

Working together towards clear EU Guidelines on the Off-Label Use of Medicinal Products

We welcome the publication by the European Commission of the long-awaited [study on off-label use of medicinal products in the European Union](#).

Commissioned in 2014 to understand the ramification of the issue, the study sheds light on the drivers behind the **increasing use of off-label medicines in Europe**, as well as the opportunities and challenges linked to it.

Most importantly, the study presents important evidence for the European Commission to **define a harmonised approach across Europe**, facilitating access to treatment for patients in need, while ensuring their safety and the respect of the EU regulatory framework.

Clear action at EU level becomes particularly urgent due to the trend in **some EU Member States of promoting the prescription of off-label medicines for reasons beyond the medical need of patients**, which creates unnecessary and avoidable risks for patients and often places healthcare professionals in the position of being liable for decisions that they have not taken of their own accord.

A number of valuable policy options are presented in the report, including ***the development of a general guideline on off-label use at the EU level, which describes the legal framework and the relation between the legal framework and professional guidelines***. This follows on from the call of the European Parliament on October 2013 to the European Medicines Agency to develop guidelines on the off-label use of medicines, on the basis of medical need and taking account of patient protection.

We strongly support the creation of EU guidelines on this matter. Indeed, since 2015, we **have been working with experts and multiple stakeholders to identify [criteria for good off-label use](#)**.

The publication of the study thus offers a unique opportunity to involve all interested stakeholders in the process and **work with the European Commission and the European Medicines Agency to urgently define and put in place clear and strong European guidelines on the off-label use of medicines**.