EMA
EUROPEAN MEDICINES AGENCY

From regulatory decision to health technology assessment: the new developments in Europe

PCWP/HCPWP joint meeting, 3 February 2026

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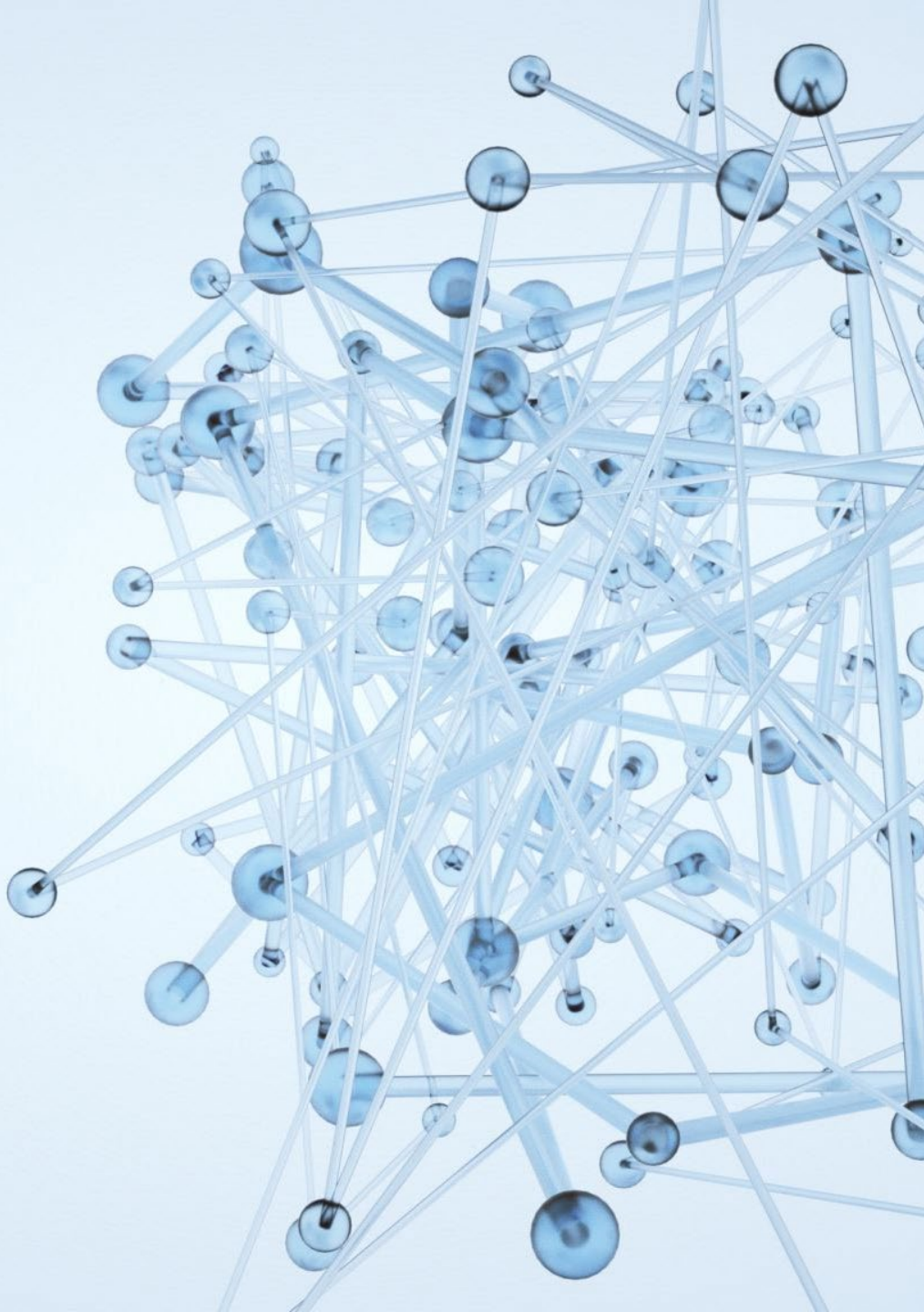
Evidence Generation Department



