



CORIMEO

E2E Live Showcase

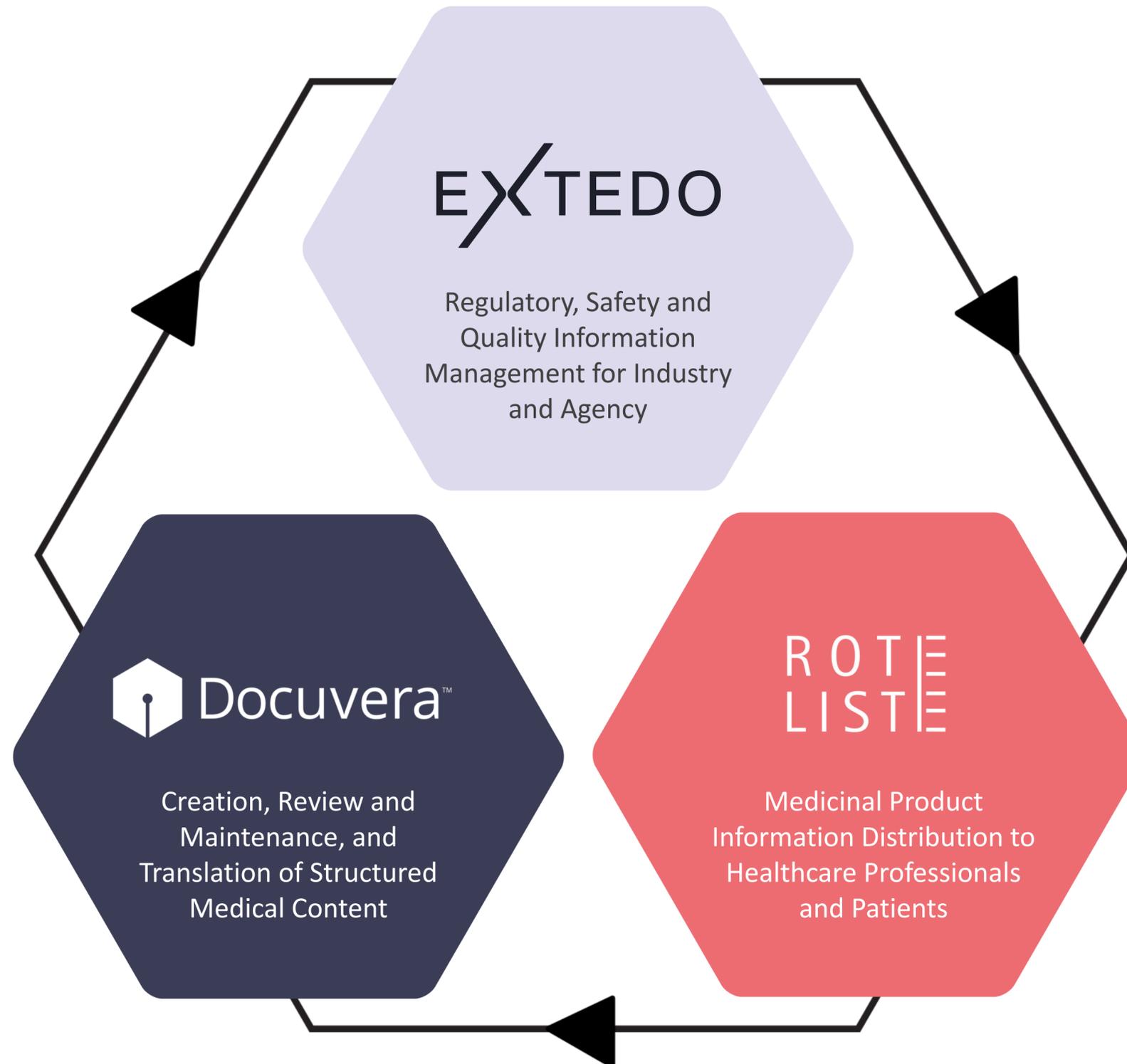
Bridging Industry, Agencies & Patients through ePI

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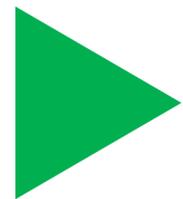
Director Strategic Projects



Together, we build the trusted bridge between industry, authorities and healthcare professionals facilitating innovative and compliant exchange of regulated information in life sciences to improve patient health.

The E2E Showcase Scenario

-  Authorized product Transformium 
-  New contra indication for pregnancy  discovered
-  Variation initiated and submitted as  **FHIR** ePI to the agency



We start our showcase with the agency review...

Elevating Industry-Agency Collaboration

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PULSE
Industry

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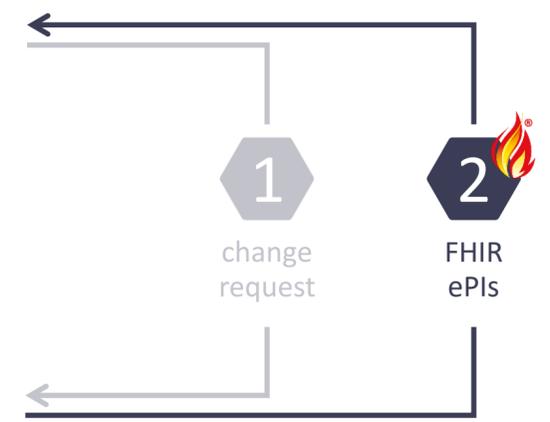


1

Situation: Contraindication is identified and reported via Pharmacovigilance system. Impacted content is assessed and regulatory activity is created. A change request is triggered to update the impacted product information accordingly.

