted manner.
S3	Swissmedic supports the development of novel therapeutic products and contributes to rapid access to innovative therapies.
P1	Swissmedic implements Swiss medical device regulation in an international network.
P2	Swissmedic uses state-of-the-art digital technologies.
M1	Swissmedic is an agile and data-centered authority.

Our Digitalisation Vision as part of our strategic goals

M1: Swissmedic is an agile and data-centered authority	P2: Swissmedic uses state-of-the-art digital technologies
In 2026, Swissmedic will be able to… Swissmedic is in a position to work internally with the therapeutic products industry and other authorities in a data-centered, secure and protected manner across borders (focus on data). Swissmedic works faster and leaner internally in the long term (focus on people and processes).	In 2026, Swissmedic will be able to… The development and secure, stable operation of new data-centered systems supports efficient and effective work at Swissmedic.

TSP

Data Strategy

TSP

Vision: The modern platforms are the basis of the digitalized "Leading Agency Swissmedic" and thus make a decisive contribution to the efficiency of Swissmedic and Swiss patient safety.

The Mission of TSP

Target Solution

The new Swissmedic portal replaces the current SAP CRM and other applications/platforms. The relevant processes and data have been optimized.
The new working environment for our internal staff and external partners is characterized by standardised data, user-friendliness and process and media consistency.

Collaboration

The external partners play an active role in data entry and maintenance.
Applications or enquiries can be processed more quickly, securely and effectively thanks to data availability and analysis options (with AI).

Mindset & Skills

Interdisciplinary teams share responsibility for the successful functional and technical design, development and replacement of systems and processes.
Cooperation with internal and external stakeholders and users is characterized by openness, respect and flexibility.
Swissmedic employees have the necessary technical, methodological and personal skills.

Swissmedic Data Strategy

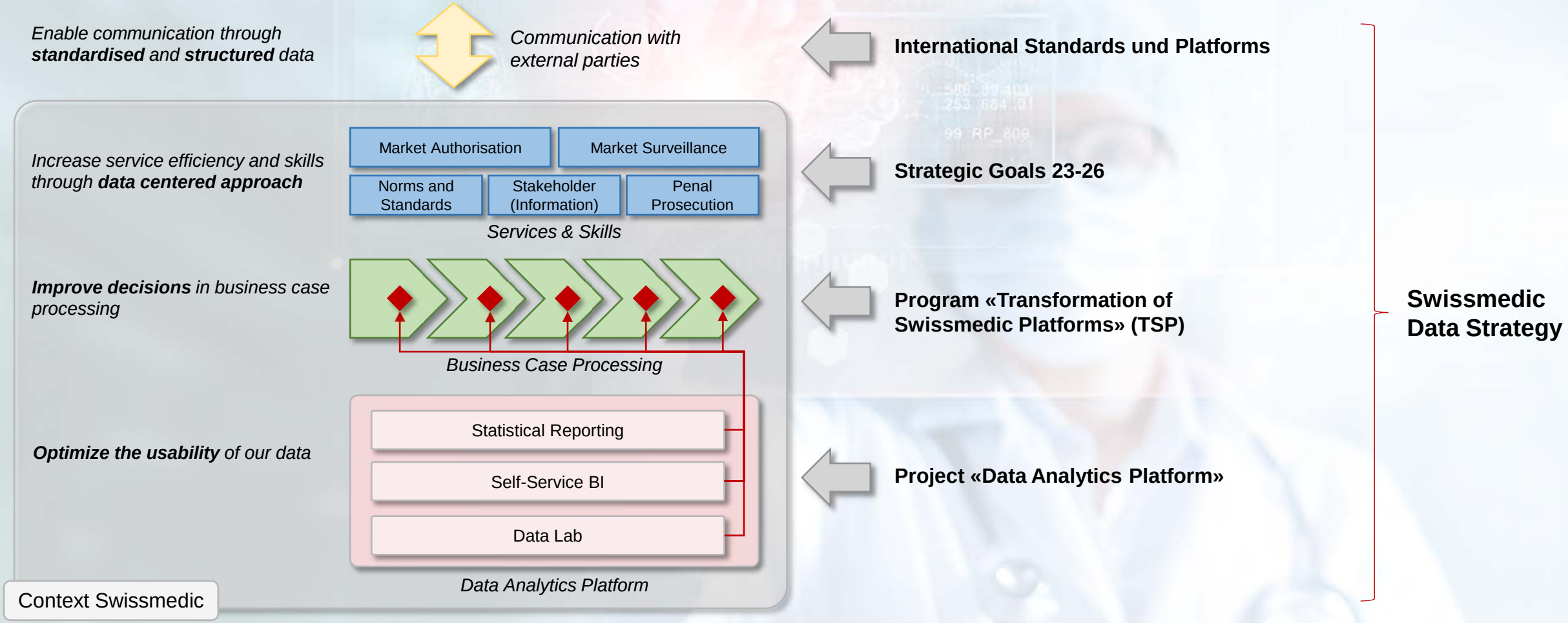
Our way to a data-centred agency

We want to be able to make well-founded decisions on the basis of our data and make the best possible use of supporting evaluations and analyses for our business case processing

We want to create the basis for working with our data securely and in compliance with data protection regulations

We operate between the poles of regulation, data protection, information security and innovation

