Regulation 9 February 2019
Ref. no. 007542/00.01.02/2018

# 4/2019

*UNOFFICIAL TRANSLATION*

**Finnish Medicines Agency Administrative Regulation**

# APPLYING FOR AND MAINTAINING A MARKETING AUTHORISATION FOR A MEDICINAL PRODUCT

## Legal basis

Medicines Act (395/87), section 2, subsection 4, section 23 a, subsection 3, and section 28 as they appear in Act 773/2009

## Target groups

Pharmaceutical manufacturers
Pharmaceutical wholesalers
Persons responsible for placing a medicinal product on the market
Finnish Food Safety Authority
National Institute for Health and Welfare
Finnish Red Cross Blood Service

## Period of validity

This Administrative Regulation will enter into force on 9 February 2019 and will remain so until further notice.

## Regulation repealed

Administrative Regulation No 2/2018

## This regulation implements the following EC legislation:

Directive 2001/83/EC (32001L0062, OJEC L 311, 28 November 2001, p. 67) as amended by Directive 2004/24/EC (32004L0024, OJEU L 136, 30 April 2004, p. 85) and Directive 2004/27/EC (32004L0027, OJEU L 136, 30 April 2004, p. 34) of the European Parliament and of the Council

Directive 2001/82/EC (32001L0082, OJEC L 311, 28 November 2001, p. 1) as amended by Directive 2004/28/EC (32004L0028, OJEU L 136, 30 April 2004, p. 58) of the European Parliament and of the Council

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# 1 GENERAL

In the European Union (EU), marketing authorisations for medicinal products are granted either by the competent national authorities (national procedure, mutual recognition procedure and decentralised procedure) or by the European Commission (centralised procedure). Registrations are granted exclusively by the competent national authorities. The national procedure can only be used in a limited number of cases, for example, when marketing authorisation or registration is applied for in one Member State only.

With this Administrative Regulation, the Finnish Medicines Agency (Fimea) brings into force the national requirements concerning applications for and maintenance of marketing authorisations for medicinal products and veterinary medicinal products, and applications for and maintenance of registrations for traditional herbal medicinal products and homeopathic and anthroposophic preparations. This Administrative Regulation is based on and has been harmonised with the following European Community (EC) pharmaceutical legislation in the Member States of the European Union and the states belonging to the European Economic Area (hereafter referred to as EEA states).

- Directive 2001/83/EC[1] of the European Parliament and of the Council on the Community code relating to medicinal products for human use as amended, hereinafter referred to as the Medicinal Products Directive

- Directive 2001/82/EC[2] of the European Parliament and of the Council on the Community code relating to veterinary medicinal products as amended, hereinafter referred to as the Veterinary Medicinal Products Directive

This Administrative Regulation also gives national regulations on variations to medicinal products.

[1] Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use; Official Journal of the European Communities No L311/67, 28 November 2001, as amended.
Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use; Official Journal of the European Communities No L136/34, 30 April 2004.
Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use; Official Journal of the European Communities No L136/85, 30 April 2004.
[2] Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products; Official Journal of the European Communities No L311/1, 28 November 2001, as amended.
Directive 2004/28/EC of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products; Official Journal of the European Communities No L136/58, 30 April 2004.

The relevant parts of Commission Regulation No 1234/2008[3] have been taken into account in them.

Guidelines for applications for marketing authorisation and registration will be discussed in more detail in Section 5 of this Administrative Regulation.

The abbreviations set out below will be used in this Administrative Regulation:

| | |
|---|---|
| CAT | Committee for Advanced Therapies |
| CHMP | Committee for Medicinal Products for Human Use |
| CMDh | Coordination Group for Mutual Recognition and Decentralised Procedures, Human Medicinal Products |
| CMDv | Veterinary Coordination Group for Mutual Recognition and Decentralised Procedures |
| CTD | Common Technical Document |
| CVMP | Committee for Medicinal Products for Veterinary Use |
| EC | European Community |
| EMA | European Medicines Agency |
| ETA | European Trade Area (EU, Iceland, Liechtenstein and Norway) |
| EU | European Union |
| EC | European Community |
| Fimea | Finnish Medicines Agency |
| GMP | Good Manufacturing Practice |
| HMA | Heads of Medicines Agencies |
| HMPC | Committee for Herbal Medicinal Products |
| HMPWG | Homeopathic Medicinal Products Working Group |
| MIA | Manufacturing and Importation Authorisation |
| MIF | Marketing Information Form |
| MRA | Mutual Recognition Agreement |
| MRL | Maximum Residue Limit |
| NtA | Notice to Applicants |

[3] Commission Regulation No 1234/2008, concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, Official Journal of the European Communities No L334/7, 12 December 2008.

| | |
|---|---|
| OCABR | Official Control Authority Batch Release Certificate |
| OMCL | Official Medicines Control Laboratory |
| PDCO | Paediatric Committee |
| PRAC | Pharmacovigilance Risk Assessment Committee |
| PSUR | Periodic Safety Update Report |
| QP | Qualified Person |

The additional instructions referred to in this Administrative Regulation can be found on the following websites:

| | |
|---|---|
| Fimea | www.fimea.fi |
| EMA | www.ema.europa.eu |
| HMA | www.hma.eu (includes links to CMDh and CMDv websites) |
| EC | www.ec.europa.eu (directives, regulations and NtA guidelines to applicants) |

# 2 SCOPE OF THE ADMINISTRATIVE REGULATION

This Administrative Regulation covers marketing authorisation and registration applications for medicinal products for human and veterinary use. It also covers applications for variations and renewals concerning these products as well as other applications relating to the maintenance of a marketing authorisation or registration. The Administrative Regulation does not cover the EU's centralised marketing authorisations procedure except where the latter applies to the placing of products on the market.

The Fimea Administrative Regulation on parallel import applies to the parallel import of medicinal products.

# 3 TYPES OF APPLICATIONS FOR MARKETING AUTHORISATION AND FOR REGISTRATION

The different types of applications for marketing authorisation and registration are set out in the Medicinal Products Directive and in the Veterinary Medicinal Products Directive.

The first marketing authorisation granted for a medicinal product and its later extensions and variations are considered to be covered by the same marketing authorisation concept. This is the case, for example, when applying the data protection period and when monitoring the availability of a medicinal product on the market. The same principle also applies to registered products, except for the application of data protection periods.

When the holder of a marketing authorisation or registration applies for marketing authorisation or registration for a new strength for the product concerned, for a new pharmaceutical form or new route of administration, the application shall bear clear references to the documentation in the previous application and the necessary study results shall be submitted. More detailed instructions on this are given in Volumes 2A and 2C of the NtA (Notice to Applicants) guidelines as regards medicinal products for human use and in Volumes 6A and 6C as regards veterinary medicinal products.

Extensions to marketing authorisations and registrations will be discussed in more detail in section 8.2.5 of this regulation.

## 3.1 Complete applications

(Article 8 of Directive 2001/83/EC; Article 12 of Directive 2001/82/EC)

A complete application shall contain the documents required under Article 8 of Directive 2001/83/EC and Article 12 of Directive 2001/82/EC compiled in accordance with Annex I to the aforementioned directives.

The data and marketing protection periods for products with new active substances are set out in section 21a of the Medicines Act.

## 3.2 Abridged applications

(Article 10 of Directive 2001/83/EC; Article 13 of Directive 2001/82/EC)

Abridged applications may bear references to the preclinical and clinical study results for a reference product as applicable. Applications for veterinary medicinal products may also bear references to study results on the safety and residue levels for a reference product as applicable. However, an administrative section, a summary or expert reports and complete quality documentation shall always be annexed to the applications, and, in applications for veterinary medicinal products, an environmental impact assessment, with the exception of marketing authorisation applications for veterinary medicinal products in accordance with Article 13c, for which the documentation requirements are presented in section 3.5.

In applications for generic veterinary medicinal products, the additional requirements presented in the Veterinary Medicinal Products Directive shall also be considered.

### 3.2.1 Applications for generic products

(Article 10.1 of Directive 2001/83/EC; Article 13.1 of Directive 2001/82/EC)

A generic product means a pharmaceutical product that is similar in composition to the reference product in terms of the type and quantity of its active substances. The generic product shall also have the same pharmaceutical form as the reference product, and its bioequivalence shall have been demonstrated by means of appropriate studies in bioavailability or (in cases where bioequivalence cannot be determined) therapeutic equivalence.

A reference product means a product that, in accordance with section 5c, subsection 1 of the Medicines Act, has been granted a marketing authorisation under section 21 of the same Act or that has been granted a marketing authorisation by a Member State belonging to the EEA under Article 8 of

Directive 2001/83/EC or Article 12 of Directive 2001/82/EC. A reference product may also be a product that has been granted a marketing authorisation by the EU.

The different salts, esters, ethers, isomers, mixtures of isomers, complexes and derivatives of the active substance in the generic product are considered to be the same active substance unless they have significantly different properties in terms of their safety or efficacy. If the latter is the case, the applicant shall submit further information on the different salts, esters or derivatives of the active substance to show that the differences in safety or efficacy are not significant as compared with the reference product. Different oral pharmaceutical forms that release the medicinal substance immediately are considered to be the same pharmaceutical form.

The bioequivalence of the generic product to the reference product shall be proven in accordance with the relevant guidelines given by CHMP and CVMP, the EMA committees for medicinal products. Studies on bioavailability do not need to be performed if the applicant for marketing authorisation can demonstrate that the generic product meets the requirements defined in these guidelines.

Additionally, when establishing the withdrawal periods for veterinary medicinal products for production animals, appropriate guidelines shall be taken into account.

