

Market exclusivity

The 10-year period after the marketing authorisation of an **orphan medicine**, during which similar medicines for the same indication cannot be placed on the market. Market exclusivity should not be confused with market protection or data exclusivity, market exclusivity refers only to orphan medicines.

In this period, the EMA (the 'Agency') and the member states shall not accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product. This protects the original marketing authorisation holder from market competition with similar medicines with similar indications once they are approved and is intended to encourage the development of medicines for rare diseases.

The period of market exclusivity is extended by two years for medicines that also have complied with an agreed paediatric investigation plan (PIP).