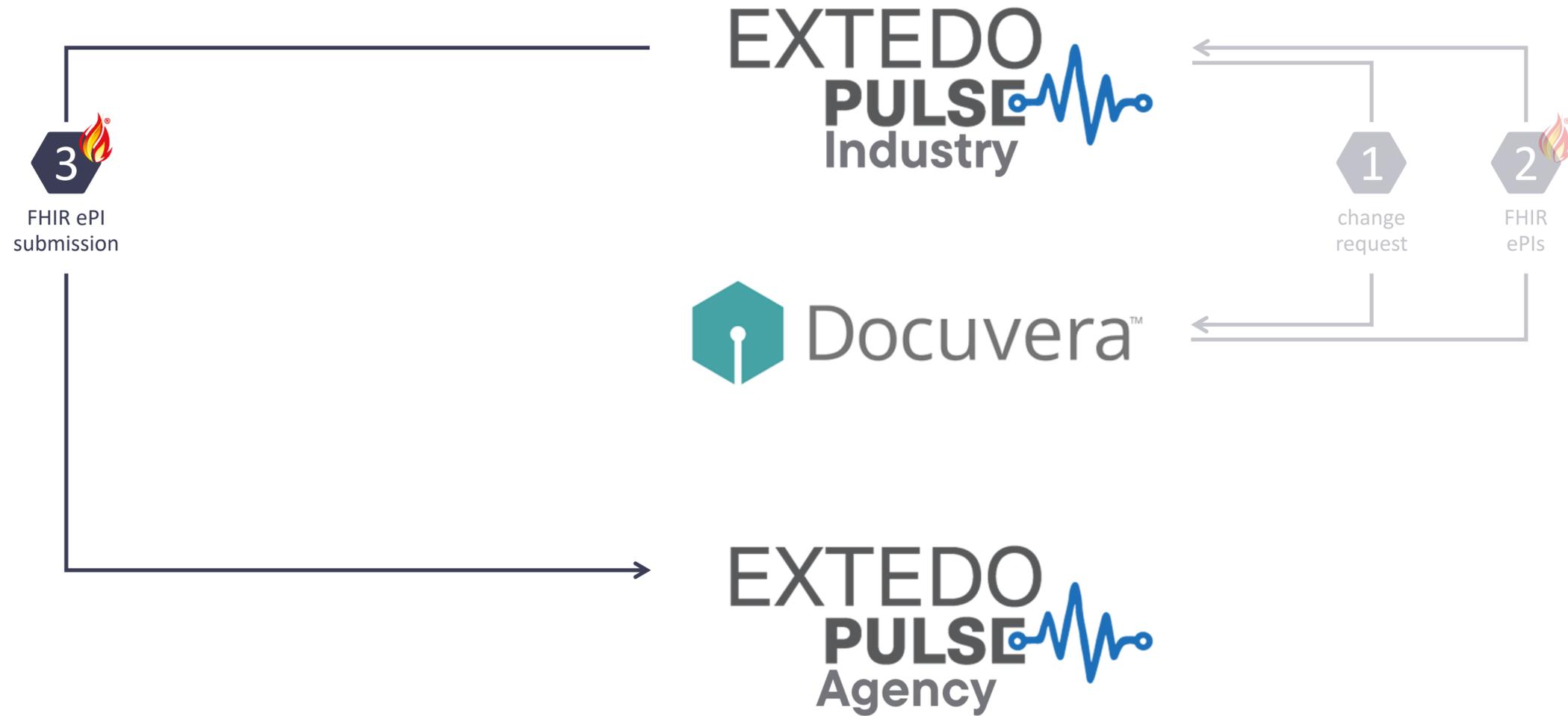
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2

After updating the relevant product information, the new versions are synchronized with the regulatory document management system via FHIR ePI.



3

Updated product information is uploaded to the agency portal as FHIR ePIs. The agency portal automatically performs a technical validation, imports the submission into the case management system, and notifies assessors of the incoming submission.



4

The agency assessor team reviews the updated product information and forwards comments and annotations on component level directly to industry via gateway.