A marketing authorisation for a generic product can only be granted if the reference product has or has had a marketing authorisation in Finland or in another EEA Member State. If the reference product has not been granted a marketing authorisation in Finland, the applicant shall state on the application form the Member State in which the marketing authorisation for the reference product has been granted. If the reference product has a valid marketing authorisation in Finland, the applicant for marketing authorisation for the generic product shall refer to the documentation submitted in the application for marketing authorisation for the reference product.

The application shall state the date on which the reference product was first granted a marketing authorisation in a Member State of the European Union in accordance with EU provisions.

A generic product can be granted a marketing authorisation even during the marketing protection period provided the generic product meets the requirements mentioned in section 3.2. The product must nevertheless only be placed on the market after the marketing protection period has expired. Protection periods are defined in section 21a of the Medicines Act.

### 3.2.2 Abridged applications of mixed type

(Article 10.3 of Directive 2001/83/EC; Article 13.3 of Directive 2001/82/EC)

Appropriate results from preclinical or clinical studies on the medicinal products and results from studies on safety and residue levels for veterinary medicinal products shall be annexed to the application if

- the medicinal product does not correspond to the definition of a generic product,

- bioequivalence cannot be demonstrated by bioavailability studies, or
- the medicinal product differs from the reference product in terms of its active substance(s), therapeutic indication, strength, pharmaceutical form or route of administration.

### 3.2.3 Applications for similar biological medicinal products

(Article 10.4 of Directive 2001/83/EC; Article 13.4 of Directive 2001/82/EC)

Results from preclinical and clinical studies specifically ordered by Fimea shall be annexed to the application if the raw materials or manufacturing processes of a biological medicinal product differ from those of the reference product. Results from preclinical and clinical studies shall be submitted in accordance with the Medicinal Products Directive and the Veterinary Medicinal Products Directive and in accordance with the relevant detailed instructions published on the EMA website. The instructions have been published on the EMA website.

## 3.3 Applications based on established medicinal use

(Article 10a of Directive 2001/83/EC; Article 13a of Directive 2001/82/EC)

An application based on well-established medicinal use (also referred to as a bibliographic application) means an application where the applicant demonstrates in detail, with references to published scientific literature, that the active substance(s) of the medicinal product has (have) an established status, recognised efficacy and an acceptable safety level in medicinal use. The active substance(s) in the product must have been used systematically and in a documented manner as a medicinal product for a minimum of 10 years within the EU. An administrative section, summaries or expert reports, quality documentation and the necessary publications shall always be annexed to a bibliographic application in full.

Applications for a marketing authorisation for veterinary medicinal products may also refer to literature concerning studies on safety and residue levels. Applications for a marketing authorisation based on the well-established use of a veterinary medicinal product may also use the evaluation report that EMA publishes in accordance with Regulation No 470/2009 on the evaluation of an MRL application (on the maximum amounts for residues of veterinary medicinal products) as part of the safety documentation.

If the applicant uses scientific literature to obtain an authorisation for a food-producing animal species and presents new study results on residue levels for the medicinal product in question pursuant to Regulation No 470/2009, as well as new results from clinical studies to obtain an authorisation for another food-producing species, third parties cannot use these study results pursuant to Article 13 of the Veterinary Medicinal Products Directive within three years of the date on which a marketing authorisation was granted for the product for which the studies were carried out. Data protection periods are defined in section 21a of the Medicines Act.

## 3.4 Applications for combination products

(Article 10b of Directive 2001/83/EC; Article 13b of Directive 2001/82/EC)

A combination product means a product that contains known active substances that to date have not been used as a combination for therapeutic purposes. Combination products are granted a separate marketing authorisation, and an application for their authorisation cannot be presented as an application for an extension to a marketing authorisation.

The Applicant shall present results from preclinical and clinical studies on the combination product. It is not necessary for the Applicant to submit the study results of a single active substance.

In veterinary medicinal combination product applications, exemption from submission of these studies in special cases based on the welfare of the animals is allowed, unless increased toxicity gives reason to suspect an increased risk of interactions.

Combination products are granted an eight-year data protection period and a 10-year marketing protection period from the first marketing authorisation granted in the EEA.

### 3.5 Applications where the applicant has obtained the consent of the original marketing authorisation holder to refer to the original marketing authorisation documentation

(Article 10c of Directive 2001/83/EC; Article 13c of Directive 2001/82/EC)

The applicant shall have the consent of the holder of the marketing authorisation for the original medicinal product to use the results of the pharmaceutical, preclinical and clinical studies included in the documentation for the original product. The product must contain the same quantities of the same active substances as the original product and have the same pharmaceutical form.

Expert statements and quality sections shall be appended to the applications.

In applications for marketing authorisation for veterinary medicinal products, the applicant must also have the consent of the marketing authorisation holder for the original medicinal product to use the results of studies on safety and residue levels.

It is not necessary to submit expert statements or quality sections with an application for a veterinary medicinal product submitted in accordance with Article 13 c.

### 3.6 Herbal medicinal products

(Article 1.30 of Directive 2004/24/EC)

Herbal medicinal products are medicinal products that contain herbal substances, herbal preparations or a combination of these as their active substances.

The same provisions as to other medicinal products also apply to applications for marketing authorisations for herbal medicinal products. Applications for marketing authorisations for herbal medicinal products are based primarily on well-established medicinal use as stated in Section 3.3. The application for marketing authorisation shall be submitted to Fimea in the

form of a complete application if the criteria for well-established medicinal use are not met.

## 3.7 Traditional herbal medicinal products

(Article 1.29 and all criteria in Article 16 a (1) of Directive 2004/24/EC)

Section 5a of the Medicines Act defines a traditional herbal substance as a medicinal product for human use that contains an herbal substance, herbal preparation or a combination of these as its active substance. In addition, it shall fulfil all the criteria for registration laid down in section 22, subsection 1 of the Medicines Act. A traditional herbal medicinal preparation may also contain vitamins or minerals if they promote the effect of herbal active substances.

The registration procedure for traditional herbal medicinal substances can, nevertheless, only be used when a marketing authorisation procedure under the Medicinal Products Directive is not possible. If there is sufficient scientific literature to prove well-established medicinal use, recognised efficacy and an acceptable safety level, the applicant shall apply for a marketing authorisation for the product. The registration procedure for traditional herbal medicinal substances may not be used if the product can be granted a marketing authorisation (see Section 3.8.1) or it can be registered as a homeopathic or anthroposophic preparation (see Section 3.8.2).

As for the documentation requirements for applications in which the active substance is included in list of herbal substances decided by the European Commission, herbal preparations and their combinations used in herbal medicinal products, a reference is made to Article 16f of the Medicinal Products Directive.

An administrative section, summaries or expert reports and quality documentation for the product in question shall always be annexed to a registration application in full. The application shall also contain sufficient literature references and expert statements to prove that the product has been in uninterrupted medicinal use for a minimum of 30 years before the date of application, including a minimum of 15 years in the EU. If the product does not meet this 15-year time limit, the matter will be decided by the Committee on Herbal Medicinal Products (HMPC).

## 3.8 Homeopathic and anthroposophic preparations

Section 5 b of the Medicines Act defines a homeopathic preparation as a medicinal product that has been manufactured from homeopathic stocks using the homeopathic manufacturing procedure described in the European Pharmacopoeia. If the description is not in the European Pharmacopoeia, the official pharmacopoeia of a Member State may be used. A homeopathic preparation may be manufactured from several homeopathic stocks. Provisions on homeopathic preparations also apply to other products that have been manufactured using homeopathic manufacturing procedures. Anthroposophic preparations are considered to be such products.

### 3.8.1 Homeopathic and anthroposophic preparations requiring marketing authorisations

(Article 16 of Directive 2001/83/EC; Article 19 of Directive 2001/82/EC)

An application for a marketing authorisation shall be made for those homeopathic and anthroposophic preparations that do not meet the criteria for registration in section 22a of the Medicines Act.

An administrative section, summaries or expert reports, quality documentation, sufficient documentation to guarantee safety and a report on the homeopathic nature of the product based on sufficient literature shall be annexed in complete form to the application for a marketing authorisation.

If an application is made for a therapeutic indication for a homeopathic or anthroposophic preparation, the application documentation shall be submitted in complete form (see Section 3.1).

### 3.8.2 Homeopathic and anthroposophic preparations to be registered

(Article 14 of Directive 2001/83/EC; Article 17 of Directive 2001/82/EC)

Homeopathic and anthroposophic preparations can be registered in accordance with section 22a of the Medicines Act only if the preparation meets all the criteria for registration set out in the section.

An administrative section, quality documentation and a report on the homeopathic or anthroposophic nature of the product based on sufficient literature shall be annexed in complete form to the application for registration.

# 4 MEDICINAL PRODUCTS FOR PAEDIATRIC USE

Medicinal products for paediatric use are regulated under Regulations No 1901/2006 and 1902/2006 of the European Parliament and of the Council.

# 5 CONTENT OF MARKETING AUTHORISATION AND REGISTRATION APPLICATIONS

## 5.1 General

When preparing marketing authorisation and registration applications, applicants shall comply with the Medicines Act (395/87) and the Medicines Decree (693/87) along with the current EU regulations and guidelines on medicinal products contained in The Rules Governing Medicinal Products in the European Union (Volumes 1-9), published on the Commission's website.

Marketing authorisation and registration applications shall also comply with the guidelines and position statements approved by EMA, CAT, CHMP, CVMP, HMPC, PRAC, CMDh, CMDv and PDCO, the latest versions of which are available on the EMA and HMA websites.

