MARKET LAUNCH INCENTIVE MECHANISM

Member states and company engagement in good faith for patients access

The company initiates contacts with each Member State: Is there an interest for supply at that moment?

2 Years (3 years for smaller companies)

3 Years (4 years for smaller companies)

6 months to approve the prolongation

Period of actual supply

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MS may

- No patient population
- Alternative therapies exist
- No infrastructure to deliver medicine
- Not interested at the moment

Agreement between the company and each Member State on the actual supply, as defined by each MS, within 2 years from MA.

Supply needs to be continuous and ensure that the relevant quantities and representations are provided

Within 60 days MS to deliver documentation

MS documentation

One of the following is needed from each MS:

- Confirm supply
- Transparency directive decisions (pricing + reimbursement)
- Waiver

Company goes ahead

Contributes to +87 million patients in the EU receiving access to innovative medicines

National competent authority for nationally authorised medicines

European Commission for centrally authorised medicines

- Decision not to ask for the supply yet for different reasons
- Start negotiations under national rules (licensing/ pricing and reimbursement)
- Supply can mean anything from targeted supply for a well-defined patient population to making it available to all healthcare providers.

34 m Period to apply for prolongation of data protection

36 m

MA + 2 years of Data Protection + 4 years

27 MS Contacts

Visit of national competent authorities