



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Adopted at the CHMP meeting of 29 March – 1 April 2016

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Ceplene , (histamine dihydrochloride), Meda AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Xagrid , (anagrelide), Shire Pharmaceutical Contracts Ltd.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Erivedge , (vismodegib), Roche Registration Limited	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Fampyra , (fampridine), Biogen Idec Ltd.,	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Buccolam , (midazolam), Shire Services BVBA	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Vibativ , (telavancin), Clinigen Healthcare Ltd,	Positive Opinion	Recommending additional renewal
Cayston , (aztreonam), Gilead Sciences International Ltd	Positive Opinion	Unlimited validity
Cinryze , (C1-esterase inhibitor, human), Shire Services BVBA	Positive Opinion	Unlimited validity
Levodopa/Carbidopa/Entacapone Orion , (levodopa / carbidopa / entacapone), Orion Corporation	Positive Opinion	Unlimited validity
Zytiga , (abiraterone), Janssen-Cilag International N.V.	Positive Opinion	Unlimited validity
Dexdor , (dexmedetomidine), Orion Corporation	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Monoclonal Antibody Sgn-30	treatment of metastatic colorectal cancer	X	