Regulations and guidelines issued by Fimea can be found on Fimea's website.

Guidelines by CMDh and CMDv for the mutual recognition procedure and the decentralised procedure have been published on the HMA website.

The above guidelines also apply to applications for registration.

If the application does not fully comply with the guidelines issued by EU or EMA, the reasons for the deviations made shall be presented in the application.

**Medicinal products for human use**

Practical instructions concerning applications for marketing authorisations for medicinal products for human use can be found in Volume 2 of the NtA guidelines. The NtA guidelines are updated from time to time, and the latest versions are published on the Commission's website.

Clinical studies

Instructions concerning clinical trials in human subjects are given in Fimea's normative guideline Clinical trials on medicinal products in human subjects. Valid Finnish legislation shall also be complied with.

**Veterinary medicinal products**

Practical instructions concerning applications for marketing authorisations for veterinary medicinal products can be found in Volume 6 of the NtA guidelines. The NtA guidelines are updated from time to time, and the latest versions are published on the Commission's website.

All animal tests shall be performed according to Directive 2010/63/EU[4] of the European Parliament and Council. Fimea's administrative regulation Clinical trials on veterinary medicinal products applies to clinical trials for veterinary medicinal products.

Veterinary residue level reports and withdrawal periods

Under Annex I to the Veterinary Medicinal Products Directive, the reports required for medicinal products for food-producing animals also include reports on residue levels. Under Article 12 of this directive, the results from studies on withdrawal periods shall be annexed to the application, showing that foodstuffs derived from the animals do not contain larger amounts of medicinal product residues than permitted.

The maximum residue limits of veterinary medicinal products and their confirmation is regulated under EC regulation No 470/2009[5]. Furthermore, Commission Regulation No 37/210[6] and any amendments to its annexes shall be taken into account. More detailed instructions on studies required for applications for the establishment of MRL values can be found in Volume 8 of the NtA guidelines and on the EMA website. Applicants shall also

[4] Directive No. 2010/63/EU of the European Parliament and of the Council, issued on 22 September 2010, on the protection of animals used for scientific purposes (text with EEA relevance), OJEU No. L 276, 20 October 2010, pp. 33–79.
[5] Regulation (EC) No. 470/2009 of the European Parliament and of the Council, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council, OJEU No. L 152, 16 May 2009.
[6] Commission Regulation (EC) No. 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (text with EEA relevance), OJEU No. L 15, 20 January 2010.

refer to Fimea's administrative regulation Clinical trials on veterinary medicinal products.

Exemption from residue level reports on veterinary medicinal products for equidae

Pursuant to Article 6 of Directive 2001/82/EC of the European Parliament and of the Council, no marketing authorisation can be granted for a veterinary medicinal product to be administered to one or more food-producing animal species unless the pharmacologically active substances contained therein are included in Table 1 in the Annex to Commission Regulation No 37/2010.

An exception to this main rule is a veterinary medicinal product administered to equidae, containing pharmacologically active substances not listed in Commission regulation No 37/2010. The precondition in this case is that the horse identification document (horse passport) carries a marking to the effect that the horse will not be culled for human nutrition. Such veterinary medicinal products shall not contain any of the active substances listed in Table 2 in the Annex to Commission Regulation No 37/2010, and they shall not, in accordance with the approved summary of product characteristics, be intended for treating a disease condition for which another medicinal product to be administered to equidae has been approved in the Community. For this special condition, refer to Article 6 of Directive No 2001/82/EC of the European Parliament and of the Council.

Prescriptions for veterinary medicinal products for food-producing animals

Veterinary medicinal products intended for food-producing animals may only be dispensed to the public against veterinary prescription (Directive 2001/82/EC). By way of exception, an exemption may be granted from the requirement for a veterinary prescription for a medicinal product intended for a food-producing animal. The preconditions for such an exemption are laid down in Directive 2006/130/EC.

## 5.2 Structure of the application

The documents for applying for a marketing authorisation and registration shall include administrative information and data sufficient to demonstrate the quality, safety and efficacy of the medicinal product.

All applications for marketing authorisation or registration for medicinal products for human use shall comply with the structure of the internationally harmonised CTD.

In marketing authorisation applications for veterinary medicinal products, the documentation shall be presented in accordance with Annex I to the Veterinary Medicinal Products Directive.

The detailed content and presentation format of an application is described in the NtA guidelines Volume 2B concerning medicinal products for human use, and Volume 6B concerning veterinary medicinal products.

## 5.3 National requirements for applications

Marketing authorisation and registration applications shall comply with the rules and guidelines generally accepted in the EU. The following national

requirements shall, however, be taken into account when an application is submitted to Fimea.

### 5.3.1 Format in which the application is submitted

An application for marketing authorisation and registration shall be submitted to Fimea. The Fimea website contains instructions on the structure, format and number of application copies. Instructions are also provided on the CMD website.

The Fimea website provides document templates and detailed instructions on drafting and submitting the summary of product characteristics and the package leaflet. Following approval, Fimea publishes the texts on its website.

### 5.3.2 Application processing fees

The fees payable for the processing of applications are prescribed in the decree of the Ministry of Social Affairs and Health on chargeable services of Fimea. The processing fee will be charged to the applicant when Fimea's notice of receipt of application has been sent to the applicant in response to the application.

The processing fee will not be reimbursed even if the applicant later withdraws the application.

An exemption from the processing fee may be given on the grounds stated in the Decree of the Ministry of Social Affairs and Health on fees chargeable by Fimea. An application for exemption from the processing fee and the reasons for it shall be annexed to the application for marketing authorisation or registration. Fimea will pass a resolution on the processing fee exemption application once the application has been received. The decision will be served on the applicant for information. If the processing fee exemption application was not accepted, Fimea will send an invoice to the applicant.

The Decree of the Ministry of Social Affairs and Health on fees chargeable by Fimea and Fimea's account details have been published on the Fimea website.

### 5.3.3 Application forms

All applications for marketing authorisation and registration, regardless of the application procedure used, shall be made on EU application forms, which can be found in Volumes 2B and 6B of the NtA guidelines.

Starting from 1 January 2016, an electronic EU application form shall be used for filing the applications.

### 5.3.4 Applicant

The applicant for marketing authorisation or registration must be the person responsible for placing the medicinal product on the market, being a natural person located in the European Economic Area or a legal person registered in the European Economic Area.

A foreign applicant may contact Fimea directly regarding application-related matters. It is nevertheless desirable that foreign applicants have a contact person in Finland. A sufficiently competent and experienced contact person will expedite the foreign marketing authorisation or registration applicant's contact with Fimea.

In the decentralised procedure and the mutual recognition procedure, the applicant is the marketing authorisation or registration holder/applicant in the Reference Member State. The application can nevertheless be transferred to a new applicant during the decentralised procedure and the mutual recognition procedure, or before a national marketing authorisation or registration is granted.

A marketing authorisation or registration may be transferred free of charge during the decentralised or mutual recognition procedure and before the granting of a national marketing authorisation or registration (see section 8.3.2).

### 5.3.5 Manufacturer

Responsibility for the medicinal product lies with the manufacturer who certifies and releases the batch of the product in the EEA. A batch of a medicinal product can only be certified and released on the EEA market by the holder of Manufacturing and Importation Authorisation (MIA). If the medicinal product is manufactured outside the EEA and there is no operative Mutual Recognition Agreement (MRA) or similar agreement between the EU and the country of manufacture, each batch shall be subjected to quality control in the Community. If a country outside the EEA has a valid mutual recognition agreement (MRA) or a similar agreement with the EU, the quality control for each batch of the medicinal product can be performed in the country of manufacture. A batch imported to the European Economic Area can only be released in the area of the European Union after a Qualified Person (QP), i.e. a person who meets the criteria for the holder of the above-mentioned MIA, has certified the batch (Fimea administrative regulation Good Manufacturing Practice).

Administrative information on an application for marketing authorisation or registration shall be provided with annexed copies of the MIA of the manufacturer responsible for the finished product and of other manufacturers located in the European Economic Area and participating in the manufacturing of the medicinal product, or a GMP certificate granted by a competent EEA authority. A GMP certificate granted by the authorities in MRA countries, or countries covered by similar agreements, regarding the manufacturer located in the country in question, is considered equivalent to a certificate granted by an EEA authority. An MIA and/or GMP certificate shall state the pharmaceutical forms that the authorisation/certificate concerns, and thus cover the pharmaceutical forms in the application. Alternatively, the application may refer to the reference number given to the manufacturer in the EudraGMDP database.

A GMP certificate granted by an EEA authority or a referral to the reference number given to the manufacturer in the EudraGMP database is required for every manufacturer that is located outside the European Economic Area and that is participating in the manufacture of the medicinal product. If there is no GMP certificate or EudraGMDP reference number, the GMP conformity of a manufacturer outside the European Economic Area is assessed by a

GMP inspection by an authority. The costs of the inspection will be charged in accordance with the Decree of the Ministry of Social Affairs and Health on chargeable services of Fimea.

The application shall be submitted with a declaration by a QP regarding the GMP conformity of the factories participating in the manufacture of the active substances used in the manufacturing of the medicinal product.

The QP declaration shall be submitted for each MIA holder in the EEA for registration who uses the active substance in its manufacturing operations and/or is responsible for the certification and release of the medicinal product batch. If there are more than one of the aforementioned MIA holders, a declaration signed by one QP only may, under certain conditions, be submitted on behalf of the QPs concerned. It is advisable to submit the QP declaration using the currently valid, predefined form that includes five subsections. Alternatively, the same information that is requested in the form can be submitted in free-form format. The predefined form for the QP declaration and instructions for using it have been published on the EMA web site.

