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About the pharmacovigilance requirements (PSUR, aRMM and DHPC) concerning parallel distribution and parallel import products, clarifications for operators

Glossary:

Direct distributor:	Holder of centralised marketing authorisation in Finland.
Parallel distributor:	No marketing authorisation, sells the direct distributor's product in Finland
Direct importer:	Holder of the DCP/MRP/national marketing authorisation in Finland
Parallel importer:	Holder of parallel import licence, sells the direct importer's product in Finland

Background

The parallel distribution and parallel import of medicines are legally based on the free movement of goods in the EU internal market. Any administrative measures restricting this fundamental freedom should be as *'light'* as possible. This is based on the principle of proportionality, as enshrined in European Union law, according to which the administrative measures of an authority cannot exceed what is necessary to achieve the objectives of the treaties.

Furthermore, according to the policy adopted by the European Medicines Agency (EMA), parallel distributors are not marketing authorisation holders and therefore not subject to the obligations of the marketing authorisation holder.

This clarification addresses the pharmacovigilance obligations with regard to periodic safety update reports (PSURs), additional risk minimisation materials (aRMMs) and direct healthcare professional communications (DHPCs).

1. PSUR obligations

The PSUR requirements for a direct distributor and a direct importer are determined according to the legal basis of the marketing authorisation and the EURD list maintained by the EMA.

Parallel distributor:

According to the policy adopted by EMA, a parallel distributor is not a marketing authorisation holder and is therefore not obliged to submit periodic safety update reports (PSURs) for evaluation. Regardless of whether a direct distributor's product is on the market in Finland, Fimea does not require parallel distributors to supply PSURs.

Parallel importer:

Chapter 4a (section 30k) of the Medicines Act and Fimea Regulation 4/2013 on Pharmacovigilance may give the impression that a parallel importer is always subject to the PSUR obligation. However, the parallel import of medicines is based on the free movement of goods in the EU internal market and any administrative measures restricting this fundamental freedom should be as *'light'* as possible. Consequently, a PSUR obligation can only arise for a potential public health-related reason. This criterion is considered on a case-by-case basis by the Finnish Medicines Agency Fimea.

Based on the above, Fimea holds that, as a rule, a parallel importer is not required to submit a PSUR as long as the direct importer's product is on the Finnish market. Additionally, Fimea holds that a parallel importer is not required to submit a PSUR even if the direct importer has removed the product from the Finnish market and only the parallel importer remains on the Finnish market.

Fimea reserves the right to require a parallel importer to submit a PSUR if the product concerned involves a justified public health-related reason to do so. If, in such an exceptional situation, a PSUR is requested to be submitted, the parallel importer shall agree with Fimea on the submission method (e.g., CESP).

2. Additional risk minimisation material (aRMM) obligations

The risk minimisation materials in accordance with the risk management plan required from the parallel distributor and parallel importer are, as a rule, similar to those required from the direct distributor or direct importer.

The direct distributor's or direct importer's product is on the market in Finland.

Fimea has approved the national version of the direct distributor's or direct importer's risk minimisation material. The material has been published on Fimea's website and distributed according to an approved plan.

The parallel distributor's or parallel importer's risk minimisation material must be identical with the direct distributor's or direct importer's material. The material must be submitted to Fimea for publication.

The material must be submitted to Fimea for approval if the content differs from that of the direct distributor's or direct importer's material. If only the direct distributor's or direct importer's logo and contact information have been replaced by the corresponding information concerning the parallel distributor or parallel importer and no other changes have been made, Fimea's separate approval for the material is not required. In this case as well, the material must be submitted to Fimea for publication.

When a direct distributor or direct importer has already distributed the material to the agreed-upon target groups in Finland when placing the product on the market, the parallel distributor or parallel importer is not required to redistribute the risk minimisation material. The material must be available on a continuous basis. The distribution of the material to the agreed-upon target group is permitted.

The risk minimisation material is updated as a result of a regulatory process.

The parallel distributor or parallel importer must submit the correspondingly updated material to Fimea for publication and distribute the material to the agreed-upon target groups.

Fimea encourages companies to engage in cooperation with regard to distribution so that the distribution would only need to be carried out once for a single product.

The parallel distribution or parallel import product is on the Finnish market, but the direct distributor's or direct importer's product is not on the market in Finland.

The responsibility for producing, updating, submitting for approval to Fimea and distributing the risk minimisation material in Finland rests solely with the parallel distributor or parallel importer.

The requirement for a risk minimisation material pertains to a specific active substance or group of active substances (e.g., as a result of a pharmacovigilance referral).

It is the responsibility of marketing authorisation holders, parallel distributors and parallel importers of products placed on the market in Finland to produce risk minimisation material for their product.

Fimea encourages pharmaceutical companies to engage in cooperation so as to only distribute one version of the risk minimisation material, in the preparation of which all the companies selling the medicine in Finland would jointly participate.

3. Requirements related to direct healthcare professional communications (DHPCs)

The DHPC only pertains to a single product, and the product has been placed on the market in Finland by a direct distributor or importer.

The direct distributor produces and submits to Fimea for approval the national version of the DHPC and its distribution plan.

The parallel distributor or parallel importer must agree with the direct distributor or direct importer on the distribution of the material to the agreed-upon target groups in Finland.

The DHPC only pertains to a single product, and the direct distributor or direct importer has not placed the product on the market in Finland and only parallel distribution or parallel import product is placed on the market in Finland.

The responsibility for producing the national version of the DHPC, preparing a distribution plan and submitting them for approval to Fimea, as well as for distributing them in Finland, rests solely with the parallel distributor or parallel importer.

The DHPC pertains to a specific active substance that may have several original marketing authorisations, generic marketing authorisations as well as parallel distribution and parallel import products.

It is the responsibility of marketing authorisation holders, parallel distributors and parallel importers of products placed on the market in Finland to produce DHPC for their product.

Fimea encourages pharmaceutical companies to engage in cooperation so as to only distribute one DHPC on the pharmacovigilance issue concerned, in the preparation of which all the companies selling the medicine in Finland would jointly participate.