

# 26th DGRA Annual Congress

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## New Regulations on Shortages - the National Perspective

Dr. Michael Horn, June 20<sup>th</sup> 2024

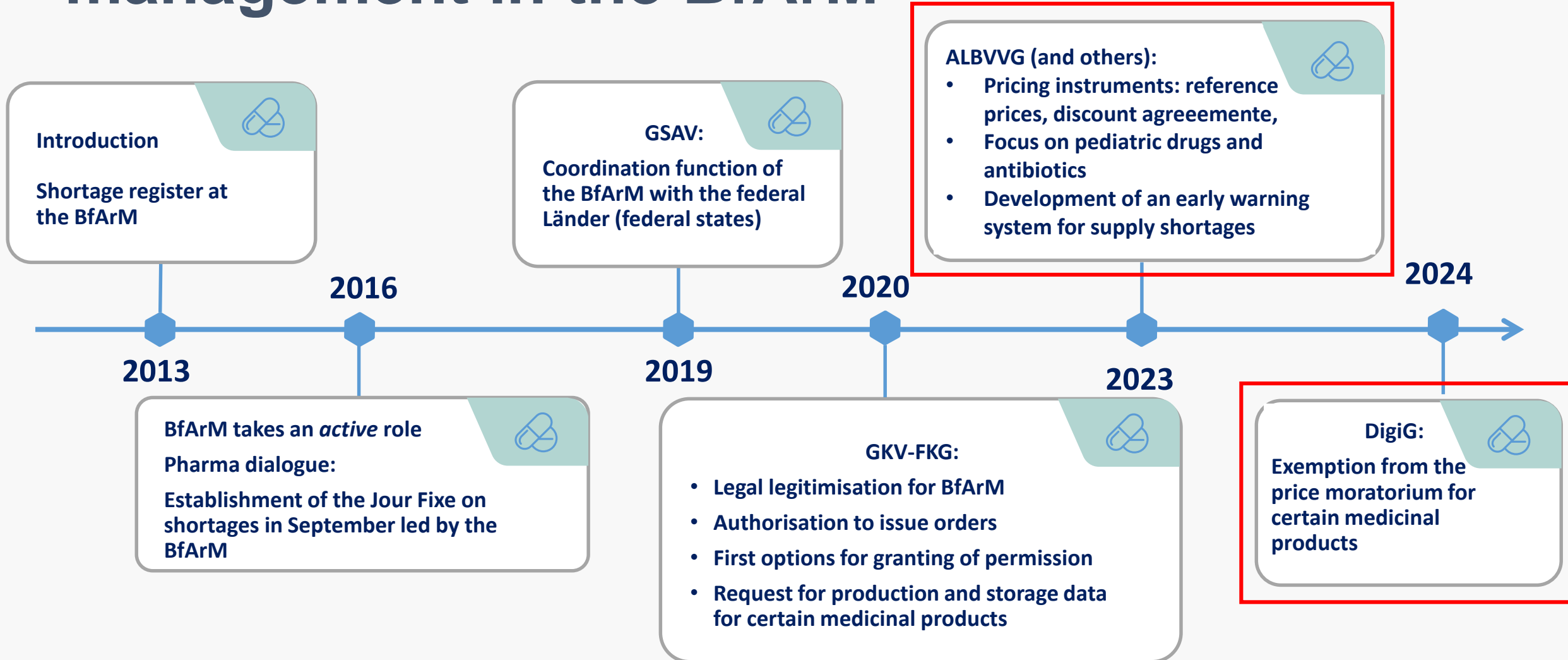
# Disclaimer

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# Agenda

- Milestones in the BfArM's management of supply shortages
- Legal options prior to the ALBVVG
- ALBVVG - Strengthening supply and restoring trust
  - Pediatric medicinal products
  - Diversification in discount agreements
- Application process according to Section 130a (3c) sentences 8 to 14 SGB V
- Development of an early warning System