### 5.3.6 Samples

Samples of the medicinal product shall not be annexed to the applications. Samples of the medicinal agents or excipients used in the products shall not be annexed either, unless particularly requested. A model of any dosing device intended for use with the medicinal product may be submitted with the application.

### 5.3.7 Trade name

The trade name may be an invented name, a common name (generic name) combined with a trade mark, the name of the manufacturer, marketing authorisation holder or its representative, or a scientific name combined with a trademark, the name of the manufacturer, marketing authorisation holder or its representative.

The invented name shall not be confusingly similar to a common name, nor may it be otherwise exaggerating or misleading, e.g. in a therapeutic or pharmaceutical sense. Neither can an invented name be identical with nor confusingly similar to the name of a medicinal product that has a different composition and that is currently on the Finnish market or has been on the market in recent years. The applicant for marketing authorisation or registration is responsible for the protection and registration of the trade name.

If a homeopathic or anthroposophic preparation derives from only one stock, the stock's scientific name and its degree of dilution shall be given as the trade name. If two or more stocks have been used in the manufacture and the product is therefore a combination product, an invented trade name may also be used.

### 5.3.8 Language requirements for the application

The application in its entirety shall be submitted in Finnish, Swedish or English. However, for a national application for marketing authorisation or registration, the proposed summaries of product characteristics, package leaflets and labelling shall be submitted in both Finnish and Swedish when the

application is submitted. In the case of the mutual recognition procedure or the decentralised procedure, the abovementioned materials shall be submitted as soon as the process has been completed.

**Summary of product characteristics**

The applicant shall draft a proposal for a summary of product characteristics in Finnish and Swedish for the application for marketing authorisation and registration. There are lists of obligatory headings to be used in the summaries of product characteristics for medicinal products. Document templates corresponding to these lists of headings and detailed instructions on the editing and submission of electronic texts can be found on the EMA and Fimea websites. Marketing authorisations and registrations that do not have a Swedish summary of product characteristics approved by Fimea must be supplemented by a Swedish summary of product characteristics by filing a Type IB variation application no later than within 3 years. This transition period of three (3) years is calculated from the entry into force of this Administrative Regulation.

Separate proposed summaries of product characteristics shall be submitted for different pharmaceutical forms of the same medicinal product. The different strengths of the same medicinal product can nevertheless be submitted in one summary of product characteristics. All subsequent information on a medicinal product shall be based on the approved summary of product characteristics.

Summaries of product characteristics are not required for the registration of homeopathic and anthroposophic products (see section 3.8.2).

**Labelling and package leaflets**

National marketing authorisation and registration applications shall comply with the provisions of the Medicinal Products Directive in relation to the labelling and package leaflets for the medicinal product in question, and for veterinary medicines, with the provisions of the Veterinary Medicinal Products Directive. The applicant shall also comply with Fimea's administrative regulation and guideline for labelling and package leaflets for medicinal products.

The applicant shall draft proposals for the package leaflets in Finnish and Swedish, as well as a draft-like proposal for labelling of each package type and strength, or account for differences between labelling for different strengths. No labelling needs to be submitted for strengths or package types that will not be placed on the market. In this case, the applicant shall file with Fimea a written declaration that the missing labelling will be submitted with a Type IB variation application prior to the potential placement on the market of the strength or package type concerned. If the different package sizes of a medicinal product come under different supply categories (over-the-counter packages and prescription packages), separate proposals for package leaflets and package labelling for both types of packages shall be annexed to the application.

User tests shall be conducted to ensure that the package leaflet for human medicinal products is comprehensible. The relevant EU guidelines shall be taken into account in the planning of the user test and its study design. When a marketing authorisation application is submitted for the national

procedure or when Finland acts as the Reference Member State in the mutual recognition procedure, the package leaflet draft may be user tested in one of the official languages of the EU. The study report on the user test can be made in Finnish, Swedish or English. The report shall be annexed to the marketing authorisation application with the proposed package leaflet by the additional clarification phase at the latest. When Finland acts as a Concerned Member State, user testing is carried out and the results submitted according to the instructions given by the Reference Member State.

# 6 PROCESSING AND DECIDING ON THE APPLICATION

## 6.1 Submitting an application to Fimea

An application for marketing authorisation and registration with the relevant documentation shall be submitted to Fimea. The address can be found on the Fimea website.

In unclear cases, before submitting the application the applicant shall contact Fimea to determine whether the product concerned is a medicinal product. If necessary, an application may be made to Fimea for a decision on classification as referred to in section 6 of the Medicines Act.

Applicants shall also ascertain from Fimea whether a variation application, a marketing authorisation or registration extension application, or a separate application for marketing authorisation or registration, shall be made.

The different package sizes and types of the same product can usually be included in the same marketing authorisation or registration. However, for certain package sizes and package types of the medicinal product, it is necessary to apply for an extension to the marketing authorisation or registration. Further guidelines can be found in Volumes 2C and 6C of NtA (Guideline on the Categorization of New Applications (NA) versus Variation Applications).

In exceptional cases, information related to an application for marketing authorisation or registration can be submitted to Fimea by parties other than the applicant or its representative. This may be the case with reports concerning raw materials used to produce the medicinal product (Drug Master Files) that the manufacturer does not want to disclose to the applicant. Such documents shall bear a clear reference to the application they are related to. They shall also contain a written authorisation allowing the authorities to use these documents in the processing of the application for the marketing authorisation or registration in question.

In the case of homeopathic and anthroposophic preparations, a dilution series manufactured from one stock is considered to constitute a single application for marketing authorisation or registration, depending on the degree of dilution. However, an application shall be made for a separate marketing authorisation or registration for each pharmaceutical form manufactured from the same stock, depending on the degree of dilution.

The applicant may withdraw the application for marketing authorisation or registration at any time during the process. The withdrawal shall be submitted to Fimea in writing.

## 6.2 Preliminary validation of an application

The preliminary validation of an application under the national procedure is carried out within 14 days of receipt of the application. The purpose of the preliminary validation is to ensure that the application can be processed and that it contains all the required documents and annexes.

The preliminary validation is an administrative examination whereby it is ensured that all the reports required for the application type have been annexed to the application.

The preliminary validation of applications to be processed under the mutual recognition procedure or the decentralised procedure follows a preliminary validation process and timetable laid out in the guidelines issued by the CMD, which are available on the CMD website.

Fimea will immediately notify the applicant of any deficiencies in the application found during the preliminary validation process. If the application concerned is processed under the mutual recognition procedure or the decentralised procedure, the Reference Member State will also be notified of the matter when Finland is the Concerned Member State (see sections 6.3.2 and 6.3.3). The missing documents shall be submitted to Fimea within two weeks.

If the deficiency is not rectified, the applicant will be requested to withdraw the application. In this case the processing fee, the application and the documents annexed to it will be returned to the applicant provided the applicant covers postage costs and other expenses. In other cases, the marketing authorisation and registration application documents submitted to Fimea will not be returned.

## 6.3 Processing the application

### 6.3.1 National procedure

Applications processed under the national procedure are primarily those for medicinal products without marketing authorisation or registration, or an application currently being processed in an EEA Member State. For later applications for marketing authorisation or registration in another Member State, the mutual recognition procedure shall be used.

Applications for the extension of marketing authorisations and registrations granted to products approved through the national procedure will also be processed using the national procedure.

Application processing times are prescribed in section 10 a of the Medicines Decree.

If the applicant obtains study results that are considered particularly important with regard to safety after the application has been submitted, they shall be submitted to Fimea immediately along with expert reports. No other new research results or changes to an application already submitted will be accepted during the process, unless Fimea specifically requests them.

Additional clarifications shall be submitted with responses relating to quality, safety and efficacy clearly grouped as separate entities. Additional clarifications for each application for marketing authorisation and registration

shall be submitted separately. With regard to individual research results, reference can be made to documents for another marketing authorisation or registration application (see the Fimea website and guidelines published by CMD for instructions on the submission of responses and the number of reply copies).

### 6.3.2 Decentralised procedure

(Article 28.3 of Directive 2001/83/EC; Article 32.3 of Directive 2001/82/EC)

The decentralised procedure is used when applying for marketing authorisation or registration in more than one Member State for a product that does not have any marketing authorisation or registration within the Community. The practical course of the decentralised procedure is described in the guidelines issued by CMD. Variation applications and notifications for medicinal products that have been granted marketing authorisation under the decentralised procedure will be processed using the mutual recognition procedure. Variation applications for registered products are processed under the national procedure.

Instructions on the submission of the applicant's replies can be found in the guidelines issued by CMD and on the Fimea website. In the decentralised procedure, the applicant selects and contacts a Reference Member State and asks it to give an assessment report as well as a proposed summary of product characteristics, a proposed package leaflet and proposed labelling within 120 days (evaluation phase I). Concerned Member States will recognise the assessment report proposed by the Reference Member State within 90 days (evaluation phase II).

The applicant may withdraw the application for marketing authorisation or registration at any time during the process. The withdrawal shall be submitted to Fimea in writing. Withdrawal of the application for marketing authorisation does not always prevent the processing of the matter in CMD, if there is a possibility that granting marketing authorisation or registration for the medicinal product may result in a serious risk to public health, or if granting marketing authorisation for a veterinary medical product is suspected to pose a potentially serious risk to human or animal health or the environment. The administrative process is described in more detail in guidelines issued by CMD.

**Finland as the Reference Member State**

When Finland is acting as the Reference Member State in the decentralised procedure for medicinal products for human use, the applicant for marketing authorisation or registration shall request Fimea to act as a Reference Member State in accordance with the guidelines provided on the Fimea website.

