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Guideline on marketing authorisation for parallel import and post-authorisation obligations

Abbreviations used in this guideline:

EU	European Union
EEA	European Economic Area
MA	Marketing Authorisation
MA(PI)	Marketing Authorisation for Parallel Imported Medicinal Product
MAH	Marketing Authorisation Holder
MAH(PI)	Marketing Authorisation Holder for Parallel Imported Medicinal Product
NLS	Norske legemiddelstandarder (Norwegian Pharmaceutical Standards)
NoMA	Norwegian Medicines Agency
SmPC	Summary of Product Characteristics
PL	Package Leaflet

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General Information

This guideline replaces the guideline version of 28th May 2014

In order to sell a medicinal product in Norway, the medicinal product must have marketing authorisation (MA) from the Norwegian Medicines Agency (NoMA).

Medicinal products get normally marketing authorisations based on the application from the manufacturer of the medicinal product. The submitted application must include documentation on quality, safety and effect of the medicinal product.

Parallel import of medicinal products to Norway takes place when a medicinal product with a valid marketing authorisation in an EU/EEA country, is parallel imported to Norway and placed on the Norwegian market in competition with a directly imported medicinal product with similar composition and a valid marketing authorisation in Norway.

According to the EEA-agreement Art. 11, legally marketed medicinal products on the national market should have a free flow within the internal market. The EEA-agreement provides for decisions prohibiting import restrictions, which implies, for example, that Norway cannot refuse parallel import of medicinal products.
These provisions do not preclude import restrictions that are justified out of consideration to the protection of human and animal life and health, according to the EEA-agreement Art. 13. Parallel import of medicinal products is therefore only allowed when public health protection is maintained.

In order to sell a parallel imported medicinal product on the Norwegian market, it is required that the medicinal product has authorisation for parallel import marketing authorisation MA(PI), granted by NoMA cf. the national Regulation for medicinal products of 18th December 2009, Art. 3-24.

Conditions for parallel import

There are no particular provisions on parallel import in the Norwegian medicinal product legislation. NoMA normally sets the following conditions for parallel import of medicinal products to Norway.

- The imported medicinal product must have a marketing authorisation in the export country
- Marketing authorisation of a directly imported medicinal product is a prerequisite for parallel import of a medicinal product.
- The medicinal product contains the same active substance and has the same therapeutic effect as the directly imported medicinal product

- Differences between the directly and parallel imported medicinal products may be accepted if these do not concern the therapeutic effect and do not raise any significant issues related to public health
- NoMA shall assess the possibility for parallel import on a case by case evaluation

Application for a marketing authorisation for parallel import

The application form has to be submitted together with the required documentation.

If the (legal) person authorised for communication on behalf of the applicant submits the application form, a «Power of Attorney» is required.

An application form for each strength and each pharmaceutical form, as well as for each export country of the same medicinal product, has to be submitted.

For parallel import of medicinal products authorised through the centralised procedure, an application must be submitted for each strength and each pharmaceutical form of the same medicinal product, with the EU as export country. Any future granting of marketing authorisation for parallel import of this type of medicinal product would include all countries in the EU/EEA.

Content of the application

The application shall include:
1. Cover letter
2. Application form issued by NoMA: Application form - marketing authorisation (in Norwegian) Markedsføringstillatelse - søknad for parallellimportert legemiddel
3. Draft of the labeling (mock-ups) in colour of the inner and outer packaging
4. Draft of the package leaflet
5. Scan and/or photography of the inner and outer packaging, as well as presentation of the contents of a package from each of the different original packages, intended for parallel import
6. Documentation on valid import authorisation granted by NoMA, if the applicant of the marketing authorisation for parallel import, MA(PI), itself shall import the medicinal product to Norway
7. Documentation from the company(s) that perform the re-labeling/repackaging on their valid manufacturing authorisation, granted by the regulatory authorities in the country/countries where the re-labeling/repackaging are performed

Any deviation from the directly imported medicinal product has to be reported in the application. Further, the applicant is required to make an assessment on the significance of this deviation of the therapeutic effect of the imported medicinal product and its use in general.

