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Your Gateway to Europe:
Market Access for Biotech and Pharmaceutical Companies

Thomas Ecker (Editor)

EU HTA 101 (Update from October 2024)

How to prepare for
European Health Technology Assessment

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The book EU HTA 101

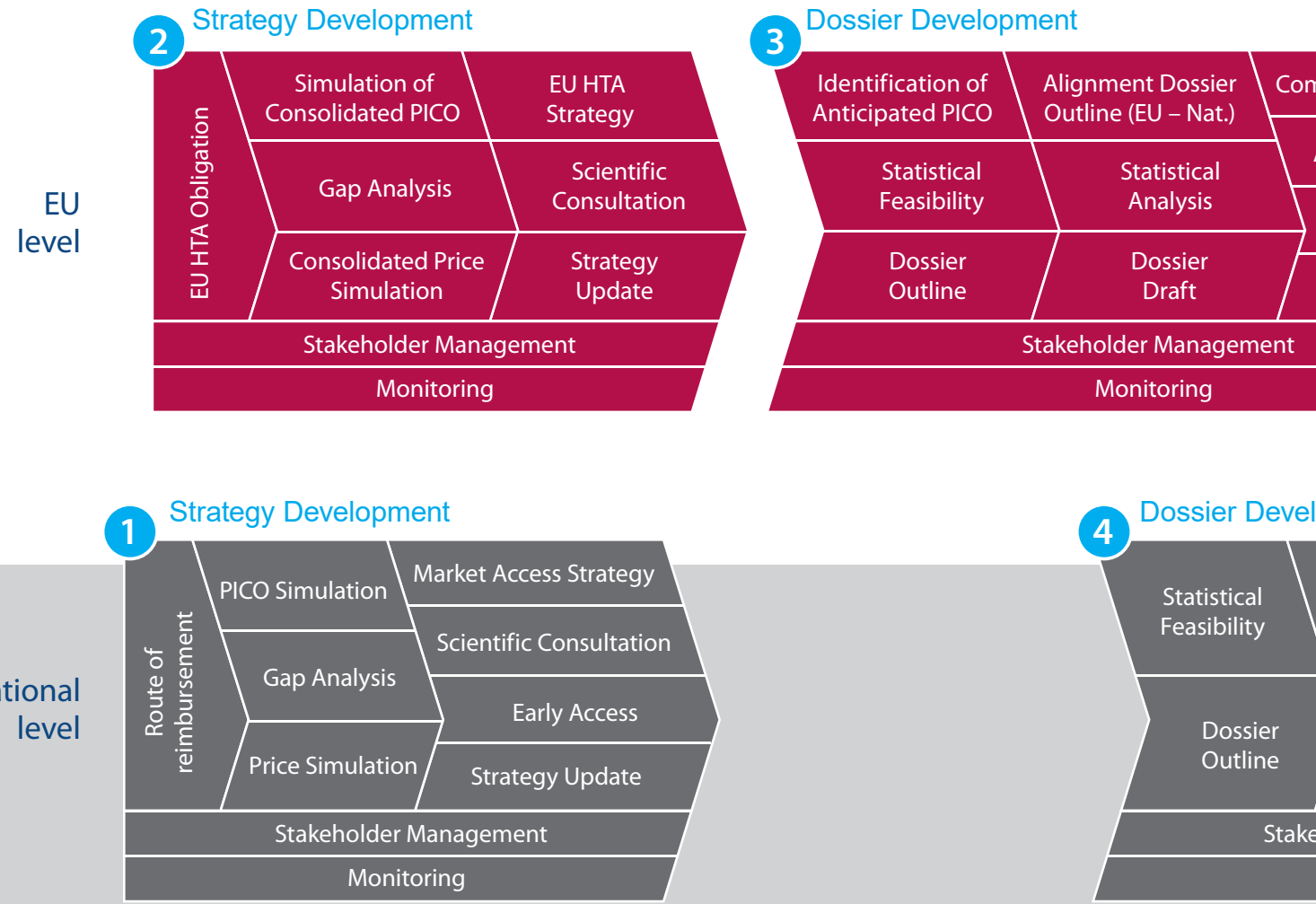
The regulation on European Health Technology Assessment (EU HTA) entered into force on 11 January 2022 and will apply from 12 January 2025. It introduces joint clinical assessments and joint scientific consultations at the European level for new health technologies, including pharmaceuticals and medical devices. While market access, pricing and reimbursement will continue to be the responsibility of EU member states, EU HTA will nevertheless have an immense impact on these national market access activities.

Content

- Practical guide for pharmaceutical companies
- A thorough overview of the EU HTA procedure
- A step-by-step approach for aligning EU HTA with national market access strategies and procedures
- Key insights to prepare for EU HTA

The Editor

Thomas Ecker is CEO of Ecker + Ecker and Accessus Health. Over the past 20 years, he has focused on HTA and the pricing and reimbursement of pharmaceuticals. In this role, he has been responsible for more than 100 dossier submissions and price negotiations in Germany. With this in-depth knowledge, he has extended his focus to include EU HTA strategy development and EU HTA dossier preparation.