For veterinary medicinal products, the applicant for marketing authorisation or registration shall request Fimea to act as a Reference Member State at least three months before the planned submission of the application. The applicant shall submit a written request to launch the decentralised procedure with preliminary information on the application for marketing authorisation or registration (application form and summary of product characteristics), on the Concerned Member States and on the proposed timetable. Fimea will discuss the timetable with the applicant.

**Finland as a Concerned Member State**

When Finland acts as a Concerned Member State in the decentralised procedure, the applicant shall submit to Fimea application documents that are identical to those submitted to the Reference Member State. The applicant and the Reference Member State will agree on the time of submitting the application documents.

### 6.3.3 Mutual recognition procedure

(Articles 28.1 and 28.2 of Directive 2001/83/EC; Articles 32.1 and 32.2 of Directive 2001/82/EC)

The mutual recognition procedure is used when applying for marketing authorisation or registration for a medicinal product in more than one Member State and when the product already has a marketing authorisation or registration in EEA Member States. The applicant shall request one of these Member States to act as the Reference Member State.

The practical course of the mutual recognition procedure is described in the guidelines issued by CMD. There are also instructions on the submission of the applicant's replies during the mutual recognition procedure in the guidelines published by CMD and on the Fimea website.

The applicant may withdraw the application for marketing authorisation or registration at any time during the process. The withdrawal shall be submitted to Fimea in writing. Withdrawal of the application for marketing authorisation will not prevent the processing of the matter in CMD if there is a possibility that granting marketing authorisation or registration for the medicinal product may result in a serious risk to public health, or if granting marketing authorisation for a veterinary medical product is suspected to pose a potentially serious risk to human or animal health or the environment. The administrative process is described in more detail in guidelines issued by CMD.

**Finland as the Reference Member State**

If the holder of a medicinal product that has been granted marketing authorisation or registration in Finland intends to apply for recognition of the marketing authorisation or registration in one or more Member States of the European Union, the holder shall contact Fimea in advance. Prior to the mutual recognition procedure, the marketing authorisation or registration holder shall ascertain that the documentation for the product has been updated to comply with the latest requirements. The holder shall send Fimea a written request for an up-to-date assessment report on the medicinal product in accordance with the guidelines issued on the Fimea website. Fimea will provide the assessment report within 90 days of receiving the request and submit it to the authorities in the Member States in which the applicant intends to apply for mutual recognition.

Fimea will launch the mutual recognition procedure at a time agreed with the applicant, once a valid application for processing and the assessment report have been submitted to all Member States concerned. A valid application for processing shall also be submitted to Fimea.

If the mutual recognition procedure results in the approval of a summary of product characteristics, a package leaflet and labelling that differ from those

previously approved by Fimea nationally, the marketing authorisation or registration holder shall submit a new proposed summary of product characteristics in Finnish and Swedish and proposals for package leaflets and labelling in Finnish and Swedish without delay. The application shall be submitted as a national Type IB variation application (see section 8.2.2).

**Finland as a Concerned Member State**

Applicants who have been granted a marketing authorisation or registration for a medicinal product in a Member State of the European Economic Area in accordance with Community provisions can apply for the recognition of this marketing authorisation or registration in Finland.

When Finland acts as a Concerned Member State in the mutual recognition procedure, the applicant shall submit to Fimea application documents that are identical to those submitted to the Reference Member State. The applicant and the Reference Member State will agree on the time of submitting the application documents.

## 6.4 Suspending the processing of an application

(Articles 17.2 and 18 of Directive 2001/83/EC; Articles 21.2 and 22 of Directive 2001/82/EC)

If an applicant submits an application concerning a medicinal product which has already been granted a marketing authorisation or registration, or if the application in question is pending in an EEA Member State, the application will not be processed through the national procedure. In such cases, the proceedings will be discontinued, and the matter will be transferred to the mutual recognition procedure in accordance with the detailed instructions published by CMD.

It is a prerequisite for the suspension of the national procedure that another Member State has granted a marketing authorisation or registration for a product with the same active substances, the same pharmaceutical form and the same strength. Moreover, the applicant shall be the same or belong to the same group or company as the marketing authorisation applicant or holder in the other Member State. Companies that have entered into a mutual agreement (e.g. a licensing agreement) or applicants who are cooperating in some other way in order to bring the medicinal product onto the market are also considered as the same applicant.

If only one Member State has granted a marketing authorisation or registration for the medicinal product in question, this Member State will become the Reference Member State. If one product has a marketing authorisation or registration in several EEA countries, one of these Member States will act as the Reference Member State in the future.

If Fimea finds that an application for the same product is being processed in another Member State, the national procedure will be suspended. The applicant will then be informed that the application will be processed using the decentralised procedure or the mutual recognition procedure.

## 6.5 Deciding on an application

If the Concerned Member States participating in a mutual recognition procedure or a decentralised procedure consider that granting a marketing au-

thorisation or registration for a medicinal product may result in a serious risk to public health, the matter will be processed in the CMD. This will also be done if granting marketing authorisation to a veterinary medical product is suspected to pose a potential serious risk to human or animal health or the environment.

If the CMD cannot agree on the application, the matter will be taken to arbitration to be processed by the CHMP or CVMP. The arbitration procedure is described in detail in the guidelines issued by CMD and in Section 3 of Volumes 2A and 6A of the NtA guidelines. Matters relating to traditional herbal medicinal products will be taken to arbitration to be processed by the HMPC if the CMD cannot agree on the application. The arbitration procedure does not apply to homeopathic and anthroposophic preparations for registration (see section 3.8.2).

Fimea can set conditions for granting marketing authorisation or registration, or obligations to perform safety or efficacy tests subsequent to the grant of marketing authorisation or registration.

When the conditions for the supply category of a medicinal product for human use are being determined, the relevant provisions in the Medicinal Products Directive shall be taken into account. For veterinary medicinal products, the relevant provisions in the Veterinary Medicinal Products Directive shall be taken into account. Moreover, the provisions on medicinal prescriptions issued by the Ministry of Social Affairs and Health and the administrative regulation on the dispensing of medicinal products issued by Fimea shall be taken into account in connection with medicinal products for human use. For veterinary medicinal products, the provisions on veterinary medicinal products issued by the Ministry of Agriculture and Forestry shall be taken into account.

Fimea may prohibit the production, import, possession, sale, distribution or use of an immunological veterinary medicinal product in the whole or part of its jurisdiction if the use of the product may interfere with the control of a veterinary disease or with the implementation of a programme against such a disease or the disease to which the product is intended to confer immunity is largely absent from the territory in question.

In its decision to grant a marketing authorisation or registration, Fimea will notify the applicant of the versions of the summary of product characteristics and the package leaflet approved for the medicinal product in question.

Fimea may also grant a marketing authorisation or registration in such a way that the marketing authorisation or registration is granted with process-approved English-language versions of the summary of product characteristics, package leaflet and labelling. If so, this will be a case of a conditional marketing authorisation or registration, in which case the medical product concerned may only be placed on the market after Fimea has approved the versions of Finnish and Swedish summaries of product characteristics, package leaflets and draft-like labelling submitted with a variation application. The variation concerned shall be applied for using a Type II variation application. A conditional marketing authorisation or registration is not possible for an application submitted under the national procedure.

# 7 MAINTAINING A MARKETING AUTHORISATION AND REGISTRATION

The holder of a marketing authorisation for a medicinal product or of a registration for a traditional herbal medicinal product shall notify Fimea of all new information necessary to assess the advantages and disadvantages of the product that were not included in the original application for marketing authorisation and registration. Fimea shall also be notified of all other changes to documentation. Provisions on the monitoring and notification of adverse effects, on the submission of safety reports and on other forms of pharmacovigilance are contained in section 4a of the Medicines Act and in the administrative regulation Pharmacovigilance and the normative guideline Reporting adverse drug reactions issued by Fimea. Detailed instructions on monitoring the adverse effects of veterinary medicinal products can be found in the administrative regulation Veterinary pharmacovigilance and in the normative guideline Reporting the adverse effects of medicinal products administered to animals. The applicant shall also take into account what is prescribed in Volume 9 B of the NtA guidelines.

Once a marketing authorisation has been granted or a traditional herbal medicinal product has been registered, the holder of marketing authorisation, marketing authorization for parallel import, or registration shall immediately report to Fimea the name of the person responsible for pharmacovigilance of the medicinal product, and the name and contact details of the Finnish contact person, if any. The holder shall keep Fimea informed of any changes in these details.

Section 30o of the Medicines Act contains provisions on the obligation of the marketing authorisation or registration holder to notify Fimea should the distribution of a medicinal product be interrupted at the holder's own initiative or the product be voluntarily withdrawn from the market for reasons related to the safety or efficacy of the product.

A competent authority will inspect all the factories participating in the manufacturing of the medicinal product located outside the European Economic Area mentioned in the valid marketing authorisation and in the registration. Inspection costs are not included in the annual fee mentioned in section 7.2.

## 7.1 Placing and maintaining a medicinal product on the market

The marketing authorisation or registration holder shall notify Fimea when a medicinal product is placed on the market or withdrawn temporarily or completely from the market pursuant to section 27 of the Medicines Act.

Placing a medicinal product on the market means that the product has been released to the supply chain (wholesalers and pharmacies, including hospital pharmacies and dispensaries) and is thus generally available to end users pursuant to section 26 of the Medicines Act.

When a product that has been granted marketing authorisation or registration is placed on the market, the marketing authorisation or registration holder shall file a notice thereof with Fimea no later than eight working days prior to the date when the product is placed on the market. Such notice is also required when the composition or the trade name changes, and when the Nordic product number (Vnr) changes.

