EMA
EUROPEAN MEDICINES AGENCY

Regulatory/HTA interface under the HTA Regulation – Update on activities

ISG meeting, 29 June 2026

Presented by Noemie Manent, HTA Collaboration Specialist, and
Michael Berntgen, Head of Scientific Evidence Generation Department

Focus of today's update

1. Operational update on the interface between Centralised Procedure (CP) and Joint Clinical Assessment (JCA)
2. Status update on parallel Joint Scientific Consultation (JSC) for medicinal products and medical devices
3. Collaboration on transparency measures and support in the identification of experts

Highlights from the first 18 months of operation at the regulatory / HTA interface

First **initial MAAs in scope of JCA production** submitted in March 2025

Since July 2025, **provision of information** from ongoing Centralised Procedures to support JCA

Evidence planning for five medicinal product developments in **parallel Joint Scientific Consultation**

First **comprehensive forecast reports (business pipeline)** covering medicinal products and medical devices provided to the HTA secretariat

Joint EMA/HTAb **position paper on evidence and uncertainty management** published

Numerous implementation **updates provided to stakeholders** (e.g. at ISG meetings)

All Implementing Acts (IA) under the HTAR adopted (EMA provided technical support)

SANTE/EMA workshops held on experience with the operations and on transparency measures, resp.

The **first three JCAs** for a centrally approved medicine **finalised** by June 2026

Identification of upcoming MAAs in scope of JCA production

Compliance rate (as of 22 June 2026):

- Notifications are still not consistently sent to the HTA Secretariat, although compliance has improved overall:
  - Reminders had to be sent to applicants for **21%** of 2025-2026 notifications
  - All applicants have now followed up, and no notifications remain pending

<u>Important to cascade standard process</u>:

- Parallel guidance for applicants on declaring products in the scope of Joint Clinical Assessment (JCA) under the HTAR
- Harmonised notification process: use of the same form (i.e. Letter of Intent) to notify the intention to submit an application.
- Important for applicant (HTD) to provide information to EMA and HTA secretariat in parallel, also for change of dates

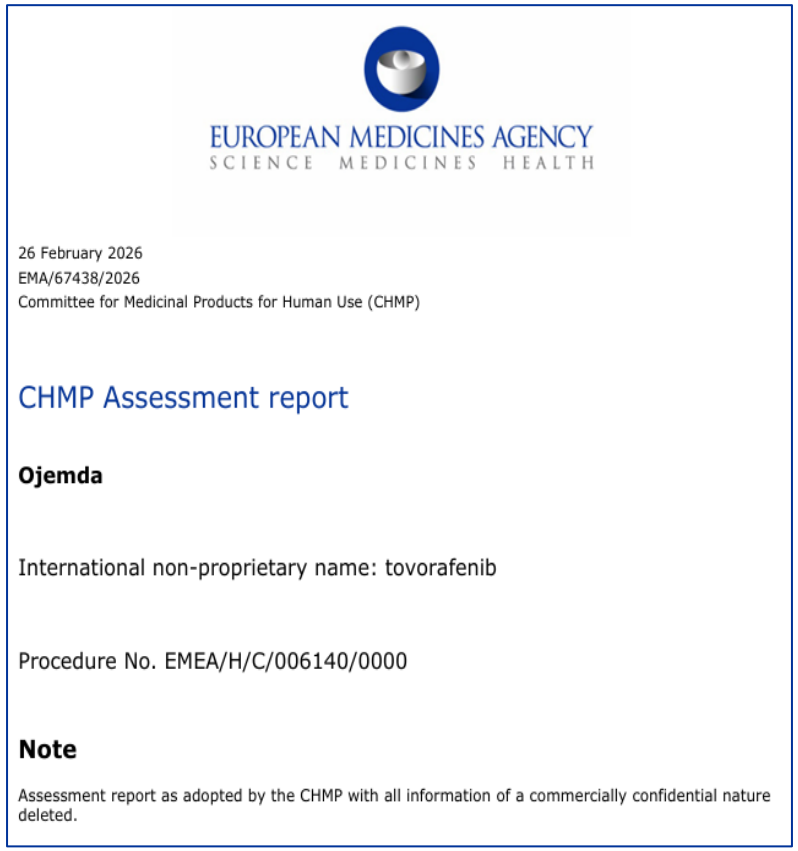
<u>Simplification from January 2026:</u> when sending to the applicant a reminder regarding the need of parallel submission of an LoI for an MAA declared as being in JCA scope, EMA does CC the HTA Secretariat for awareness and follow-up, as required

List of MAAs with JCA production requiring exchange of information **Based on the HTA secretariat listing Joint Clinical Assessments** (24/06/2026)

