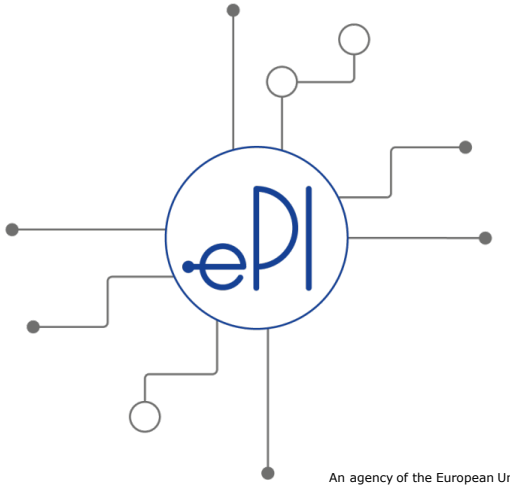
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

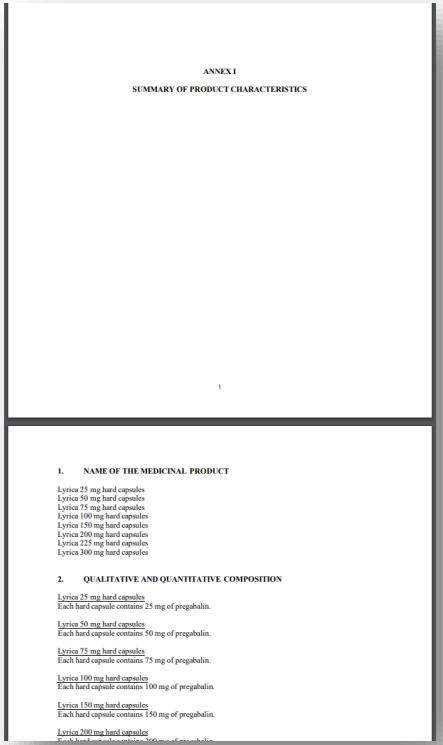
HMA
Heads of Medicines Agencies

European Commission

Electronic Product Information (ePI) for EU medicines



Towards electronic solutions for product information



ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lyrica 25 mg hard capsules
Lyrica 50 mg hard capsules
Lyrica 75 mg hard capsules
Lyrica 100 mg hard capsules
Lyrica 150 mg hard capsules
Lyrica 200 mg hard capsules
Lyrica 225 mg hard capsules
Lyrica 300 mg hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyrica 25 mg hard capsules
Each hard capsule contains 25 mg of pregabalin.

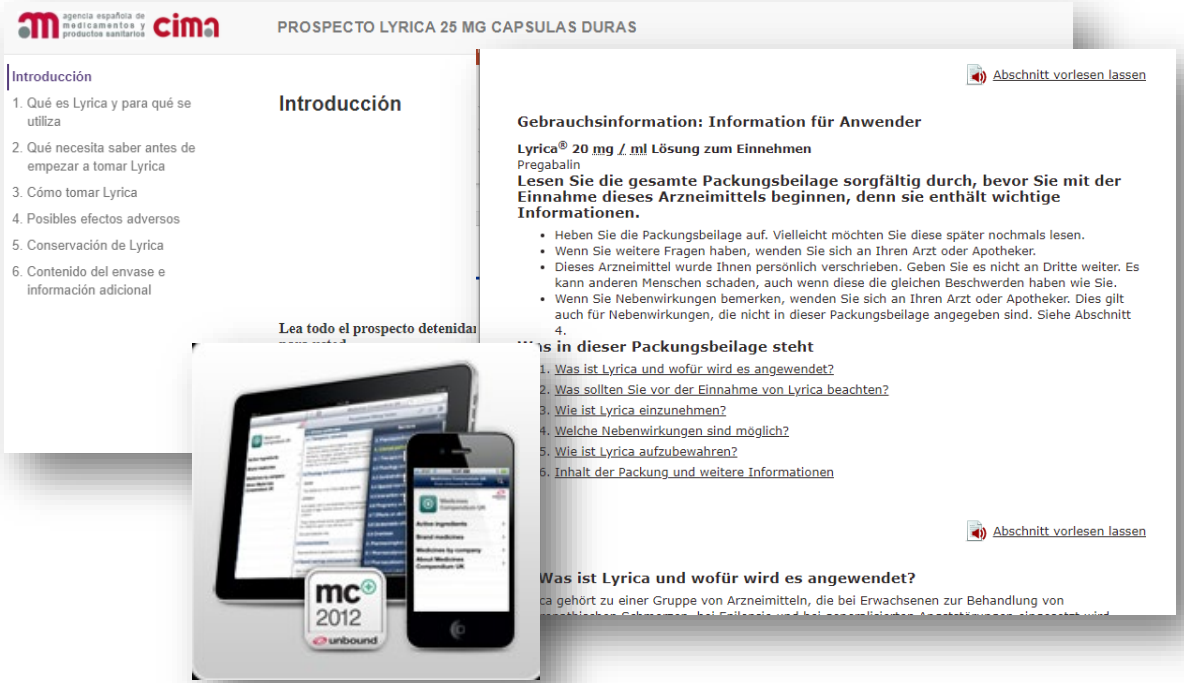
Lyrica 50 mg hard capsules
Each hard capsule contains 50 mg of pregabalin.

