<u>Call for patient organisation</u> <u>representatives to join the Committee</u> <u>for Orphan Medicines</u>

04/12/2017

Deadline for applications is 20 December 2017

The European Commission's Directorate-General for Health and Food Safety has launched a call for expressions of interest to represent patient organisations in the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP).

The call aims to fill three positions for <u>COMP members</u> nominated by the European Commission to represent patient organisations. These members participate in the meetings of the Committee alongside the members nominated by each Member State, Iceland and Norway, as well as an additional three members nominated by the European Commission based on a recommendation from the EMA.

The three members representing patient organisations will be appointed for a term of three years from 1 July 2018, which can be renewed. The deadline for the submission of applications to the European Commission is 20 December 2017. Further information on the application procedure and the assessment criteria is available on the Commission's website.

The COMP has a strong tradition of involving patient representatives in its work. Its main task is to examine applications sent by companies and decide whether their medicines can be designated as 'orphan'. An orphan medicine is used in the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare, which means it affects no more than five in 10,000 people in the European Union (EU).

The role of a patient organisation representative in the COMP is to give a voice to patients and ensure their needs are taken into account in the Committee's decision-making process. Although a medical background is not required, candidates may benefit from a sound knowledge of medical and, to a certain extent, regulatory issues related to medicines in the EU.

Representatives of patient organisations participate in the COMP procedures in the same way as other Committee members. They are expected to attend monthly Committee meetings at EMA and to actively contribute to scientific discussions, examine documents and make comments with a specific focus on the target group they represent.

Representatives of patient organisations are also members of the EMA's Pharmacovigilance Risk Assessment Committee, Paediatric Committee and Committee for Advanced Therapies.

The European Commission will appoint the patient organisation members after consultation with the European Parliament.