Guidelines for requesting withdrawal of a marketing authorisation (MA) or deletion of information from drug catalogues

Withdrawal of MA means that the marketing authorisation is no longer valid and thereby it is prohibited to market the product.

Deletion of information from drug catalogues means that information about the drug is deleted from both the drug price list and drug information catalogue (SmPC, patient information and other information about the medicine), this means that the product can no longer bee prescribed, marketed or sold but the marketing authorisation is still valid and therefore the medicine can be relaunched on the market given that conditions for marketing ar met and publication in the drug catalogue is requested by the M.A. holder.

Application submitted by the MA holder/agent

An application for withdrawal of a marketing authorization or deletion of information from drug catalogues must be received by the Icelandic Medicines Agency at least two months before the requested entry into force and will will come into effect the first day of the requested month.The following **application form** must be completed and sent to afskraningar@lyfjastofnun.is.

The Icelandic Medicines Agency strongly encourages marketing authorization holders to inform relevant doctors/healthcare persons and pharmacies in a timely manner about medicines to be withdrawn from the market, including information on when the medicine will no longer be available. This applies in particular to essential medicines, medicines that have been broadly prescribed and medicines that are the only ones of their kind on the market, so that there is an opportunity for doctors change treatment if applicable. The reasons for the discontinuation of the medicine and information on other available treatments should be provided, as appropriate. It is also important to provide pharmacies with similar information so that patients can be guided. The marketing authorization holders or their agents should also publish the information on their website; waitlist/back-order report . Before withdrawing medicines or individual packs from the market, marketing authorization holders must check whether it will affect vulnerable groups of patients for instance children and take steps to meet patients' needs.

Reporting of Medicine shortages

Medicine shortages caused by deletion from drug catalogues/withdrawal of MA shall be notified to the Icelandic Medicines Agency in due time or no less than two months before stock out. Medicine shortages can be reported here. Ideally shortages and deletion from drug catalogues/ withdrawal of MA should be reported/requested simultaniously.

Withdrawal of MA and deletion of information from drug catalogues can be applicable to specific pharmaceutical forms, strengths, packages and pack sizes. When, the whole MA is not withrawn and

texts are common to strenghts/pharmaceutical forms, this is done by applying for a change terms of the MA (type C.I.7) in addition to the submission of the application form for withdrawal of the M.A.