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Press Office

## Opinions on annual reassessments, 5-year renewals

Adopted at the CHMP meeting of 19-22 September 2011

**Table 1.** Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Atriance</b> (Nelarabine), Glaxo Group Ltd.	Positive opinion	Marketing Authorisation remains under exceptional circumstances
<b>Aldurazyme</b> (Laronidase), Genzyme Europe B.V.	Positive opinion	Marketing Authorisation remains under exceptional circumstances
<b>Riloncept Regeneron</b> (riloncept), Regeneron UK Ltd.	Positive opinion	Marketing Authorisation remains under exceptional circumstances
<b>Firdapse</b> (Amifampridine), BioMarin Europe Ltd.	Positive opinion	Marketing Authorisation remains under exceptional circumstances

**Table 2.** Opinions for 5-year renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Adrovanse</b> (Alendronic Acid / Colecalciferol), Merck Sharp & Dohme Ltd.	Positive opinion	Recommending additional renewal
<b>Copalia</b> (Amlodipine / Valsartan), Novartis Europharm Ltd.	Positive opinion	Unlimited validity
<b>Dafiro</b> (Amlodipine / Valsartan), Novartis Europharm Ltd.,	Positive opinion	Unlimited validity
<b>Exforge</b> (Amlodipine / Valsartan), Novartis Europharm Ltd.	Positive opinion	Unlimited validity
<b>Imprida</b> (Amlodipine /	Positive opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Valsartan), Novartis Europharm Ltd.,		
<b>Insulin Human Winthrop</b> (Insulin Human), Sanofi-aventis Deutschland GmbH,	Positive opinion	Unlimited validity