# Milestones of supply shortage management in the BfArM



# Legal options prior to the ALBVVG

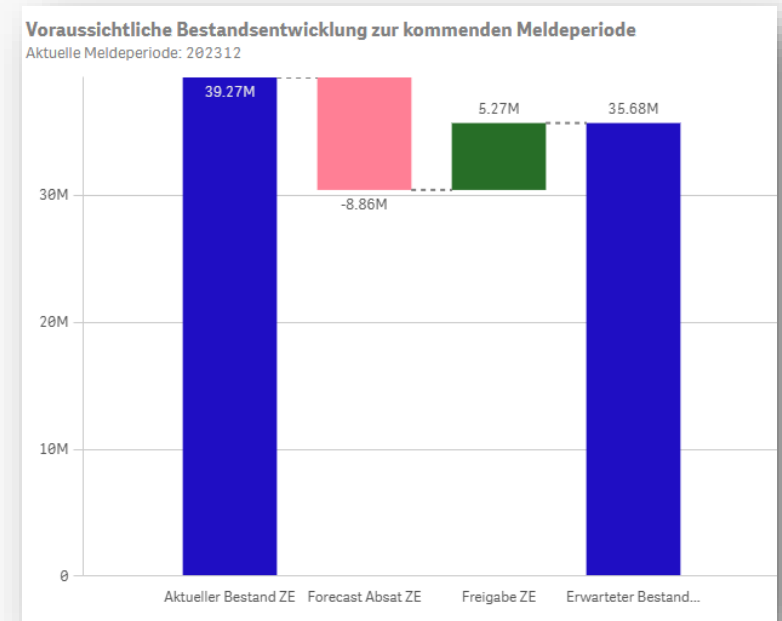


# Legal options prior to the ALBVVG

- Measures required in the short term
  - Ad hoc actions in coordination with the Advisory Council ("daily business") since 2016
    - Coordinated action by all interest groups, authorities and organizations, e.g.
      - Therapy recommendations
      - Communication for HCP and the public
  - Facilitating imports
    - Announcement of the supply shortage in accordance with Section 79 (5) AMG
    - Granting of import permission for medicinal products authorized in Germany in non-German language by the BfArM (from 2020, extended in 2023)
  - BfArM order to wholesalers and pharmaceutical companies (since 2020), e.g.
    - Quota system for supply-relevant medicinal products
    - Stockpiling for supply-critical medicines

# Legal options prior to the ALBVVG

- Measures with short to medium-term impact
  - Information on production and available stocks if required
    - From 2020 for pharmaceutical companies and wholesalers
- Measures with a medium to long-term effect
  - Periodic information on production and available stocks (from 2020)



ALBVVG

Strengthening supply and restoring trust

Multifaceted causes –  
multifaceted measures





# ALBVVG

## What has changed and what new tasks have been assigned to the BfArM?

- **Focus so far**
  - Supply shortage management for supply-critical medicinal products
  - Focus on the hospital sector
- **Focus of ALBVVG: Generics und Forecast**
  - Strengthening the supply situation, especially in outpatient care
  - Further provisions to avoid supply shortages
  - Further options and simplifications to mitigate supply shortages

# Strengthening supply and restoring trust: ALBVVG (1)

- **Extended information obligations** towards the BfArM
  - Specific active ingredient manufacturers used
  - Stock levels in hospitals and hospital supply pharmacies for certain medicines
- Extended options for granting of permission for BfArM
  - for medicinal products authorized in Germany not in German language
  - now also for outpatient care
- Strengthening of the advisory council
- Further new tasks for the BfArM
  - Duty to inform health insurance funds when contracting discount agreements
  - Obligation to inform the public: Categorisation of reported supply shortages into supply-relevant and supply-critical supply shortages
  - Development of an early warning system for drug shortages

# Strengthening supply and restoring trust

## ALBVVG (2)

- Creation of **incentive systems for companies**
  - Possibility of increasing the reference prices
  - **Diversification** in discount agreements (so-called EU lot)
    - Off-patent antibiotics (valid since the ALBVVG came into force)
    - List of off-patent oncological medicinal products (published in the Federal Gazette on 12.04.2024)
- **Special focus for pediatric medicinal products**
  - Increasing prices
  - Cancellation of reference prices for medicinal products on the pediatric drug list
  - Prohibition of discount agreements

# Pediatric medicinal products and reference prices for medicines



# ALBVVG Pediatric Drug List (Section 35 (5a) SGB V)

- Pre-publication on BfArM homepage on 27/07/2023
  - List contains authorized medicinal products
    - with dosages suitable for pediatric use and/or
    - in dosage forms suitable for children
  - Parenterals used exclusively in pediatrics
- In accordance with ALBVVG, the list first came into force on 01.02.2024
- The list is updated monthly
- Currently, 1346 medicinal products (at PZN level) are on the [list](#)

The screenshot shows a webpage with a light green header. The breadcrumb navigation at the top reads 'Lieferengpässe > ALBVVG'. The main title is 'Arzneimittel-Lieferengpass-bekämpfungs- und Versorgungsverbesserungsgesetz (ALBVVG)'. Below the title is a section for 'Inhaltsverzeichnis' with a plus icon. The main text states that the law was published in the Federal Law Gazette on July 26, 2023. It also mentions the responsibilities of the BfArM and the Advisory Board for Supply Shortages. A final paragraph notes that the law took effect on July 27, 2023, and that the BfArM has published a list of medicines under Section 35(5a) of the AMG, considering age-appropriate dosage forms and strengths for children up to 12 years old.

