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Schweizerisches Heilmittelinstitut

The Substance Database at Swissmedic: Potential Application and Use of GInAS

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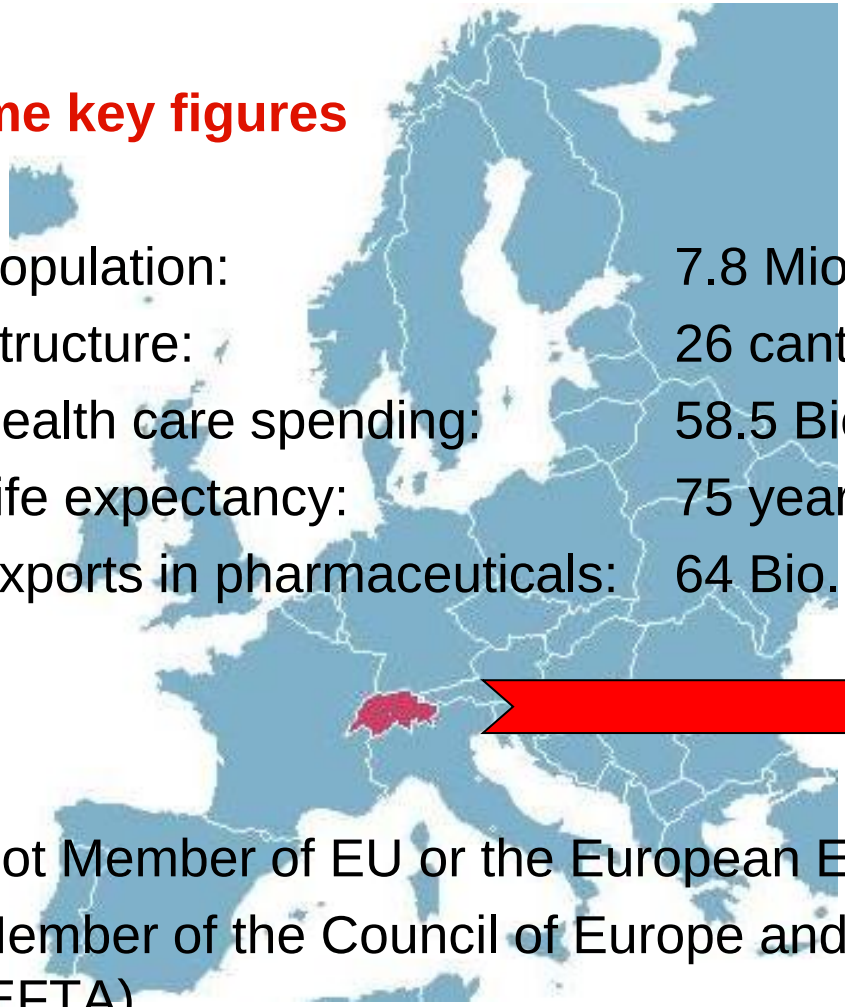
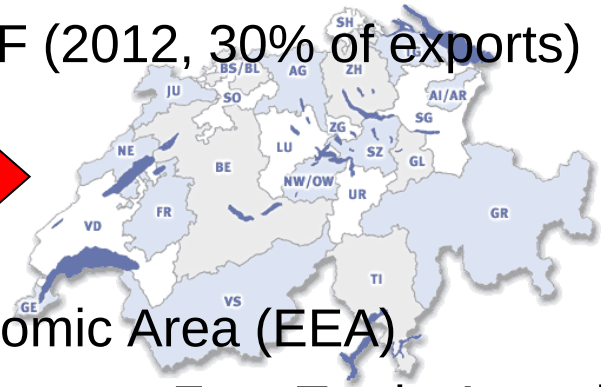
Switzerland – an “Island” in Europe



Some key figures

- Population: 7.8 Mio.
- Structure: 26 cantons, 4 national languages
- Health care spending: 58.5 Bio CHF (2008)
- Life expectancy: 75 years
- Exports in pharmaceuticals: 64 Bio. CHF (2012, 30% of exports)



- Not Member of EU or the European Economic Area (EEA)
- Member of the Council of Europe and European Free Trade Association (EFTA)

Swissmedic – an „SME“

Some key figures

• Budget:	≈ 90 Mio. CHF
Federal contribution:	14.7 Mio CHF (< 20%)
• Staff:	360 FTE
• Medicinal products authorised:	8’600
• New marketing authorisations*:	730
• NCE‘s approved (human and vet.)*:	27
• Medical devices:	EU-System