If a party other than the marketing authorisation holder or its representative intends to import to Finland a medicinal product for which a marketing authorisation has been granted by an institution of the European Union, the importer shall notify the Finnish Medicines Agency and the marketing authorisation holder of the import. The notification must be made within one month prior to the planned commencement of the import.

The marketing authorisation or registration holder shall at the same time also notify pharmacies, hospital pharmacies and dispensaries that the product has been placed on the market. Pharmacies do not need to be notified of products meant exclusively for hospital use. For traditional herbal medicinal products and homeopathic and anthroposophic preparations, the notification shall be submitted to Fimea and to pharmacies. An exemption from this requirement is made for products that were approved for sale in institutions other than pharmacies at the time of their registration and that are not intended to be sold at pharmacies. For these products, it is sufficient to notify Fimea that the product has been placed on the market.

This notification shall be made using a predefined form that is available on the Fimea website. The notification shall also clearly state the pack sizes and types as well as the Vnr numbers covered by the notification.

If the supply of a medicinal product or a certain package on the market is discontinued or there are such interruptions in supply that make the product effectively unavailable to end users, Fimea shall be notified two months before the discontinuation or interruption begins in the same manner as described above regarding placing a product on the market.

Additionally, holders of marketing authorisations, marketing authorisations for parallel import and registrations shall promptly notify the Finnish Medicines Agency of the actions they have taken with regard to the discontinuation of, and temporary interruptions to, keeping a medicinal product on the market, the cancellation of a marketing authorisation or a decision of not applying for a renewal of a marketing authorisation and of the grounds thereof. If such actions are based on adverse effects, efficacy, a negative risk to benefit ratio, or problems with drug safety, the European Medicines Agency must also be notified. If actions have been taken outside of the EU and EEA for reasons related to adverse effects, efficacy, a negative risk to benefits ratio or problems with drug safety, the Finnish Medicines Agency and the European Medicines Agency must be notified immediately. This does not apply to veterinary medicines.

If a medicinal product has not been placed on the market within three years of the granting of marketing authorisation or registration or if its supply on the market has been interrupted continuously for three years, the marketing authorisation or registration will expire.

Under section 29 of the Medicines Act, Fimea may decide, for reasons related to human or veterinary health, for other special reasons, or at the marketing authorisation or registration holder’s request, that the marketing authorisation or registration will not expire, even though the medicinal product has not actually been placed on the market. More information is given on the Fimea website.

When a marketing authorisation or registration expires, the marketing authorisation or registration holder shall immediately withdraw all medicinal

products on the market from medicinal product wholesalers, pharmacies, hospital pharmacies and dispensaries.

Under section 26 of the Medicines Act, the marketing authorisation or registration holder shall guarantee as far as possible that the medicinal product that has been granted marketing authorisation and the registered traditional herbal medicinal product are continuously available to medicinal product wholesalers and pharmacies in accordance with patients' and users' needs.

## 7.2 Annual fees

An annual fee is payable for each year following the year in which the marketing authorisation or registration was granted, as laid down in the Decree of the Ministry of Social Affairs and Health on chargeable services of Fimea. Account details for Fimea are available on the Fimea website. Fimea will send an invoice for the annual fee to the marketing authorisation or registration holder or to the representative indicated by the holder approximately two months before the authorisation year for the product ends. The fee is payable one month before the end of the authorisation year. If the fee is not paid by the due date, the marketing authorisation or registration will expire on the last day of the authorisation year.

The marketing authorisation or registration holder is responsible for paying the annual fee by the due date. Non-receipt of an invoice does not constitute sufficient grounds for non-payment of the fee.

According to the Decree of the Ministry of Social Affairs and Health on chargeable services of Fimea, the annual fee may be waived in certain cases. An application for exemption from the annual fee shall be submitted at least four months before the end of the authorisation year for the product. The necessity of the medicinal product for treatment shall be demonstrated in the application. A report on the value of the product sales at wholesale prices in Finland during the preceding twelve months shall also be annexed, itemised according to pack sizes. Hospital sales in relation to total sales shall also be specified.

### 7.2.1 Cancelling a marketing authorisation or registration

The marketing authorisation or registration holder or a person or company authorised by the holder shall submit a written notification before the end of the authorisation year on a specific form available on the Fimea website if the authorisation is to be cancelled and the annual fee left unpaid. Fimea will send a confirmation to the marketing authorisation or registration holder for cancelling the marketing authorisation or registration only if specifically requested. If the notification of cancellation does not specifically state the date from which the marketing authorisation or registration is to be cancelled, the authorisation will be cancelled from the date of the notification of cancellation. However, a marketing authorisation or registration cannot be cancelled retroactively.

Additionally, holders of marketing authorisations, marketing authorisations for parallel import and registrations shall promptly notify the Finnish Medicines Agency of the actions they have taken with regard to the discontinuation of, and temporary interruptions to, keeping a medicinal product on the market, the cancellation of a marketing authorisation or a decision of not applying for a renewal of a marketing authorisation and of the grounds

thereof. If such actions are based on adverse effects, efficacy, a negative risk to benefit ratio, or problems with drug safety, the European Medicines Agency must also be notified. If actions have been taken outside of the EU and EEA for reasons related to adverse effects, efficacy, a negative risk to benefits ratio or problems with drug safety, the Finnish Medicines Agency and the European Medicines Agency must be notified immediately. This does not apply to veterinary medicines.

## 7.3 Period of validity

The marketing authorisation and registration for a medicinal product are only valid on the terms set out at the time they were granted. The marketing authorisation or registration expires if the marketing authorisation or registration holder has not complied with the terms stated in section 29 of the Medicines Act, under which Fimea may cancel the marketing authorisation or registration if it is shown by new studies or otherwise that the prerequisites for granting a marketing authorisation or registration no longer exist. A marketing authorisation or registration can be suspended while the necessary studies are conducted if there is reasonable suspicion that this is the case.

Marketing authorisations and registrations are valid for five years from the date on which they were granted.

A marketing authorisation and registration will expire if the annual fee mentioned in section 7.2 is not paid by the prescribed date or if the marketing authorisation or registration is not renewed as specified in section 7.4.

## 7.4 Renewing a marketing authorisation and registration

With the exception of the cases mentioned in section 7.3, marketing authorisations and registrations are valid for five years, after which they shall be renewed. An application for the renewal of marketing authorisation or registration shall be submitted to Fimea for medicinal products for human use at least nine months and for veterinary medicinal products at least six months before the date on which the marketing authorisation or registration for the product expires. The marketing authorization and registration will remain valid during the processing of the renewal application. If an application is not submitted, the marketing authorisation or registration will expire.

All marketing authorisations and registrations for medicinal products shall be renewed at least once according to the Medicinal Products Directive and the Veterinary Medicinal Products Directive, after which they are valid indefinitely. If justified for reasons relating to pharmacovigilance, the marketing authorisation or registration can be renewed for the first time for a five-year term only. The guidelines provided in section 7.2.1 apply to any decision of not applying for a renewal of a marketing authorisation based a change in the benefit-risk ratio.

Renewing the registrations for homeopathic and anthroposophic preparations registered before 1 January 1994 is not relevant at this stage.

### 7.4.1 Content of applications for the renewal of marketing authorisation or registration processed under the national procedure or the mutual recognition procedure

Applications for the renewal of marketing authorisations and registrations shall be submitted in writing on the EU renewal application forms published in Volumes 2C and 6C of the NtA guidelines. Starting from 1 January 2016, an electronic EU application form shall be used for filing the applications.

The guidelines on the renewal of a marketing authorisation or registration referred to in the NtA, as well as the guidelines published by the CMD in its web services, must be taken into account when the application is prepared. The requirements laid down in the guidelines apply to products that have been registered or received marketing authorisation under the national, mutual recognition, or decentralised procedure.

In connection with the renewal, only such amendments as are in accordance with the CMD guidelines may be made to the summary of product characteristics, package leaflet or labelling.

If the renewal application for a marketing authorisation or registration is rejected, the annual fee paid in advance for the following authorisation year will be returned at the applicant's written request. If the applicant wishes to transfer the marketing authorisation or registration to a new holder in conjunction with the renewal, this shall be stated in the letter accompanying the renewal application (see section 8.3.2, Transferring a marketing authorisation or registration to a new holder).

## 7.5 Batch-specific control

### 7.5.1 Vaccines, blood- and plasma-derived medicinal products and antiserums for human use

Vaccines, blood- and plasma-derived medicinal products and antiserums fall within the scope of batch-specific control.

Immunoprophylactic vaccines fall within the scope of batch-specific control; products used for immunotherapy do not. Blood- and plasma-derived medicinal products are products in which the active ingredient or other component (e.g. carrier) is derived from human blood or plasma. Antiserums are antiseral products produced in animals.

For medicinal products for human use that fall within the scope of batch-specific control and have been granted a marketing authorisation or an exemption or a special permit in Finland (including temporary special permits), the manufacturer, the marketing authorisation holder or the importer shall submit an Official Control Authority Batch Release certificate (OCABR) issued by an Official Medicines Control Laboratory (OMCL) and a Marketing Information Form (MIF) identifying the batch imported to Finland, signed by the marketing authorisation holder's or importer's Qualified Person (QP) to Fimea for each batch intended for sale or consumption. Exceptions to this requirement are those medicinal products for which no OCABR procedure exists. For such products, batch analysis certificates as well as batch release certificates, signed by a QP, and declarations on the batch and dose quantities to be imported to Finland shall be submitted to Fimea. If the product originates from a third country, a batch release certificate signed by a QP based in the EEA shall be submitted to Fimea.

