Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures

Adopted at the CHMP meeting of 19-22 October 2015

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Aldurazyme, (laronidase), Genzyme Europe BV	Positive Opinion	Marketing Authorisation exceptional approval lifted

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Caprelsa, (vandetanib), AstraZeneca AB,	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Holoclar, (ex vivo expanded autologous human corneal epithelial cells containing stem cells), Chiesi Farmaceutici S.p.A.,	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Xiapex, (collagenase clostridium histolyticum), Swedish Orphan Biovitrum AB	Positive Opinion	Recommending additional renewal

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Name of medicinal product (INN) MAH	Outcome	Comments
ProQuad, (measles, mumps, rubella and varicella vaccine (live), Sanofi Pasteur MSD SNC	Positive Opinion	Unlimited validity
Xeplion, (paliperidone), Janssen-Cilag International N.V.	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	**Rejected**
Abaloparatide	treatment of osteoporosis in postmenopausal women		X
Bezlotoxumab	prevention of Clostridium difficile infection (CDI) recurrence in adult patients receiving antibiotic therapy for CDI	X	
Cabozantinib	treatment of renal cell carcinoma	X	
Inotuzumab ozogamicin	treatment of relapsed or refractory b cell Acute Lymphoblastic Leukaemia		X
Sofosbuvir / Velpatasvir	treatment of genotype 1-6 chronic hepatitis C virus (HCV) infection in adults	X	
Venetoclax	treatment of adult patients with chronic lymphocytic leukaemia in the presence of 17p deletion		X