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Inspections, Human Medicines Pharmacovigilance and Committees Division

COMP work plan 2018

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The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

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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 (2016/C 424/03).
- Improve the quality of initial orphan designation applications by sharing COMP experience and improving recommendations, in particular with regards to prevalence.
- Ensure consistency, transparency, quality and detail of the grounds of opinions given by the COMP on significant benefit at the time of marketing authorisation.

Activities in 2018

- Implement the work on Orphan maintenance assessment reports (OMAR). Create OMARs for all MAA procedures including the reassessments at extension of indication.
- Seek views on the utility and content of the OMAR by end of Q2 2018 with external stakeholders, including payers and HTA bodies. Consider the comments and adjust the content of the OMAR if deemed necessary.
- Track and record topics which arise as a result of the implementation of the Commission Notice (2016/C 424/03).
- Improve recommendations and guidance to sponsors in line with the Commission Notice (2016/C 424/03) in particular with regards to:
  - Initial orphan designation
  - Maintenance
  - Type II variations

  COMP topic leader: Lesley Greene

  Other Committee participants:

Member/Alternate	Name	Member State
Chair	Bruno Sepodes	
Member	Brigitte Blöchl-Daum	AT
Member	Kateřina Kopečková	CZ
Member	Frauke Naumann-Winter	DE
Member	Vallo Tillmann	EE
Member	Ingeborg Barišić	HR
Member	Armando Magrelli	IT
Member	Michel Hoffmann	LU
Member	Violeta Stoyanova	NL
Member	Bożenna Dembowska-Bagińska	PL

Member/Alternate	Name	Member State
Member	Daniel O'Connor	UK
Member	Pauline Evers	Patients' organisations representative
Member	Mario Ricciardi	Patients' organisations representative
Member	Kerstin Westermark	Nominated by EC
Member	Giuseppe Capovilla	Nominated by EC

- Create a new guidance, and decide on the best format of this, to replace the "COMP recommendation on elements required to support the medical plausibility and the assumption of significant benefit for an orphan designation, EMEA/COMP/436/01", taking into account the Commission Notice (2016/C 424/03) and principles identified by the working group on significant benefit when assessing criteria for orphan designation (at designation and at marketing authorisation).

  COMP topic leader: Lesley Greene

  Other Committee participants:

Member/Alternate	Name	Member State
Chair	Bruno Sepodes	
Member	Brigitte Blöchl-Daum	AT
Member	Kateřina Kopečková	CZ
Member	Frauke Naumann-Winter	DE
Member	Martin Možina	SI
Member	Vallo Tillmann	EE
Member	Karri Penttilä	FI
Member	Ingeborg Barišić	HR
Member	Armando Magrelli	IT
Member	Michel Hoffmann	LU
Member	Violeta Stoyanova-Beninska	NL
Member	Bożenna Dembowska-Bagińska	PL
Member	Daniel O'Connor	UK
Member	Pauline Evers	Patients' organisations representative
Member	Mario Ricciardi	Patients' organisations representative
Member	Kerstin Westermark	Nominated by EC
Member	Giuseppe Capovilla	Nominated by EC

- Continue the work on defining conditions in the context of the orphan regulation:

  – Finalise a publication with lessons learned, based on important cases from COMP activities.

  COMP topic leader: Daniel O'Connor

Other Committee participants:

Member/Alternate	Name	Member State
Member	Frauke Naumann-Winter	DE
Member	Ingeborg Barišić	HR
Member	Violeta Stoyanova-Beninska	NL
Member	Kerstin Westermark	Nominated by EC

- Analysis of non-clinical models
  - Initiate analysis of data from non-clinical models in infectious diseases and ophthalmology.

COMP topic leader: Eva Malíková

Other Committee participants:

Member/Alternate	Name	Member State
Member	Fernando Méndez Hermida	ES
Member	Melinda Sobor	HU
Member	Dinko Vitezic	HR
Member	Armando Magrelli	IT
Member	Michel Hoffmann	LU
Member	Robert Nistico	MT
Member	Violeta Stoyanova-Beninska	NL
Member	Dinah Duarte	PT
Member	Eva Malíková	SK
Member	Mario Ricciardi	Patients' organisations representative
Member	Giuseppe Capovilla	Nominated by EC

- Continue the work on prevalence methodology:
  - Finalise the update of the document "Points to Consider on the calculation and reporting of the prevalence of a condition for orphan designation" (COMP/436/01);
  - Development of strategies to implement recommendations stemming from the workshop on Prevalence (December 2017) when assessing orphan designation.

COMP topic leader: Frauke Naumann-Winter

Other Committee participants:

Member/Alternate	Name	Member State
Member	Vallo Tillmann	EE
Member	Geraldine O'Dea	IE
Member	Irena Rogovska	LV
Member	Giuseppe Capovilla	Nominated by EC

- Implement the new on-line working tools for handling the procedures:
  - User testing of software and system
  - Training of all COMP members in the software
  - Implementation of the software as the working tools for COMP

COMP topic leader: Armando Magrelli

Other Committee participants:

Member/Alternate	Name	Member State
Member	Eva Malíková	SK
Member	Armando Magrelli	IT
Member	Brigitte Bloechl-Daum	AT
Member	Frauke Naumann-Winter	DE
Member	Karri Penttilä	FI
Member	Ingeborg Barišić	HR
Member	Lyubina Todorova	BG

2. Horizontal activities and other areas

2.1. International activities

2.1.1. Exchange of information

Key objectives

- Understanding of the similarities and differences between the concepts of significant benefit and added therapeutic value as used by HTAs
- Increase collaboration and understanding of procedures between HTA bodies and COMP at time of market authorisation

Activities in 2018

- Establish a process for provision of information on significant benefit review at time of authorisation to HTAs.
- Review the relevance of the content of the OMAR for HTAs.

COMP topic leader: Bruno Sepodes

Other Committee participants:

Member/Alternate	Name	Member State
Member	Frauke Naumann-Winter	DE
Member	Dan O'Connor	UK
Member	Armando Magrelli	IT
Member	Ingrid Wang	NO

Member/Alternate	Name	Member State
Member	Karri Penttilä	FI
Member	Violeta Stoyanova-Beninska	NL
Member	Dinko Vitezic	HR
Member	Martin Možina	SI