Application for variations

Updated 25 October 2021

Marketing authorisation holders must apply for authorisation of any change (variation) to the summary of product characteristics and the documents based on which a medicine has been granted a marketing authorisation.

The variation application must be submitted to the Danish Medicines Agency if the change concerns a marketing authorisation that we have granted.

Human and veterinary

Guideline on variations to marketing authorisations for medicinal products

Obligations regarding updates of Active Substance Master Files (ASMF/DMF)

Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (PDF file)

Amending of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (PDF file)

Commission Delegated Regulation (EU) 2021/756 of 24 March 2021 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (PDF file)

Addendum to the Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures (2021/C 215 I/01) (PDF file)

The European Commission's guidelines of 16.05.2013 on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to

the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures

Information on EDQM's procedure for withdrawal or suspension of Certificates of Suitability

Requirements for marketing authorisation holders for medicinal products containing active substances in the form of mesilates, (di)isetionates, tosilates or besilates

Temporary repackaging of medicines with a marketing authorisation

Forms

The European Commission's application form for variation to a marketing authorisation (human and veterinary)

European Medicines Agency/CMDh explanatory notes on Variation Application Form (Human medicinal products only) (PDF file)

CMD

Human

CMD(h) best practice guides for the submission and processing of variations in the mutual recognition procedure

CMD(h) Examples for acceptable and not acceptable groupings for MRP/DCP products

CMD(h) Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) 1234/2008

CMD(h): Q/A-list for the submission of variations

Veterinary

CMD(v) best practice guides for the submission and processing of variations in the mutual recognition procedure

Human and veterinary

Request to CMD for a recommendation on the classification of an unforeseen variation under Article 5 (PDF file)

Request to CMD for a recommendation on the classification of an unforeseen variation under Article 5 (Word)

Questions and answers

The Danish Medicines Agency's questions and answers on variations

Invoices in connection with variation applications

Invoices in connection with variation applications (national and MRP procedures)

Did you get answers to your questions?

Yes | No

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