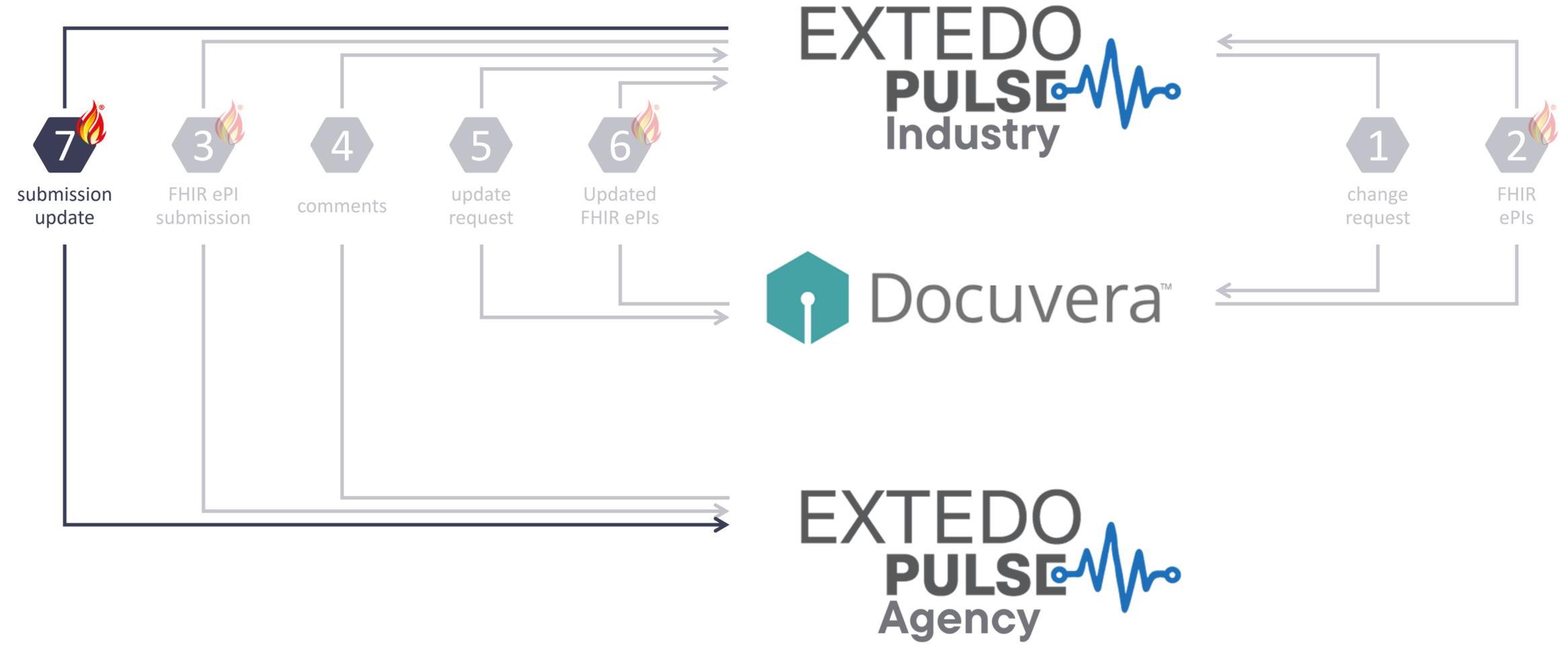
5

Regulatory Management reviews the agency comments and, if agreed, forwards the update requests directly at component level to the authoring team.



