**Recommendations for submission of supplementary information**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **INN** |  | **Signal (EPITT No)** |  | **PRAC** |  | **Action for MAH** | **MAH** |
|  |  |  |  | **Rapporteur** |  |  |  |
|  |  |  |  |  |  |  |  |
| Adalimumab |  | Autoimmune |  | Ulla Wändel |  | Supplementary | AbbVie Ltd |
|  |  | haemolytic anaemia |  | Liminga (SE) |  | information requested |  |
|  |  | (AIHA) and |  |  |  | (submission by |  |
|  |  | haemolytic anaemia |  |  |  | 09/12/2015) |  |
|  |  | (HA) (18447) |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Alogliptin; |  | Arthralgia (18489) |  | Menno van |  | Supplementary | Takeda Pharma |
| Linagliptin |  |  |  | der Elst (NL) |  | information requested | A/S; Boehringer |
|  |  |  |  |  |  | (submission by | Ingelheim |
|  |  |  |  |  |  | 09/12/2015) | International |
|  |  |  |  |  |  |  | GmbH |
|  |  |  |  |  |  |  |  |
| Carbidopa, |  | Intussusception |  | Qun-Ying |  | Supplementary | AbbVie Ltd |
| levodopa |  | (18424) |  | Yue (SE) |  | information requested |  |
|  |  |  |  |  |  | (submission by |  |
|  |  |  |  |  |  | 09/12/2015) |  |
|  |  |  |  |  |  |  |  |
| Ibrutinib |  | Peripheral |  | Julie |  | Assess in the next | Janssen-Cilag |
|  |  | neuropathy |  | Williams |  | PSUR (submission by | International NV |
|  |  | (18480) |  | (UK) |  | 21/01/2016) |  |
|  |  |  |  |  |  |  |  |
| Mitotane |  | Sex hormone |  | Dolores |  | Supplementary | Laboratoire HRA |
|  |  | disturbances and |  | Montero |  | information requested | Pharma, SA |
|  |  | development of |  | Corominas |  | (submission by |  |
|  |  | ovarian macrocysts |  | (ES) |  | 09/12/2015) |  |
|  |  | (18301) |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Peginterferon |  | Acquired |  | Qun-Ying |  | Supplementary | Roche |
| alfa-2a |  | haemophilia (18476) |  | Yue (SE) |  | information requested | Registration |
|  |  |  |  |  |  | (submission by | Limited |
|  |  |  |  |  |  | 09/12/2015) |  |
|  |  |  |  |  |  |  |  |
| Ustekinumab |  | Pemphigoid (18469) |  | Julie |  | Supplementary | Janssen-Cilag |
|  |  |  |  | Williams |  | information requested | International N.V. |
|  |  |  |  | (UK) |  | (submission by |  |
|  |  |  |  |  |  | 09/12/2015) |  |
|  |  |  |  |  |  |  |  |

**3. Other recommendations**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **INN** |  | **Signal (EPITT No)** |  | **PRAC** |  | **Action for MAH** | **MAH** |
|  |  |  |  | **Rapporteur** |  |  |  |
|  |  |  |  |  |  |  |  |
| Adalimumab |  | Convulsion (18211) |  | Ulla Wändel |  | No action | AbbVie Ltd |
|  |  |  |  | Liminga (SE) |  |  |  |
|  |  |  |  |  |  |  |  |
| Boceprevir |  | Hyponatraemia |  | Isabelle |  | Monitor in PSUR | Merck Sharp & |
|  |  | (18350) |  | Robine (FR) |  |  | Dohme Limited |
|  |  |  |  |  |  |  |  |
| Fluoroquinolones: |  | Retinal detachment |  | Valerie |  | No action at this stage | Not applicable |
| ciprofloxacin; |  | (15914) |  | Strassmann |  |  |  |
| enoxacin; |  |  |  | (DE) |  |  |  |
| flumequine; |  |  |  |  |  |  |  |
| levofloxacin; |  |  |  |  |  |  |  |
| lomefloxacin; |  |  |  |  |  |  |  |
| moxifloxacin; |  |  |  |  |  |  |  |
| norfloxacin; |  |  |  |  |  |  |  |
| ofloxacin; |  |  |  |  |  |  |  |
| pefloxacin; |  |  |  |  |  |  |  |
| prulifloxacin; |  |  |  |  |  |  |  |
| rufloxacin |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Sitagliptin |  | Intestinal obstruction |  | Menno van |  | Monitor in PSUR | Merck Sharp & |
|  |  | (18251) |  | der Elst (NL) |  |  | Dohme Limited |
|  |  |  |  |  |  |  |  |