



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2018
EMA/225940/2018
Committee for Medicinal Products for Human Use (CHMP)

Submission of comments on 'Draft qualification opinion on Proactive in chronic obstructive pulmonary disease (COPD)' (EMA/810227/2017)

Comments from:

Name of organisation or individual

European Lung Foundation

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).



1. General comments

Stakeholder number <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	<p>European Lung Foundation (ELF) welcomes the development and validation of a tool to monitor physical activity in patients with COPD. The integration of patient-reported outcome measures into clinical trials plays a crucial role in ensuring that the evidence from scientific studies provides answers to the questions which are important to patients. Developing tools which collect patient-reported outcomes in a systematic and robust way will help to ensure that patient experience is considered within the clinical trials process in a rigorous way.</p> <p>We know that physical inactivity plays an important role in COPD, with potentially severe consequences for patients (Vaes et al, <i>ERJ</i> 2014, http://erj.ersjournals.com/content/44/5/1199). Furthermore, many patients with COPD value the opportunity to integrate low-level physical activity into their day to day lives and giving up small daily tasks, such as walking to the shops or doing housework, is often an early indicator of worsening symptoms. Clinicians play an important role in motivating COPD patients to do physical activity as a part of their treatment.</p>	<p>The European Medicines Agency is thankful for the comments provided by the European Lung Foundation highlighting the importance of physical activity in COPD, and supporting the qualification opinion on Proactive in COPD.</p>

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	<p>Traditional physical activity tools are not sensitive enough to capture these small but important changes in the day to day life of someone with COPD, resulting in poor capture of real-world experiences.</p> <p>The importance of physical activity in helping people with COPD to stay well and finding ways to better measure patient experience were highlighted as priorities in the European Respiratory Society (ERS) COPD audit and a subsequent workshop with COPD patients facilitated by ELF and ERS. Further details are available in the following publication: http://breathe.ersjournals.com/content/9/5/350</p> <p>The D-PPAC and C-PPAC measure two aspects of physical activity which are important to patients – amount of activity and difficulty. ELF would welcome the approval of these PRO tools for use in clinical trial settings. We believe this would address the current gap in assessing physical activity in COPD research.</p>	