

## Mutual recognition and decentralised procedures finalised in 2006-2010 with new active substances

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In accordance with Directive 2004/27/EC amending Directive 2001/83/EC, the periods of data and market exclusivity are determined based on the submission date of the initial application for marketing authorisation:

- 6 or 10 years data exclusivity (depending on the Member State) for reference products where the initial application was submitted before 30 October 2005
- 8 years of data exclusivity + 2 years of market protection for reference products where the initial application was submitted as of 30 October 2005

The CMDh has compiled this list as the submission date is not always mentioned in the Public Assessment report for MRP/DCPs. The list contains new active substances submitted in accordance with Article 8(3) where the MRP or DCP was finalised in 2006-2010. For the sake of completeness, also biological products where no biosimilar applications are expected have been included.

### **A. Applications where the initial marketing authorisation application was submitted before 30 October 2005**

Active substance	Procedure Number	Product Name in RMS
bendamustine	DE/H/1250/001/DC	Levact
blood coagulation factor VIII and human von Willebrand factor in combination	DE/H/0471/002/MR	Wilate 900
carbetocin	UK/H/0838/001/MR	Pabal
clostridium botulinum type A neurotoxin complex	DE/H/0722/001/MR	Xeomin
haemophilus influenzae type b capsular polysaccharide conjugated to tetanus toxoid	UK/H/0954/001/MR	Menitorix
human normal immunoglobulin	DE/H/0473/001/MR	Gamunex 10 %
xenon	DE/H/0696/001/MR	LENOXe

**B. Applications where the initial marketing authorisation application was submitted 30 October 2005 or later**

<b>Active substance</b>	<b>Procedure Number</b>	<b>Product Name in RMS</b>
bilastine	DE/H/2300-2301/001/DC	Bilaxten/Bilton/Bitosen
cannabinol	UK/H/2462/001/DC	Sativex
dapoxetine	SE/H/0718/001-002/DC	Priligy
ferric carboxymaltose	UK/H/0894/001/DC	Ferinject
green tea leaves	DE/H/1659/001/DC	Veregen
pitavastatin	UK/H/1555-1558/001-002/DC	Livalo/Alipza/Vezeptra/Pitavastatin
tafluprost	DE/H/0991/001-002/DC	Taflotan
tapentadol	DE/H/2020-2021/001-007/DC	Palexia/Yantil