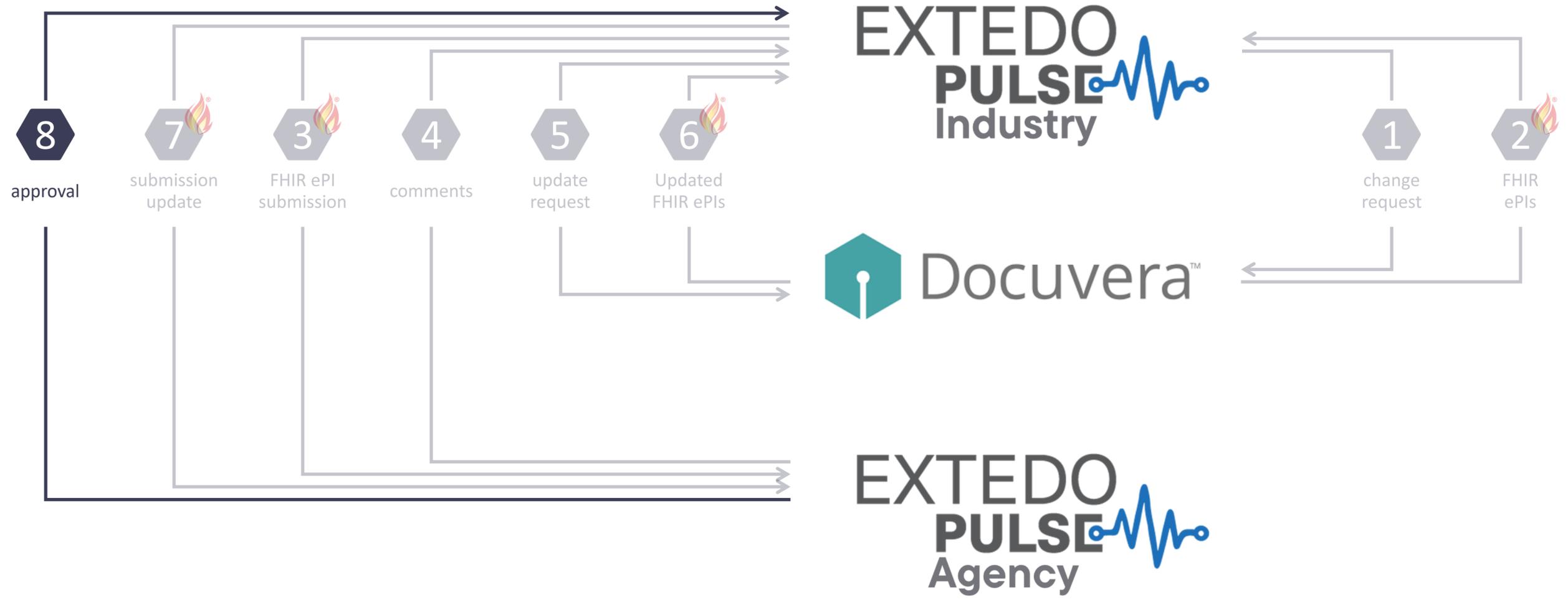
6

Updated ePIs, based on agency comments, are synchronized with the regulatory document management system.



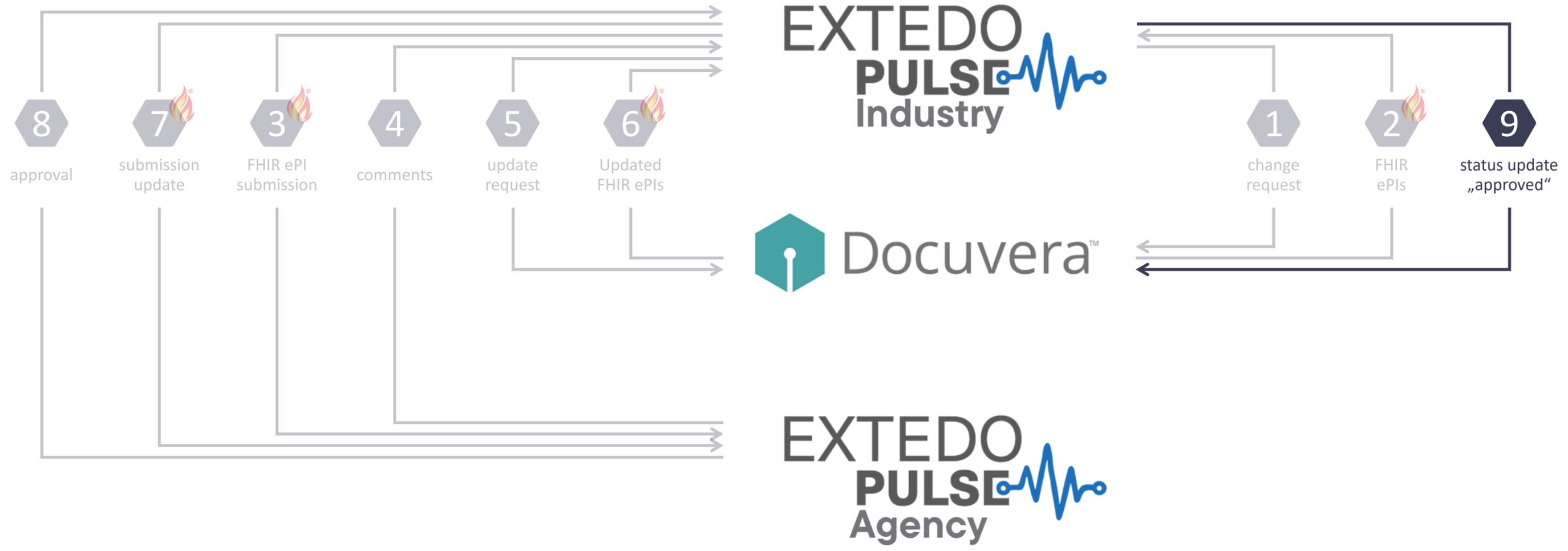
7

Updated content is uploaded to agency portal in FHIR format.