* Data for 2012

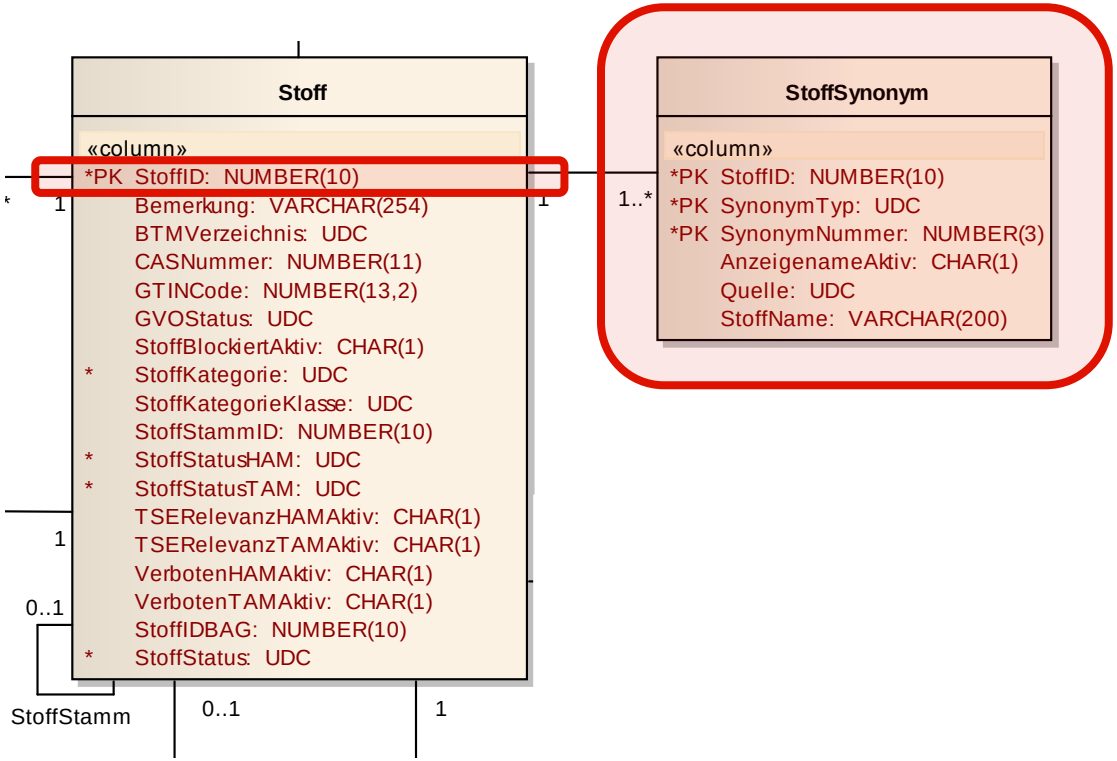
Strategy for Standards Implementation

Enabler for interoperability	The adoption of international standards is fundamental to the ability to **collaborate and share information** with partner regulators and for the interoperability with Swiss, European and global industry
Fast follower strategy	Swissmedic will be a fast-follower for adoption of standards, **implementing standards in line with the EU** and other leading agencies but recognizing any appropriate differences and priorities in regulating the Swiss market
Business driven approach	The implementation of standards aims to realize the **potentials for increased efficiency** in the Swissmedic core processes (through automation and streamlining)

Substance Data at Swissmedic

- Swissmedic does not store any information on chemical structures or on protein/nucleic acid sequences in its substance registry
- Identification of substances is purely done based on their names: A number of alternative names are stored for each substance in order to facilitate identification
- Drawbacks are the risk of duplicate datasets, particularly in the case of excipients (where nomenclature can be ambiguous)
- System is based on SAP CRM (since June 2013)

Our Data Model for Substances …



… is very simple

Data elements stored for Substances

- Swissmedic internal ID (SAP GUID)
- Standard ingredient role
- Narcotics category (based on the Swiss narcotics law [BetmG])
- Parent substance (for salts, solvates, prodrugs, etc. …)
- CAS number (if existing)

- Some flags
  (e.g. approved for human products, veterinary products)

- Internal substance classification
  (synthetic, biologic, recombinant, etc. …)

Data elements stored for Substances

- Synonym(s) (= name[s] of the Substance)
- Type of synonym
  - Latin name (mandatory, primary synonym for Swissmedic)
  - English name, German name, French name, Italian name
  - Commercial name(s)
  - Systematic chemical name (IUPAC nomenclature) …
- Source of synonym
  - INN (International Non-proprietary Name)
  - Pharmacopeia (e.g. EP, USP, JP, Ph. Helv.)
  - National Formulary
  - Cosmetic Ingredient Dictionary …
- UNII Codes stored as synonyms since Mai 2013

