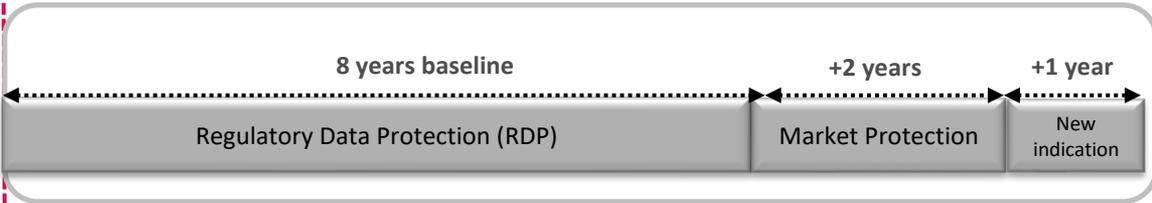


Date of EMA Market Authorisation

**CURRENT**

**Medicinal Products**



**Up to 11 yrs**  
**+“8+2+1”**  
Inc. 2 yrs of automatic market protection and +1 yr extension for new indications of Significant Clinical Benefit

**PROPOSED CHANGES**



**Up to 11 yrs**  
**“8+1+1+1”**  
Automatic market protection period reduced to +1 yr and +1, +1 yr for unmet need/comparative clinical trials etc; and new indications

**CURRENT**

**Orphan Designated Products**



**10 yrs**  
10 yrs baseline for each orphan indication

**PROPOSED CHANGES**



**Up to 11 yrs**  
9 yrs baseline, up to 11 yrs for breakthrough products addressing unmet need