

- **Drug shortages**
– frequent and ongoing trouble –
reasons and measures

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Conflicts of interest with regard to the content of the lecture

- Financial or owner interests:
Martinelli Consulting GmbH; co-owner
- Activities for the pharmaceutical industry and other health care companies:
Consulting via Martinelli Consulting GmbH (Hospitals, nursing homes)
- Grants / Donations :
 - none
- Personal relationships:
 - Quite some; irrelevant for the lecture.
- Other memberships:
 - GSASA (Board); Pharmasuisse, AKB (Member); Blistersuisse (Board)
BDP des Kantons Bern (Präsident); BDP Schweiz (Board)

The basic problem of worldwide supply

- Improved access of "emerging markets" to medicines (especially Brazil, India, Russia, China) -> higher demand, especially for "older" products / substances
- Cost pressure, changed pricing, market pressure
-> „lean-management“, „just-in-time“, „supply-chain“, „gmp“
- Increased quality requirements („the heparin case“)
- Tenders in other countries (e.g. Germany)
- Accentuated by country-specific requirements for packaging and labeling (e.g. not one mass product for all countries, but country-specific packaging as an intended basic requirement).

The basic problem of supply

Switzerland-specific

- Size of the Swiss market: In Switzerland, something is a "niche product", which is often a standard product abroad.
- -> Deregistration of "uneconomic" products.
- -> no registration of potentially uneconomic products.

e.g. : Cerubidin® : deregistration in Switzerland, available in France only for the double price. Insurances only pay the «old» Swiss Price.

Rules for Pricing of niche products ???

Functional separation between the Confederation and the cantons: **Therapeutic Products Act**

- With the Therapeutic products act and its regulations, the Confederation is setting the framework for safe and orderly supply of medicines (Art. 1) :

Art. 1 Zweck

¹ Dieses Gesetz soll zum Schutz der Gesundheit von Mensch und Tier gewährleisten, dass nur qualitativ hoch stehende, sichere und wirksame Heilmittel in Verkehr gebracht werden.

² Es soll zudem:

- a. Konsumentinnen und Konsumenten von Heilmitteln vor Täuschung schützen;
- b. dazu beitragen, dass die in Verkehr gebrachten Heilmittel ihrem Zweck entsprechend und massvoll verwendet werden;
- c. dazu beitragen, dass eine sichere und geordnete Versorgung mit Heilmitteln, einschliesslich der dafür nötigen fachlichen Information und Beratung, im ganzen Land angeboten wird.

Functional separation between the Confederation and the cantons: **The Constitution**

- The cantons are responsible for the provision of healthcare for their population.
- According to the Federal Constitution, the Confederation has only limited competencies in the field of health. They are essentially limited to the following areas:
prevention, transplantation, complementary medicine, human research, genetics, health insurance, handling of food, handling of medicines, narcotics ->
Federal Constitution Art. 117, 118, 119

Possible remedies

1. The federation takes the responsibility for the safe and orderly supply of medicines
 2. The federation sets the framework conditions in such a way that, given the circumstances, a secure and orderly supply is possible.
 3. Prior to the revision of the therapeutic products act and the regulations, the state did not assume any responsibility and set the framework conditions so that the secure supply could only be maintained with the help of illegal measures.
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AMBV (since 1.10.2010)

Art. 36²⁵ Einfuhr nicht zugelassener verwendungsfertiger Arzneimittel

³ Eine Medizinalperson, die über eine Detailhandelsbewilligung des zuständigen Kantons verfügt, darf solche Humanarzneimittel in kleinen Mengen ohne Bewilligung einführen, sofern:²⁶

- a. das Arzneimittel für eine bestimmte Patientin oder einen bestimmten Patienten oder aber für Notfälle bestimmt ist;
- b.²⁷ das Arzneimittel von einem Staat mit einem vom Institut als gleichwertig anerkannten Zulassungssystem zugelassen ist oder eine Touristin oder ein Tourist ein im Wohnsitzstaat zugelassenes Arzneimittel benötigt; und
- c. ...²⁸
- d.²⁹ für das betreffende Arzneimittel:
 1. in der Schweiz kein alternativ einsetzbares Arzneimittel zugelassen ist,
 2. ein alternativ einsetzbares Arzneimittel in der Schweiz zugelassen, aber auf dem schweizerischen Markt nicht erhältlich ist, oder
 3. eine Umstellung der Medikation nicht angemessen ist.

Simplification of approval for niche preparations

VAM (since 1.10.2010)

2. Abschnitt: Kennzeichnung und Arzneimittelinformation

Art. 14 Sprache

⁵ Die Angaben nach den Absätzen 1–3 können in nur einer Amtssprache oder in Englisch abgefasst sein, wenn das Arzneimittel ausschliesslich für die Anwendung im Spital vorgesehen ist und entsprechend gekennzeichnet wird. Die Gesuchstellerin stellt sicher, dass den Anwenderinnen und Anwendern auf Wunsch zusätzliche Informationen in einer der Amtssprachen zur Verfügung gestellt werden können.²⁴

-> this article is rarely used!