For an additional delivery from a previously approved batch, either a batch distribution declaration (MIF) or a declaration on the batch to be delivered and the quantity of doses (by email, for example) is sufficient.

Fimea can also request a sufficient quantity of samples, the package leaflet and the labelling as necessary.

The certificates shall be submitted to Fimea primarily in PDF format to the e-mail address BATCH.CONTROL@fimea.fi at least seven days before the batch is released for consumption. The batch can be released for consumption unless otherwise ordered by Fimea.

### 7.5.2 Veterinary vaccines, immunoglobulins and antiserums

Immunoprophylactic veterinary vaccines, immunoglobulins and antiserums fall within the scope of batch-specific control; products for immunotherapy do not.

For veterinary medicinal products that fall within the scope of batch-specific control and have been granted a marketing authorisation or a special permit in Finland, the manufacturer, the marketing authorisation holder or the importer shall submit the manufacturer's quality control certificate and a batch release certificate issued by an OMCL to the Virology Research Unit of the Finnish Food Authority for each batch intended for sale or consumption. The certificates shall be submitted in PDF format to the e-mail address batch.release@ruokavirasto.fi (or batch.release@foodauthority.fi) If the batch is not certified according to Article 81 of the Veterinary Medicinal Products Directive, the Finnish Food Authority may certify the batch upon request..

A batch of medicines may be released for consumption after the research unit has examined the certificate, certified the batch or inspected the batch at the national level. The batch may be released for consumption only based on a notification by the research unit. When requested by Fimea or the Finnish Food Authority, a sufficient quantity of samples from the batch intended for sale or consumption shall be submitted for examination by the Finnish Food Authority, in addition to the certificates. The examination of samples does not prevent the product from being released for consumption. Finland applies the OCABR procedure in accordance with Article 82 of the Veterinary Medicinal Products Directive to live rabies vaccine baits.

# 8 VARIATIONS TO THE MARKETING AUTHORISATION AND REGISTRATION

## 8.1 General

Holders of marketing authorisations and registrations shall follow the technical and scientific development of their products and present the resulting changes to their medicinal products in accordance with the procedures given below.

Commission Regulation No 1234/2008 concerns the processing of variations to marketing authorisations granted under mutual recognition or decentralised procedures, and of medicinal products that have been under an

arbitration procedure. The variation applications for these products are processed under the mutual recognition procedure.

The variation applications for products registered under mutual recognition or decentralised procedures are processed under the national procedure.

Variations to medicinal products granted marketing authorisations or registrations under the national procedure will be processed pursuant to the same Regulation mentioned above.

Notifications or applications for variations to marketing authorisations or registrations granted under the national procedure, the mutual recognition procedure and the decentralised procedure shall be submitted in writing on EU application forms published in Volumes 2C and 6C of the NtA guidelines. Starting from 1 January 2016, an electronic EU application form shall be used for filing the applications.

The processing of a variation application is subject to a fee as laid down in the Decree of the Ministry of Social Affairs and Health on fees chargeable by Fimea. The processing fee will be charged to the applicant when Fimea has received the application. The amount of the processing fee will depend on the final content of the variation application. If any circumstances are discovered during the processing of the application that affect the amount of the application fee, Fimea will be entitled to issue an additional invoice or credit note.

The applicant may withdraw the variation application at any time during the process. The withdrawal shall be submitted to Fimea in writing. The processing fee will not be reimbursed if the assessment of the application has already been started.

Data protection periods for medicinal products for human use and for veterinary medicinal products are prescribed in section 21a of the Medicines Act.

If significant preclinical or clinical studies have been carried out for a new indication for a commonly accepted medicinal agent, a one-year data protection period can be granted for it as prescribed in section 21c of the Medicines Act. Applications for this one-year data protection period shall be made to Fimea, which decides the matter.

Under section 23b of the Medicines Act, if extensive preclinical or clinical studies have been carried out to remove one of the conditions under which the marketing authorisation was granted, the marketing authorisation holder for another product containing the same active substance cannot apply for the removal of the condition on the basis of these study results before one year has elapsed from the date on which the condition for the marketing authorisation for the reference product was changed.

The provisions concerning placing a medicinal product on the market are contained in section 7.1 above.

## 8.2 Categories of variations to marketing authorisation and registration

The variations are categorised as follows:

- Type IA minor variations that are submitted within a year of implementation

- Type $IA_{IN}$ minor variations that shall be submitted immediately after implementation
- Type IB variations
- Type II major variations requiring authorisation
- Urgent safety restrictions
- Extensions to a marketing authorisation or registration

The European Commission has published guidelines on the classification of variation applications on its website. The Commission guidelines are updated on a regular basis, and the categories may be changed based on Article 5 of Commission Regulation No 1234/2008.

The European Commission has also published on its website guidelines on the implementation of variations, with regard to variation applications processed under the national procedure, the mutual recognition procedure and the centralised procedure.

### 8.2.1 Type IA variations requiring notification

Type IA variations are listed in the abovementioned Commission guidelines. Type IA variations can usually be submitted to Fimea within 12 months of the implementation of the variation. Exceptions are certain Type IA variations that shall be submitted to Fimea immediately after implementation. These variations are marked in the categorisation guidelines as $IA_{IN}$.

An application form and reports on compliance with the guideline requirements shall be annexed to the notification. In addition, the notification shall contain the necessary variations to the documents as stated in the Commission guidelines.

If the Type IA variation(s) apply to one or more products of one marketing authorisation or registration holder, the holder may submit these variations to Fimea as one grouped notification.

When the Type IA variation application is processed under the national procedure, Fimea will notify the marketing authorisation or registration holder about which variations are rejected. The marketing authorization or registration holder must immediately stop applying a rejected variation.

The appropriateness of Type IA variation notifications, both those under the national procedure and those under the mutual recognition procedure, will be reviewed within 30 days.

If the proposed variation results in changes to the summary of product characteristics, the package leaflet or labelling for the medicinal product, new proposed documents shall be annexed to the notification. The applicant shall also submit the aforementioned previously approved texts in which the changes have been clearly marked. Fimea will inform the applicant of the identification data (date) of the approved document (summary of product characteristics or package leaflet) for the variation notification.

Type IA variations are handled according to Commission Regulation 1234/2008. The administrative process is described in more detail in guidelines issued by CMD.

### 8.2.2 Type IB variations requiring notification

Commission Regulation No 1234/2008 defines a Type IB variation requiring notification as a variation which is neither a minor variation of Type IA nor a major variation of Type II nor an extension.

The categorisation guidelines published by the Commission mention examples of Type IB variations and their documentation requirements. Based on Article 5 of Commission Regulation No 1234/2008, a previously unclassified variation application can also be classified as another type of variation besides Type IB.

Fimea must receive notification of Type IB variations before their implementation. An application form and reports on compliance with the guideline requirements shall be annexed to the notification. In addition, the notification shall contain the necessary variations to the documents as stated in the guidelines issued by the European Commission.

The appropriateness of Type IB variation notifications under the national procedure as well as under the mutual recognition procedure will be reviewed within 30 days. After a possible clock-stop, the appropriateness of the notification will be reviewed within the next 30 days. Fimea will notify the applicant of the approval or rejection of a variation processed under the national procedure.

When a previously unclassified Type IB variation application is inspected, Fimea may order it to be changed into a Type II variation.

If the proposed variation results in changes to the summary of product characteristics, the package leaflet or labelling for the medicinal product, new proposed documents shall be annexed to the notification. The applicant shall also submit the aforementioned previously approved texts in which the changes have been clearly marked. Fimea will inform the applicant of the identification data (date) of the approved document (summary of product characteristics or package leaflet) for the variation notification.

Type IB variations are handled according to Commission Regulation 1234/2008. The administrative process is described in more detail in guidelines issued by CMD.

### 8.2.3 Type II variations (variations requiring authorisation)

Commission Regulation No 1234/2008 and the classification guidelines published by the Commission lists the variations that are considered Type II. Additionally, variations that may have a significant impact on the quality, safety or efficacy of the product, and variations recommended in Article 5 of Commission Regulation No 1234/2008, shall be submitted as Type II variation applications. The marketing authorisation holder may directly apply for a Type II variation status for a previously unclassified variation. When a previously unclassified Type IB variation application is inspected, Fimea may order it to be changed into a Type II variation.

Type II variations require applying for authorisation by Fimea. The required material shall be annexed to the application for authorisation: additional information on the variation applied for, resulting changes to the documents, and an expert opinion, review or summary justifying the variation.

Fimea will process Type II variations to medicinal products that have been granted a marketing authorisation or registration under the national procedure within 60 days of receiving the valid application, except for those variations that will be processed within 90 days. After a possible clock-stop, the appropriateness of the variation will be reviewed within the next 30 days. A decision will be issued on all Type II variations, whether they are part of the national procedure or the mutual recognition procedure.

If the proposed variation results in changes to the summary of product characteristics, package leaflet or the labelling for a medicinal product that has been granted a marketing authorisation or registration under the national procedure, the new proposed documents and the previously approved documents mentioned above, in which the changes are clearly marked, shall be annexed to the application.

It is not necessary to annex proposals for national summaries of product characteristics, patient leaflets or sales package labelling to a Type II variation application in a mutual recognition procedure when the application is submitted. National texts shall be submitted to Fimea only immediately after the mutual recognition procedure has ended as electronic (Word) documents.

Type II variation applications are handled in accordance with Commission Regulation 1234/2008. The administrative process is described in more detail in guidelines issued by CMD.

