

Period of Exclusivity

A period of exclusivity refers to a time after a medicine is authorised during which no other similar medicines with the same indications (intended uses) may be authorised. This protects the medicine from competition during the period of exclusivity. There can be several separate market exclusivities relating to designated conditions.

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