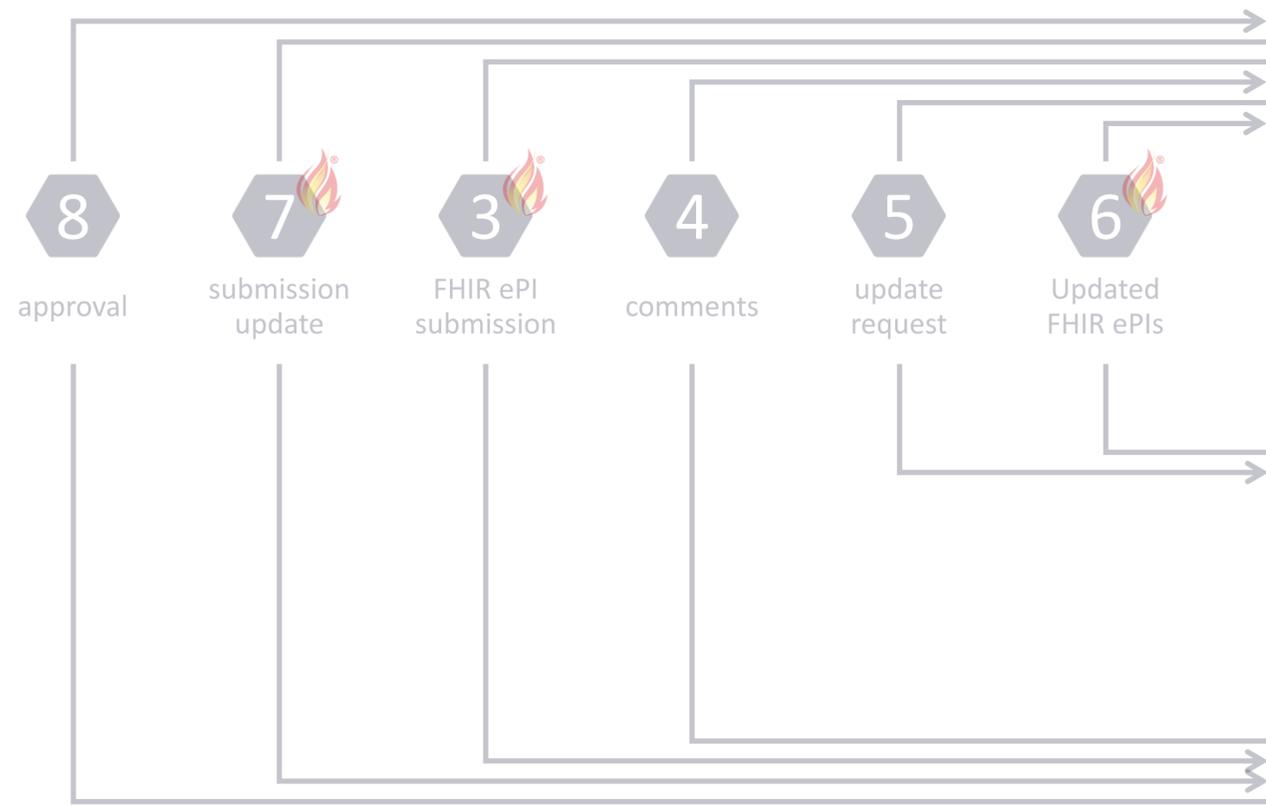
8

The regulatory agency approves the submitted variation.

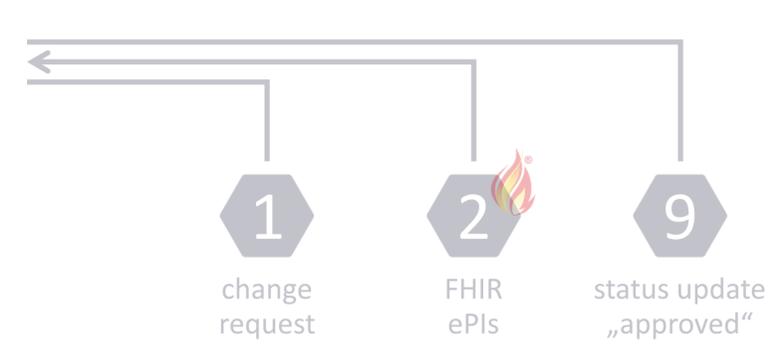


9

Information on agency approval is synchronized across systems, updating the relevant product information status to 'approved'.



