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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 16-19 July 2012

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

| Name of medicinal product<br>(INN) MAH | Outcome          | Comments  |
|--|------------------|---|
| <b>Prialt</b> (Ziconotide), Eisai Ltd. | Positive Opinion | Marketing Authorisation remains under exceptional circumstances |

**Table 2.** Opinion for renewals of conditional Marketing Authorisation

| Name of medicinal product<br>(INN) MAH | Outcome | Comments |
|--|---------|----------|
| N/A                                    |         |          |

**Table 3.** Opinion for 5-Year Renewal applications

| Name of medicinal product<br>(INN) MAH  | Outcome          | Comments                        |
|---|------------------|---------------------------------|
| <b>Glubrava</b> (Pioglitazone / Metformin Hydrochloride), Takeda Global Research and Development Centre (Europe) Ltd. | Positive Opinion | Recommending additional renewal |
| <b>Olanzapine Neopharma</b> (Olanzapine), Neopharma Ltd.  | Positive Opinion | Unlimited validity              |
| <b>Atripla</b> (Efavirenz / Emtricitabine / Tenofovir   | Positive Opinion | Unlimited validity              |



| Name of medicinal product (INN) MAH   | Outcome          | Comments                        |
|---|------------------|---------------------------------|
| Disoproxil Fumarate), Bristol-Myers Squibb and Gilead Sciences Ltd.   |                  |                                 |
| <b>Cervarix</b> (Human Papillomavirus Vaccine [Types 16, 18] (Recombinant, Adjuvanted, Adsorbed)), GlaxoSmithKline Biologicals S.A. | Positive Opinion | Unlimited validity              |
| <b>Cialis</b> (Tadalafil), Eli Lilly Nederland B.V.   | Positive Opinion | Unlimited validity              |
| <b>Nevanac</b> (Nepafenac), Alcon Laboratories (UK) Ltd.  | Positive Opinion | Unlimited validity              |
| <b>Tasigna</b> (Nilotinib), Novartis Europharm Ltd.   | Positive Opinion | Unlimited validity              |
| <b>Tesavel</b> (Sitagliptin), Merck Sharp & Dohme Ltd.  | Positive Opinion | Unlimited validity              |
| <b>Torisel</b> (Temsirolimus), Pfizer Ltd.  | Positive Opinion | Recommending additional renewal |
| <b>Zavesca</b> (Miglustat), Actelion Registration Ltd.  | Positive Opinion | Unlimited validity              |

**Table 4.** Accelerated Assessment Procedures

| Substance (Chemical/Biological) | Intended indication(s) | Accelerated Assessment Request |          |
|---------------------------------|------------------------|--------------------------------|----------|
|                                 |                        | Accepted                       | Rejected |
| Chemical                        | leukaemia              | X                              |          |