Educational symposia

ISPOR 2024

cencora

Booth #621

ISPOR Europe 2024 Symposium Host

Educational symposium

Ready for 2025? How lessons learned from national system reforms can guide our response to the new EU HTA regulations

November 18, 2024 | 15:15 - 16:15 | Room 116






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Our global consulting team is part of Cencora – a leading provider of services supporting healthcare stakeholders globally

Wholesale distribution

- 27 Wholesale DCs(US)
- 294 Wholesale DCs (EU)

3P Logistics

- 7 Warehouses (US & CA)
- 29 Warehouses (EU)
- 3 Specialty Rx DCs (US)

Global consulting

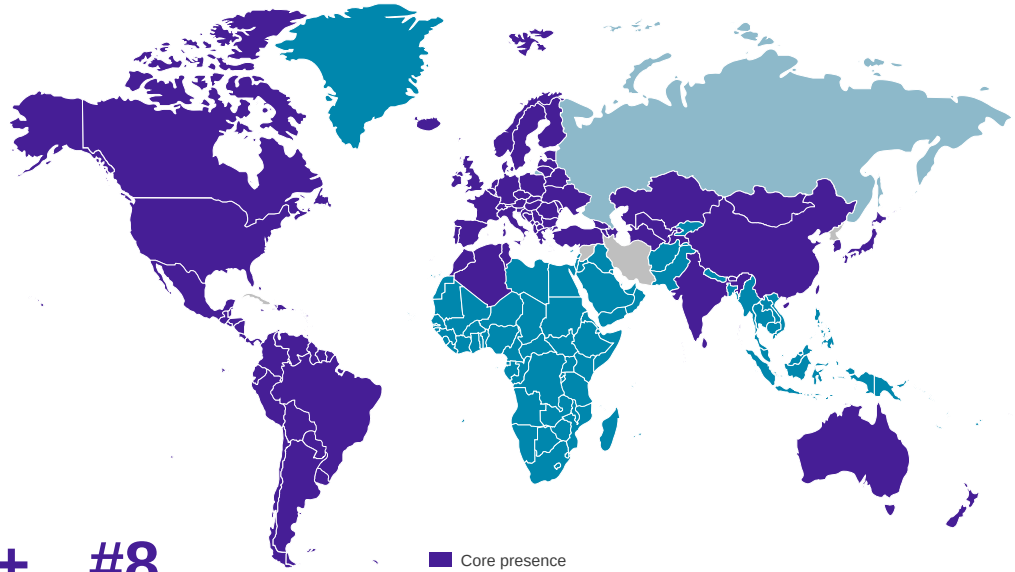
- 28 countries with local market access support
- 3000+ consultant experts worldwide

Pharmacy network

- 5,200 GNP across US
- 9,600+ Alphega across Europe
- 12 Specialty Pharmacy Network[23]

Patient services

- 30+ years experience in US and Canada
- Flexibility to provide adherence services broadly