# ALBVVG Pediatric Drug List (Section 35 (5a) SGB V)

- Consequences for medicines on the pediatric list:
  - The GKV-Spitzenverband (National Association of Statutory Health Insurance Funds) shall cancel the applicable reference prices for the corresponding medicinal products within **four** months of the publication of the list (Section 35 (5a) SGB V)
  - Pharmaceutical companies can increase the sales price by up to 50 per cent of the last applicable reference price (Section 130a (3d) SGB V)
  - Extended stockholding obligation for the wholesalers for medicinal products on the list (4 weeks) (Section 52b Para. 2 sentence 2 AMG)
- Current situation
  - Many medicinal products benefit from the new regulations
  - A significant improvement in availability has not yet been observed
  - An evaluation is being carried out to determine where improvements may be needed

Arzneimittel-Lieferengpass-  
bekämpfungs- und Versorgungs-  
verbesserungsgesetz (ALBVVG)

Inhaltsverzeichnis

Das Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz (ALBVVG) wurde am 26. Juli 2023 im [Bundgesetzblatt](#) veröffentlicht.

Mit dem Gesetz werden auch die Verantwortlichkeiten des BfArM und des am BfArM angesiedelten [Beirats für Liefer- und Versorgungsengpässe](#) im Bereich der Überwachung von Lieferengpässen und der Verbesserung der Versorgung gestärkt.

Mit Inkrafttreten des Gesetzes am 27.07.2023 ist vom BfArM nach Anhörung des Beirats nach § 52b Absatz 3b AMG eine Liste von Arzneimitteln unter Berücksichtigung altersgerechter Darreichungsformen und Wirkstärken zu veröffentlichen, die insbesondere zur Behandlung von Kindern bis zur Vollendung des zwölften Lebensjahres notwendig sind.

# ALBVVG - Section 35 (5b) SGB V (supply-critical active ingredients)

- Further options for increasing prices
- The BfArM may, after consulting the Advisory Council
  - recommend an increase in the reference price for medicinal products with a supply-critical active pharmaceutical ingredient by 50 per cent on the basis of the pharmaceutical companies' sales prices or by 50 per cent on the basis of the price level relevant for the application in accordance with Section 130a (3a)
- Current situation
  - published in the Federal Gazette
    - Natriumperchlorat
    - Benzylpenicillin-Benzathin
  - a list of off-patent oncological medicinal products is in progress

# Diversification in discount agreements (so-called EU lot)





# ALBVVG - Section 130a (8a/8b) SGB V

- Another aim of the ALBVVG is to diversify the production of off-patent medicinal products
  - Off-patent antibiotics in accordance with Section 130a (8a) SGB V
  - Further active pharmaceutical ingredients in accordance with Section 130a (8b) SGB V
    - List of off-patent oncological medicinal products in accordance with Section 130a (8b) SGB V (published in the Federal Gazette on 12.04.2024)
    - Section 130a (8b) SGB V refers to Section 130a (8a) SGB V

# ALBVVG - Section 130a (8a) SGB V (discount agreements)

- The aim is to avoid supply shortages and to ensure a diversified, demand-driven supply of off-patent antibiotics
- Tendering for at least half of the batches, with production of the active ingredients
  - in the EU or an EEA member state
  - or countries with corresponding trade agreements in place, if at least half of the active substances required to fulfil the agreement pursuant to sub-section 8 sentence 1 for the manufacturing of the medicinal products mentioned in Sentence 1 are produced in the European Union or in a contracting state of the European Economic Area.
- Upon request, the BfArM shall provide the health insurance funds or their associations
  - **information on the manufacturing site** of the active pharmaceutical ingredient of a pharmaceutical company actually used in the production of the discounted medicinal product,
  - if this is necessary for **the decision on the award** or the **review of the fulfilment** of the agreement

