BPI Bundesverband der Pharmazeutischen Industrie e.V.

EU HTA Impact on Innovation: Expectations and challenges for Germany

Julia Rumsch

German Pharmaceutical Industry Association

Brussels Liaison Office

EUnetHTA 21 proposed timeline

- EUnetHTA 21 has proposed three scenarios for the JCA timelines:
  - **For new chemical entities the JCA process starts 2 months after submission to the EMA**;
  - For new indications of already approved products (Type II variation) and for accelerated regulatory procedures for new chemical entities, the JCA process starts at the point of time of submission to the EMA;
  - In case there is a label change at time of CHMP opinion, the JCA process has to be stopped and re-started at a later point with a reformulation of the PICO(s), introducing a clock-stop for the JCA. **EUnetHTA21 proposes to further develop this process, and to consider its inclusion in the implementing act (on JCA).**
- The EUnetHTA 21 proposal does not clarify timelines for responding to clarifying questions from the assessors.
- Only 5 days have been proposed for the factual accuracy check

EUnetHTA 21 proposed timeline

1. Member State PICO survey to select the scope of the assessment, based on Member States identified needs. More than one PICO expected.

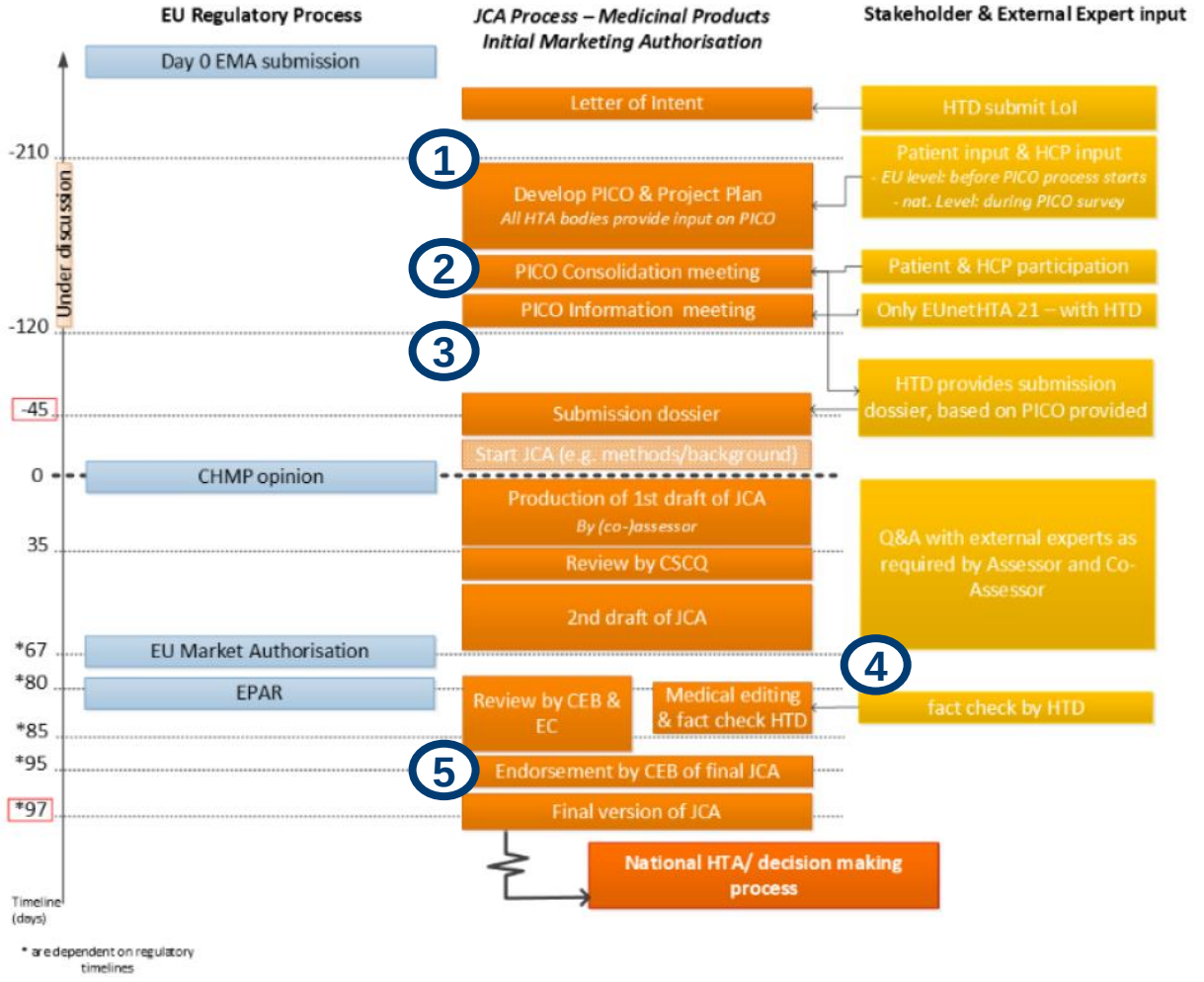
2. Company is informed of PICO(s) and is given 75 days to prepare the dossier

