Enhancing consistency in wording of therapeutic indications to support healthcare decision-making

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EMA’s human medicines committee ([CHMP](https://www.ema.europa.eu/en/glossary/chmp)) has developed a [paper](https://www.ema.europa.eu/documents/regulatory-procedural-guideline/wording-therapeutic-indication-guide-assessors-centralised-applications_en.pdf)to strengthen consistency when defining therapeutic [indications](https://www.ema.europa.eu/en/glossary/indication) in the [product information](https://www.ema.europa.eu/en/glossary/product-information) of medicines. The document is intended to guide assessors in the [national competent authorities](https://www.ema.europa.eu/en/glossary/national-competent-authority) who are responsible for evaluating [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) and extension of [indication](https://www.ema.europa.eu/en/glossary/indication) applications received by EMA. It outlines key elements that assessors should consider when evaluating the therapeutic [indications](https://www.ema.europa.eu/en/glossary/indication) proposed by the applicant, for example, whether a medicine is considered as first- or second-line treatment and whether it should be used in combination with another product. In this context, the paper takes into account some of the needs of healthcare decision-makers such as healthcare professionals and [health technology assessment (HTA) bodies](https://www.ema.europa.eu/en/glossary/health-technology-assessment-body).

A therapeutic [indication](https://www.ema.europa.eu/en/glossary/indication) for a given medicine is the primary source of information for its use. It should clearly state the disease/condition that a medicine is intended to treat and the patient group clearly benefiting from it. EMA evaluates the therapeutic [indications](https://www.ema.europa.eu/en/glossary/indication) that companies apply for as part of their application for a new [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) or a change to the [indication](https://www.ema.europa.eu/en/glossary/indication) of an existing [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation).

Stakeholders, who rely on this information for their work, have raised concerns that therapeutic [indications](https://www.ema.europa.eu/en/glossary/indication" \t "_blank" \o "A medical condition that a medicine is used for. This can include the treatment, prevention and diagnosis of a disease.)may be worded inconsistently and can contain varying levels of detail. Primarily, healthcare professionals need this important information to choose the best treatment for their patients. In addition, a therapeutic [indication](https://www.ema.europa.eu/en/glossary/indication" \t "_blank" \o "A medical condition that a medicine is used for. This can include the treatment, prevention and diagnosis of a disease.)serves as the starting point for assessment of the relative effectiveness of a new medicine by HTA bodies, who require clear and precise [indications](https://www.ema.europa.eu/en/glossary/indication) to allow them to make recommendations on pricing and reimbursement of medicines.

Similarly, EU healthcare payers, who look at a medicine’s cost-effectiveness, its impact on healthcare budgets and the seriousness of a disease, also rely on this information.

The development of the guide follows discussions with EUnetHTA and the payers’ community as part of their interactions with EMA to help improve timely and affordable access of patients to new medicines. It was adopted by the [CHMP](https://www.ema.europa.eu/en/glossary/chmp) at its October 2019 meeting.

The guide currently focuses on the therapeutic [indication](https://www.ema.europa.eu/en/glossary/indication) of a medicine in section 4.1 of the [Summary of Product Characteristics](https://www.ema.europa.eu/en/glossary/summary-product-characteristics) (SmPC). Further guidance may also be developed through continuous reflection with stakeholders.