ePIL Pilot Germany
Reaching more patients with structured information

Paul Kamm (Rote Liste Service)

9th Healthcare Symposium
Berlin, 10th September 2024

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Electronic patient information leaflets in the EU Pharma Package

EUROPEAN
COMMISSION

Brussels, 26.4.2023
COM(2023) 192 final

2023/0132 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

(Text with EEA relevance)

{SEC(2023) 390 final} - {SWD(2023) 191 final} - {SWD(2023) 192 final} - {SWD(2023) 193 final}

European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2024)0220

Union code relating to medicinal products for human use

European Parliament legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0192),

– having regard to Article 294(2) and Article 114(1) and Article 168(4), point (c), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0143/2023),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 25 October 2023[1],

– after consulting the Committee of the Regions,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the opinion of the Committee on Industry, Research and Energy,

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Electronic patient information leaflets are a reality

Example ibuprofen

Electronic Medicines Compendium
https://www.medicines.org.uk › pil · Diese Seite übersetzen

Ibuprofen 400 mg film-coated tablets (PL 16363/0523)

The Patient **Information Leaflet** (**PIL**) is the leaflet included in the pack with a medicine. {info_black}. Last updated on emc: 12 Mar 2024. {pdf} View or print ...

Health Products Regulatory Authority (HPRA)
https://www.hpra.ie › uploaded › swedocuments PDF

Ibuprofen 200 mg Film-coated tablets ...

Read all of this **leaflet** carefully before you start taking this medicine because it contains important **information** for you.

Electronic Medicines Compendium
https://www.medicines.org.uk › pil.12380.pdf PDF

Information for the patient Ibuprofen Pain relief gel 5% w/ ...

Read all of this **leaflet** carefully before you start using this medicine because it contains important **information** for you. Always use this medicine exactly ...

windows.net
https://mhraproductsprod.blob.core.windows.net › ... PDF

Ibuprofen 200mg Tablets (FPL) P & GSL - Leaflet Size

PATIENT **INFORMATION LEAFLET**. Please read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Geneesmiddeleninformatiebank
https://www.geneesmiddeleninformatiebank.nl › h... PDF

Ibuprofen Strides 600 mg filmomhulde tabletten ...

Read all of this **leaflet** carefully before you start taking this medicine because it contains important **information** for you. - Keep this **leaflet**. You may need to ...

Health Products Regulatory Authority (HPRA)
https://www.hpra.ie › uploaded › swedocuments PDF

Information for the user ibuprofen PACKAGE LEAFLET

Read all of this **leaflet** carefully before you start taking this medicine because it contains important **information** for you. Always take this medicine exactly as ...

MRI - Home
https://mri.cts-mrp.eu › portal › odata › Download PDF

Information for the patient Ibuprofen B. Braun 600 mg solution ...

Package leaflet: Information for the patient. **Ibuprofen** B. Braun 600 mg solution for infusion **ibuprofen**. Read all of this leaflet carefully before you are ...

Drugs.com
https://www.drugs.com › pdf › leaflet PDF

Ibuprofen 400mg Tablets

Ibuprofen is useful for the relief of rheumatic and muscular pain, the pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, ...