# ALBVVG - Notification of active pharmaceutical ingredient manufacturers

- Development of an online portal for the notification of active pharmaceutical ingredient manufacturers
- in operation since February 2024 for
  - finished medicinal products according to Section 52b para. 3f AMG
  - medicinal products in ad hoc consultations with the higher federal authorities in accordance with Section 52b para. 3e AMG
  - medicinal products for an EU lot in the case of discount agreements
    - Off-patent Antibiotics
    - List of off-patent oncological medicinal products

**Meldung aktiver Wirkstoffhersteller (ALBVVG)**

Gemäß § 52b Absatz 3e und 3f AMG sind dem BfArM die Herstellungsstätten der bei der Herstellung des Arzneimittels tatsächlich verwendeten Wirkstoffe mitzuteilen.

Weiter sind diese Informationen auf der Grundlage des § 130a Absatz 8a und 8b SGB V dem BfArM zur Verfügung zu stellen. Mit dem Meldeportal können die Daten qualitätsgesichert erfasst und übermittelt werden.

**Wirkstoffhersteller (ALBVVG)** Login

Anwendung zur Meldung aktiver Wirkstoffhersteller im Rahmen des ALBVVG

[Wirkstoffhersteller \(ALBVVG\)](#)

Keine Zugangsdaten vorhanden?  
Informationen und Anleitungen siehe Service-Bereich:  
→ [Zugangsdaten beantragen und Benutzerverwaltung](#)

# ALBVVG - Notification of active pharmaceutical ingredient manufacturers

- Relevant Tasks
  - Batch information
  - German trade number
  - Selection of the manufacturer
  - Verification of the collected data
- Upload options and / or an import interface is in preparation

**Batch information**

Please first select a medicine for which you wish to submit a notification using the entry number (Eingangsnummer=ENR).  
Please check that the name of the active substance is correct and that it is not a duplicate of an already existing entry.

ENR \*

Batch number

Date of batch

**1. A**

**Select**

Please allow at least one

PZN \*

**Allocation of batch-related active substance manufacturers**

**Summary of information**

**General information** [Edit](#)

PNR: 8002429  
Name: Michael Horn  
Name des einreichenden Unternehmens: BfArM Bundesinstitut für Arzneimittel und Medizinprodukte

**Batch information** [Edit](#)

Eingangsnummer: 5000001  
Name: Ethanol-Wasser-Gemisch 70 % (V/V)  
Chargennummer: 12345678  
Chargengröße: 500000  
Freigabedatum der Charge: 20.06.2024  
Date of batch expiration: 31.05.2026

**Select German Pharmazentralnummer (PZN)** [Edit](#)

PZN: 00000112

**1. Active substance - Ethanol 70% (V/V)** [Edit](#)

Active substance manufacturer: 8800010 - Test-BfArM; Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Deutschland

# ALBVVG - Section 130a para. 8b SGB V (supply-critical medicinal products)

- Further options for increasing prices
- After consulting the advisory council, the BfArM can
  - recommend to the BMG that individual off-patent medicinal products with **supply-critical** active ingredients or off-patent supply-critical active ingredients that are critical to care in a specific therapeutic area be classified as medicinal products with an **expected or existing market concentration** that is relevant to health care. (Section 130a para. 8b SGB V)
  - The product list must be published in the Federal Gazette.
  - Section 130a para. 8a SGB V 8a also applies to off-patent medicinal products that have been classified in accordance with Section 130a para. 8b SGB V
- List of off-patent oncological medicinal products was published in the Federal Gazette on 12.04.2024

# Application process in accordance with Section 130a (3c) sentences 8 to 14 SGB V

- German act to accelerate the digitalization of the healthcare system (DigiG) of 26 March 2024
- Application for exemption from the so-called price moratorium in accordance with § 130a, Paragraph 3a, Sentence 1 of the German Social Security Code (SGB V) if the following conditions are fulfilled cumulatively:
  1. A discount is applicable in accordance with Section 130a, para. 3a, sentence 1 of the SGB V
  2. there is a recommendation in accordance with Section 35, para. 5a or 5b, SGB V
  3. no therapeutic alternatives are available → BfArM assesses within 14 days
  4. the medicinal product cannot be distributed economically even after an price increase. → BAFA assesses within 14 days (Federal Office for Economic Affairs and Export Control)
- If the conditions are fulfilled, a new price can be agreed
- The application is submitted to the GKV-Spitzenverband (National Association of Statutory Health Insurance Funds)



