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Press office

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

Adopted at the CHMP meeting of 23–26 May 2016

Table 1. Opinions for annual re-assessment applications

| Name of medicinal product (INN) MAH | Outcome | Comments |
|--|------------------|---|
| ATryn , (antithrombin alfa), GTC Biotherapeutics UK Limited | Positive Opinion | Marketing Authorisation remains under exceptional circumstances |
| Scenesse , (afamelanotide), Clinuvel (UK) Limited | 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 |
|---|------------------|---|
| Xalkori , (crizotinib), Pfizer Limited | Positive Opinion | Recommending renewal of conditional Marketing Authorisation |

Table 3. Opinion for 5-Year Renewal applications

| Name of medicinal product (INN) MAH | Outcome | Comments |
|--|------------------|--------------------|
| ATryn , (antithrombin alfa), GTC Biotherapeutics UK Limited | Positive Opinion | Unlimited validity |
| Byetta , (exenatide), AstraZeneca AB | Positive Opinion | Unlimited validity |



| Name of medicinal product (INN) MAH | Outcome | Comments |
|--|------------------|--------------------|
| Edurant , (rilpivirine), Janssen-Cilag International N.V. | Positive Opinion | Unlimited validity |
| Eviplera , (emtricitabine / rilpivirine / tenofovir disoproxil), Gilead Sciences International Ltd | Positive Opinion | Unlimited validity |
| Komboglyze , (saxagliptin / metformin hydrochloride), AstraZeneca AB | Positive Opinion | Unlimited validity |
| Levetiracetam Accord , (levetiracetam), Accord Healthcare Ltd | Positive Opinion | Unlimited validity |
| Levetiracetam Teva , (levetiracetam), Teva B.V. | Positive Opinion | Unlimited validity |
| Luminity , (perflutren), MAH: Lantheus MI UK Ltd. | Positive Opinion | Unlimited validity |
| Pramipexole Accord , (pramipexole), Accord Healthcare Ltd | Positive Opinion | Unlimited validity |
| Sprycel , (dasatinib), Bristol- Myers Squibb Pharma EEIG | Positive Opinion | Unlimited validity |
| Vyndaqel , (tafamidis), Pfizer Limited | Positive Opinion | Unlimited validity |

Table 4. Accelerated assessment procedures

| INN | Intended indication(s) | Accelerated Assessment Request | |
|--------------------|--|--------------------------------|----------|
| | | Accepted | Rejected |
| Glibenclamide | Treatment of neonatal diabetes, paediatric formulation (ready to use oral suspension of glibenclamide) to be used in newborns, infants and children. | X | |
| Etirinotecan Pegol | Treatment of patients with locally recurrent or metastatic breast cancer (MBC). Prior therapy should have included an anthracycline, a taxane and capecitabine (ATC). | X | |

| INN | Intended indication(s) | Accelerated Assessment Request | |
|-------------|---|--------------------------------|--|
| Midostaurin | <p>Indicated as a combination therapy for the treatment of patients with newly diagnosed acute myeloid leukaemia who are FLT3 mutation-positive and who are eligible to receive standard induction and consolidation chemotherapy.</p> <p>Indicated for the treatment of patients with aggressive systemic mastocytosis (ASM) or mast cell leukemia (MCL) with or without an associated hematologic non-mast cell lineage disorder (AHNMD).</p> | X | |