Big Picture


Enable communication through **standardised** and **structured** data
Communication with external parties
International Standards und Platforms
Increase service efficiency and skills through **data centered approach**
Market Authorisation
Market Surveillance
Norms and Standards
Stakeholder (Information)
Penal Prosecution
Services & Skills
Strategic Goals 23-26
Improve decisions in business case processing
Business Case Processing
Program «Transformation of Swissmedic Platforms» (TSP)
Swissmedic Data Strategy
Optimize the usability of our data
Statistical Reporting
Self-Service BI
Data Lab
Data Analytics Platform
Project «Data Analytics Platform»
Context Swissmedic

Strategic directions for implementation

Organisation, Culture, Employees, Skills

- Data Literacy
- Organisational Model

Gradual establishment of a data organization with the corresponding roles and an organizational model suitable for Swissmedic (Hub&Spoke)

Identification of resources and skills development in the business areas and IT

External Stakeholder, Standards

- International Standards

Establishment of a standards support group to coordinate the international development of standards and developments within SMC (in particular TSP)

Data Governance, Data Protection, Information Security

- Data Protection Regulations
- Information Security
- Data Governance Principles

Establishment of data governance based on the structure of business objects

Data Architecture

- Structured and Unstructured Data
- Seamless Information Flow

Establishment of a data architecture and development of a new (specialized) Swissmedic data model

Data Management, Archiving

- Historisation of Data
- Data Quality and Data Availability
- Regulatory Requirements for Archiving

Establishment of data management principles and R&R

Analytics and AI

- Data Platform
- Analytic - Governance

Development of a data analytics platform as a core element for improving the analyzability of our data and AI use cases