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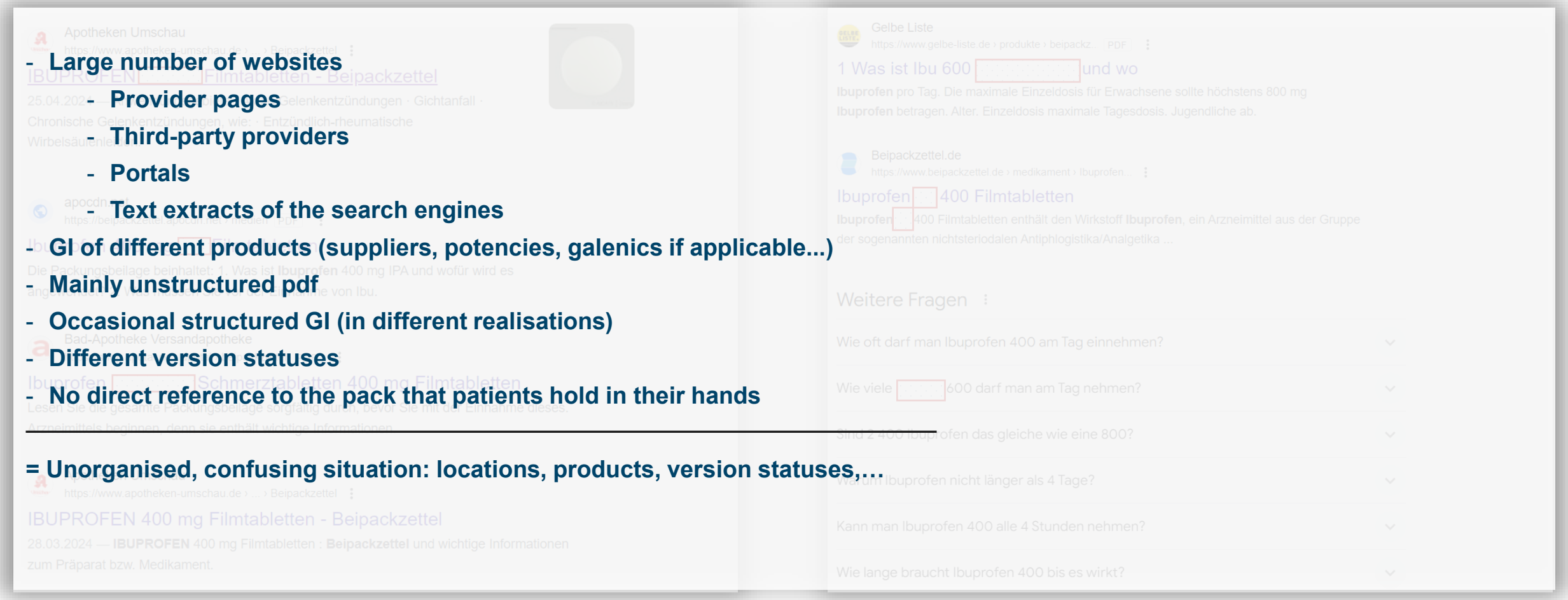
Google search result, search term "Ibuprofen package leaflet" Visited on 31/05/2024

Electronic patient information leaflets are a reality

Example ibuprofen



- Large number of websites
  - Provider pages
  - Third-party providers
    - Portals
    - Text extracts of the search engines
- GI of different products (suppliers, potencies, galenics if applicable...)
- Mainly unstructured pdf
- Occasional structured GI (in different realisations)
- Different version statuses
- No direct reference to the pack that patients hold in their hands

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= Unorganised, confusing situation: locations, products, version statuses,…

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Google search result, search term "Ibuprofen package leaflet" Visited on 31/05/2024