Market Access Core Model

The EU Market Access Core Model describes key activities, inputs and implications between national market access and EU HTA.

National and European level

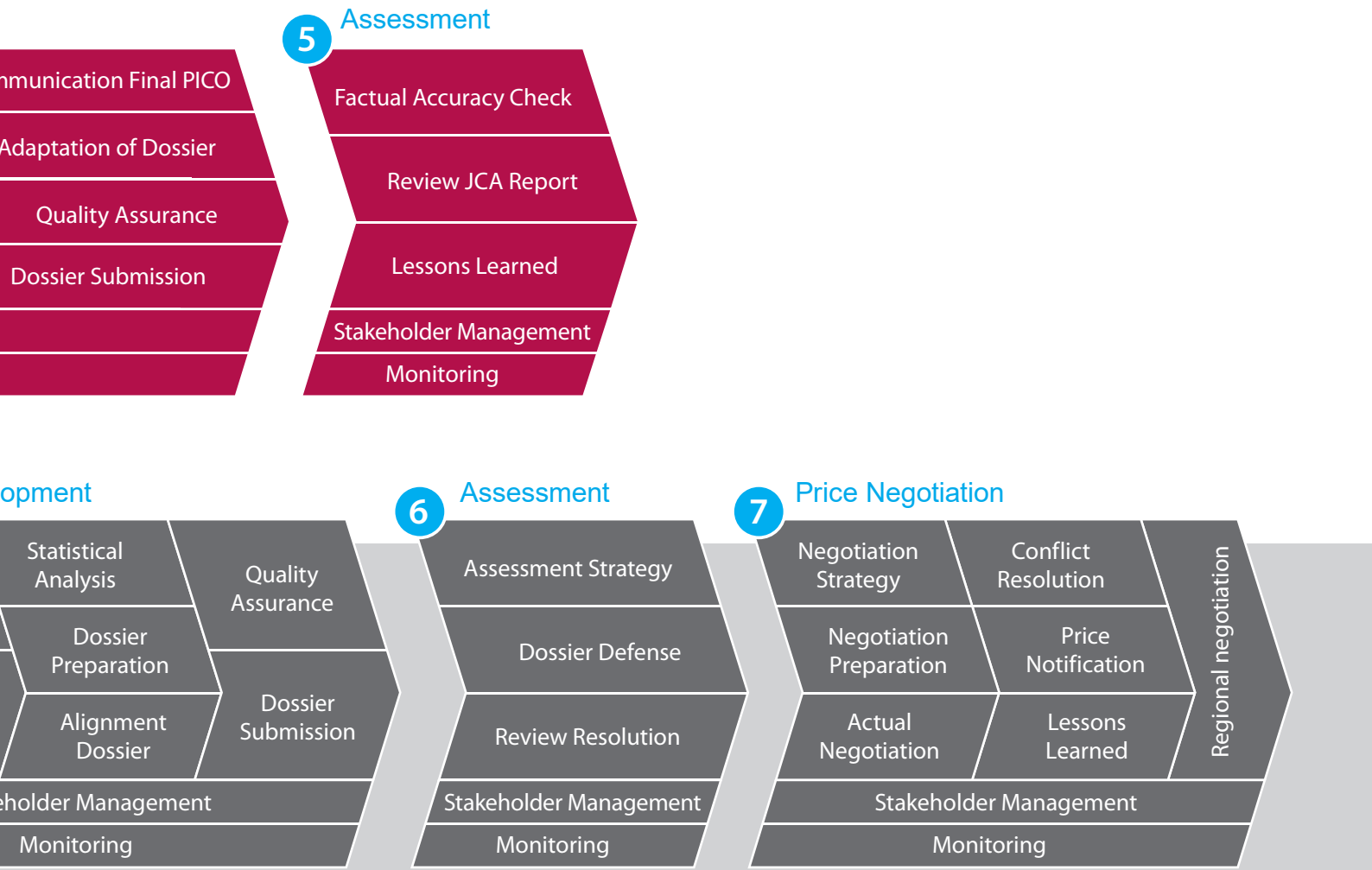
The national market access workstream can be delineated from a pharmaceutical company`s perspective with four distinct phases: strategy development, dossier development, assessment, and price negotiation.

There are three distinct phases that form the EU HTA workstream: strategy development, dossier development and assessment.

Stakeholder management and monitoring activities are crucial and should be addressed continuously throughout all phases of both workstreams.

Alignment

The national market access workstream and the EU HTA workstream need to be managed simultaneously to prepare for product launch as both workstreams are linked to each other, leading to a total of 59 work packages in the EU Market Access Core Model.



Nat. = National PICO = Population, Intervention, Comparator, Outcome JCA = Joint Clinical Assessment

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