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EMA/CHMP/81751/2015
Committee for Medicinal Products for Human Use (CHMP)

Simponi

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: golimumab

Procedure No. EMEA/H/C/000992/PSUV/0058

Period covered by the PSUR: 07 April 2013 – 06 April 2014

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Scientific conclusions

The MAH reviewed within this PSUR reported cases of device failures and adverse events related to the auto-injector and maladministration. The vast majority of the 566 cases were non-serious (553/566), and all of the device-related events were non-serious. The most frequently reported PTs were Device malfunction (75.2%; 497/661) and inappropriate schedule of drug administration 10.6%; (70/661). Among the 566 cases, 389 (68.7%) cases also reported the PT Drug dose omission and 57 (8.6%) cases also reported Underdose for most events that potentially occurred as a result of the device malfunction. The most frequently reported device malfunction or failure issue was the firing of the device, followed by issues with the auto-injector button. It was noted that in at least one case, there was uncertainty regarding how to interpret the yellow indicator: "the yellow indicator was only half way up the window after the injection and the reporter was unsure if the full dose was delivered". This issue has been discussed thoroughly within a PRAC signal procedure regarding Humira (adalimumab), and resulted in an update of the Package Leaflet, clarifying the functioning of the auto-injector. The PRAC recommended that a smilar update is implemented for Simponi in the "instructions for administration" section of the Package Leaflet under the heading "*Check the window – a yellow indicator confirms proper administration"* by adding the following as bullet points:

- The yellow indicator is connected to the plunger of the pre-filled pen. If the yellow indicator is not shown in the window, the plunger has not advanced adequately, and the injection has not occurred.
- The yellow indicator will fill about half of the viewing window. This is normal.

Therefore, in view of available data, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Simponi, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance golimumab is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.