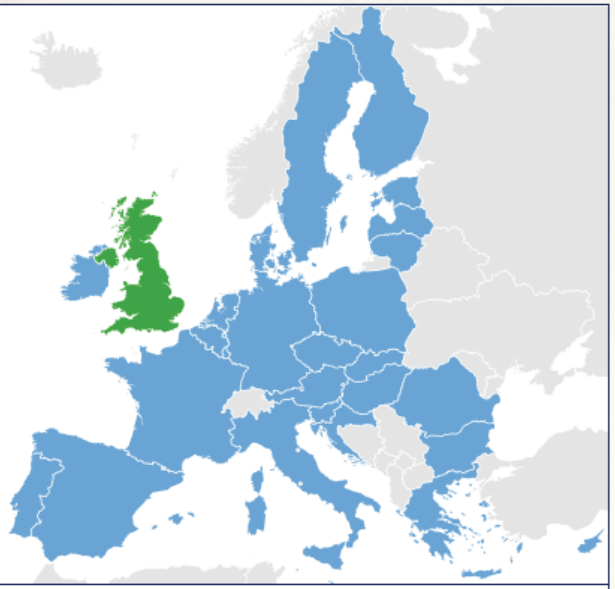
EU countries are responsible for the management of **health service and medical care** and the **allocation of resources*.**

***The Treaty on the functioning of the European Union (consolidated version art. 168(7))**

448 mio
inhabitants

27
countries

27
different Healthcare systems



European Public Health Insurance Systems

All European countries have some form of public health insurance, usually compulsory for citizens and residents.

Most public systems provide a baseline level of care, including outpatient, inpatient, dental, and medication services.

The co-payments required can be different between countries.

In practice, two main models exist, but no country applies them in a "pure" form.

