EUROPEAN ASSESSMENT OF RELATIVE EFFICACY AT TIME OF LAUNCH (European REA)

- Key messages for external engagement -

Today, there are wide variations in access to innovative medicines across Europe. The number of products and the speed with which they are made available to patients differ by country.

- Different approaches to assess a product's value lead to inconsistent access decisions for the same product.
- Different evidence requirements in the assessment process create duplication across countries, leading to delays in market access.

To improve patient access in Europe, EFPIA is committed to co-develop a system for scientific European REA that

- accelerates the assessment process through harmonization of clinical data requirements and reduction of duplicative assessments
- reduces access differentials through an EU-wide view on a product's relative clinical performance

In order for European REA to improve market access it must be

- undertaken by a strong scientific body that assesses the relative clinical performance only, while economic assessments must be local to account for diversity in health systems
- separate from the marketing authorization process, but done concurrently to save time
- fully integrated in national market access processes

Centralized REA is a solution tailored to the European debate, and is not as such replicable in other regions of the world.

- it addresses the problem of duplication between public health systems that have developed independently over time and now request different types of evidence on the value of innovative medicines prior to granting market access.
- the European Commission envisages a European REA system by 2020 and is currently open to engage with stakeholders in shaping strategy and details.
- Industry remains opposed to HTA assessment at EU level.

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