Bundesinstitut  
für Arzneimittel  
und Medizinprodukte

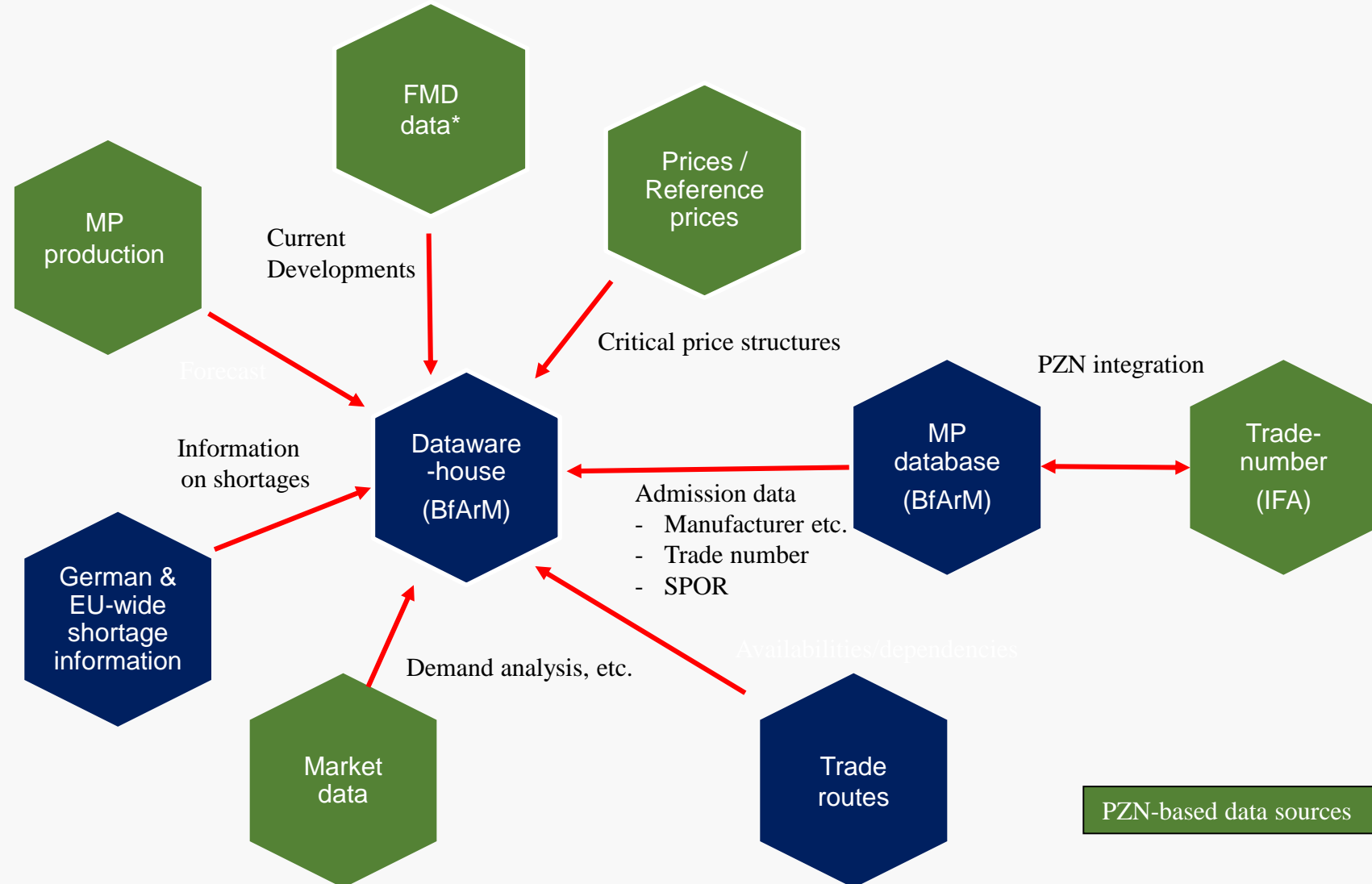
# Development of an early warning system



# Early warning system for supply-relevant shortages

## Target structure

- Crosslinking of already existing data
- Option of integrating additional data sources, such as EDQM
- Current status:
  - Cooperation agreements have been signed
  - Integration of trading numbers (PZN) has been completed
  - Integration of external data started



\*FMD data: only in context with the reimbursement of costs



# Thank you for your attention

