8 November 2018
EMA/COMP/699916/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

COMP work plan 2019

The activities outlined in the COMP work plan for 2019 has been agreed taking into consideration the Agency's business continuity plans (BCP) due to its physical move from the Agency's current premises in the UK to the new premises in the Netherlands.
The Agency is currently implementing its phase 3 BCP which may be complemented with an additional set of temporary suspensions/reductions as of 1 January 2019, the latter to be launched as part of phase 4 of the BCP. Temporary suspension/scaling back of activities is currently scheduled to last until 30 June 2019, see enclosed link for additional information.

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1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. Designation and maintenance of orphan medicines

Key objectives

- Continue to implement and monitor changes introduced by the Commission notice 2016/C 424/03 on the Application of Articles 3, 5 and 7 of Regulation (EC) No 141/2000 on Orphan Medicinal Products.
- Optimise the quality of initial orphan designation applications and maintenance by sharing COMP experience with stakeholders.

Activities in 2019

- Seek views on the utility and content of the Orphan Maintenance Assessment Report (OMAR) with external stakeholders, including payers and HTA bodies. Consider the comments and adjust the content of the OMAR if deemed necessary.
- Collaboration with EC on the study on 'Evaluation of the legislation on medicines for children and rare diseases (medicines for special populations)'.
- Track and record topics which arise as a result of the implementation of the Commission Notice (2016/C 424/03).
- Pro-actively ensure collaboration between committees with suitable inter-committee flow.

  The COMP members, in particular those with dual committee membership to liaise and inform the other Committee of the discussions in COMP. COMP members to liaise with CHMP/or CAT member in case of rapporteurship or co-rapporteurship.

- Continuous review of and regular updates on the new on-line working tools (IRIS) for handling the procedures.