

27 June 2019
EMA/CMDh/204499/2019

Report from the CMDh meeting held on 25-27 June 2019

Implementation of outcome of Art. 31 referral on angiotensin-II-receptor antagonists (sartans) containing a tetrazole group

The CMDh reminds MAHs of medicinal products concerned by the Art. 31 referral on angiotensin-II-receptor antagonists (sartans) containing a tetrazole group to submit the necessary variations to implement the outcome of the referral immediately, in order to avoid regulatory action being taken by National Competent Authorities. MAHs should take note that there are several variations necessary as immediate action after publication of the Commission Decision (inclusion of conditions, amendment of API specification with interim limits and to ensure that a control strategy for nitrosamines is in place). MAHs should take into account the guidance provided by the CMDh in the CMDh press releases of March and April 2019 as well as in a dedicated Questions and Answers document published under "Advice from CMDh".

Cover Note to list of safety concerns per RMP of active substances per product

The CMDh agreed an update of the Cover Note to List of safety concerns per approved RMP of active substances per product. With the update of the cover note further information is provided on the purpose of the list, the Harmonisation of RMP Project (HaRP), how the list is updated and on the implementation of harmonised lists of safety concerns. The updated document will be published on the CMDh website under "Pharmacovigilance, RMP".

Harmonisation of RMP Project (HaRP)

As part of the Harmonisation of RMP Project (HaRP), the HaRP peer review group has finalised 21 assessment reports including as outcome an agreed harmonised list of safety concerns per active substance. The CMDh adopted the assessment reports, which will be published on the CMDh website under "Pharmacovigilance, RMP". The "list of safety concerns per approved RMP of active substances per product" will be updated to delete the currently published lists of safety concerns of products containing these active substances and links to the assessment reports with the harmonised list of safety concerns will be added.

Medicinal products containing dextromethorphan

During the assessment of the PSUSA on dextromethorphan the PRAC considered that changes to the SmPC (sections 4.4 and 4.9) and PL (sections 2 and 3), as agreed during the PSUSA, should also be included in the product information of combination products containing dextromethorphan. The same implementation timelines apply.

**Valid for all dextromethorphan containing medicinal products
(including combination products)**

Medicinal products containing methylphenidate

During the assessment of the PSUSA on methylphenidate the PRAC requested all MAHs to update their RMPs within 3 months, taking into account the new core safety specification(s), which will be published on CMDh website in the list of safety concerns per approved RMP of active substances per product (<https://www.hma.eu/464.html>). In addition, all MAHs are requested to delete the specific follow-up questionnaires.

Outcomes of informal PSUR work-sharing procedures

The CMDh has adopted the conclusions of the PSUR assessment for:

- LENOXe 100% (V/V) (Xenon)

which may require changes to the product information or introduction of other risk minimisation measures.

The public summary will be published on the CMDh website under "Pharmacovigilance, PSURs, Outcome of informal PSUR worksharing procedures".

MAHs of the products concerned should implement the outcome of the assessment by the appropriate variation or other procedure (as advised) within 90 days of publication.

Change in the Presidency of the Council of the European Union

The June 2019 CMDh meeting was the last one under the Romanian Presidency of the Council of the European Union. Finland will take over the Presidency in July 2019. Mrs Paivi Jutila will be the appointed Presidency Vice-Chairperson of the CMDh during the Finnish Presidency of the Council of the European Union.

Implementation of Commission Decisions after Article 30 referral procedures

A link to the Commission decision, including SmPC, package leaflet and labelling, on the finalised Article 30 referral procedures for Septanest and associated names will be published on the CMDh website.

Generic companies are encouraged to contact the Reference Member State to harmonise the product information of the medicinal products authorised via MRP/DCP to conform to the Commission Decision,