Memorandum to Landspítali, Amgros and LIS
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How to obtain a marketing authorisation for a medicinal product in Iceland in an easy way

Iceland can participate in DCPs and MRPs like any other EU/EEA member state. Following is a short summary of a simple approach when Iceland is the only CMS in an MRP or a repeat MRP.

Zero day repeat MR Procedures

The goal of the so-called *Zero day repeat MR Procedure* is to make the repeat MRP as simple as possible for the applicant and for the RMS.

These are normal repeat MRPs, except the Icelandic Medicines Agency (IMA) confirms in advance that the agency will not have any comments or questions, i.e. IMA will accept the dossier as approved in the already finalised DCP or MRP. This includes the SmPC, labelling and PIL. The RMS does not have to update the assessment report. If the marketing authorisation in the DCP or MRP has been renewed infinitely, an extra renewal in Iceland is not required. Simply speaking, Iceland is just added to the procedure.

The applicant must however contact IMA and then the RMS in advance of such procedures.

The applicant submits the dossier in Iceland (the normal way). If a consolidated eCTD version is not available, all previous sequences can be submitted separately and this should be discussed with IMA for each procedure.

The RMS is in charge of the procedure and the RMS fee is decided by the RMS. Some RMSs collect only an administrative fee for such procedures.

When the application has been submitted in Iceland, and in the RMS (in a way decided by the RMS), the RMS creates the procedure in CTS and informs IMA. Following this, IMA communicates a confirmation to the RMS that IMA has received a valid application and that IMA has no comments. Consequently, the RMS finalises the procedure with a positive outcome and Iceland becomes a CMS in the procedure. Opening and closing the procedure can therefore take place in one day, although usually this process takes a few days.

After the procedure has been closed the normal national phase starts, i.e. the applicant submits a high quality Icelandic translation of the SmPC, labelling and PIL. In most cases, IMA can usually manage to issue the Icelandic marketing authorisation within 30 days after receiving the translations. If necessary this national phase can be processed in a shorter time-period.

Many EU/EEA member states have acted as RMS in such zero day procedures where Iceland is added as the only new CMS.

Zero day MR Procedures

These are procedures where a new MRP is created for Iceland. The Nordic medicines agencies have acted as RMS in such procedures. The products are purely nationally authorised in the RMS and usually old. In some cases, a consolidated dossier may not be available. In these cases, the applicant and IMA discuss what is considered acceptable for submission.

The RMS is in charge of the procedure and may request an English translation of the nationally approved SmPC, labelling and PIL. As with the zero day repeat MR Procedure, the RMS decides the fee in the RMS.

Otherwise, the procedure for all intents and purposes the same as for the repeat MRP, i.e. IMA accepts the dossier as it is approved in the RMS without any comments or questions. The national phase is the same as with the zero day repeat MR Procedure.

Fees in Iceland

IMA's fee Tariff contains information about fees when Iceland is acting as a CMS, i.e. as in the zero day procedures described above (see page 6). To give an example, the fee for a generic product in one pharmaceutical form and one strength is 307,000 ISK (≈ 2,230 EUR). As per article 10 of the fee Tariff, IMA can reduce the application fee to ISK 41,000 (≈ 300 EUR) under certain circumstances. The basic criteria for such reduction of fees is when no product is marketed and there is a need for such a product.

For more detailed information please see https://www.ima.is/publications/news/nr/4277 and https://www.ima.is/media/Leyfisveitingar_lyfja/Zero-day-procedure---2013-09-04.pdf or contact the Icelandic Medicines Agency – ima@ima.is