Agenda

Introduction

IDMP Initiatives in Switzerland

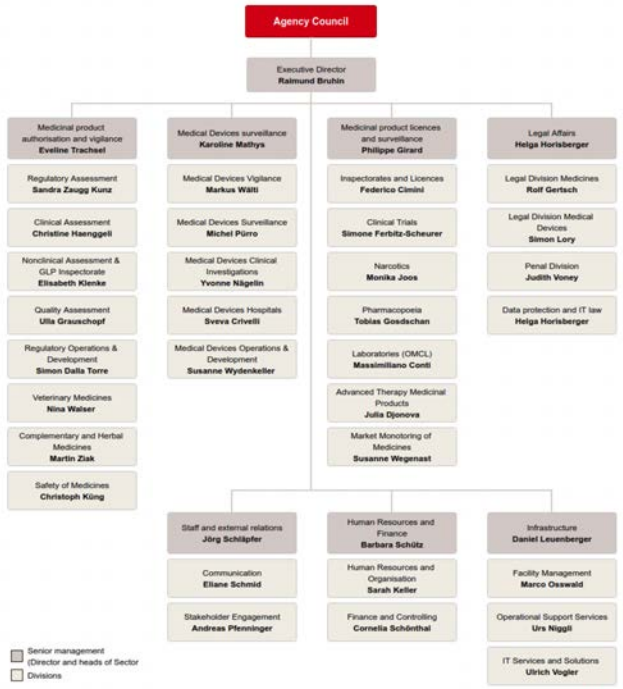
Swissmedic’s Approach

Swissmedic IDMP Implementation: Current Status

Discussion

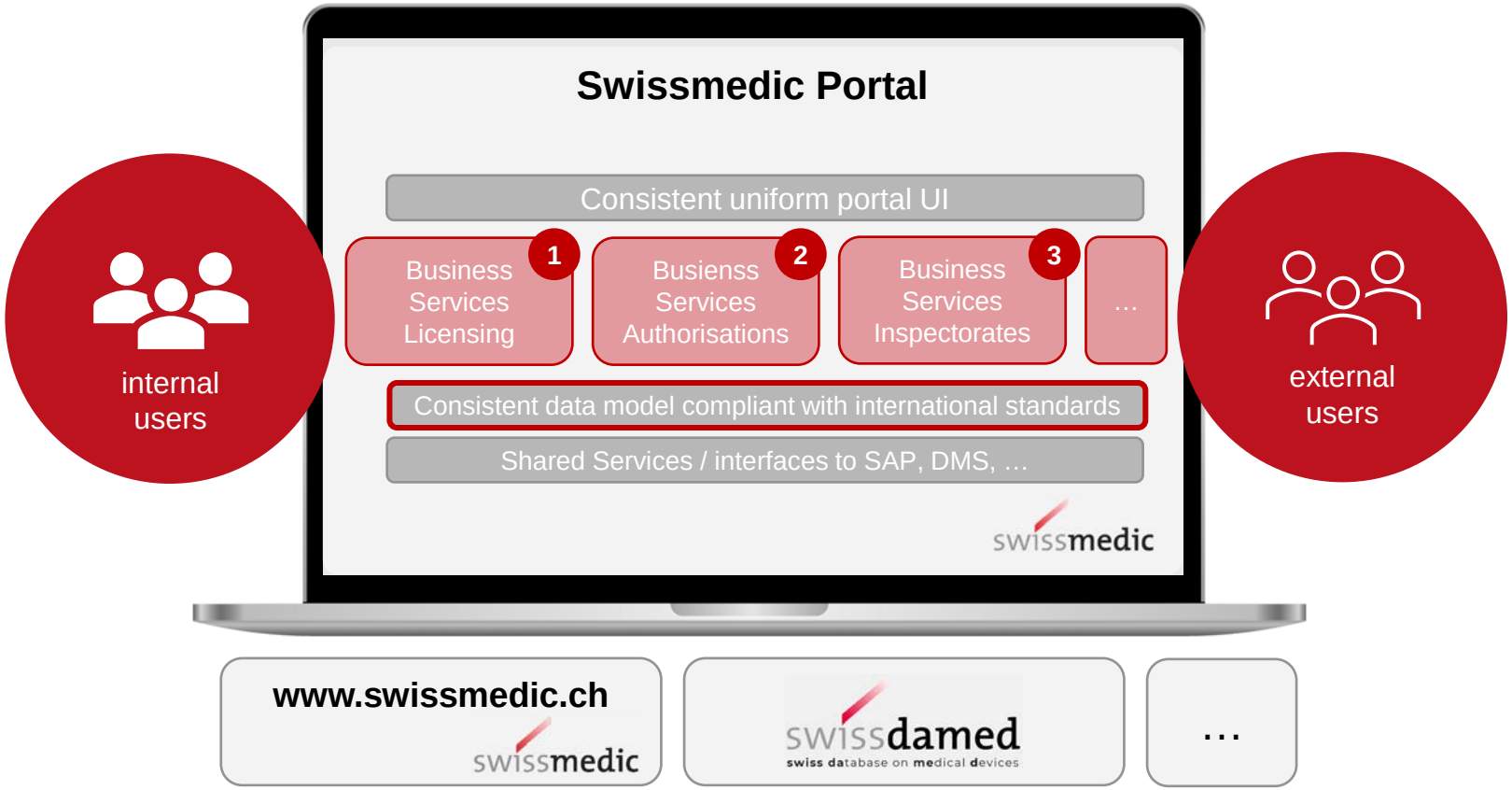
Next Steps

Portal architecture / high-level concept



Lifecycle of medicines

Lifecycle of medical devices

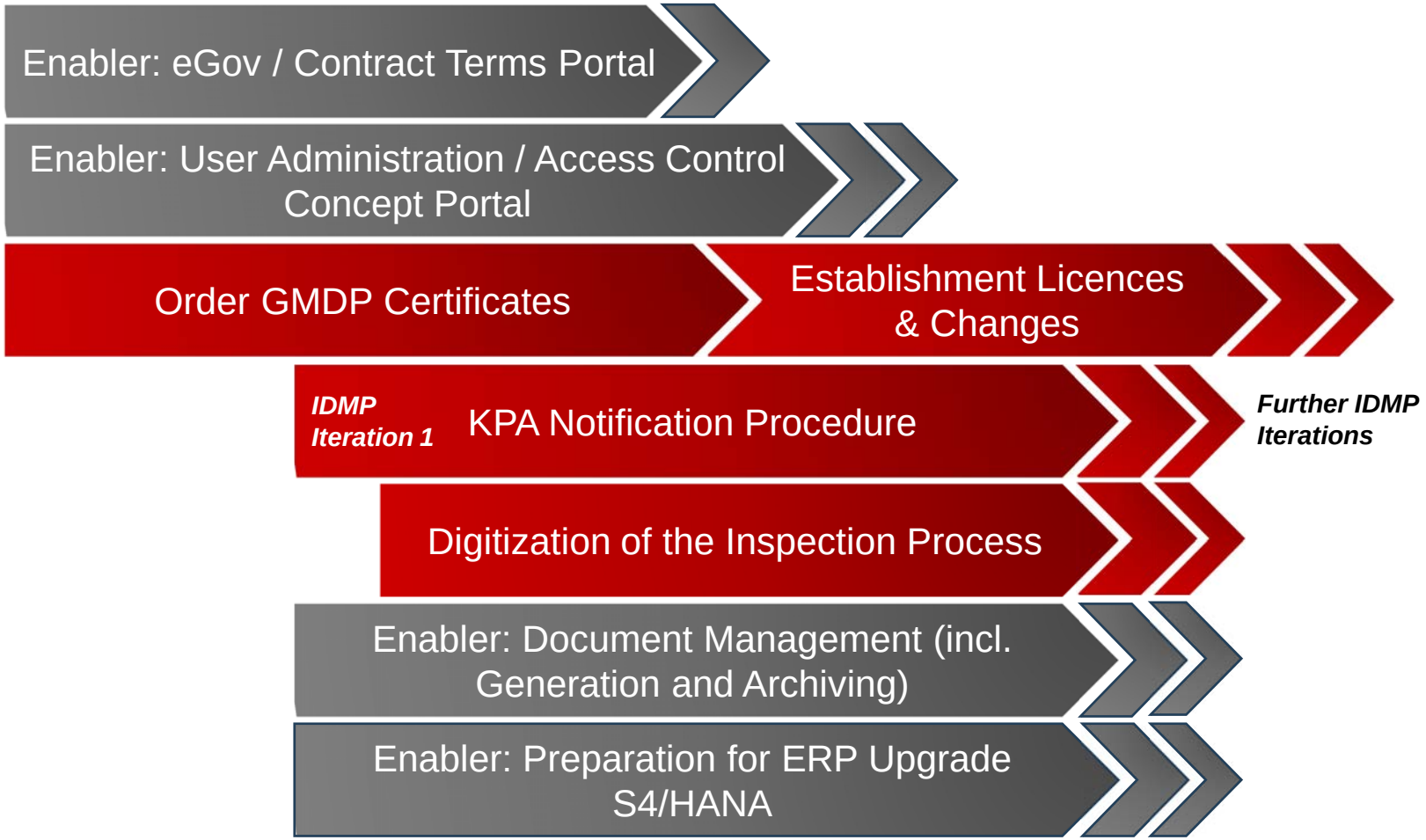


Harmonized coexistence of Swissmedic's platforms in the interaction with our external stakeholders / customers