Beveridge Model

– Tax-based financing

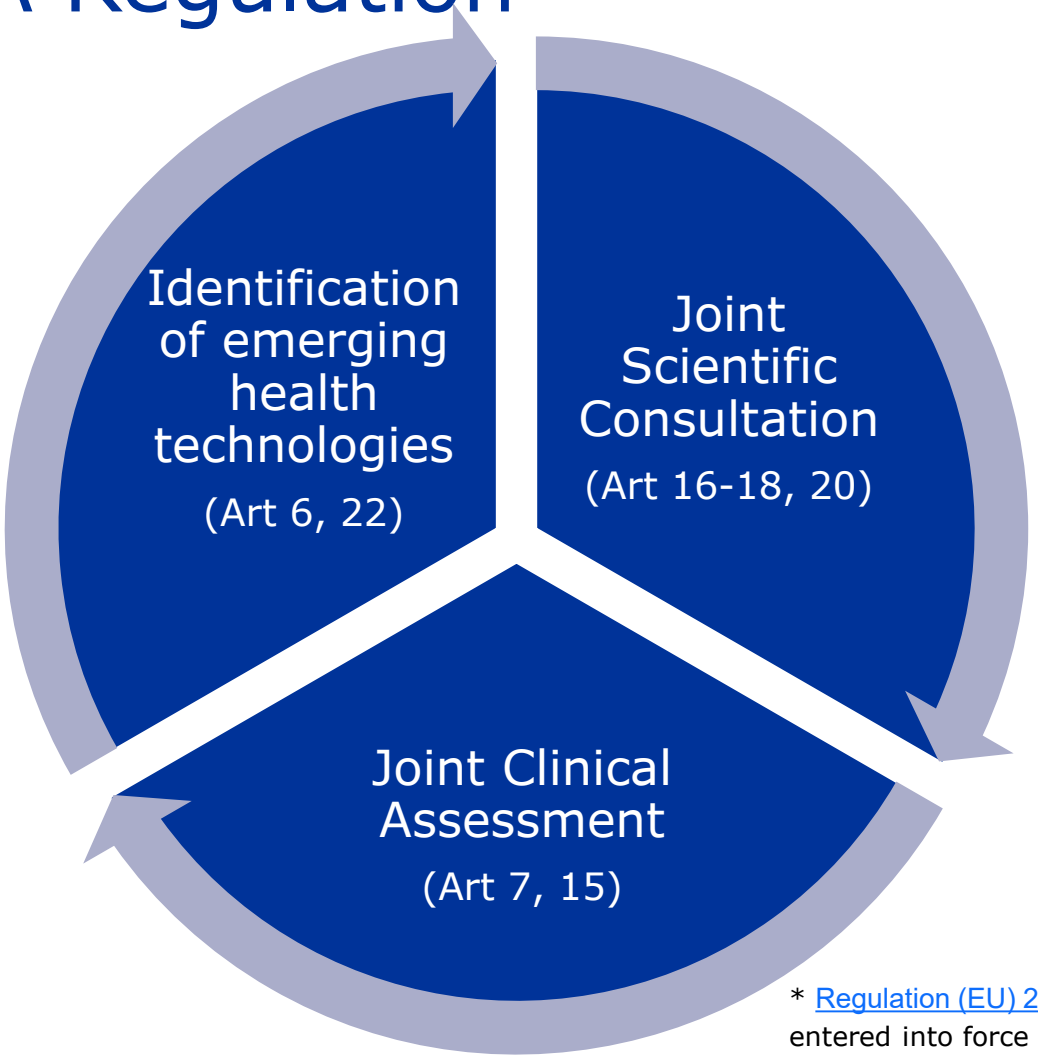
Bismarck Model

– Funded through non-profit insurance organizations
– Mandatory contributions from employers and employees

*Article 168(7) of the Treaty on the functioning of the European Union

Antje Behring, RAPS Convergence October 2025

Reminder "Regulatory/HTA interface" under the HTA Regulation*



Transversal elements in the Regulation to facilitate such work, supported by the European Commission, include the sharing of confidential information

- **"Joint"** refers to collaborative work amongst HTA bodies
- Respect of separate **remits** (regulators vs HTAs)
- **Scope** of activities cover medicinal products and medical devices / IVDs

* Regulation (EU) 2021/2282, entered into force in Jan 2022 and applies as of Jan 2025

Implementing Acts relevant for operations at the regulatory/HTA interface

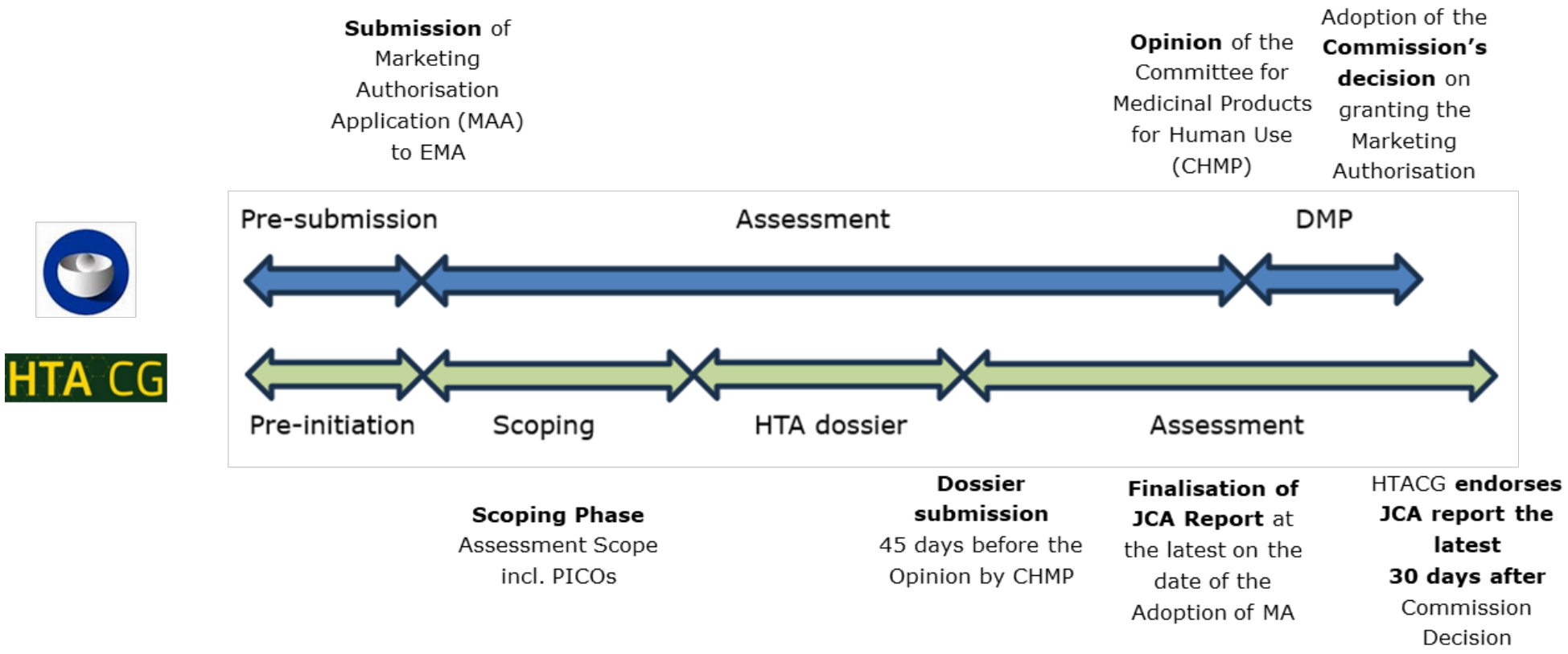
Procedural rules for **JCA of medicinal products** *	Adopted 23 May 2024
Procedural rules on **cooperation with the EMA** *	Adopted 18 October 2024
Procedural rules for the **management of conflicts of interest**	Adopted 25 October 2024
Procedural rules for **JSC of medicinal products** *	Adopted 18 December 2024
Procedural rules for **JSC of medical devices and IVD medical devices** *	Adopted 24 January 2025
Procedural rules for **JCA of medical devices and IVD medical devices**	Adopted 17 October 2025

