



## SUPPLY SHORTAGES

# DAPI develops Digital Twin

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**Supply shortages have unfortunately been an inconvenient problem for years. Currently, the issue is also becoming apparent, for example, in the supply of fever syrup for children. The German Institute for Drug Use Evaluation (DAPI) [Deutsches Arzneiprüfungsinstitut e. V. (DAPI)] has set itself the objective of detecting supply shortages more precisely and more quickly.**

As a non-profit institute, the German Institute for Drug Use Evaluation (DAPI) [Deutsches Arzneiprüfungsinstitut e. V. (DAPI)] is constructively involved in the issue of supply shortages - also internationally. Supply problems ought to be detected more quickly and more precisely. The aim is to secure the provision of medicines.

In order to make existing and emerging supply shortages more recognisable and manageable for pharmacists, the DAPI has established the method of the so-called digital twin. The "recipe" for this consists of the following three elements (see also box).

### "Recipe" for a digital twin

A digital twin refers to a computerised model of a tangible or intangible object that can be used for various purposes. A digital twin requires three elements:

- (1) the real object to be mapped,
- (2) the digital twin in virtual space and
- (3) Information linking the two.

The object [here: pharmacy software] that uses sensors [here: wholesale queries] to collect data about e.g. condition or position [here: medicine availability] is connected to a system that receives, processes and evaluates the sensor data [here: DAPI M]. Digital twins can thus improve the operational and also financial performance of an object such as a plant or a service [here: medicine supply]. Digital twins are created by experts and from collected real-time data of the objects (2).

## The real object to be mapped

If we regard the supply of patients with medicines, we start with the production of active ingredients and additives and end up with the hospital and public pharmacies via pharmaceutical companies, importers, intermediaries and wholesalers.

As an alternative to wholesalers, pharmacies can also purchase medicines directly; or the supply via pharmacies is indirect, e.g. via the doctor's consultation supplies.

Supply shortages, if they lead to undersupplying of patients with medicines, are associated with risks for patients. Pharmacies therefore make additional efforts to counteract supply shortages.

In addition to the classic (additional) stockpiling, the supply can be guaranteed to a certain degree by the pharmacist through substitution with a comparable medicine, if necessary in consultation with the doctor, including in-house production. At present, pharmacies are given more room to manoeuvre, so that substitution can usually take place without a new prescription.

## The digital twin in virtual space

Various data sources provide the following information as "basic ingredients" of the "recipe":

- A directory of active ingredient manufacturers is the EDQM CEP Database (3). The Certificate of Suitability of Monographs of the European Pharmacopoeia (CEP) is used as an option in the respective marketing authorisation dossier as proof of the necessary active ingredient quality (4). Although the CEP database is extensive, it is unfortunately incomplete and in particular does not provide any information on which of the listed active ingredient manufacturers a pharmaceutical company has (currently) commissioned for the production of its batches of medicinal products.
- The Federal Institute for Drugs and Medical Devices (BfArM) [Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)] places information on supply shortages reported to the BfArM (e.g. with reason and period) online in a legally standardised database. This information comes from the pharmaceutical company, in accordance with the voluntary commitment to report supply shortages (5). Normally, over-the-counter medicines are not included.

- The Medicines Commission of German Pharmacists (AMK) [Arzneimittelkommission der Deutschen Apotheker (AMK)] provides pharmacovigilance-relevant information from the authorities, institutions and pharmaceutical companies in its AMK News (6) and provides information on (batch-) recalls and batch reviews (7). The AMK maintains its own "news database" for this purpose.
- Information on the (non-)availability of medicines, based on queries by pharmacies to the pharmaceutical wholesalers supplying them, can be automatically and systematically recorded, evaluated and processed and made available in "real time". The proof of concept (PoC) was provided by DAPI with the project "DAPI M - Availability Monitor (DAPI M)" ["DAPI M-Nichtlieferbarkeitsmonitor" (DAPI M)] with the support of pharmacies and the pharmacy software company aposoft (8). In the current roll-out of the pilot phase, further pharmacy software houses are being connected. A pharmacy with linked software can initiate the data delivery to DAPI M by itself by simply ticking the DAPI M option in the software settings. That is all, no additional effort beyond that.

## Information linking the two

The availability information from wholesale queries is automatically and immediately transmitted from the pharmacy software to DAPI M (two analysis examples over time: see Fig. 1 and Fig. 2).