Program Roadmap 2024

Business functions & features

Enabler for business functions and features



Further topics 2024

- *User Interaction Concept*
- *Audit Trail*
- *Signatures*
- *Regulatory Data*
- *Business partners*

Swissmedic organisation chart

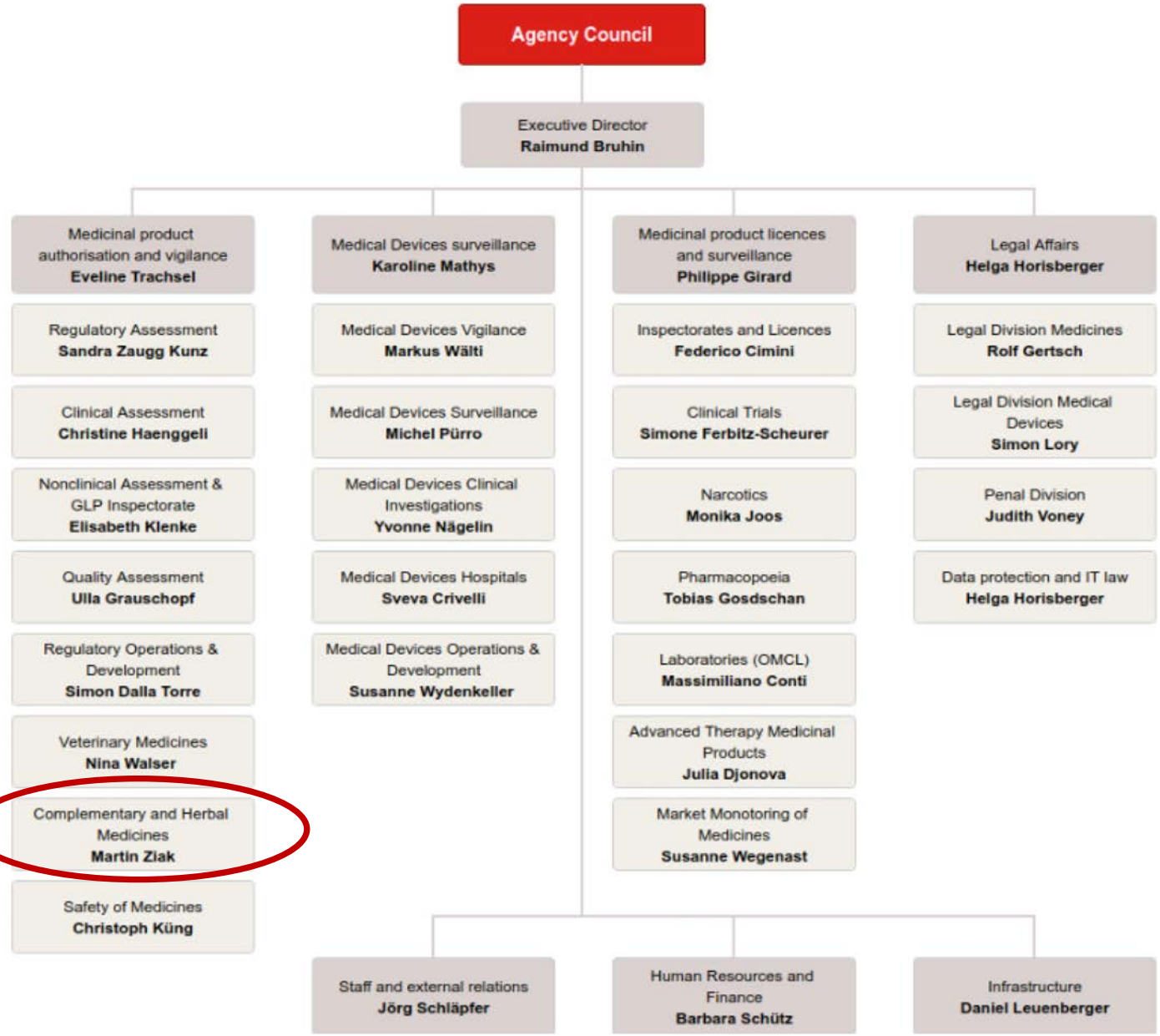
(status as of March 2024)

- Link on full view

Senior management (Director and heads of Sector

Divisions

Division Complementary and Herbal Medicines **Martin Ziak**



Medicinal products: Authorisations by type of product *

Medicinal products

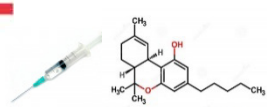
Complementary

Herbal

Simplified authorisation

Noti-fication

Number of authorisations by type of product	2022	2021
Human medicinal products	**5,765**	**5,756**
.....		
Complementary and herbal medicines	**12,273**	**12,302**
Phytopharmaceuticals	413	434
Homeopathics	606	617
Anthroposophics	355	368
Ayurvedic medicinal products	1	1
Tibetan medicinal products	5	7
Other alternative treatments	5	5
Homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication	10,868	10,870
Chinese medicines with no indication	20	0



*Swissmedic Annual Report

TransformationSwissmedicPlattform: KPA Notification procedure «VISION»

- **ONE process - ONE system**
  Integration of the notification procedure into the existing authorisation business processes at Swissmedic. These are standardised in the new Swissmedic Portal.
- **No media discontinuities** in data collection and assessment -> increased efficiency
- **Plausibility check and automation by the system**, i.e. only complex applications need to be processed by the assessor. -> Added value generated through focusing
- Elimination of separate programme support by IT and specialist departments -> **saving resources**
- **Common, standardised (IDMP) databases** facilitate maintenance, communication and queries
- **User-friendly, guided application** for internal and external users