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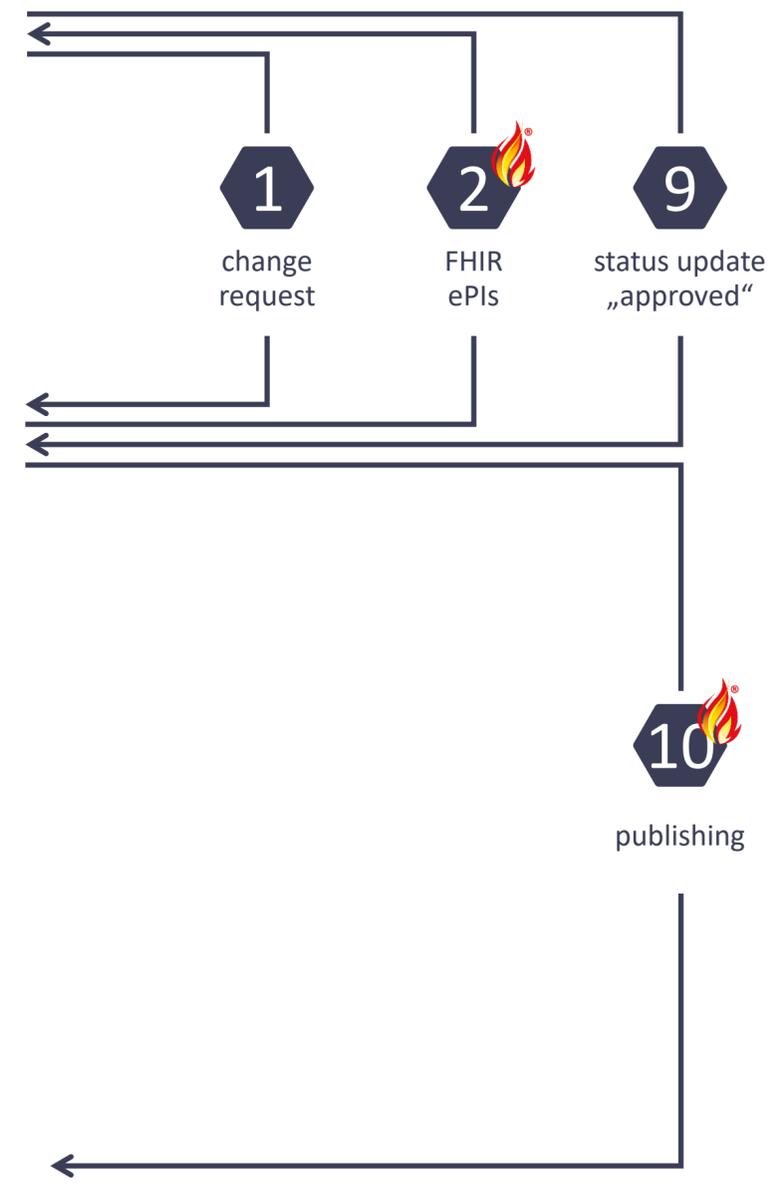
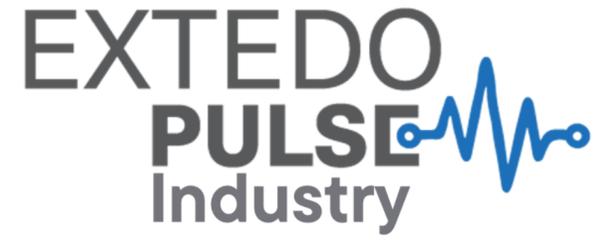
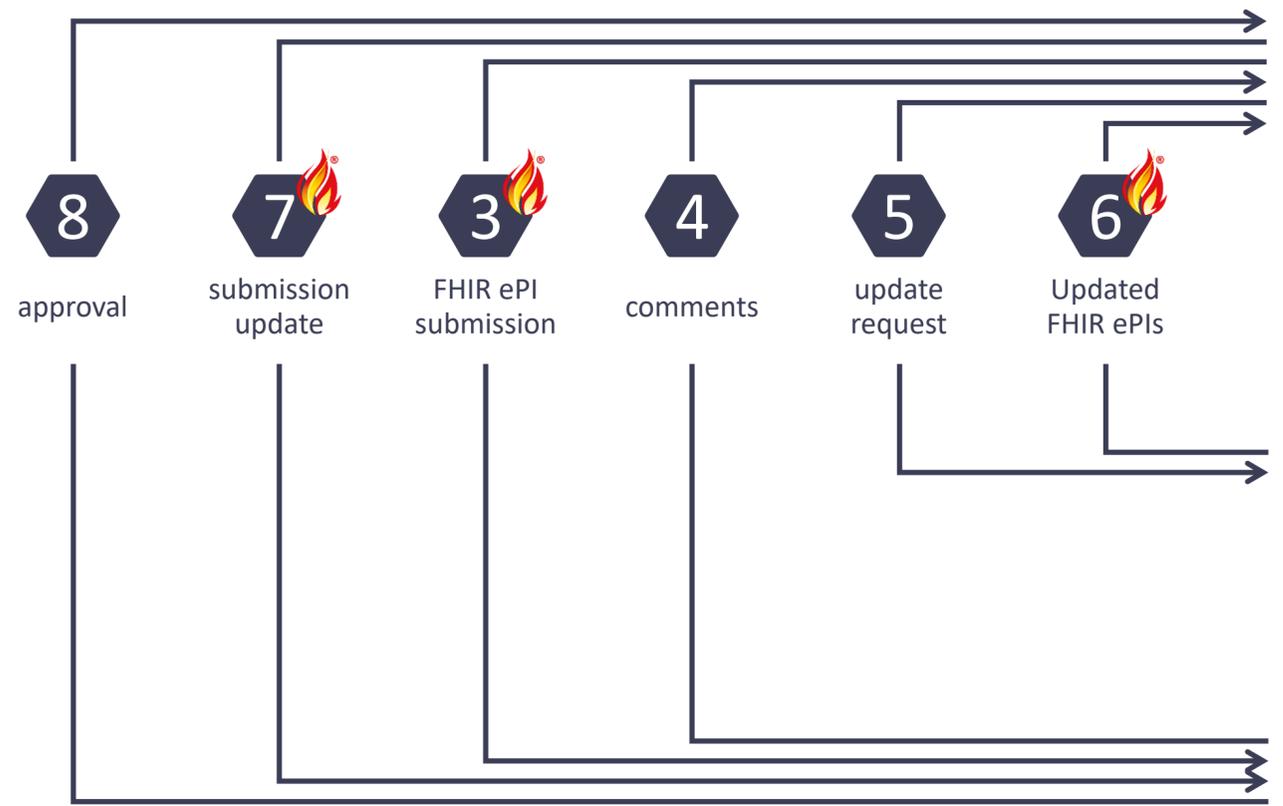


Healthcare Professionals →
Patients →

ROTE
LISTE

10

The approval status update triggers the release and publication of product information across various channels.