Linked with information from the other data sources, the data is fed into a modelling process. DAPI is currently investigating the possibility of using artificial intelligence (AI) to make predictive statements from this data, in particular about the progression of supply shortages.

As a result of the virtual space for the real object (the real world), the following feedback should be possible:

- (1) Assessment of the current availability situation
- (2) Signal generator for current critical shortage situations
- (3) Prediction of future progression of availability or shortage situations, e.g. in 14 or 30 days' time

## DAPI supports the European supply shortage project

In addition to the DAPI's national focus on supply shortages, the Institute is also involved internationally, to prevent supply shortages.

Since the end of 2021, DAPI has been part of the German delegation to the pan-European supply shortage project "Medicines Shortage Reporting Initiative (MedSRI)" which is led by the General Pharmaceutical Council of Spain. Regular project discussions take place among delegations representing pharmaceutical associations from France, Germany, Ireland, Italy, the Netherlands, Portugal and Spain.

The project aims to create a harmonized (pharmacy-based) reporting system on supply incidences in order to anticipate possible supply problems and enable stakeholders to take measures to prevent or mitigate them.

## The European MedSRI project design harmonises with DAPI M

For the planned proof-of-concept phase of the MedSRI project, the aligned project design of the MedSRI and DAPI M projects is beneficial:

- (1) Reporting unavailability of medicines at pharmacy level via the pharmacy software;
- (2) Incidence KPI: Proportion of pharmacies in the total panel that report unavailability of medicines.

## DAPI as licensed partner of SNOMED International

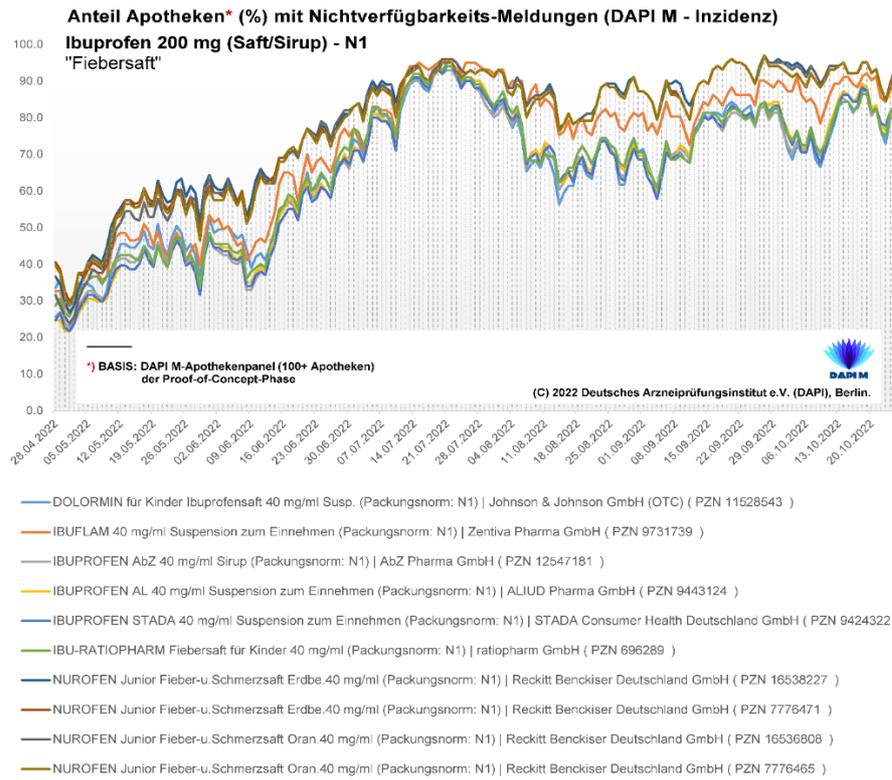
Consolidation across borders requires a common "language" of medicine coding. One of the most comprehensive medical terminologies worldwide is the Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT). DAPI is a licensed partner of SNOMED International (9) and is involved, for example, in cooperation with the SNOMED German Translation Group (GTG). Information on GTG projects can be found in the GTG Community Browser (10).