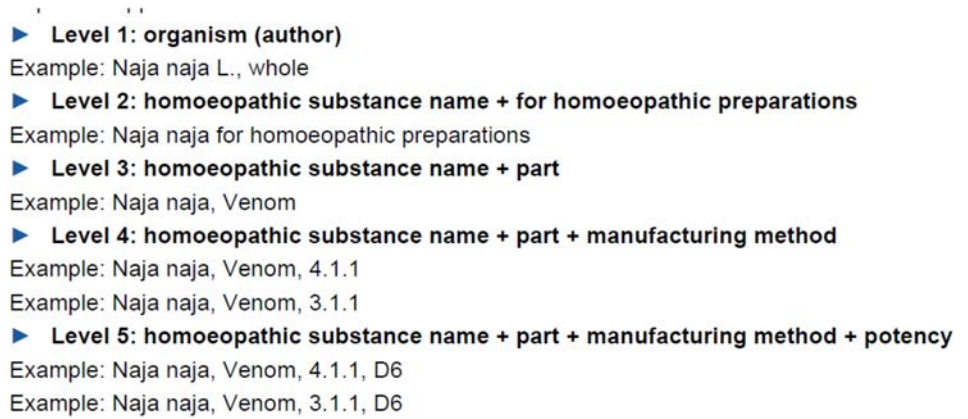
KPA: IDMP International Guides

- Homeopathics:
  EU-SRS Homoeopathics guide, version 1.0

- Herbals: Guide draft version in preparation.

- No IDMP guides for Traditional Chinese Medicine, Ayurveda,….

➢IDMP International Guides will be considered if possible and if available



Connections to eCTD 4.0, ePI, Accumulus and CTIS

eCTD 4.0

- Swissmedic plans to implement eCTD 4.0 in coordination with the EU timelines (fast follower).
- There is an overlap of information in the eCTD and IDMP. In particular, the information in the forms will contain a lot of IDMP data in the future.
- With the introduction of the electronic application form (eAF) harmonised with the IDMP, Swissmedic will examine how to deal with the redundancies.

Conclusions

- A reduction in the scope of Module 1 eCTD is being considered.
- A reduction of Module 3 eCTD is not foreseen at the moment. → M4Q(R2) ICH

Please check for updates: eCTD v4.0 (swissmedic.ch)

Connections to eCTD 4.0, ePI, Accumulus and CTIS

Accumulus (Regulatory Cloud Platform)

- Swissmedic is in contact with Accumulus and we observe the development of the platform.
- If the Accumulus platform would be selected for Project Orbis or Access, Swissmedic would use the platform as well.

Insights from the discussions with Accumulus

- Opportunity for regulatory innovation (exchange on the level of regulatory activities)
- 3rd party cloud application: thorough audit needed for productive use
- Focus on features like co-working between agencies and handling of questions
- IDMP not in focus yet

Connections to eCTD 4.0, ePI, Accumulus and CTIS

Electronic product information (ePI)

- Swissmedic is monitoring developments in the EU
- We have not yet clarified how such a solution can be legally introduced
- Technical implementation of the standard still needs to be evaluated (based on EU standard?)

Clinical Trials Information System (CTIS)

- Swissmedic does not participate in CTIS (data standard: BASEC of swissethics.ch)
- Submission of clinical trials is a TSP topic, but not an IDMP topic
- Investigational Medicinal Product and new substances are not yet part of IDMP data model v1, but will be considered at a later date

Agenda

Introduction

IDMP Initiatives in Switzerland

Swissmedic’s Approach

Swissmedic IDMP Implementation: Current Status

Discussion

Next Steps

Update IDMP Data Model Swissmedic

Achievements

Swissmedic IDMP Data Model:

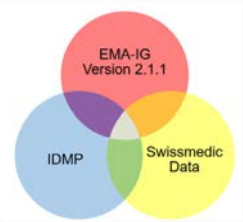
- Developed an internal SMC data model based on the 5 ISO IDMP-standards
- Challenged the current data model on internal and external business value
- Prioritized the interoperability of the data model and FHIR structure

Additional data fields*:

- Special Measures (PSUR)
- Physical Characteristics (Scoring)

Data fields not collected*:

- Name Parts
- Risk of supply shortage



*subject to change, not exhaustive

Controlled Vocabularies:

- 17 Swissmedic specific lists, e.g.:
  - *Medicinal Product Category* is more detailed than EMA
  - *Regulatory Authorisation Type* and *Procedure Type* have a different legal basis
  - *Scoring* is an additional list not used by EMA

➢ By building the **new Swissmedic data model** on the basis of ISO IDMP, a **foundation for global interoperability** between health authorities and other institution is formed.

Update IDMP Data Model Swissmedic

Current Focus

Granularity of Quality data

- Assess data scope for Packaged Medicinal Products, Shelf Life, Storage, Manufactured Item

Specified Substances

- Define data structure based on EU-SRS Homoeopathics guide
- Assess migration rules to new data structure