Notification of patentee

When applying for parallel imports from Bulgaria, Estonia, Croatia, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, Czech Republic or Hungary, the applicant shall attach documentation that the patentee or the holder of the supplementary protection certificate, or whoever derives their rights from this, is notified in accordance with the relevant regulations. Reference is made to the Norwegian Regulation to the Patent Act of 14thDecember 2007 no. 1417 Art.100 and the Norwegian Regulation on medicinal products of 18thDecember 2009, Art 3-25. If this documentation is missing, an opportunity to deal with it shall be given, cf. the Norwegian Regulation for medicinal products Art.5-1, second paragraph. If the matter is still not settled within the time limit, the application will be rejected, according to the Regulation for medicinal products Art. 5-9, first paragraph, b.

If the documentation requirement is met, the marketing authorisation application cannot be refused, even if there are objections from the licensee.

For parallel import of medicinal products authorised through centralised procedure, the above-mentioned notification process is required in like manner, if the applicant wants to make parallel imports from any of the aforementioned countries, prior to the submission of the application. If the applicant does not want to carry out this notification process prior to the submission, but at a later date, post-marketing authorisation, the patentee or the holder of the supplementary protection certificate, or whoever derives their rights from this, has to be notified at least one month before the import is carried out. Documented notification has to be submitted to NoMA.

NoMA does not take any position on patent disputes between the applicant and the licensee. If the licensee has objections to the import on patent rights ground, from a juridical aspect, the licensee, as for other referrals regarding parallel import, may do so by instituting proceedings in the courts.

Labelling

Draft of the labelling of the parallel imported medicinal product shall be designed by following the packaging of the directly imported medicinal product as standard (i.e. according to the Norwegian Regulation on medicinal products Art.3-29 to 3-41).

Perforated blister

Perforated blisters shall be formed as unit dose blisters. They shall be marked with the required information on each peelable unit, according to Art.3-35, from the Norwegian Regulation on medicinal products.

The name of the marketing authorisation holder, MAH(PI), shall be stated on the blister, but this is not required on each peelable unit.

Storage conditions

Storage conditions are set according to Appendix III to the QRD templates for human

medicinal products. Any storage conditions other than "No special precautions for storage" shall be presented on the packaging.
The parallel importer shall always relate to the approved storage conditions in the export country.

MA-holder (PI), importer, re-packer

Company name and address is presented in the following format: <company name>, <city/place>, <country, other than Norway>. Country code may be accepted instead of country name.

Manufacturer

The manufacturer shall be featured on the outer packaging. The manufacturer is the one responsible for the batch release in the export country for the mentioned batch intended for sale on the Norwegian market. There may exist several manufacturers of the medicinal product in the export country, but only the manufacturer that is registered for the current batch will be featured on the outer packaging. Manufacturer(s) must be reported to the Norwegian Medicines Agency. When the MA (PI) is granted, one or more manufacturers shall be registered. If there are changes on manufacturer(s) after providing MA(PI), these shall be reported to NoMA by applying for variation.

The manufacturer's address shall be indicated in the following format: <company name>, <city / place>, <country, other than Norway>. Country code may be accepted instead of country name.

Differences

When differences between directly and parallel imported medicinal product occur (such as (Invented) Name, how the tablet appears, calendar pack) they shall be clearly stated on the outer packaging front panel and, if space, on the inner packaging.

Re-labeling / repackaging

In case of re-labeling, texts other than in Norwegian, may be used on the packaging material. The content may be accepted if it is not in conflict with the mandatory Norwegian requirements for labeling. Text in other language than Norwegian may be stuck over (re-labeled) with Norwegian text label. In such cases, re-labelling has to be prepared so well that the underlying text does not shine through. It shall be ensured that the label sits so well that it does not fall off nor easily can be removed.

It is mandatory to submit to NoMA clean text and mock-up of the re-labeled package, i.e. how the package is planned to be re-labeled. Approval shall be granted for both design (location of the label on the original packaging) and text content. The inner labeling has to be displayed as it is intended to be brought out on the market. As for blisters/strips, copy or scan of the blister with the necessary labeling featured, is required submitted.

It is possible for the parallel importer to repack the parallel imported medicinal product instead of re-labelling it.

