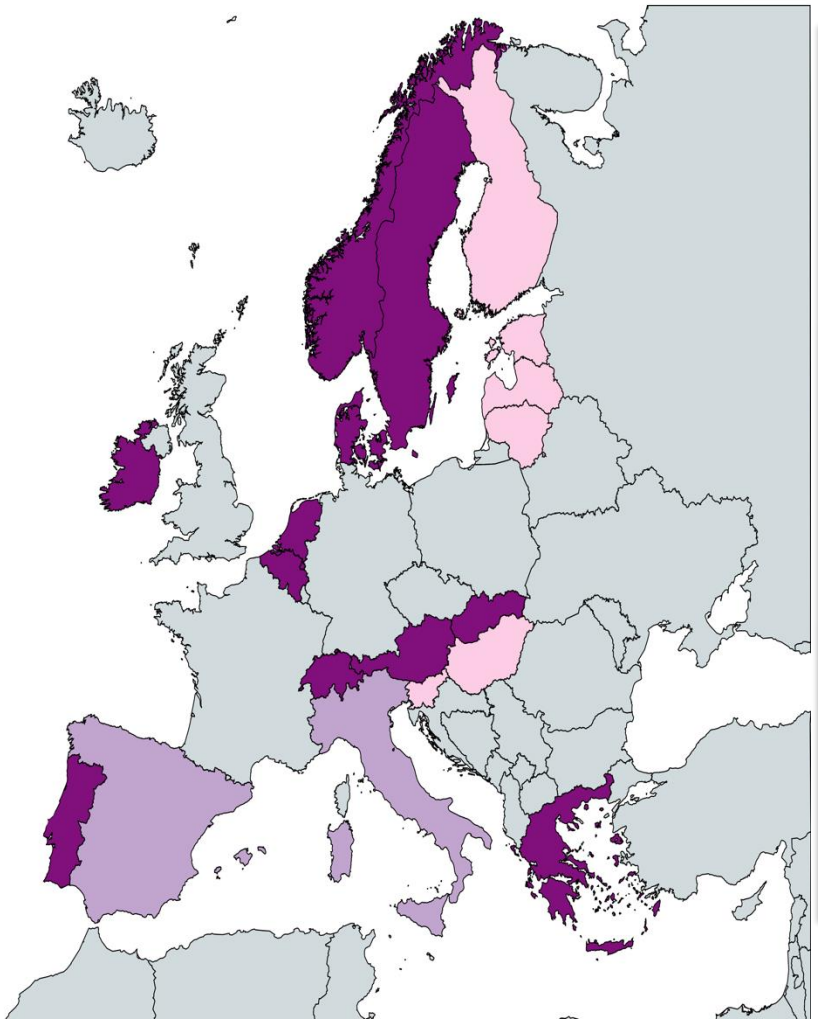
International Horizon Scanning Initiative (aisbl/ivzw)

Supporting the EU HTA Regulation : Forecasting the JCA pipeline through horizon scanning

Introduction: IHSI – one common Horizon Scanning



Not-for-profit A.I.S.B.L. under Belgian law

Member states funded & governed via Executive Committee (EXCO) & Board of Directors (BOD)

Independence: No industry funding or influence

Collaboration: IHSI encourages data and information sharing and collaboration

No direct engagement or confidential data exchange with the industry

IP Ownership: IHSI owns the data, database, infrastructure, and AI models

Hard data: empowering Healthcare Decision-Makers in IHSI Member states

Horizon Scanning in the HTA framework

The JCA process runs on strict timelines. Member States and the HTACG need advance intelligence on which products are approaching the JCA scope.

IHSI Intelligence

- Forecast of products entering JCA scope
- Proactive resource allocation
- Early patient and expert involvement
- Faster, better-informed access decisions

Support to the EHT subgroup

Forecasting which products will enter the JCA Scope

A structured forecast identifying medicinal products expected to fall within the scope of Joint Clinical Assessment, **serving as a planning tool, among other data sources**, for the **Emerging Health Technologies (EHT) subgroup** of the HTACG.

What It Contains

- Products identified from Phase II/III trials
- Expected EMA submission timelines
- Therapeutic indication and target population
- Assessment of JCA scope eligibility
- Anticipated impact on healthcare systems (where requested)

Who Benefits

HTACG Annual work planning and JCA selection

Member States National capacity and resource planning

Stakeholders Early patient and expert preparation

Methodology

Building the Forecast: Data Collection

1 IHSI extraction

- Estimated submission timeline
- Regulatory status
- Oncology/ATMPs

2 Forecast production

- Scoring of the products
- High score equals likely submission

IHSI relies exclusively on publicly available data.

TTMR Scoring Logic

Time to market rationale: Estimating likelihood of EMA submission

Each product is scored against four criteria.