- **Level 1: organism (author)**

Example: Naja naja L., whole

- **Level 2: homoeopathic substance name + for homoeopathic preparations**

Example: Naja naja for homoeopathic preparations

- **Level 3: homoeopathic substance name + part**

Example: Naja naja, Venom

- **Level 4: homoeopathic substance name + part + manufacturing method**

Example: Naja naja, Venom, 4.1.1

Example: Naja naja, Venom, 3.1.1

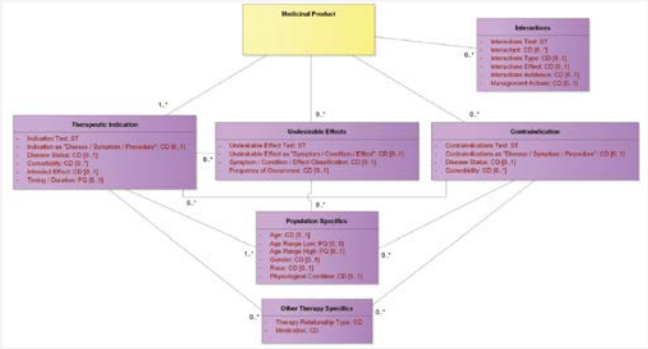
- **Level 5: homoeopathic substance name + part + manufacturing method + potency**

Example: Naja naja, Venom, 4.1.1, D6

Example: Naja naja, Venom, 3.1.1, D6

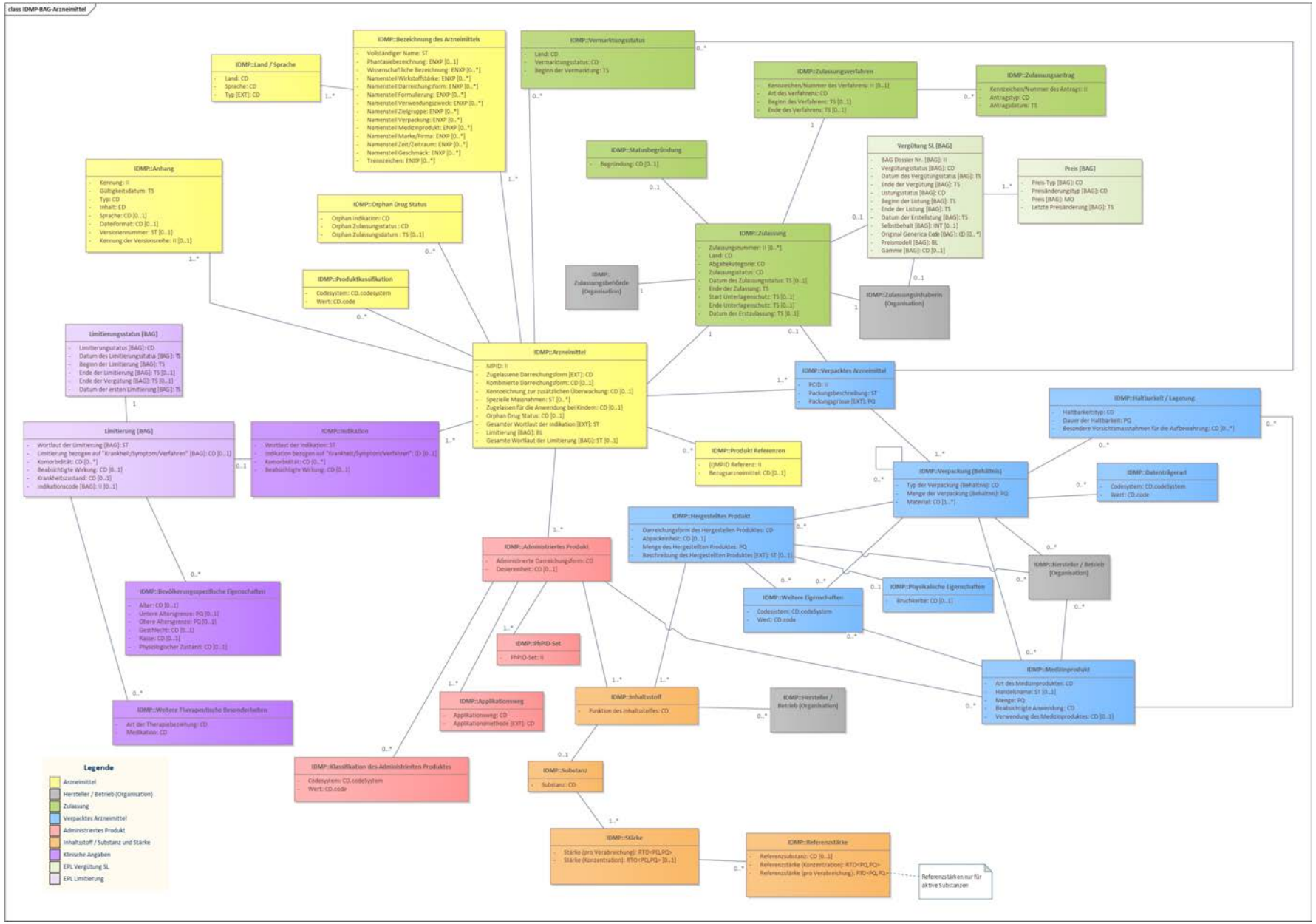
Therapeutic Indications

- Align on Code System(s)
  - MedDRA, SNOMED, ICD..



➢ The goal is to **finalise** the **scope** of the **IDMP data model** (data elements and standards) and define the **granularity** of capturing **homoeopathic substances** for the new database.