* Reference to interface with EMA

Rules on the information EMA shares/facilitates:

- for **planning/forecasting** of joint clinical assessments (JCA) and joint scientific consultations (JSC) for medicines/devices — ***Articles 2 & 3***
- for **identifying experts** (e.g., patients, clinical experts) — ***Article 5***
- on general **scientific and technical matters** related to HTA beyond assessments — ***Article 6***
- concerning the **security of sharing** and **protection of confidential information** exchanged — ***Articles 7 and 8***

Marketing Authorisation Application and Joint Clinical Assessment are in parallel



First MAAs with JCA production in parallel

Based on the list of ongoing Joint Clinical Assessments published by the HTA secretariat (status: 20 January 2026)

International non-proprietary name (INN) / Common Name	Indication - Summary	Substance type (classification)
Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded	Treatment of melanoma	ATMP
Tovorafenib	Treatment of paediatric low-grade glioma (LGG)	Chemicals
Sasanlimab	Treatment of bladder cancer	Biologicals
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
Camizestrant	Treatment of adults with locally advanced or metastatic breast cancer	Chemicals
Tarlatamab	Treatment of extensive-stage small cell lung cancer	Biologicals
Catequentinib	Treatment of synovial sarcoma or leiomyosarcoma	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

Provision of information from the Centralised Procedure to inform Joint Clinical Assessment

Principles: 1/ respect of separate remits; 2/ exchange **through secretariats** only; 3/ information to be appropriate and relevant

After CHMP adoption of questions, EMA to provide to the HTA secretariat:

- Clinical major objections or clinical other concerns that might impact the therapeutic indication(s) of the medicinal product proposed by the applicant
- Clinical major objections related to non-full marketing authorisation (e.g conditional marketing authorisation or marketing authorisation under exceptional circumstances)

Identification of such questions is without prejudice to the final outcome of the regulatory assessment as well as of the HTA assessment.

Updates on timelines based on the adopted timetables.

Review: after 12 months of experience (including usefulness and efficiency)

Continued experience since July 2025, with EMA providing:

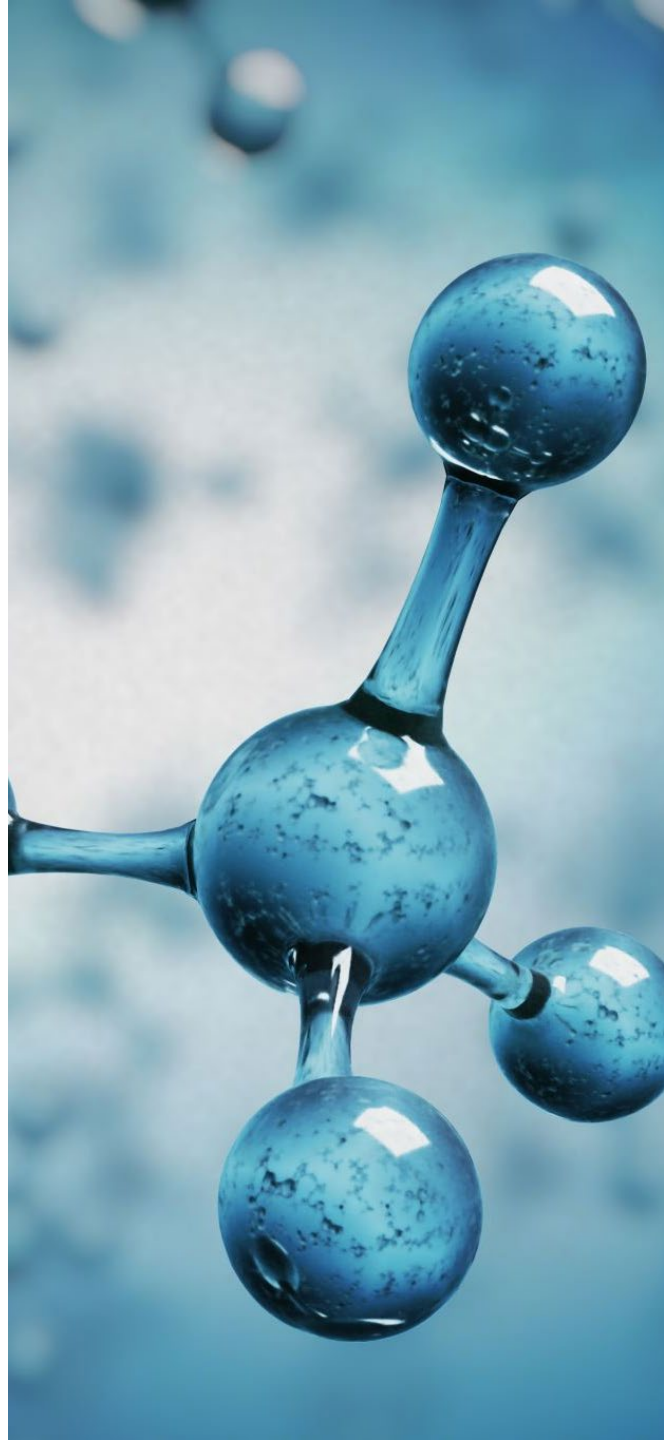
- an extract from adopted documents, acc. to principles
- information on next procedural timelines.

All information is based on what the applicant received as part of the ongoing procedure.

Parallel Joint Scientific Consultation (JSC) for medicinal products

- In 2025, **4 requests for parallel JSC*** (aka parallel EMA/HTA scientific advice) were selected by the JSCSG
  - Two parallel JSCs concern oncologic conditions, and the other two non-oncologic rare diseases.
- For 2026, **parallel JSC on medicinal products** to be envisaged
  - In the context of **the joint scientific consultations** on medicinal products (refer to 2026 Work Programme for the request periods):
    - Parallel scientific advice and special development aspects or product types | European Medicines Agency (EMA)
    - Dates of 2026 SAWP-H meetings and submission deadlines

***one JSC for oncology indication withdrawn**



Expert identification (patients and HCPs) in the context of JCAs and JSCs

- So far, provision of information on suitable **individual experts for 16 different conditions**
  - glioma, melanoma, bladder cancer, breast cancer, colorectal cancer, Duchenne Muscular Dystrophy, early Alzheimer's disease, hepatocellular carcinoma, lung cancer, ovarian, fallopian tube, or primary peritoneal cancer, pancreatic ductal adenocarcinoma, papillomatosis, spinal muscular atrophy, synovial sarcoma, Angelman syndrome, extensive burns
- Different modalities are currently being explored by the HTA Unit (batch-wise requests, timing vs involvement)
- EMA is participating in a working group under the HTA Stakeholder Network

Joint HTAb*/regulatory position paper on evidence and uncertainties

- Strong preference for randomised evidence
- Opportunities to complement pre-licensing data
- Estimand framework as valuable, shared language
- Improving outcome collection / analysis / reporting
- Availability of individual participant data
- Effect estimation by indirect comparisons
- Complement clinical trial data with real-world data
- Decision making under uncertainty

Position paper

*HTAb: HTA bodies

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 will apply from 12 January 2025.

In the preparatory phase for the implementation of the HTAR (January 2022 – January 2025), this webpage aims at informing national authorities, health technology developers and stakeholders about the development of implementing legislation in accordance with the powers conferred to the Commission by the co-legislators.

In the implementation phase of the HTAR (beyond January 2025, when joint HTA work will start), this webpage will include all the information required by Article 30.3 of the HTAR.

– Factsheet on implementation of the Regulation

EMA