Parallel importers who do the repackaging or re-labeling need a manufacturing authorisation. Manufacturer authorisation is granted on application to NoMA. The company that is authorised for repackaging must be located in an EU/EEA country. It is sufficient to present the manufacturing authorisation from the Authority in the country concerned. A copy of the manufacturing authorisation has to be enclosed/attached to the application for marketing authorisation for parallel import.

Conditions relevant to the MA-application are set out in the application form. For instance, for the blisters that are planned to be repacked. The number of blisters laid in the re-labeled/repacked package shall also be mentioned in the application form. It is mandatory to put same type blisters in one package. It is prohibited to cut off or in any other manner split a blister.

Package leaflet (PL)

A draft package leaflet shall be designed according to the Norwegian Regulation for medicinal products, Art.3-42 to 3-56. The direct importer's package leaflet is normally used as a template for the draft of the package leaflet for the parallel imported medicinal product.

Declaration of excipients
Excipients shall be listed as in the Norwegian pharmaceutical standards (Norske legemiddelstandarder, NLS)

Storage conditions
Storage conditions are set according to Appendix III to the QRD templates for human medicinal products. Every storage condition other than "No special precautions for storage» shall be featured on the packaging.
The parallel importer should refer to the approved storage conditions in the export country.

MAH(PI), importer, repacker
Complete addresses shall be displayed in the package leaflet.

Manufacturer
The manufacturer shall be featured in the package leaflet. The manufacturer is the one responsible for the batch release in the export country for the relevant batch intended for sale on the Norwegian market. There may be several manufacturers of the medicinal product in the export country, but only the manufacturer listed for the relevant batch shall appear in the package leaflet.
Manufacturer(s) shall be reported to NoMA. When the MA(PI) is granted, one or more

manufacturers shall be registered. If there are any changes in manufacturer(s) post MA(PI) authorisation, they should be provided for by variation application to NoMA.
The full manufacturer's address has to appear in the package leaflet.

Other information
Any differences between the directly and the parallel imported medicinal product have to be presented. Such examples are difference in storage conditions, differences in tablet appearance, calendar packaging and different medicinal product names ((Invented) Names).

The regulatory legislation does not prohibit gathered information about all strengths related to a pharmaceutical form are included in the same package leaflet, even when a parallel importer has approval for only some of the strengths.
NB! NOMA assesses only the strength and the country of origin applied for in the relevant application, with regard to the comments/information given.

NoMA does not approve the parallel importer's package leaflet.

Repackaging
Parallel importers, who present package leaflet with Norwegian text in the package, must have manufacturing authorisation. A manufacturer authorisation is granted on application to NoMA. The company that is authorised for repackaging must be located in an EU/ EEA country. It is sufficient to present *the manufacturing* authorisation *from the Authority in the country concerned. A copy of the manufacturing* authorisation *has to be attached to the application for marketing* authorisation *for parallel import.*

Summary of Product Characteristics (SmPC)

The parallel importer may refer to the SmPC of the directly imported medicinal product. If the direct importer no longer has the medicinal product on the Norwegian market, and it does not update the Norwegian SmPC, the parallel importer shall provide for translation to Norwegian of the SmPC from the export country. The parallel importer has always the responsibility for presenting or referring to the relevant SmPC in Norwegian.

Scan and/or photography of the inner and outer packaging, as well as the contents of the package

Scan and / or photography of the inner and outer packaging, as well as the contents of a package of each of the different original packages that are intended for parallel import, have to be enclosed/attached.
However, it is possible to submit only a scan and/or photography of the smallest package size, given that the parallel importer verifies that the other package sizes intended for re-labeling/repacking are designed similarly.

The Norwegian Medicines Agency may request that samples are forwarded at any time during the application management.

Prescription group
Upon issuing a marketing authorisation for parallel import, the parallel imported medicinal product is granted with the same prescription group as the directly imported medicinal product. If, at a later point of time, the directly imported medicinal product is granted with an exemption from the prescription requirement for one or more packages, then the parallel importer has to apply for the same prescription exemption, for the same package size(s), accordingly. In this application, a draft of the new package leaflet and draft of the new labeling (mock-ups) have to be attached; in the case of the prescription group CF, it may be required another package leaflet and labeling, depending on the package size.