IDMP Data Model Federal Office of Public Health (FOPH)

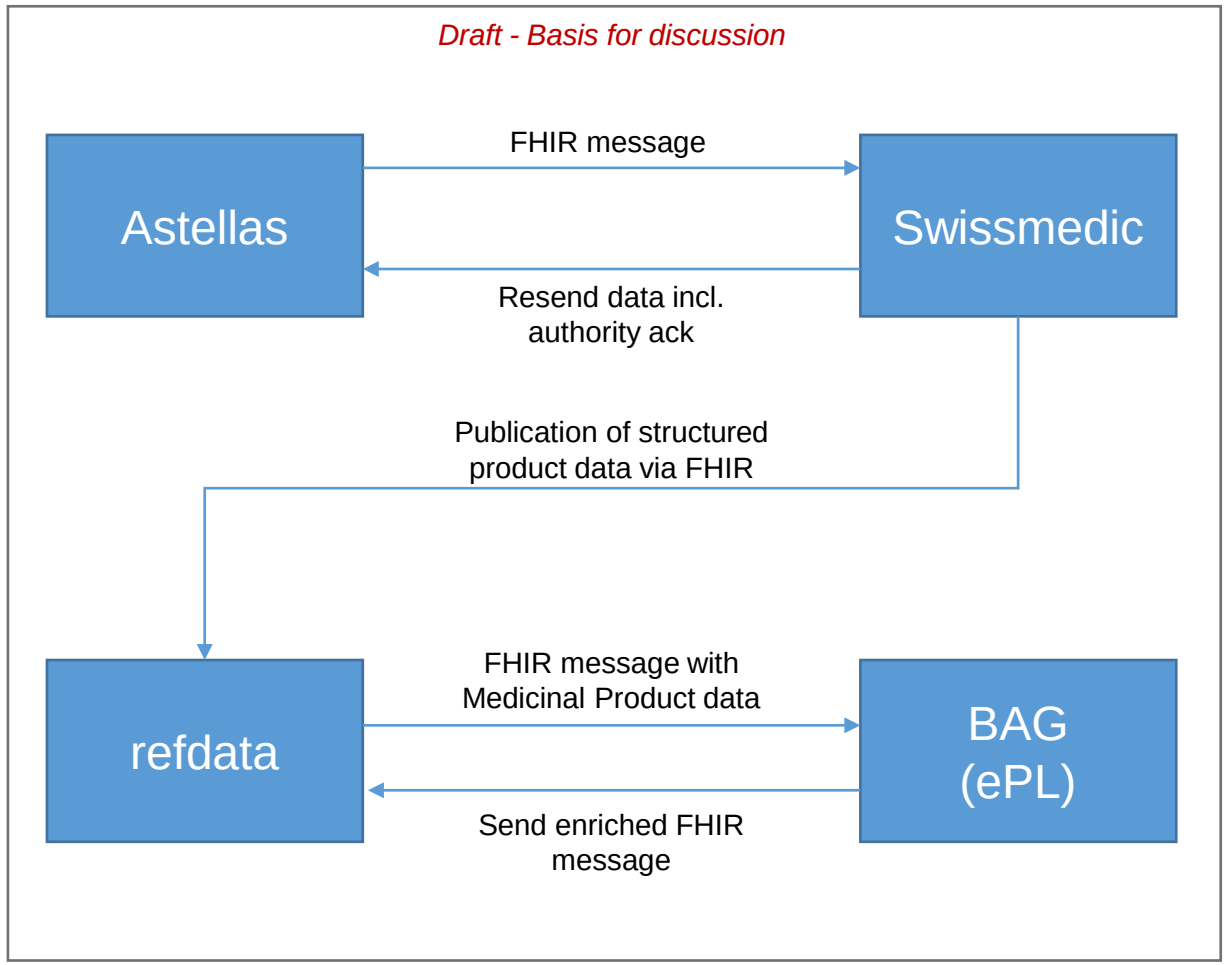


Updated IDMP Pilot – New Stakeholder

The updated pilot project allows all participating organizations to **gain experience** with **FHIR messages**, its **enrichment,** the IDMP data model and will provide **valuable insights for** the upcoming **Swissmedic IDMP Implementation Guide**.