Stoff: ibuprofenum

Zurück

Sichern | Abbrechen | Neu

Stoff

Bearbeiten

Anzeigename:	ibuprofenum	BTM-Verzeichnis:			
Stoffkategorie:	Wirkstoff	GTIN-Code:			
Stoffkategorieklasse:	Wirkstoff-Deklaration	Verbotener Stoff...	☐	Verbotener Stoff...	☐
CAS-Nummer:	15687-27-1	TSE-Relevanz	☑	TSE-Relevanz	☑
Stoff Stamm:		GVO-Status:			
		Stoffstatus HAM:	zugelassen	Stoffstatus TAM:	nicht zugelassen
Stoff blockiert:	☐	Stoff Status:	aktiv		
Stoffbemerkung:		Stoff ID BAG:			

Stoff Synonyme

Liste bearb.

Synonym Typ	Stoffname	Anzeigenam...	Quelle
Lateinischer Name	ibuprofenum	☑	europäische Pharmakopöe, 2.Ausg.
englische Bezeichnung	ibuprofen	☐	
französische Bezeichnung	ibuprofène	☐	europäische Pharmakopöe, 2.Ausg.
Unique Ingredient Identifier	WK2XYI10QM	☐	FDA Substance Registration System (SRS)

Abhängige Stoffe (Derivate und Salze)

Stoffname
ibuprofenum argininum
ibuprofenum lysinum
ibuprofenum natricum dihydricum

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Stoff: ibuprofenum lysinum

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Stoff

Bearbeiten

Anzeigename:	ibuprofenum lysinum	BTM-Verzeichnis:			
Stoffkategorie:	zusammenges.Wirkstoffe & Salze	GTIN-Code:			
Stoffkategorieklasse:	Wirkstoff-Deklaration	Verbotener Stoff...	☐	Verbotener Stoff...	☐
CAS-Nummer:	57469-77-9	TSE-Relevanz	☑	TSE-Relevanz	☑
Stoff Stamm:	ibuprofenum	GVO-Status:			
		Stoffstatus HAM:	zugelassen	Stoffstatus TAM:	nicht zugelassen
Stoff blockiert:	☐	Stoff Status:	aktiv		
Stoffbemerkung:		Stoff ID BAG:			

Stoff Synonyme

Liste bearb.

Synonym Typ	Stoffname	Anzeigenam...	Quelle
Lateinischer Name	ibuprofenum lysinum	☑	von empfohlener DCI abgeleitete Bezeichnung
englische Bezeichnung	ibuprofen lysine	☐	von empfohlener DCI abgeleitete Bezeichnung
unsystematisches Synonym	Ibuprofenum L-Lysinum	☐	
unsystematisches Synonym	Lysinum 2-(P-Isobutylphenyl)-Propionicum	☐	
Unique Ingredient Identifier	N01ORX9D6S	☐	FDA Substance Registration System (SRS)

Abhängige Stoffe (Derivate und Salze)

Stoffname
Kein Ergebnis gefunden

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Product-specific Substance Data

- For each component of a medicinal product, an instance of each substance is created in order to store information specific for this substance in the context the concerned product

- Link to the substance (by substance ID [SAP GUID])

- Information captured is very specific to Swiss national regulations (mainly used to derive the labeling of the products)

Product-specific Substance Data

- Ingredient role (tailored to Swiss specific legal requirements)
- Information regarding mandatory labeling*
- Information regarding animal or human origin*
- Information regarding genetically modified organisms*
- Flag for NCE (i.e. not previously approved in Switzerland)

- Link to information regarding manufacturing**:
  - Manufacturer with link to manufacturer DB (addresses & permissions)
  - Information identifying the DMF (Drug Master File)
  - CEP Number (Certificate of Suitability to the Monographs of the EP)

* Swiss legal requirements (reflected in labeling)

** for active ingredients only

Number of Entries in Our Database

Number of substances in registry before migration to SAP:

- 11‘607 (active ingredients as of September 2012)
- 15‘070 (all substances as of September 2012)

Number of substances in registry after migration to SAP:

- 8‘631 (active ingredients as of September 2013)
- 12‘046 (all substances as of September 2013)

Potential Uses of GInAS

- Provides access to a much richer data source with a lot more data stored on the individual substances.
- Benefit from the structure-based registration process in GInAS for new substances thus eliminating the danger to generate duplicates.
- Advantages can be realized without developing a complex own structure-based system.

Potential Interoperability With GInAS

- Linking from Swissmedic's current substance registry to GInAS using the new global ID (generated by GInAS)

- Swissmedic is already preparing for future interoperability by means of a mapping exercise to the current FDA SRS
  - ca. 60% of active ingredients mapped already to UNII codes
  - ca. 50% of all substances mapped currently

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