diGItal ePIL
structured information for patients

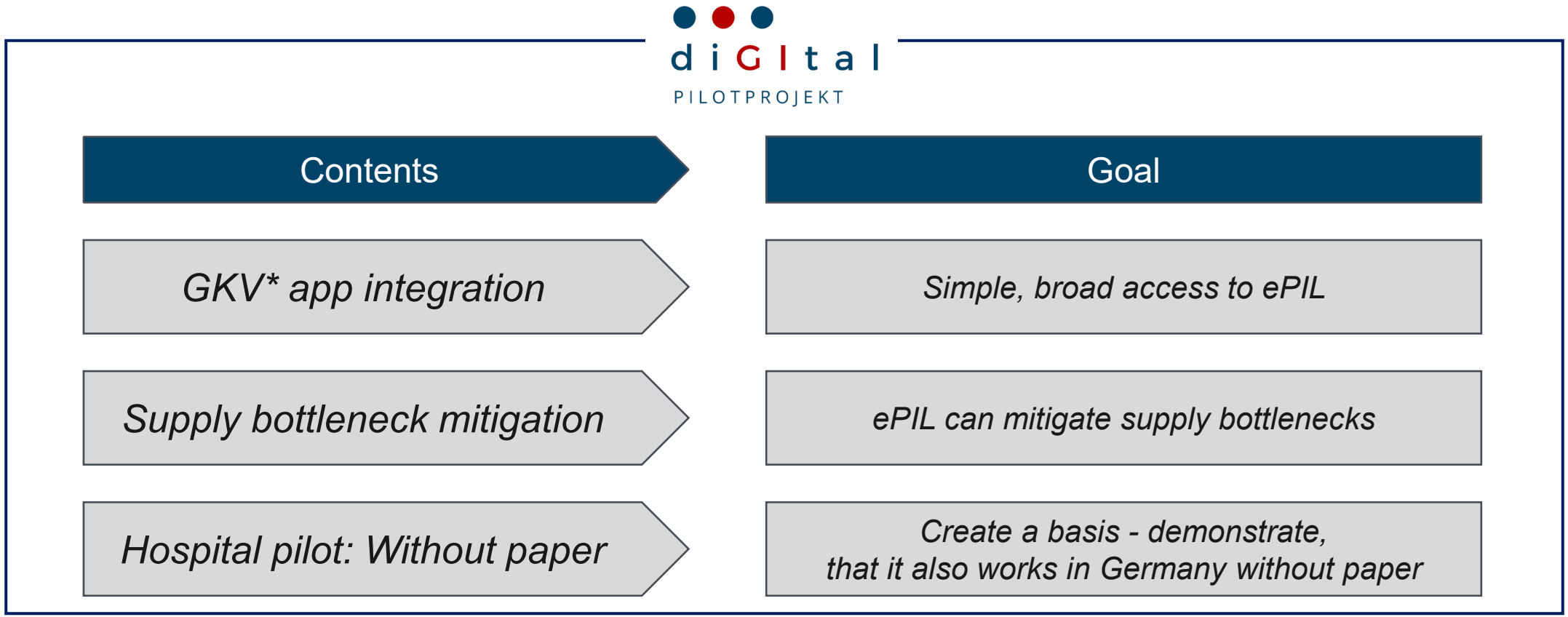
Create prerequisites

Demonstrate utilisation

Generate arguments

Paving the way to a paperless future

Use cases pilot project



ePIL: Provide once - use and share as widely as possible

*GKV is the German abbreviation for statutory health insurances

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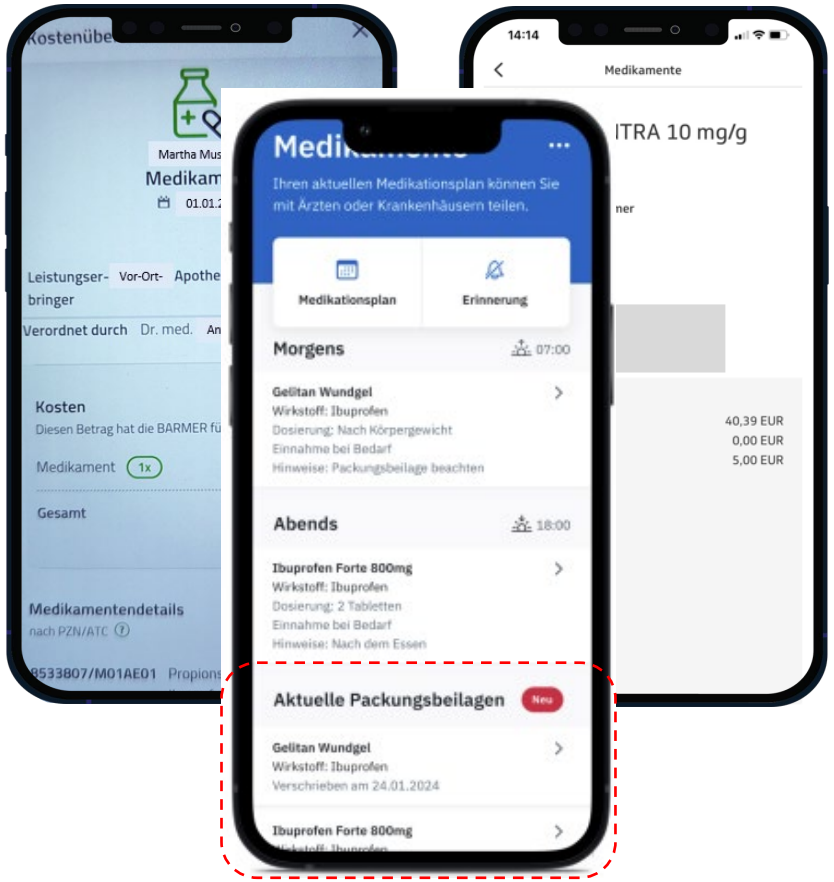
GKV apps



Visualisation of a possible integration

Overview

There is already an **ideal digital channel for easy & broad access** to digital user information: **GKV* apps**

Many major health insurances already offer an overview of **prescribed and billed medications** in their apps.

Medicines are usually stored with **metadata** such as **PZN** and, in future, the **batch designation.**

In the near future, medicines with an **e-prescription function will be stored** in the apps **immediately**, including relevant metadata.