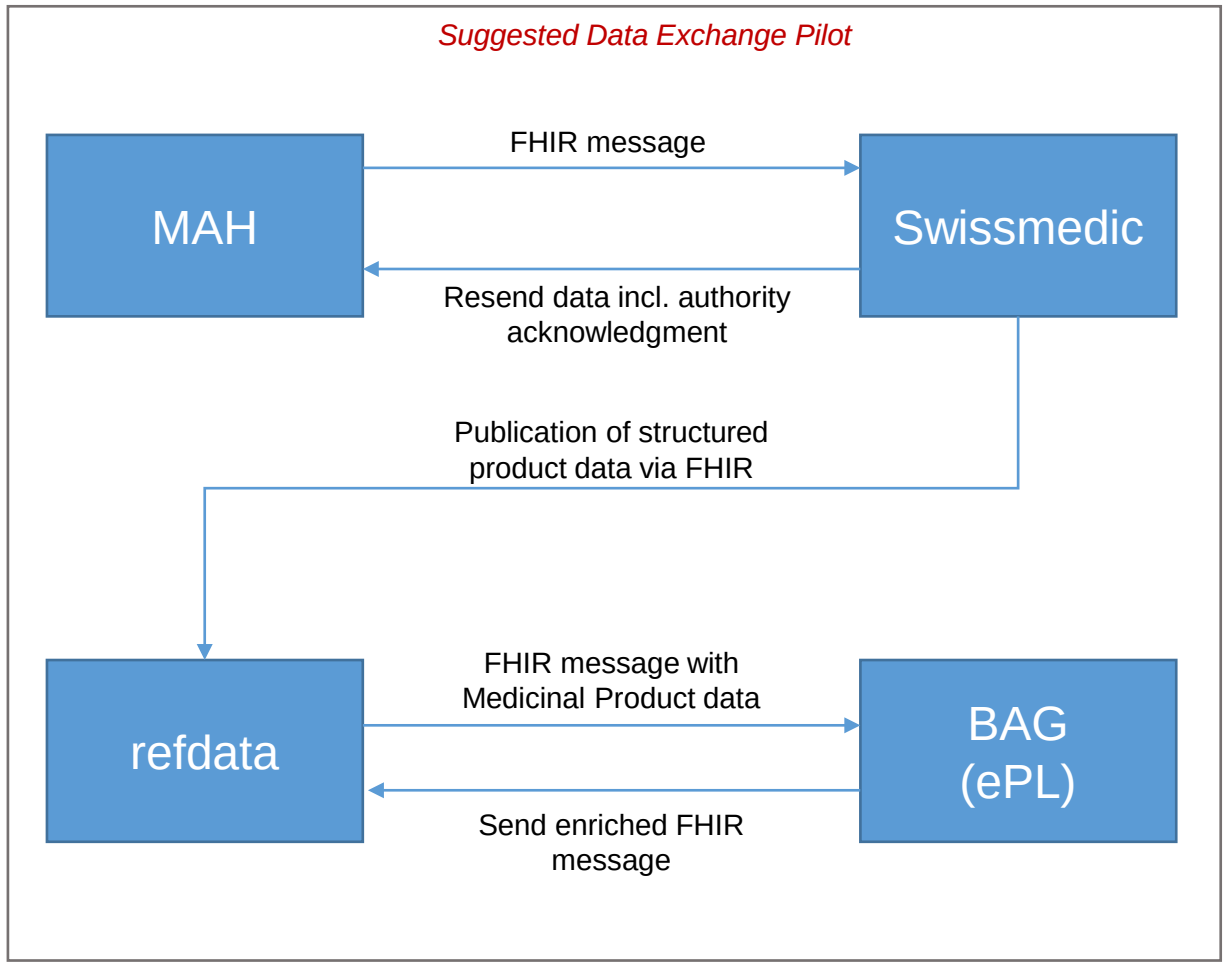
Data flow:

- Astellas Pharma AG sends a FHIR message with reduced IDMP data set of their medicinal products to Swissmedic
- Swissmedic will review the data set and then forward the data to Refdata (TBD: data provider)
- Refdata compares the IDMP dataset with its data and checks for possible enrichment of the dataset for further use with its stakeholders (Hospitals, Doctors, Pharmacies)
- Refdata will send data set to BAG for data enrichment of the FHIR message
  - E.g. Population Specifics



Updated IDMP Pilot – Data elements and CVs

- Goal is to test a **reduced IDMP data set**
  - < 59 Data elements
    - 17 Swissmedic CVs
    - 14 EMA CVs (RMS)
    - 11 EDQM CVs
    - 11 International CVs (WHO, HL7, ISO,)
- Reasons for Swissmedic specific lists
  - Legal requirements
  - Different tasks of EMA and Swissmedic (Marketing Status)

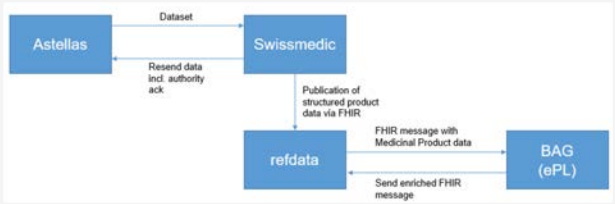


Update IDMP Data Model Swissmedic

Next Steps

Updated IDMP Pilot:

- Finalise data scope
- Align and define business processes with stakeholders
- Align on Swiss FHIR standards
- Communicate roadmap



Swissmedic IG V1.0

- Based on EMA IG Chapter 2 and focused on Pilot data scope
- Plan: regular exchange with IDMP Advisory Group

Homoeopathic Substance Database

- Implementation of database based on the Specified Substance structure
- Transfer of homoeopathic substance data from legacy system into new database

➢ Moving forward, we will focus on **scoping of the IDMP Pilot,** the **development of the Swissmedic Implementation Guide** and the development of the **homoeopathic substance database.**

Agenda

Introduction

IDMP Initiatives in Switzerland

Swissmedic’s Approach

Swissmedic IDMP Implementation: Current Status

Discussion

Next Steps

Stakeholder Involvement and Further Exchange

The IDMP implementation within TSP will take place *in iterations* and *according to priorities*

- Short-term need for stakeholder feedback (several times a year)
- Swissmedic would like to *demonstrate ideas and visible results to stakeholders* (e.g. details on the data model or the scope of the implementation guide, at a later stage: wireframes)
- Coordination of the communication between participants (e.g. for the data exchange pilot)

Stakeholder Involvement and Further Exchange

Strategic topics

SMC Regulatory Roundtable

KPA Roundtable

SMC GMP/GDP Roundtable

Concept level

SMC IDMP Advisory Board

User focused

(?)

KPA User Group

GMDP User Group

Data Model / IG / Exchange Pilot

Discussion: Submitted Questions

See separate list with questions from the stakeholders:

IDMP Advisory Board Meeting March 2024: Stakeholder Questions

Discussion: Further Topics

- …?

Agenda

Introduction

IDMP Initiatives in Switzerland

Swissmedic’s Approach

Swissmedic IDMP Implementation: Current Status

Discussion

Next Steps

Next steps

- The future exchange should take place at shorter intervals in accordance with the previous discussion on stakeholder involvement
- As soon as results are available in TSP that are suitable for a stakeholder review, Swissmedic will inform the IDMP Advisory Board and establish a more regular exchange