Nevertheless, hurdles remain for importation

- Each hospital must import by itself; if a hospital supplies an imported product to another, the product must be approved; Exceptions are only possible by taking advantage of the "assistance obligation".
- Wholesalers are not allowed to store imported products not authorized in CH; so the time axis for replenishment procurement is longer than with products stored in Switzerland.

Consequence

- The relief is very helpful
- Provides a higher motivation to approve niche preparations with low income prospects in Switzerland (for example Tranexamic acid)
- Better conditions for the approval of niche products and ensuring a secure supply

BUT: There is no supply guarantee !

How can the "system" react?

Mandatory reporting of drug shortages of essential preparations to a platform with the following functions:

1. Survey of residual stocks and consumption figures in all hospitals (or the Swiss market) and estimation of the range of remaining stocks.
 2. Ensure the fair distribution of the remaining stock
 3. Ensuring the procurement of alternative preparations (for foreign preparations short-term granting of an import license for the Swiss supplier, the hospitals or third parties).
 4. In case of long-term drug shortages, disposal of production documents as well as the issuance of short-term manufacturing consent to manufacturers, hospitals, army pharmacy.
 5. To ensure the insurance-admissibility of the substitute products at the effective costs (for outpatient patients), as well as the availability of an additional remuneration for inpatient therapies for the duration of the bridging measures.
- -> Function : Federal office for national economic supply

What is an essential drug ?

" Medical Necessity" criteria of the FDA* :

Any drug product used to diagnose, treat, or prevent a serious disease or medical condition for which there is no other drug that is judged by CDER medical staff to be an appropriate substitute or there is an inadequate supply of an acceptable alternative as determined by the DSS. Off-label uses of approved drugs, marketed unapproved drugs, and IND drugs may be considered medically necessary. Patient inconvenience alone is an insufficient reason to classify a drug product as medically necessary.

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm079936.pdf> (Stand : 5.9.2017)

This Means :

Medical Necessity has nothing to do with: Turnover, number of packs.

But with: substance and / or form, situation in individual cases (patient, operation, use, illness)

-> often parenteral drugs are affected.

Basic requirements; GSASA's proposal based on the ASHP*

- Defined and standardized notification of drug shortages to the information and coordination platform, with the necessary information still to be defined.
 - Drug shortages expected (notifications as early as possible; up to 6 months in advance)
 - Drug shortages : Reasons for the shortage. Indication of the duration
(mandatory)
- Keeping compulsory stocks for essential products and communicating to the information and coordination platform when preparations are delivered from this stock

How can the "system" react?

- Both at Swissmedic and at the FOPH, the potential risk of distorting the market when a products has simplified condition for approval.
- Swissmedic -> Transitional solutions (product in foreign package).
- FOPH
 - > 20% Co-Payment; temporary suspension
 - > product gamme (e.g., if a company delivers only ampoules but no tablets); temporary approval
 - > remuneration of imported products

The difference between the focus on "national provision" and the "patient safety"

- Motion Sommaruga for packaging and labeling of medicines: Brand name / active ingredient ratio 1: 2
- "Branded" generics are hardly accepted in hospitals.
- Packaging and labeling in highly complex processes is essential!

What consequences has a drug shortage for the System «fmi» ?

- Assessment of risks:
naming, packaging, form, dosage, etc.
- Information of >100 prescribing doctors in 10 institutions
- Changes of prescriptions – Prescriptions trigger electronic processes.
- Modification of databases for CPOE'S (KISIM, PDMS, Oribis, Tecost, Sage, CareCoach).
- Change of the preparatory processes (el. wards, Blisterpack etc.)

Our biggest problem : early communication

- In the real world : No to very late information
- “sit out” the problem; Pharmacy as a fig leaf -> first focus is the last supplier (mainly (hospital)-pharmacies); not the industry
- No Crisis-Management. A drugshortage is a crisis ! -> weak Crisis Management has a huge influence on reputation
- Limited understanding of the processes to the patient. The problem stops at the entrance to the pharmacy.....

Drugshortage.ch

drugshortage.ch

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Mutationen der letzten 7 Tage

Die Mutationen der letzten 7 Tage in der Übersicht.
Um Details zu erfahren klicken Sie auf das einzelne Medikament.

Zur Gesamtübersicht geht's hier : [Link](#)

Mutationen der letzten 7 Tage

Anzahl offene Lieferengpässe

248

Goals of Drugshortage.ch

1. Through the central platform, professional health care professionals are informed about drugshortages at an early stage and are enabled to react.
2. The information is given irrespective of the cause of the drug shortage and irrespective of whether or not the drug is essential or not.
3. Often care-givers are suspected of being badly organized. This platform is also designed to provide transparency to patients.
4. The platform helps that companies become more sensitive dealing with drug shortages.

Conclusion

- The Federal office for national economic supply has the focus on "national supply"; This is important, however, in everyday life (at the moment) it is the smallest problem (with exceptions : e.g. vaccines)
- Top priority is patient safety. Patient safety is a result not (only) from the product, but also from the process -> uncertainty of the patients, complex hospital- / home situation, established procedures.
- Drugshortage.ch does not solve the problem, but the database creates transparency and sensitivity to drug shortages.

Thank you for your attention!



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