100+
countries

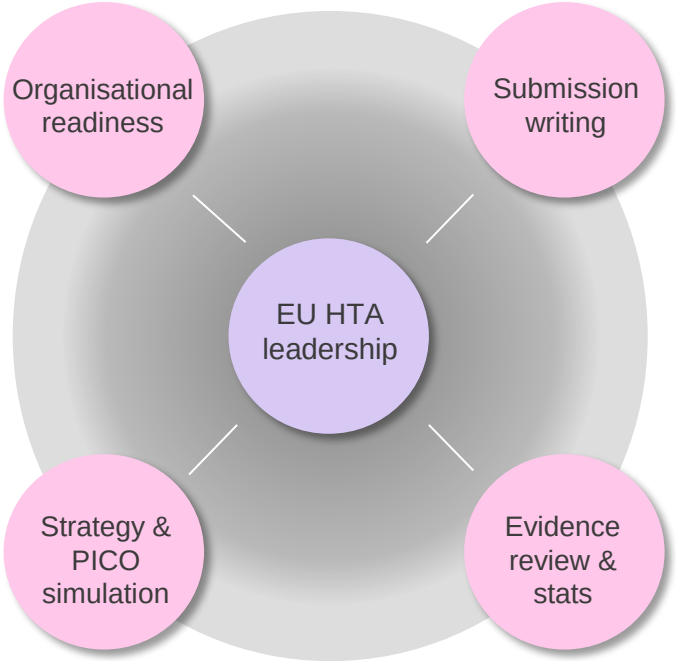
1,300+
global locations

$235B+
global revenues

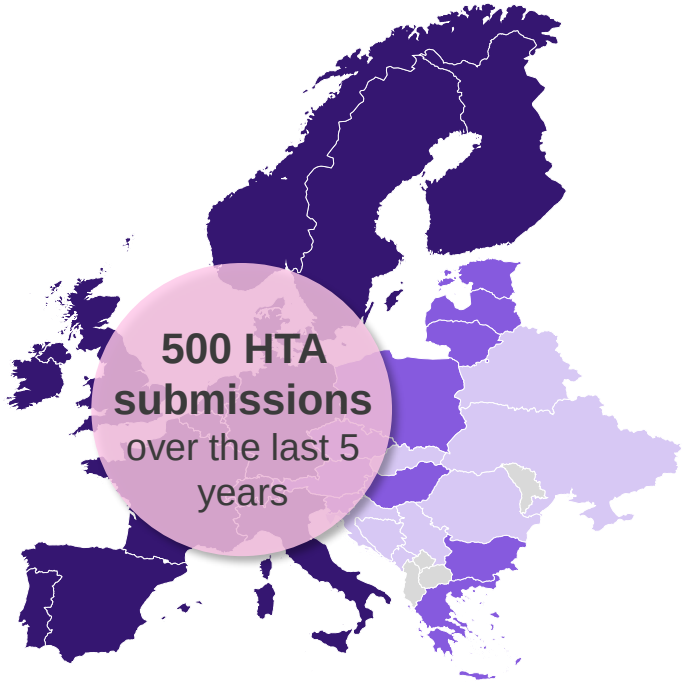
#8
Global Fortune 500 list

Sources: AmerisourceBergen, PharmaLex (Internal Documents)

With deep HTA experience across Europe, our EU HTA centre of excellence is helping to shape policy and JCA best-practice