International non-proprietary name (INN)/common name	Indication - Summary	Substance type
Tovorafenib	Treatment of paediatric low-grade glioma (LGG)	Chemicals
Onasemnogene abeparvovec	Treatment of 5q spinal muscular atrophy (SMA)	ATMP
Lurbinectedin	Maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)	Chemicals
Tarlatamab	Treatment of extensive-stage small cell lung cancer	Biologicals
Camizestrant	Treatment of adults with locally advanced or metastatic breast cancer	Chemicals
Senaparib	Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer	Chemicals
Relacorilant	Treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer	Chemicals
Ensartinib	The treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Chemicals
Zopapogene imadenovec	Treatment of respiratory papillomatosis in adults	ATMP
Sintilimab	Treatment of non-squamous non-small cell lung cancer in adults	Biologicals
Sonrotoclax	Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)	Chemicals
Taletrectinib	Treatment of adults with ROS1 positive advanced non-small cell lung cancer	Chemicals
Zamtocabtagene autoleucel	Treatment of adults with large B-cell lymphoma	ATMP
Cosibelimab	Treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma	Biologicals
Lunsotogene parvec	Treatment of biallelic OTOF variant-associated hearing loss in adults and children	ATMP
Catequentinib	Treatment of synovial sarcoma or leiomyosarcoma	Chemicals
Autologous melanoma-derived tumor infiltrating lymphocytes ex vivo-expanded	Treatment of melanoma	ATMP
Sasanlimab	Treatment of bladder cancer	Biologicals

EPAR/JCA report published | CHMP Opinion adopted/JCA on-going | MAA/JCA on-going | JCA discontinued/MAA withdrawn or on-going

Complementary assessments publicly available at European level



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2026
EMA/67438/2026
Committee for Medicinal Products for Human Use (CHMP)

CHMP Assessment report

Ojemda

International non-proprietary name: tovorafenib

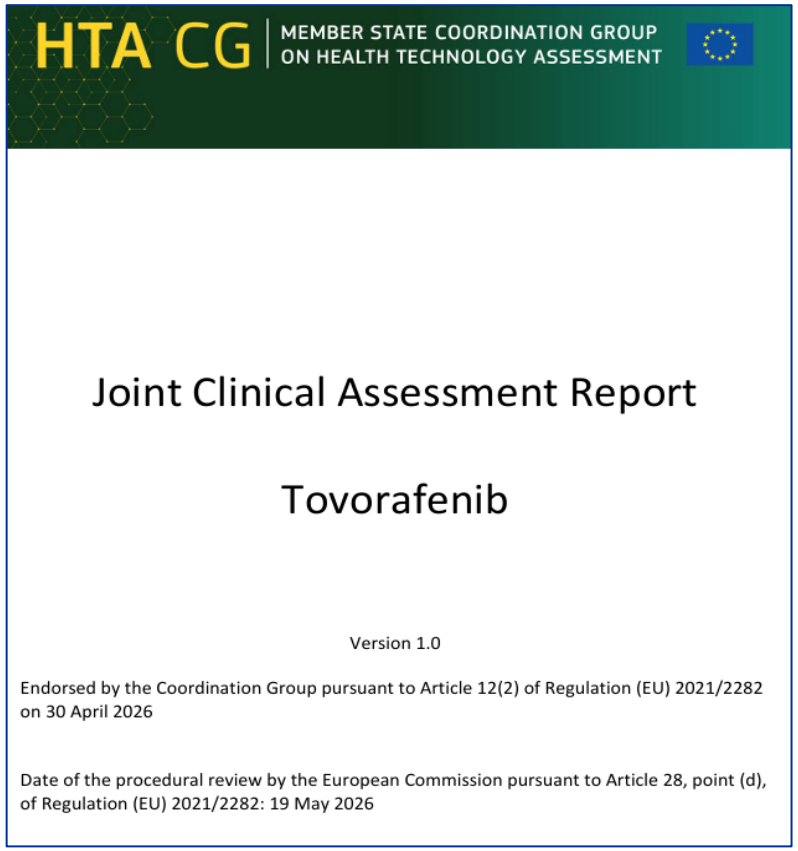
Procedure No. EMEA/H/C/006140/0000

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

EPAR for Ojemda, tovorafenib

A significant milestone due to the application of the HTA Regulation in Europe!



HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Joint Clinical Assessment Report