Lyrica 75 mg hard capsules
Each hard capsule contains 75 mg of pregabalin.

Lyrica 100 mg hard capsules
Each hard capsule contains 100 mg of pregabalin.

Lyrica 150 mg hard capsules
Each hard capsule contains 150 mg of pregabalin.

Lyrica 200 mg hard capsules



agencia española de medicamentos y productos sanitarios cima

PROSPECTO LYRICA 25 MG CAPSULAS DURAS

Introducción

1. Qué es Lyrica y para qué se utiliza
2. Qué necesita saber antes de empezar a tomar Lyrica
3. Cómo tomar Lyrica
4. Posibles efectos adversos
5. Conservación de Lyrica
6. Contenido del envase e información adicional

Introducción

Lea todo el prospecto detenidamente

Abschnitt vorlesen lassen

Gebrauchsinformation: Information für Anwender

Lyrica® 20 mg / ml Lösung zum Einnehmen
Pregabalin
Lesen Sie die gesamte Packungsbeilage sorgfältig durch, bevor Sie mit der Einnahme dieses Arzneimittels beginnen, denn sie enthält wichtige Informationen.

- Heben Sie die Packungsbeilage auf. Vielleicht möchten Sie diese später nochmals lesen.
- Wenn Sie weitere Fragen haben, wenden Sie sich an Ihren Arzt oder Apotheker.
- Dieses Arzneimittel wurde Ihnen persönlich verschrieben. Geben Sie es nicht an Dritte weiter. Es kann anderen Menschen schaden, auch wenn diese die gleichen Beschwerden haben wie Sie.
- Wenn Sie Nebenwirkungen bemerken, wenden Sie sich an Ihren Arzt oder Apotheker. Dies gilt auch für Nebenwirkungen, die nicht in dieser Packungsbeilage angegeben sind. Siehe Abschnitt 4.

Was in dieser Packungsbeilage steht

1. Was ist Lyrica und wofür wird es angewendet?
2. Was sollten Sie vor der Einnahme von Lyrica beachten?
3. Wie ist Lyrica einzunehmen?
4. Welche Nebenwirkungen sind möglich?
5. Wie ist Lyrica aufzubewahren?
6. Inhalt der Packung und weitere Informationen

Abschnitt vorlesen lassen

Was ist Lyrica und wofür wird es angewendet?