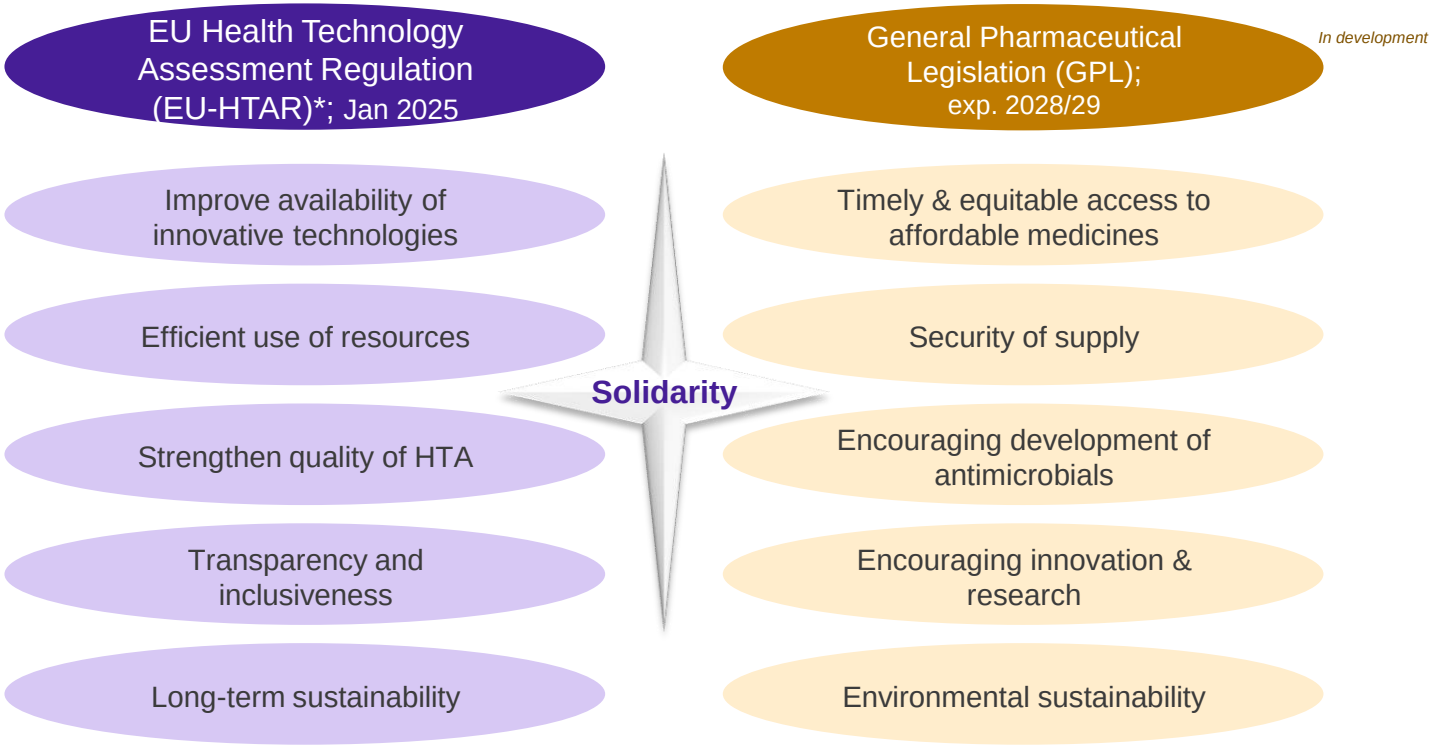


25 years' experience



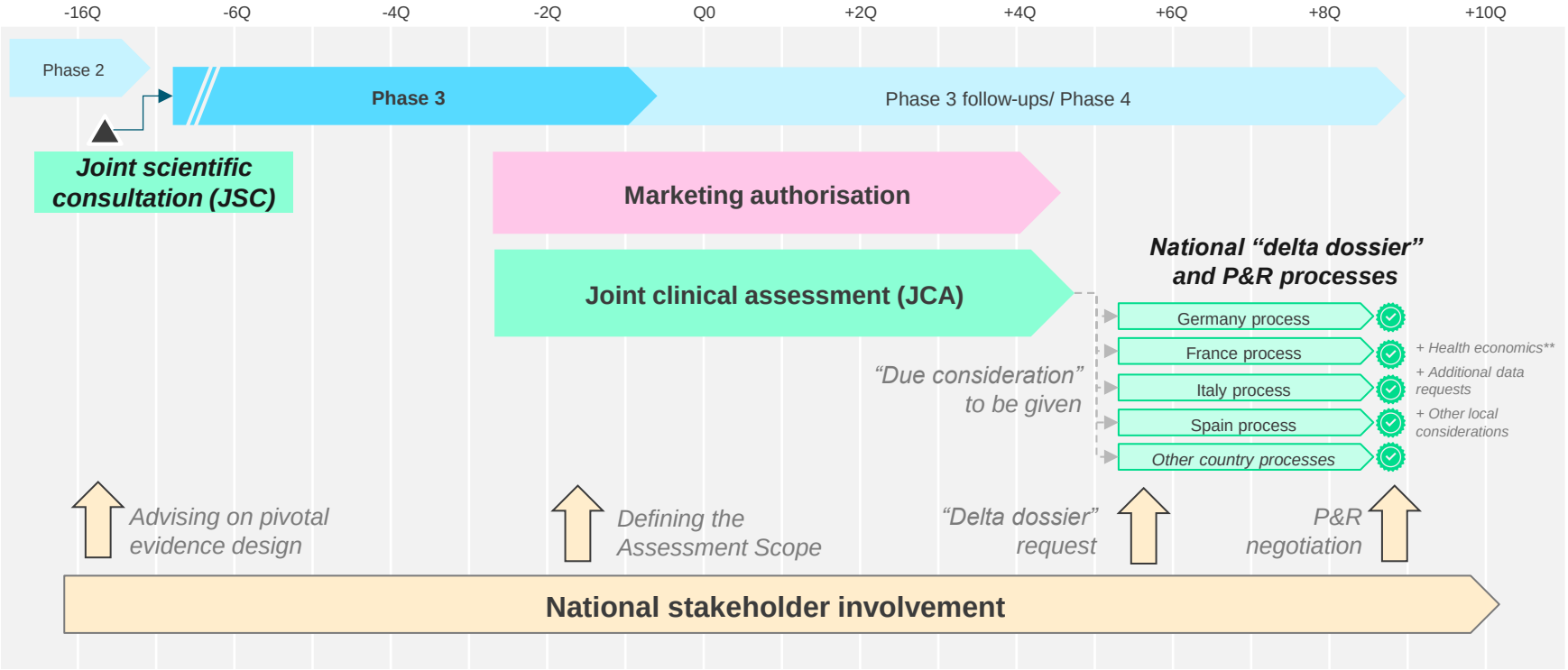
250+ consultants across Europe

EC objective of the new Regulation:
Faster and equal patient access at the heart of policy changes in Europe



*Regulation (EU) 2021/2282

National stakeholder input is integral to the new HTA regulation, from early evidence planning, through to “delta dossiers”



Note: timelines of EMA processes differ for each asset and also under accelerated timelines. What is shown is an illustrative example only. JCA process is anchored to EMA process, however, and aims to have a JCA report endorsed 30 days after the EC decision on marketing authorization. *Pricing & reimbursement processes vary in timing across countries; this is illustrative only. **Not considered by all markets/nations.