## Robust results require support

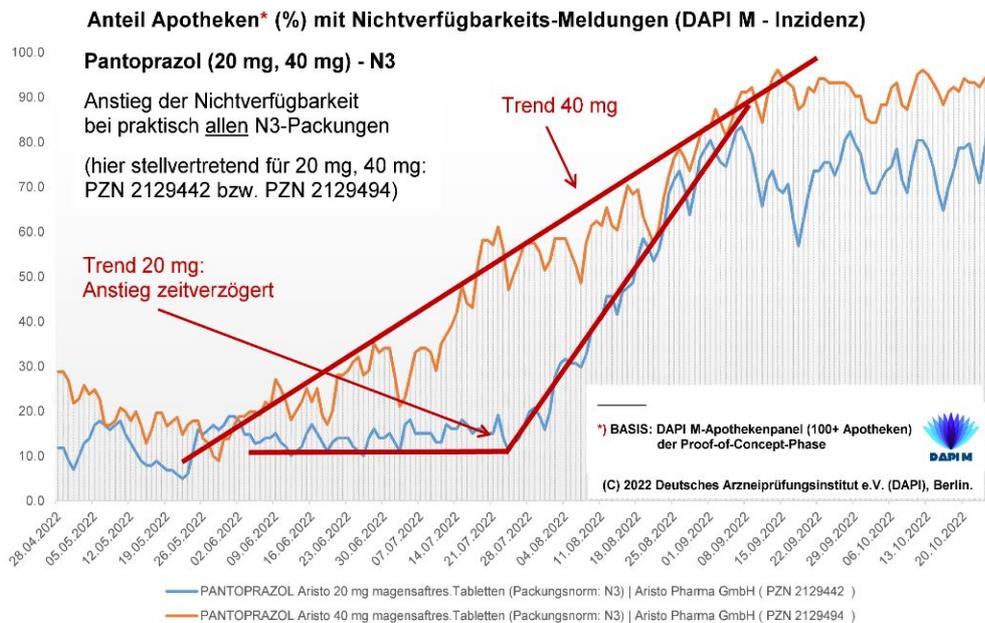
For reliable results and a high resilience of DAPI M, a high rate of participation by pharmacies is essential.

If a pharmacy software is already connected to DAPI M, the pharmacies concerned have been informed of this by the software company. A pharmacy with linked software can initiate the data delivery to DAPI M by itself by simply ticking the DAPI M option in the software settings. That is all, no additional work beyond that.

If a software house is not yet connected, DAPI will be pleased to provide the software house with comprehensive support in integrating it.



**Fig. 1:** DAPI M analysis: Development of the unavailability of "fever syrup" in DAPI M Pharmacy Panel (May - October 2022).



**Fig. 2:** DAPI M analysis: Pattern of a noticeable increase in unavailability using the example of Pantoprazole N3 packs (~100 tablets) 40 mg and delayed 20 mg strength.

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(1) [https://www.aerzteblatt.de/nachrichten/137188/Laumann-sieht-keine-Hinweise-auf-generellen-Medikamentenengpass vom 07.09.2022](https://www.aerzteblatt.de/nachrichten/137188/Laumann-sieht-keine-Hinweise-auf-generellen-Medikamentenengpass-vom-07.09.2022)

(2) Gabler Business Dictionary [Gabler Wirtschaftslexikon] - <https://wirtschaftslexikon.gabler.de/definition/digitaler-zwilling-54371/version-277410>

(3) European Directorate for the Quality of Medicines & HealthCare (EDQM) - Council of Europe; Certificate of Suitability of Monographs of the European Pharmacopoeia (CEP) Database - <https://extra-net.edqm.eu/page7/page8/page8.html>

(4) BfArM: Certificate of Suitability of Monographs of the European Pharmacopoeia (CEP) - <https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Validierung/CEP/artikel.html>

(5) BfArM: Published supply shortage notifications - <https://anwendungen.pharmnet-bund.de/lieferengpassmeldungen/faces/public/meldungen.xhtml>

(6) AMK News - <https://www.abda.de/fuer-apotheker/arzneimittelkommission/amk-nachrichten/>

(7) AMK: Recalls, batch recalls and batch reviews - <https://www.abda.de/fuer-apotheker/arzneimittelkommission/rueckrufe-chargenrueckrufe-und-chargenueberpruefungen/>

(8) Prisma Datensysteme GmbH, Moormerland / aposoft - <https://www.aposoft.de/unternehmen-ueber-uns/>

(9) SNOMED International - <https://www.snomed.org/>

(10) German Translation Group - <https://confluence.ihtsdotools.org/display/GTG>; Published content in the GTG Community Browser - <https://confluence.ihtsdotools.org/pages/viewpage.action?pageId=146867123>

Picture credit: Pixabay.com/hexagon-3420935