Lyrica gehört zu einer Gruppe von Arzneimitteln, die bei Erwachsenen zur Behandlung von

Problem statement

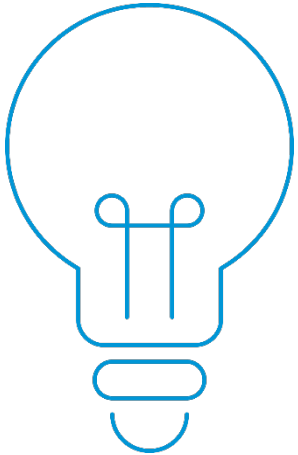
Need to expand public access and dissemination of unbiased, up-to-date, regulator-approved PI for all medicines in the EU

Need to facilitate access to PI data across different regulatory procedures

Growing administrative burden of maintaining and updating Word/PDF files

ePI Key Principles

ePI is authorised, statutory product information for human medicines (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured format created using a **common EU electronic standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.



Key principles: adopted by HMA and EMA, published January 2020

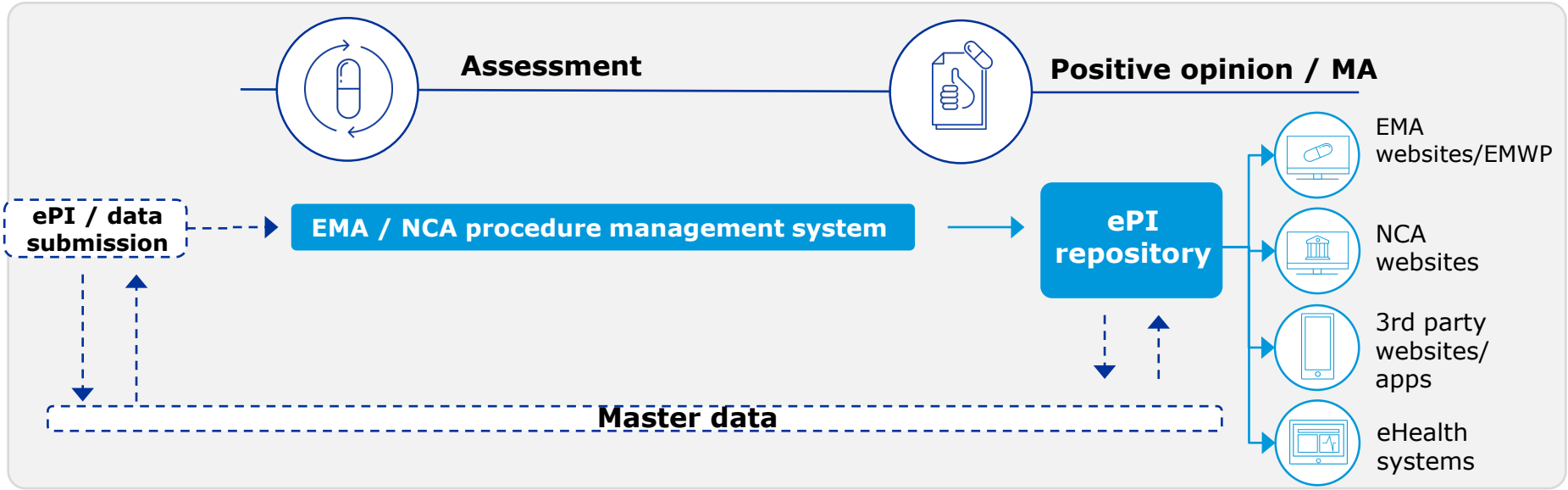
ePI facilitates dissemination to patients and healthcare professionals

Access medicine ePI on phone/tablet → Seek reminder of how to take medicine → **Go to 'How to take your medicine' Option to watch video**

Support rapid roll out of COVID-19 vaccines and therapeutics → Use QR code to link to national language PL → **Delivery of vaccine to all EU countries**

Future vision

ePI seamlessly integrated with all EMA/NCA systems supporting medicines assessment



ePI deliverables in 2021

#1

Create an **EU Common Standard for ePI** based on FHIR to support harmonisation across the EU and collaboration across the network

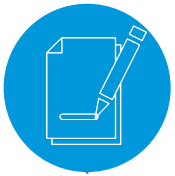
#2

Provide a **proof-of-concept prototype** using the EU common standard. The prototype will be used for a design and technical feasibility study to generate example FHIR-based documents associated with product data to publish on a website.