3. Deadline for submitting dossier is 45 days prior to CHMP opinion

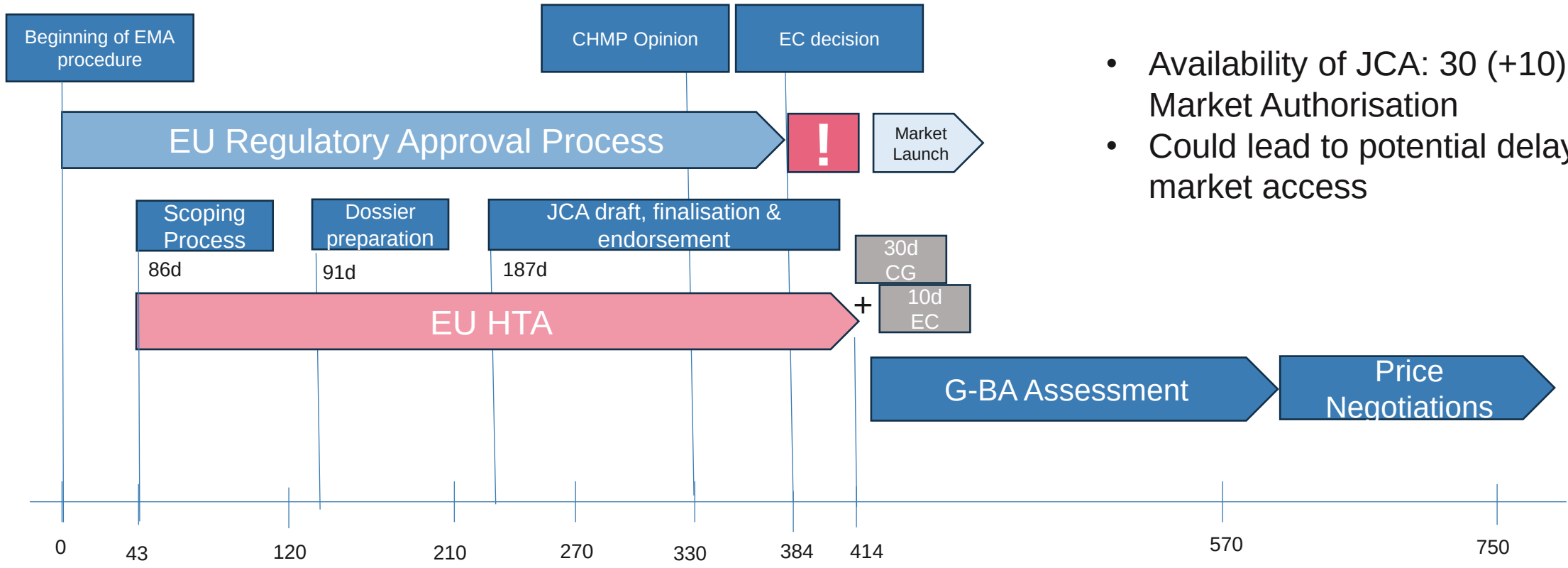
4. The developer will have the opportunity to provide comments to point out any errors in the draft report with a factual accuracy check

5. The Joint Clinical Assessment report shall be endorsed by the Coordination Group no later than 30 days after European Commission's marketing authorisation

Industry stakeholders have commented that the timelines are too short for e.g. updating the dossier in the case of a label change or responding to questions from the Assessors.



Availability gap for innovations?



- Availability of JCA: 30 (+10) after Market Authorisation
- Could lead to potential delay of market access

EUnetHTA21 PICO(s) exercises

- EUnetHTA12 has published **three pilot PICO(s) exercises** for medicinal products, where they have piloted the Member States' PICO survey and PICO generation process for three products **without companies involvement**

- Pluvicto: Total of 6 consolidated PICO(S) were generated, with 2 in the full licensed population and 4 in subpopulations
- Ebvallo Tabelecleucel: Total of 5 consolidated PICO(s) were generated, with 1 in the full population and 4 in subpopulations
- Pombiliti: Total of 9 consolidated PICO(s) were generated, with 4 in the full population and 5 in subpopulations

The high number of PICO(s) generated, and large number of comparators showcases the **need for additional guidance for consolidation of PICO(s) and the need for interactions** between assessors and companies during the scoping process

Priorities for EU HTA

- The complexity of HTA processes across Member States require significant administrative and financial resources and time from developers and can cause access delays.
- **The EU HTA procedure must lead to sufficient harmonisation of existing methodologies and wide uptake of joint EU HTA reports**, to avoid the risk of additional clinical assessments being demanded at Member State level, with increasing burdens for developers and delays in patients' access to innovative treatments.
- The Joint Scientific Consulations must be offered to all developers and broad involvement of all relevant stakeholders must be ensured.

Revision of the General Pharmaceutical Legislation & HTA

- Impact of the revision on HTA processes -

EC Proposal – Pharmapackage
(26th of April 2023)

→ Better access for patients across Europe + Creating an attractive regulatory system

Possible Impact/ interplay with HTA Reg:

- Changes in regulatory timelines/ accelerated assessment: max. 150 days + max. 64 days
- Modulation of RDP/ ME
- Conditional MA

BPI Bundesverband der Pharmazeutischen Industrie e.V.

KONTAKT

Julia Rumsch

Tel: + 32 25 00 89 61
Email: jrumsch@bpi.de