FDA Submission

2	Submitted to FDA
0	Not submitted

Regulatory Intent

2	EU or EU+US referenced
2	Regulator unspecified
1	US only
0	Not pivotal

Regulatory Designations

3	Phase III + EU designation / PIP
2	Phase I or II + EU or EU+US
1	Phase III + US only
0	Phase III + no designation

Data Readout

3	Positive results
1	Results pending / projected
0	Negative results

JCA Pipeline Forecast

IHSI Database · Oncology & ATMPs · EU MAA until Q2 2027 · March 2026

165

products in JCA scope

37 high-probability (Score ≥ 7)

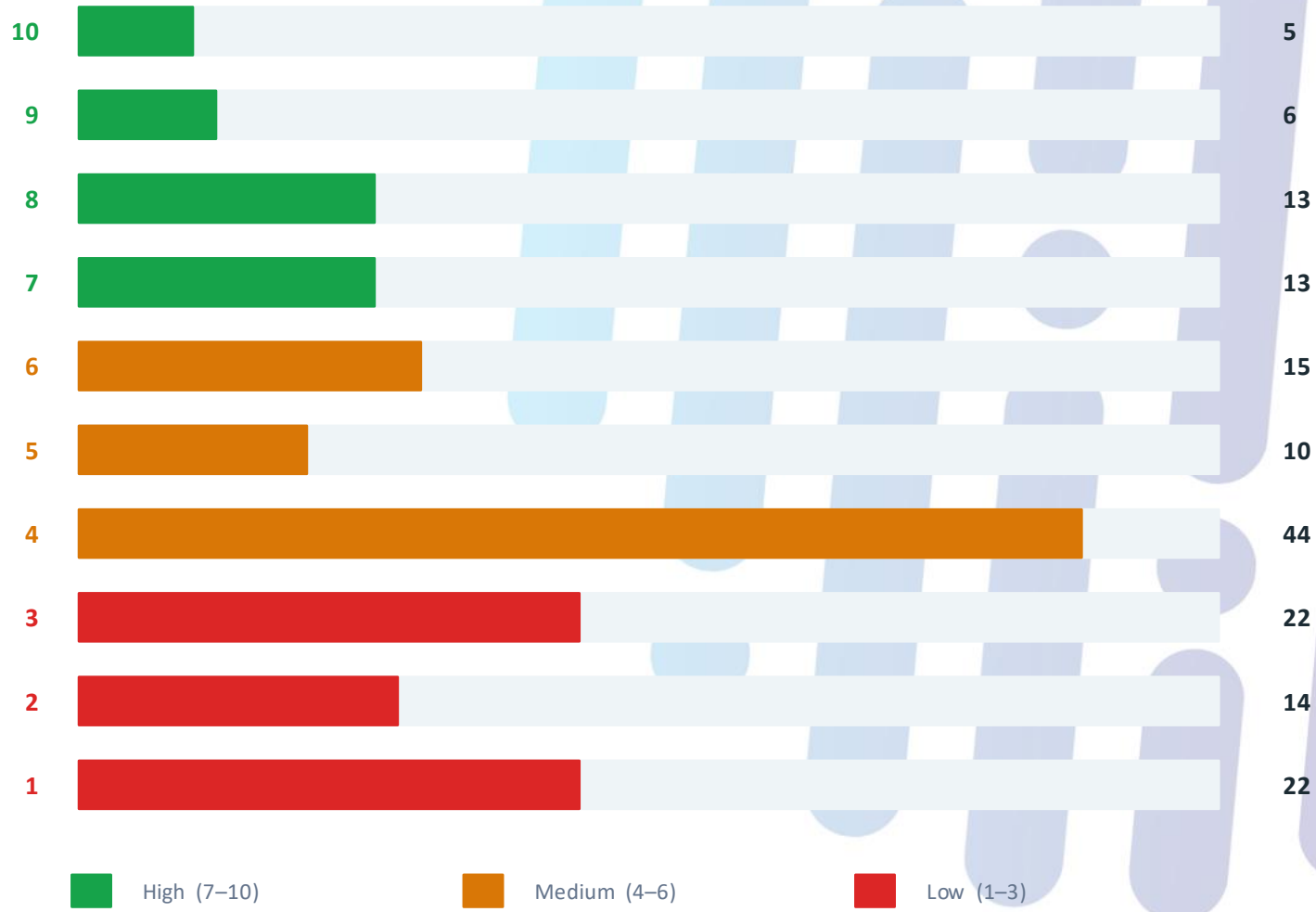
45 with Orphan designation

20 ATMPs

4.4 avg. score (out of 10)

Score distribution

Number of products per score — higher score = more likely to submit an EU MAA



Thank you.