The aim is to make it easier for patients to **provide structured product information for patients** through existing channels to **keep barriers of access low!**

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Mitigation of supply shortages

Overview: Supply shortages

Digital patient information leaflets can help to **alleviate supply shortages** and make it easier for patients to access information.

ALBVVG permits the marketing of packs in other languages if patients are given access to product information in an "appropriate manner".

The packs are supplied **unchanged** with a foreign package leaflet. **DMC is** used **for access to ePIL** in the national language. **Standardise processes**, increase efficiency.

The aim is to make it easier for **patients to access products and their instructions for use** in German in the context of supply bottlenecks.

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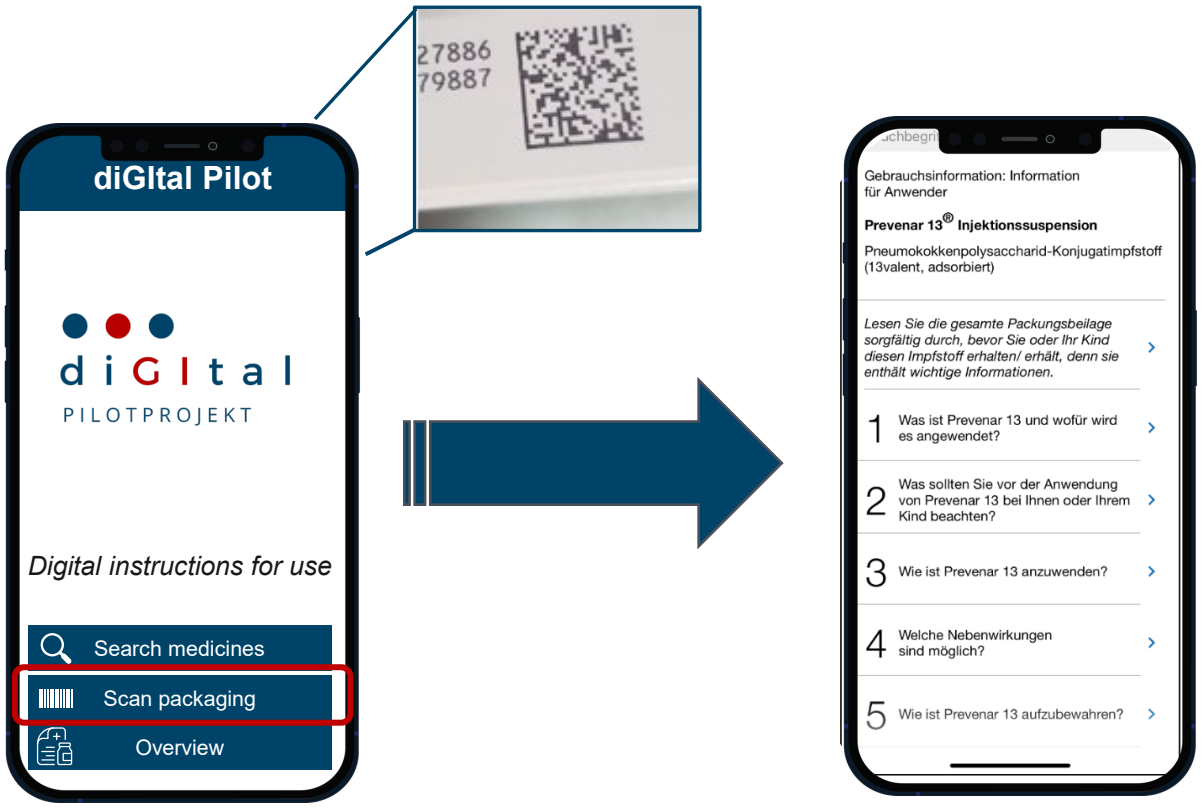
Mitigation of supply shortages
Scan DMC of pack in foreign language - Display GI in German language



Exemplary visualisation of an ePIL App

Status Quo

- Scan functions can be used to scan data matrix codes on packs - the digital usage information is displayed based on the metadata.
- Data Matrix Codes contain relevant data and the corresponding German versions of the ePIL for foreign packs can be displayed via stored NTIN / GTINs.

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Hospital packs

Overview: Hospital without paper

The printed patient information leaflet for medicinal products can be **completely replaced by an ePIL** in clinical practice.

