

Annex I a: Declaration on Good Off-Label Use Practice

The EBC actively supports the adoption of EU-level guidelines on off-label use of medicines, a policy option presented in the European Commission's [Study on off-label use of medicinal products in the European Union](#) published last February. Off-label use is the practice of using a medicine outside its authorised indication. This is often necessary in areas of unmet medical needs but also poses challenges in terms of patient safety. The way in which member states deal with off-label use is currently not harmonized in the EU.

Recently we have witnessed a growing trend in some EU-countries of prescribing medicines off-label without a medical rationale, often as a cost-saving measure. In this context the EBC, together with 8 other pan-European organizations, supports the [Declaration on Good Off-Label Use Practices \(GOLUP\)](#). This document calls on the European Medicines Agency (EMA) and other national regulatory bodies to adopt strict guidelines on the practice of off-label use, thereby taking steps to ensure that public health is not undermined by economic interests.

We would kindly like to ask you to consider signing the GOLUP-declaration on behalf of your NBC. The EBC aims to generate support for the declaration among a broad group of stakeholders, in this regard support of your Brain Council would be crucial.

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