Fee
A fee shall be paid for each application, i.e. for each strength and each pharmaceutical form, and for each export country of the directly imported medicinal product. A fee list is available on NoMA's website.

Management of the application
If the application is incomplete, the applicant shall be requested to correct the deficiencies in accordance to the Norwegian Regulation for medicinal products Art. 5-1, second paragraph. If the matter is still not settled within the time limit, the application will be rejected, according to the Norwegian. Regulations on Medicines Art. 5-9, first paragraph a. The application shall be assessed when it is complete and fees are paid. The management deadline has a 120 days' timeline starting from the day when all the required information from the export country is received.

Granting authorisation for parallel import
The marketing authorisation shall be granted, when the conditions for parallel import are fulfilled, and the medicinal product name, labeling, package sizes, packaging and technical equipment are approved.

Post-marketing obligations for parallel imported medicinal product

Price
The price for prescription medicinal products that have MA(PI) has to be approved by NoMA. An approved price will not be available until a MA(PI) is granted. The application form is available on the Norwegian Medicines Agency's website.

Approval of samples
It is not mandatory to submit the sample package.
Norwegian Medicines Agency may ask for a scan and/or photography of the printed inner and outer packing.

Renewal
A renewal application for the marketing authorisation has to be sent to NoMA, no later than nine months before the due date. A relevant renewal application form is available on NoMA's website. It is not necessary to enclose/attach mock-ups. If the marketing authorisation is not renewed before its expiration, an immediate decision of MA(PI) withdrawal shall take effect, without further verification to the MAH. The application form is available on the Norwegian Medicines Agency's website: Application form - renewal (in Norwegian) Markedsføringstillatelse - fornyelse for parallellimportert legemiddel

Fee
A fee for each application for renewal has to be paid, i.e. for each strength and each pharmaceutical form, and for each export country of the same medicinal product. A fee list is available on NoMA's website.

Variations
The parallel importer has to keep informed about any changes to the parallel imported medicinal product. NoMA has to be informed continuously on this matter by sending a relevant application form for updates. The Application forms are available on NoMA's website: Application form - variation (in Norwegian) Markedsføringstillatelse - endringssøknad for parallellimportert legemiddel

NoMA has to be informed if the parallel imported medicinal product changes appearance, excipients declaration, package size, package type, and pharmaceutical form; MAH in the export country, manufacturer, shelf life, storage conditions, registration status or MA-number in the export country. The same applies if the parallel imported medicinal product with MA(PI) changes package size or manufacturer. An updated application has to be submitted also in the cases when the directly imported medicinal product is updated, which may lead to differences between the parallel imported and directly imported medicinal product. The parallel medicinal product may still be on the Norwegian market, unless NoMA decides otherwise.
Norwegian Medicines Agency must immediately be informed, if the Power of Attorney for a representative of the marketing authorisation holder has declined. MAH(PI) shall immediately notify on who may be the new representative.

Withdrawal
If the conditions for parallel import no longer are considered to be fulfilled, the MA(PI) shall be withdrawn.
NoMA has to be informed when the MAH(PI) no longer intends to maintain the authorisation for the medicinal product. A withdrawal form is available on NoMA's website.

Sunset clause
According to the Norwegian Regulation for medicinal products of 18th December 2009, Art. 8-4, first paragraph, the marketing authorisation is withdrawn, if the medicinal product is not followed by actual placing on the Norwegian market within 3 years from the MA(PI) approval.

A MA(PI) shall be withdrawn, if the parallel imported medicinal product, previously placed on the Norwegian market, no longer is on the market for a period of three consecutive years.
The Sunset clause procedure was implemented 10th January 2010.

Reporting of adverse events

NoMA encourages that all suspected adverse events following use of parallel imported medicinal products, reported to the parallel importer, are forwarded to the MAH for the original medicinal product. Parallel importers are encouraged to follow reporting requirements as described in the GVP Module VI, and Volume 9B (Notice to Applicants) for medicinal products for human and veterinary use, respectively.

Contact:

MAH(PI) - parallellimport@noma.no

Adverse events (human) - bivirkninger@noma.no

Adverse events (veterinary) - vet.felles@noma.no