RWE4Decisions REAL WORLD EVIDENCE

Roundtable Report

WHO Europe Novel Medicines Platform Guide Principles for Managed Entry Agreements

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Background and Objectives

On 20 February 2025, RWE4Decisions, in collaboration with WHO Europe Novel Medicines Platform (NMP), convened a roundtable to discuss the NMP draft principles for Managed Entry Agreements (MEAs). The meeting brought together a wide range stakeholders, including HTA bodies and payers, regulatory agencies, European and international organisations, patient groups, clinicians, industry, analytics experts and academic experts/researchers, to exchange perspectives on the framework and explore its role in enhancing access to innovative medicines across Europe.

The WHO Europe NMP was established in 2022 following the Oslo Medicines Initiative, with the aim of fostering transparency, sustainability and solidarity in healthcare systems. As part of this effort, the NMP is developing a set of guiding principles for MEAs, designed to support Member States in structuring agreements that optimise patient access to novel therapies while ensuring long-term healthcare sustainability.

The draft MEA principles are built around a structured yet flexible framework to drive the reimbursement negotiation and if needed, national data collection. This can be applied across different national contexts. The principles include:

- MEA Codification System: A structured decision-support tool to guide what type of MEA could be considered based on the types of uncertainty surrounding a treatment. It categorises agreements by the complexity of technology utilisation and required evidence, ensuring that decisions are made with a clear understanding of potential risks and benefits.
- MEA Process Flowchart: A step-by-step guide outlining the four key phases of an MEA:
    - *Selection Phase:* Identifying whether an MEA is appropriate and if so, what type – purely financial preferred, otherwise outcomes-based agreements.
    - *Contracting Phase*: Establishing agreements between stakeholders, including financial arrangements and conditions for data collection, if needed.
    - *Implementation Phase*: Monitoring and evaluating data collection to assess treatment effectiveness and financial sustainability.
    - *Managed Exit Phase*: Reassessing evidence to determine future reimbursement decisions and ensuring smooth transitions for patients.
- MEA Checklist: A practical tool detailing key considerations for each phase of the MEA process, ensuring that essential elements such as data collection, stakeholder engagement, and risk management are systematically addressed.

The MEA principles aim to provide a common reference for decision-makers and ensure greater predictability in the adoption of innovative medicines. These principles are designed to be adaptable, allowing Member States to implement them in a manner aligned with national healthcare structures and existing processes.

Key Takeaways from the Roundtable Meeting

Participants recognised the value of the draft principles in fostering consistency and improving decision-making across healthcare systems. Stakeholders shared constructive insights during the roundtable and highlighted opportunities to refine and strengthen the flowchart further:

- **Enhancing Clarity of Traffic Light System**: The traffic lights could be misinterpreted as a restrictive mechanism; various alternative classification approaches were suggested.
- **Strengthening Stakeholder Engagement**: Health Technology Developers, patient and clinical experts should be involved in more stages.
- **Data Governance:** Improving transparency of data collection should improve data quality and enhance effectiveness of MEAs to deliver robust real-world evidence for reassessment.
- **Flexibility for Diverse Healthcare Systems**: The framework's adaptability is essential to accommodate varying national healthcare structures, regulatory environments, type of health technology and existing MEA frameworks.
- **Balancing Financial and Outcome-Based Agreements**: MEAs need to consider both financial sustainability and outcomes that demonstrate patient benefit, to support early access to innovative treatments.
- **Integration with Other NMP Initiatives**: The MEA principles need to be aligned with other NMP projects, such as horizon scanning and the Access Dashboard, to ensure a more comprehensive, affordable approach to medicine access.
- **Considerations for Implementation**: Effective implementation requires clear governance structures, ongoing monitoring, and mechanisms to incorporate real-world evidence into decision-making.

Next Steps

Building on the valuable input from the roundtable, WHO Europe NMP will continue refining the draft MEA principles, with finalisation expected by June 2025. An open consultation process will be launched in the coming weeks. This will provide an opportunity for broader written feedback, allowing stakeholders to contribute insights that will enhance the applicability and impact of the finalised principles.

The consultation will play a key role in shaping a robust and widely accepted set of principles that support timely and equitable access to innovative therapies while maintaining sustainable healthcare systems. This collaborative approach aims to ensure that MEAs remain a practical and effective tool for addressing uncertainty while accelerating patient access to high-value treatments.

For further information on the WHO Europe Novel Medicines Platform and upcoming consultation opportunities, please reach out to euro-nmp@who.int

About WHO Europe Novel Medicines Platform

The WHO Regional Office for Europe Access to Novel Medicines Platform (NMP) aims to improve equitable access to high-cost, novel medicines throughout the WHO European Region, ensuring that all patients receive necessary treatment without financial hardship. The Platform was established to respond to concerns that the escalating costs of novel medicines have restricted access and increased health inequities.

The primary objectives of the NMP include fostering collaboration among stakeholders, enhancing transparency, promoting solidarity, ensuring sustainability in health care systems, and addressing market failures. To date, it has brought together 51 Member States and 49 non-State actors – 25 nongovernmental organizations (NGOs) representing patient, professional and civil society organizations; 6 industry organizations; and 18 partner organizations.

For more information, visit the WHO NMP website at https://www.who.int/europe/groups/the-novel-medicines-platform

About RWE4Decisions

RWE4Decisions is an HTA/Payer-led multi-stakeholder Learning Network, which, in 2024, developed of a set of new Stakeholder Actions to generate better real-world evidence for HTA/payer decisions about highly innovative technologies.

The work has been commissioned by the Belgian National Institute of Health and Disability Insurance (NIHDI) and is led by a multi-stakeholder Steering Group with a wider community of contributors including HTA bodies and payers, regulatory agencies, patient groups, clinical teams, industry, analytics experts and academic experts/researchers. The RWE4Decisions Secretariat is provided by FIPRA, with sponsorship by the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Astellas, AstraZeneca, Gilead, MSD, Roche and Takeda.

For more information, visit our website at www.rwe4decisions.com

If you wish to join the RWE4Decisions Learning Network, of if you have questions, get in touch at secretariat@rwe4decisions.com

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