Subject: Public Consultation on PAES
Delegated Act on Post-Authorisation Efficacy Studies

Content of the opinion:

Over several years, the introduction of innovative medicines has led to significant progress in the prevention and treatment of diseases that have always posed a problem for medicine. A large number of innovative medicines and copies of them ('generics') have been placed on the market. Currently, after registration for clinical trials in the 'fourth phase', trials are conducted which improve knowledge of medicines that have already been registered. However, the trials most often only examine indications shown on the product data sheet. Post authorisation, the efficacy of medical products is not tested. Sometimes it turns out that in practice the efficacy for the authorised indications is low, but the medication is still used by doctors (as a result of their observations) for indications other than those shown on the safety data sheet. The efficacy of a large number of the medicines produced by the pharmaceutical industry is uncertain. Additional efficacy studies might eliminate medicines of little or no proven therapeutic value. The search for even better medicines does not affect the need to verify the efficacy of medicines which are already on the market and often have been for several years. Therefore, to evaluate efficacy after authorisation, verification of efficacy after authorisation seems to be the most appropriate method.

Here it is important to bear generics in mind. As we know, the procedure for introducing generic medicines is significantly shorter. They do not require clinical trials because they contain the same active substance as the original medicine. Only bioequivalence studies confirming the bioequivalence of the generic with the original medicine are needed. In practice it often happens that, despite the bioequivalence of the medicine lying in the range of 80 to 100%, it does not have the same efficacy as the original medicine. It seems this is linked to the type of active substance used, auxiliary substances used, and the technological process.

There is a real demand for generics because they reduce the costs of treatment and facilitate access to treatment for greater numbers of patients. However, there seem to be

no rules on the generics with no proven efficacy flooding the pharmaceutical market. Often several dozen generic medicines containing the same substance exist on the market, the efficacy of which has not been confirmed by any of the efficacy trials. One example (mentioning no names) would be medical products for reducing blood cholesterol. A large number of equivalent products currently exist on the pharmaceutical market. While this provides a choice, their efficacy has not been proven in any trials. Patients have repeatedly had their medicines changed; this creates an unnecessary financial burden and has also required the hospitalisation of patients due to the lack of a reaction to the drug. Hospital admissions resulting from a lack of drug efficacy are not monitored.

In short, any additional evaluation of the efficacy of medicines is a good idea. It is also a good idea to mobilise bodies to comply with such studies after marketing authorisation has been granted. The pharmaceutical industry should produce medicines which have been proven to be effective and safe.

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