Healthcare Professionals →
Patients →

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Leveraging FHIR-based ePIs across our systems streamlines the process and enhances collaboration—enabling faster and more efficient delivery of information to healthcare professionals and patients



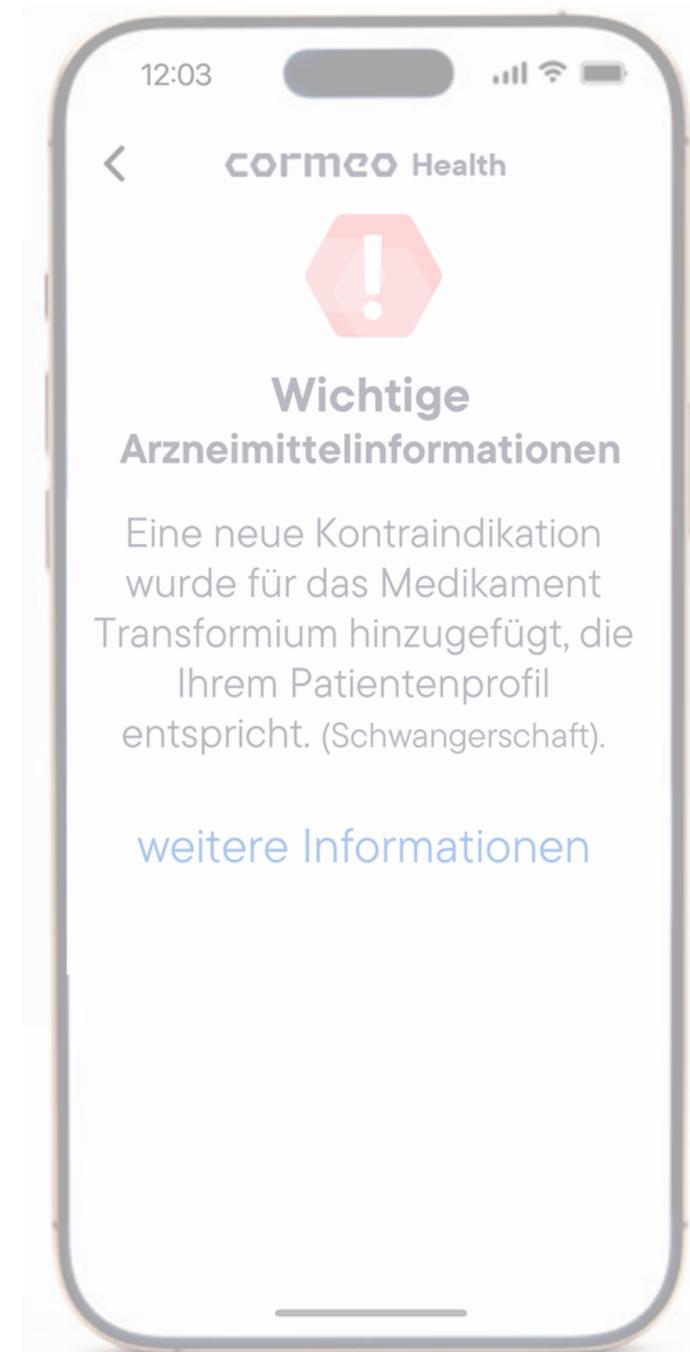
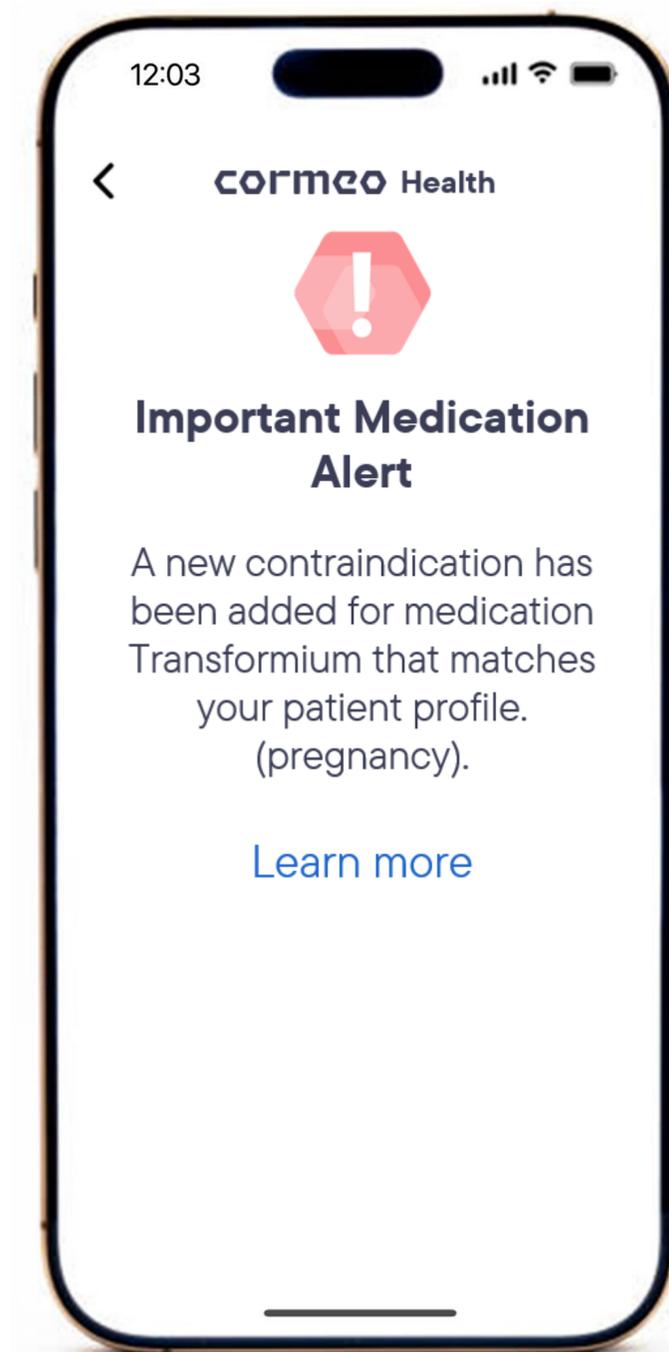
A Patient's View