#3

Provide a realistic medium-term **vision and road map** towards achieving the benefits for stakeholders, HMA, EC, EMA as outlined in the Key Principles for ePI in the EU

ePI milestones 2021 and beyond



June 2021

Draft EU Common Standard published

Consultation begins

July 2021

Information and exploratory workshops

End 2021

Proof-of-concept prototype completed

EU Common Standard and roadmap adopted

ePI set-up project

2021

Pilot phase (EMA & some NCAs)

2022

Transition to implementation

Timeline dependent on pilot outcome

ePI consultation

Consultation methods

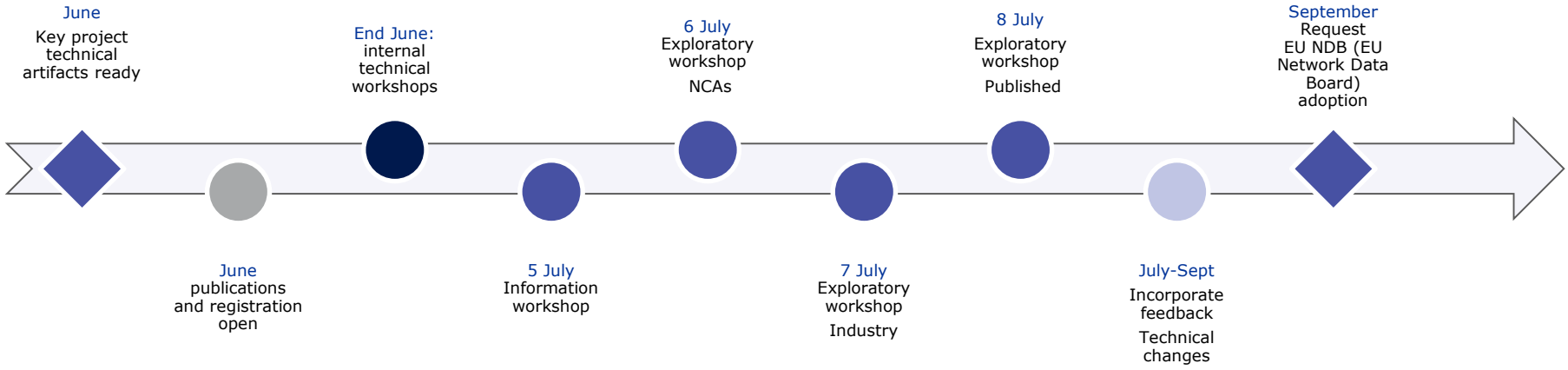
- Information workshop (no pre-requisite for joining)
- Exploratory workshops (participants with a technical background *e.g. Mandatory working knowledge of at least one programming language and REST services. Participants use their own workstations, with pre-installed tools.*)
- Consultation feedback via survey tool

Objectives

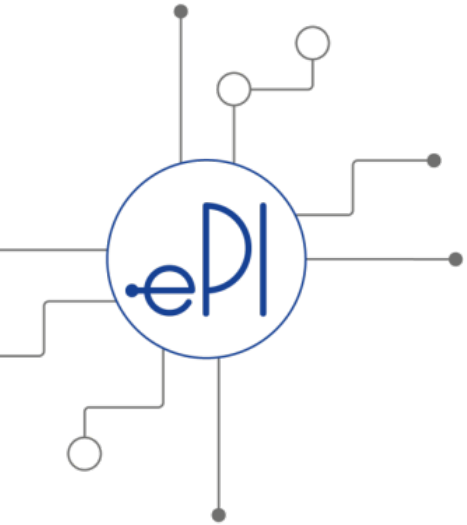
1. **Information workshop**: Introduce all participants to the draft EU Common Standard for ePI;
2. **Exploratory workshops**: to provide technical scenarios on how to use the API and to receive input from developers on:

- Feedback on the capabilities offered by the ePI API
- Expected use of the ePI API (operations, volume and frequency)
- Innovative user stories of the data exposed by the ePI

ePI consultation



Any questions?



Further information

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See websites for contact details

European Medicines Agency www.ema.europa.eu
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