Tovorafenib

Version 1.0

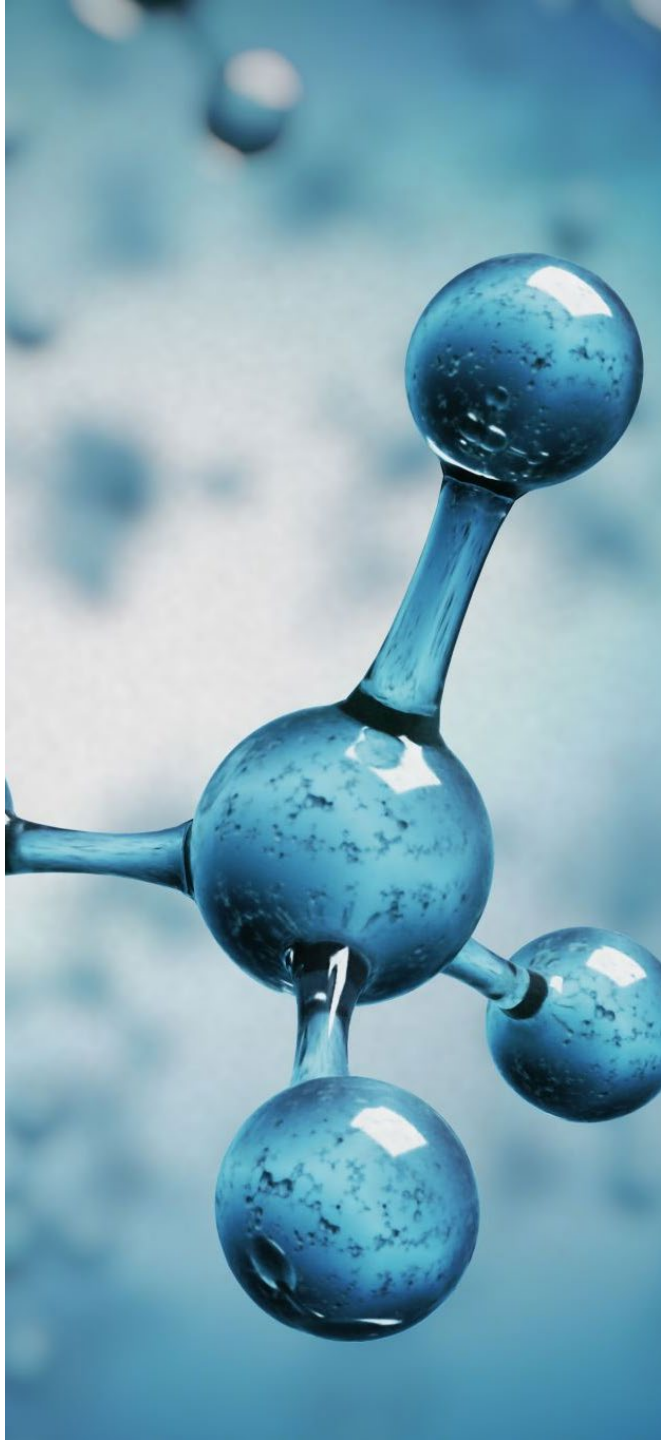
Endorsed by the Coordination Group pursuant to Article 12(2) of Regulation (EU) 2021/2282 on 30 April 2026

Date of the procedural review by the European Commission pursuant to Article 28, point (d), of Regulation (EU) 2021/2282: 19 May 2026

JCA for Ojemda, tovorafenib

Parallel Joint Scientific Consultation (JSC) for medicinal products

- Since the launch pf the HTA Regulation:
  - **5 parallel JSCs** (aka parallel EMA/HTA scientific advice):
    - 3 completed : two rare diseases unrelated to oncology and one cancer related condition)
    - 2 on-going : one cancer related condition and one rare disease non-cancer
- For more information:
  - 2026 Work Programme for the request periods
  - Parallel scientific advice and special development aspects or product types
  - Dates of 2027 SAWP-H meetings and submission deadlines



Recent developments of EMA/HTACG/HTA Unit collaboration

Strong EMA/HTA CG collaboration supporting the **identification of patients and healthcare professionals** :

- EMA was consulted **4 times via bulk requests** to identify patients and Health care professionals for participation in JCA and JSC and EMA proceeded to identifications of experts for 32 diseases.

EMA and HTA Unit had several sessions to collaborate on the **transparency measures and publication** of HTA dossier and JCA report Linkedin :

- Shared experience gained through the CDP's redaction and publication operations (e.g. template)
- Mapping HTA dossier versus CDP/CTIS: synergy acknowledged with possibility to refer to CDP portal/CTIS public website for the common parts of the HTA & MAA dossiers (CSR and clinical overview)

EMA and HTA Unit started exchanging on the identification of application including **a new therapeutic indication** for medicinal product with a JCA report published

Ongoing work to establish an HTACG-EMA platform for **horizontal issues of scientific or technical nature** on evidence and uncertainty management

For more on HTAR implementation and contact information, see here

Implementation of the Regulation on health technology assessment

Page contents

The Regulation (EU) 2021/2282 on health technology assessment (HTAR) entered into force on 11 January 2022 and applies from 12 January 2025.

This webpage aims at informing national authorities, health technology developers and stakeholders about the implementation of the Regulation.

All the information required by Article 30.3 of the HTAR will also be published on this website.

- Press release
- Memo
- Joint Clinical Assessments
  - Factsheet
- Joint Scientific Consultations
  - Factsheet
- Factsheet on implementation of the Regulation
- Joint clinical assessment of medicinal products: Submission of early information by health technology developers