1

Upon event, cormeo health insurance App will inform patients about relevant updates based on their individual electronic patient profile.

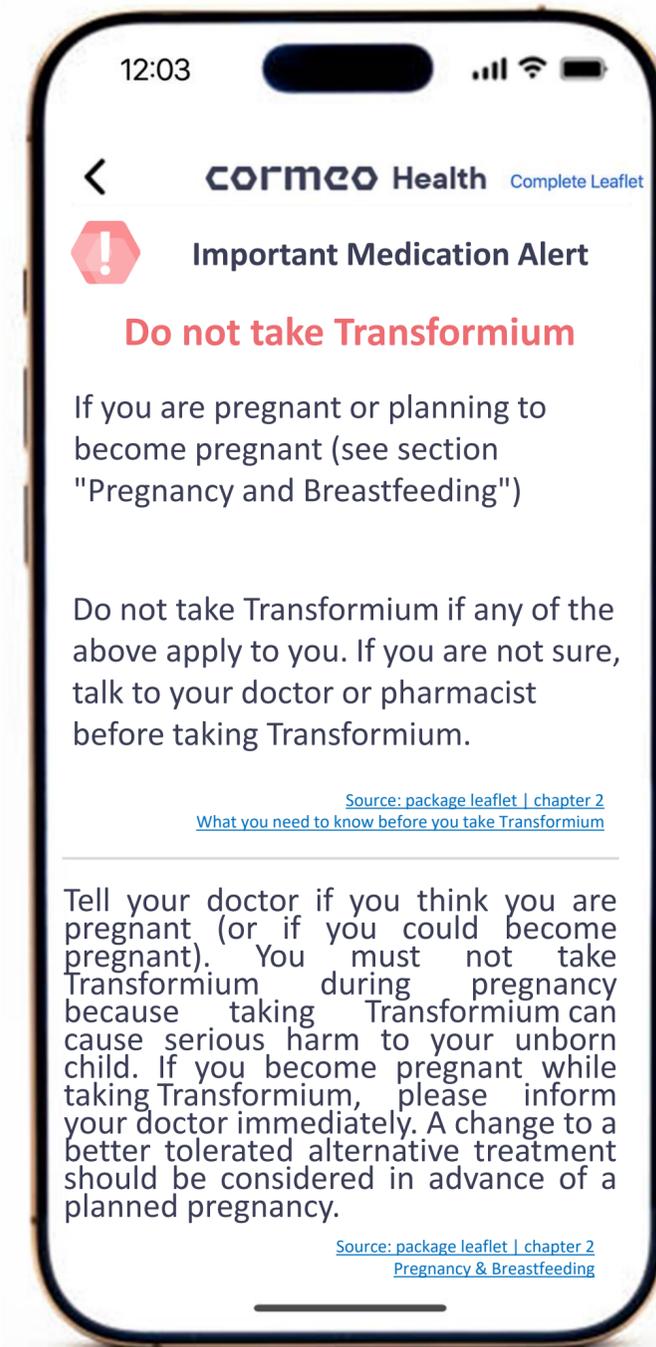
cormeo health is a fictitious health insurance app to demonstrate information distribution towards patients.



corneo health is a fictitious health insurance app to demonstrate information distribution towards patients.

2

Entering corneo Health, further information will be revealed concerning the notification. In the patient's preferred language...



Alert details are revealed matching the patients profile & the IDMP based component metadata.

corneo health is a fictitious health insurance app to demonstrate information distribution towards patients.

3

corneo health show relevant information and highlight the potential impact based on the individual patient's profile.

- Elevating Industry-Agency Interaction and Exchange**
- Transforming data into information shared in time**
- Facilitates content-level data exchange**
- Promotes interactive collaboration between industry & agency**
- Accelerates time to market with rolling submissions**
- Direct agency interaction on content level**



Q&A

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