Decisions on additional year of market protection/data exclusivity for new therapeutic indication agreed by the CMDh

**Oxynal/Targin (oxycodone/naloxone)**

Following an Article 13 referral for Oxynal/Targin (DE/H/XXXX/WS/044), the CHMP reached a positive opinion in December 2014 on the authorisation of a new therapeutic indication ("Second line symptomatic treatment of patients with severe to very severe idiopathic restless legs syndrome after failure of dopaminergic therapy"). Subsequently, an extension of the market exclusivity from 10 to 11 years under Art. 10(1) was granted to Oxynal/Targin (Mundipharma GmbH). This decision would have been late for granting an additional year of market exclusivity as the first 8 years after approval have been expired on 31.05.2014.

However, DE has already approved the same indication for a national duplicate procedure on 07.05.2014. As part of the (global) marketing authorisation of Mundipharma GmbH, the new indication was confirmed and results in an additional year of market protection for the entire product starting from 31.05.2016.

**Somatuline Autogel 60mg, 90 mg, 120 mg solution for injection (lanreotide acetate) (UK/H/9013/001; DE/H/1144/001-003)**

The CMDh agreed by consensus on an additional one year period of data exclusivity in accordance with Article 10(5) for the new indication for Somatuline (lanreotide) Autogel ("treatment of Grade 1 and a subset of Grade 2 (Ki67 index up to 10%) gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of mid-gut, pancreatic or of unknown origin where hind-gut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease"). The scope of data exclusivity corresponds with the agreed indication. The implementation date is used as start date of the additional year of data exclusivity. For this procedure, the start date of the additional year of data exclusivity is 29.03.2015.
Palexia/Yantil oral solution (DE/H/2020/010-011/II/027, DE/H/2021/010-011/II/026)

The CMDh discussed the request for an additional year of market exclusivity under Art. 10(1) in variations for Palexia (DE/H/2020/010-011/II/027) and Yantil (DE/H/2021/010-011/II/026) oral solution. The RMS is in agreement to grant the indication for the oral solution in children from 2 years of age and older (single- and multiple dose, hospital setting only).

The request for an additional year of market exclusivity is based on a high unmet need currently for the treatment of acute pain, particularly in the very young children. Opioids are the gold standard for the treatment in moderate to severe pain not only in adults, but also in children. However, none of the opioids on the market has explicitly been developed for children with a respective structured study programme and dosing strategies for children have been determined only empirically. In addition, morphine underlies a complex metabolism with active metabolites leading to high inter-individual variation in exposure especially in very young children. In contrast, tapentadol has a low drug-drug interaction potential and no active metabolites.

The CMDh agreed by consensus on the additional year of market exclusivity under Art. 10(1) for Palexia (DE/H/2020/010-011/II/027) and Yantil (DE/H/2021/010-011/II/026) and results in an additional year of market protection starting from 19.08.2020 for the global marketing authorisation.