Key: JSC – Joint scientific consultation; JCA – Joint Clinical Assessment; JSC – Joint Scientific Consultation; EMA – European medicines agency; EC – European commission; MS – Member states; HTA – Health technology assessment; PICO – Population intervention comparator outcome; P&R – Pricing and reimbursement

German EU HTAR readiness: G-BA and IQWiG

- **G-BA and IQWiG intensively involved** in developing JCA & JSC guiding principles:
  - fully **supporting the harmonization** across EU member states
  - underlining **importance** of high-quality, independent, and transparent evaluations
  - **G-BA acts as JSC coordination** contact until end of 2024.
  - **Commitment that JCA reports must be included** in the early benefit assessment procedure. Minor changes in national process expected and to be finalized soon as needed
  - G-BA & IQWiG acknowledge:
    - **implementation complexity:** big differences among EU HC systems
    - Importance of **national responsibilities** to decide on the added benefit as well as P&R. Member states can consider national healthcare needs and constraints.

German EU HTAR readiness: Industry requirements
(companies (HTD), vfa, BPI, B.A.H, …)

- **Better involvement of health technology developers (HTDs)**:
  - **HTDs** must be recognized as **key players** and as such must be involved appropriately and constructively in the entire EU HTA process.
  - HTDs need **additional consultations on complementary national** clinical analyses to supplement the European benefit assessment if needed.
- **Ring-fencing AMNOG timelines**: The JCA report is not approved until 30 days after marketing authorization. Risk of delayed initiation of the AMNOG process.
- **Strengthen the orphan drug regulation**: the additional benefit of orphan drugs is considered proven with regulatory approval. Evidence versus a comparator need only be provided after the revenue threshold of EUR 30 million has been exceeded.
- Request a **review of extensive AMNOG requirements**, exceeding other European systems.
  - **Create context-specific assessment methods:** Assessment methods must be adapted more closely to the clinical and regulatory context and applied flexibly. **Orphan drugs and ATMPs require adapted methods** (incl. surrogate endpoints, indirect treatment comparisons and real-world evidence).
- **Ensure capacity for scientific advice (JSC):** Sufficient capacity and expertise must be available at EU level for timely and high quality JSC (Joint Scientific Advice).

The French EU HTAR readiness:

- **HTA regulation** seen as a way to improve access to new technologies with high quality assessment
  High level of involvement of Haute Autorité de Santé (HAS) in HTAR activities (as previously in EUnetHTA)
- **Context (1)** French HTA process characteristics:
  - Main focus on assessment of clinical benefit and additional clinical benefit (SMR, ASMR)
  - Preparation of a **clinical assessment** report by internal reviewers + external experts
  - Assessment report discussed by the Transparency committee : **appraisal phase**
  - Economic evaluation conducted in parallel
- **Context (2)** Early Access Program since 2021
  - Till October 2024 : **172** requests Pre (**76**) or Post (**96**) marketing authorization (MA). **122** accepted
- **HTAR = no revolution.** No legislative changes necessary*.
- **No change**
  - in Transparency Committee doctrine for medicinal product appraisal
  - In requests for pre-MA Early Access
- **Some changes***
  - Post-MA Early Access: no filing of data or analysis already transmitted at EU level.
  - National early dialogues: still possible (written procedure) ONLY if product not selected for JSC
  - Updated documentation to submit national applications

HAS website: page dedicated to HTAR >

***** Preliminary analysis - Discussions underway with the Ministry and the European Commission

The Spanish EU HTAR readiness:

- The **Spanish authorities have made good progress** in incorporating the knowledge and being on top of the process
  - **Capacity** at the MoH and AEMPS
  - **Communication** on how they will operate
  - No EU leadership
- They have designed a **new legal framework** which should embody all potential changes
  - The new legislation is due soon (before end 2024?)
  - **Regions** are following, not taking the lead
  - The process is still **Budget Impact** led
  - The ‘new’ law should bring with it the reallocation of Budget to do things (**no fresh money**)
- **Companies are not very familiar** with the implications of the process at a local level
  - They cannot prepare
  - It is likely that no major changes
- **Patients do not really know how to participate**

The Polish EU HTAR readiness:

- **political perspective:**
  - pro or anti-European approach
  - the **Presidency of the Council** of the EU
- **policy perspective:**
  - HTA embedded in pharmaceutical reimbursement system
- broader **CEE perspective:**
  - diverse countries in the region
- resources perspective:
  - **limited human & financial resources**
- **legal perspective:**
  - adaptation of national legal frameworks (still) needed
- the most important perspective
  - **patients' perspective** - access gap
  - **(faster) access to new innovative & valuable medicines for patients in need**

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Thanks for your attention