

Patient-reported outcomes (PROs) underrepresented in summaries of product characteristics (SmPCs) on new drugs

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Before a new drug enters the market, the pharmaceutical company must submit a summary of product characteristics (SmPC) as part of

marketing authorization. This should contain all relevant study data and information on the safe and effective use of the drug, preferably from randomized controlled trials (RCTs). Patient-reported outcomes (PROs) are also highly relevant here, as by means of these outcomes, patients themselves assess how a medical intervention affects symptoms or health-related quality of life, for example. These subjective endpoints are very important for the assessment of the benefits and harms of drugs: In order to reflect the patient perspective, the collection of data on PROs in clinical trials has therefore increased markedly in recent years.

In the early benefit assessment of drugs in Germany according to the Act on the Reform of the Market for Medicinal Products (AMNOG), after marketing authorization [pharmaceutical companies](#) must submit the complete evidence on a new [drug](#) in their dossiers. IQWiG's subsequent dossier assessments explicitly consider PROs.

For their [article](#) in the *Journal of Patient-Reported Outcomes*, IQWiG researchers, together with an external expert from the Drug Commission of the German Medical Association, first investigated the extent to which RCTs included in dossier assessments contained evaluable data on PROs: This was the case in about three-quarters of the RCTs. They then checked whether these data were also reported in the corresponding SmPCs. Result: In SmPCs on new drugs, PRO data are only reported for 46% of RCTs with evaluable PRO data, and are thus clearly underrepresented. The analyses show that SPCs often fails to include the main study results on symptoms and health-related quality of life. Therefore, SPCs should urgently be improved in order to adequately consider the patient perspective.

More information: Susanne Haag et al, Results on patient-reported outcomes are underreported in summaries of product characteristics for new drugs, *Journal of Patient-Reported Outcomes* (2021). [DOI: 10.1186/s41687-021-00402-1](#)

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