An **exemption authorisation** is required and pilot products must be approved by the authorities.

The packs are **supplied without package leaflets** and the hospitals are informed, for example, by means of delivery notes.

The aim* is to enable the omission of printed ePIL for pilot products and to **show that handling and access to ePIL is made easier as a result.**

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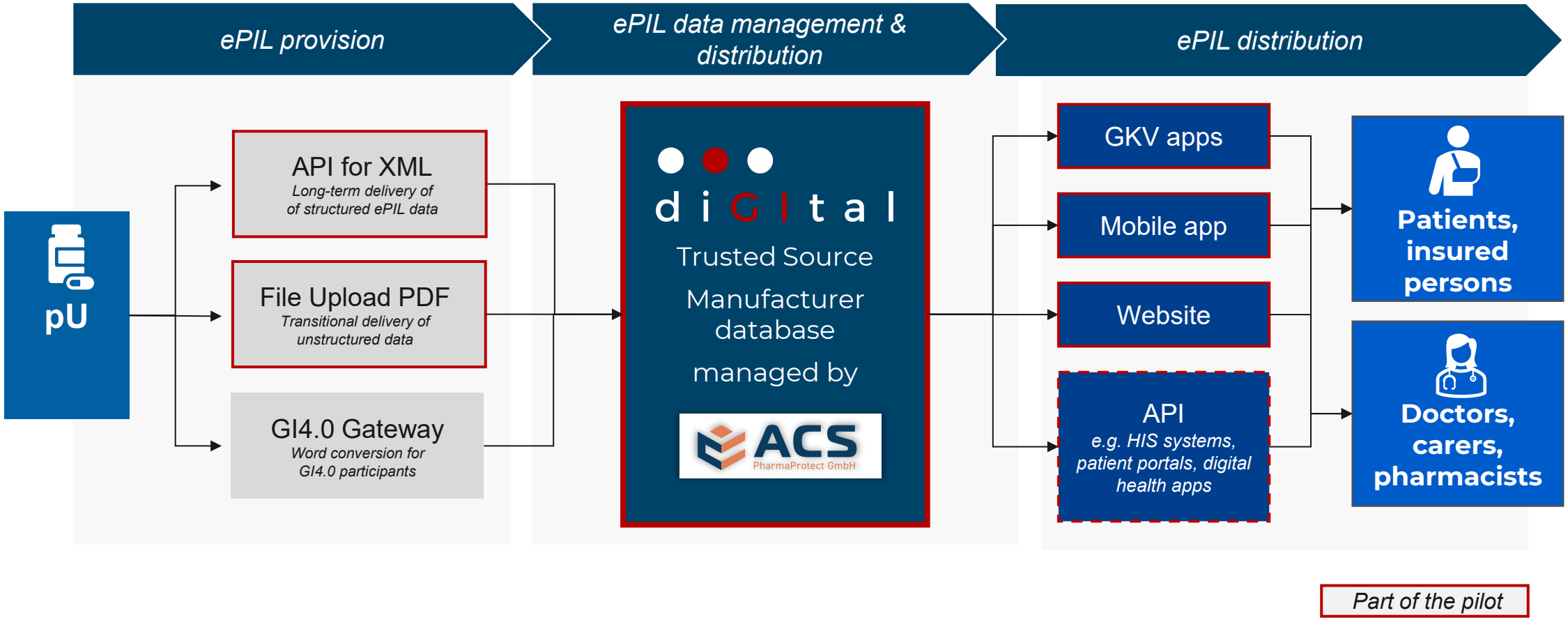
**Adapted and changed compared to planning status at the beginning of 2024*

Technical view: provision, database, distribution



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Benefits for pharmaceutical companies

Preparation for legal obligation
Participation in the pilot is a simple way to start digitising and structuring ePIL

First steps from "pdf" to structured data
The experienced project management team supports you with all questions relating to implementation

Gaining experience
Gain experience, create and test infrastructures before mandatory introduction

Efficiency gains in the event of supply bottlenecks
ePIL can help directly with supply bottlenecks and increase process efficiency

Insights for your own communication
Pilot participants receive access to the pilot-relevant marketing materials

Bringing digital GI to the patient
Support of digital strategies, e.g. making ePIL available on mobile devices via company websites

Testing paperless scenarios
First paperless use cases in hospitals

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Thank you very much!

If you have any questions, please contact the project team:
info@di-gi-pilot.de

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