Section 35, subsection 2 of the Medicines Act defines a specific type of packaging known as an emergency package. An application for the use and distribution mentioned in the Medicines Act can be submitted if an emergency package is necessary because of the nature and indication of the medicinal product.

An authorisation for an emergency package may be sought for a medicinal product that is considered necessary for urgent medical treatment to be started immediately. Such urgent initiation of treatment is mainly needed for the treatment of infections and acute pain. An emergency package is only intended to suffice for 1 to 2 days of treatment.

An authorisation for an emergency package is always sought nationally as a Type II variation. The rationale for the need of this type of package shall be annexed to the variation application.

### 8.2.4 Urgent safety restrictions

Notwithstanding the above provisions, the marketing authorisation holder may set temporary restrictions deviating from the summary of product characteristics on the use of a medicinal product in accordance with Article 22 of Commission Regulation No 1234/2008. This may be done when it is suspected that the product may pose a threat to human or animal health if it is used according to the summary of product characteristics.

Urgent restrictions may include restrictions on the indications or dosage or, for veterinary medicinal products, restrictions on target animal species. They may also include withdrawal periods or the addition of contraindications or warnings. Fimea shall be immediately notified of such measures. If Fimea does not take any measures within 24 hours of the notification, the restriction on use is considered to be approved.

The timetable for implementing urgent safety-related restrictions is agreed with Fimea. After the notification has been submitted, the MAH shall immediately submit an application to Fimea for a variation to the marketing authorisation in accordance with the classification guidelines published by the Commission. The application shall be submitted within a maximum of 15 days from the date on which the urgent safety-related restriction was made.

Fimea may also introduce urgent safety-related restrictions of a temporary nature. In this case, the MAH shall immediately submit to Fimea a variation application on the matter according to the classification guidelines published by the Commission. The safety-related restrictions stated by Fimea shall be taken into account in the application. In these cases, too, the application shall be submitted within a maximum of 15 days from the date on which the urgent safety-related restriction was made.

The above guidelines also apply to registered products.

### 8.2.5 Extensions to a marketing authorisation and registration

(Annex I to Commission Regulation (EC) No 1234/2008)

In some cases, the change to a marketing authorisation or registration already granted is so considerable that an application shall be made for an extension to the marketing authorisation or registration for the medicinal product. Changes to the marketing authorisation requiring an extension to the marketing authorisation or registration are presented in Annex I to Commission Regulation (EC) No 1234/2008. Further guidelines can be found in Volumes 2C and 6C of NtA (Guideline on the Categorisation of New Applications (NA) versus Variation Applications).

### 8.2.6 Grouping variations

In accordance with Article 7 of Commission Regulation No 1234/2008, the MAH may in certain cases group several variations together into one application. These cases are listed in Annex III of Commission Regulation No 1234/2008.

If a grouped variation application contains variation applications of various levels, the application shall be submitted and it will be processed according to the requirements for the most extensive variation application. The administrative process is described in more detail in guidelines issued by CMD.

Variation applications for medicinal products granted marketing authorisation or registered under the national procedure and those registered under the mutual recognition or the decentralised procedure can be grouped together.

### 8.2.7 Worksharing procedure

In accordance with Article 20 of Commission Regulation No 1234/2008, the MAH may in certain cases apply for worksharing procedure for a Type IB variation, Type II variation or variation grouping.

The administrative process is described in more detail in guidelines issued by CMD.

## 8.3 Other notifications and changes to a marketing authorisation and registration

### 8.3.1 Changes to labelling and package leaflets for medicinal products

Fimea shall be notified of any changes to the labelling and package leaflets for medicinal products for human use 90 days before the changes are made, in accordance with Article 61.3 of the Medicinal Products Directive. Labelling changes in veterinary medicinal products are variation applications in accordance with Commission Regulation No 1234/2008. An accompanying letter, new proposed package leaflets and labelling, and the previously approved documents in which the changes are clearly marked shall be annexed to the notification.

The change may be made unless Fimea states within 90 days that the change has not been approved. Fimea will inform the marketing authorisation or registration holder of the approved version (date) of the document (package leaflet).

Notifications concerning package leaflets or labelling harmonised under the mutual recognition procedure or the decentralised procedure will be processed as detailed in the guidelines issued by the CMD.

Electronic package leaflets do not need to be submitted for registered homeopathic and anthroposophic preparations. These preparations only need a package leaflet in exceptional cases.

### 8.3.2 Transferring a marketing authorisation or registration to a new holder

The transfer of a marketing authorisation or a registration to a new holder must be granted authorisation by Fimea, which will be processed within 120 days of the arrival of a valid application for processing at Fimea. The application shall be submitted by the present marketing authorisation holder. A separate application may be made for the transfer, in which case the transfer is subject to a fee, as laid down in the Decree of the Ministry of Social Affairs and Health on chargeable services of Fimea. However, the transfer is included in the annual fee if it is carried out in conjunction with the renewal of the marketing authorisation or registration.

Applications for the transfer of a marketing authorisation or registration may take the form of a letter stating the name of the product, its strength, pharmaceutical form, marketing authorisation or registration number and to whom the marketing authorisation or registration is to be transferred (i.e. the new holder's name, address and the contact person). An agreement on the transfer showing that the marketing authorisation or registration and the associated responsibilities and liability will be transferred to the new holder in their entirety shall also be annexed to the application, along with proposals for summaries of product characteristics, package leaflets and labelling.

The new marketing authorisation or registration holder shall submit the name and contact information of the person responsible for pharmacovigilance to Fimea. Any changes to pharmacovigilance shall be submitted according to Commission Regulation No 1234/2008, observing the guidelines for Good Vigilance Practices (GVP) provided on the EMA website.

The marketing authorisation or registration is transferred to the new holder on the day Fimea issues a decision on approval of the transfer, or at a time separately agreed upon with the applicant. The new marketing authorisation or registration holder shall submit a notification when the medicinal product has been placed on the market with the new holder's labelling. At the same time, the new marketing authorisation or registration holder shall ensure that the previous holder's packages are withdrawn from medicinal product wholesalers, pharmacies, hospital pharmacies and dispensaries. Fimea's provisions on potential simultaneous marketing are set out in section 8.4 of this Administrative Regulation.

### 8.3.3 Dose-dispensing package

The term dose-dispensing package is used to describe a package size for a medicinal product that is used for dispensing medicines as single doses for individual patients for a specific treatment period.

Authorisation for a dose-dispensing package size can be applied for medicinal products that have been granted a marketing authorisation under the national, mutual recognition and centralised procedures using the national Type IB variation application.

Results of stability studies must be provided where the product is stored outside its original packaging (25°C, 60% relative humidity). The results shall cover the entire shelf life of the product applied for. A report on the product's photosensitivity must also be provided.

The aforementioned stability study results may also be submitted for a package size that has already been approved for the assessment of suitability for dose-dispensing using the national Type IB variation application.

## 8.4 8.4 Availability on the market of a product in packages of two different holders, in two different compositions or under two different names, and other exceptions

A medicinal product cannot be on the market simultaneously in the packages of two different marketing authorisation holders, in two different compositions or with two different names. However, if the transfer to the new holder of responsibilities and liability relating to the packages of the old holder in connection with the transfer of the marketing authorisation or registration has been included in the contract between the holders, the packages of the old holder and the new one can be simultaneously released for distribution for a maximum of six months. When the medicinal product concerned is a registered product that has not been ordered to be only sold at pharmacies at the time of registration, the packages belonging to the old holder may not be released for distribution in Finland to product retailers.

Similarly, for a justified reason, packages corresponding to the new composition and the old one, as well as one and the same product under both its new trade name and the old one, may be simultaneously released for distribution in Finland for a maximum of six months. In all such cases, the

marketing authorisation or registration holder shall present the request for simultaneous marketing and the justification in connection with the variation application in question.

For a justified reason, Fimea may grant a batch-specific exemption from the requirements of the marketing authorisation or the registration, having received a separate application by the marketing authorisation or registration holder, if an interruption in the availability of a product critical for the Finnish pharmaceutical services would otherwise be expected.

# 9 GUIDANCE AND INFORMATION

Fimea will provide, on request, guidance and advice on the application of this normative guideline.

# 10 ENTRY INTO FORCE

This Administrative Regulation enters into force on 9 February 2019.

Director General Eija Pelkonen

Head of Section Leena Pietilä

**DISTRIBUTION**

Pharmaceutical manufacturers

Pharmaceutical wholesalers

Persons responsible for placing medicinal products on the market

Finnish Food Authority

National Institute for Health and Welfare

Finnish Red Cross Blood Service

**FOR INFORMATION**

Parliamentary Ombudsman

Chancellor of Justice

The Ministry of Social Affairs and Health

Ministry of Trade and Industry

Ministry of Agriculture and Forestry

The Social Insurance Institution of Finland

National Supervisory Authority for Welfare and Health

The Finnish Consumer Agency

Pharma Industry Finland

Finnish Generic Pharmaceutical Association

Finnish Importers of Veterinary Medicines

Finnish Game and Fisheries Research Institute

Finnish Association of Pharmaceutical Distributors

Central Organisation of Health and Food Trade in Finland

Health Product Wholesalers' and Manufacturers' Association

Finnish Natural Product Traders' Association

The Finnish Grocery Trade Association

University of Helsinki, Faculty of Veterinary Medicine

University of Helsinki, Faculty of Pharmacy

University of Helsinki, Faculty of Medicine

University of Eastern Finland, Faculty of Health Sciences, School of Pharmacy

University of Eastern Finland, Faculty of Health Sciences, School of Medicine

University of Eastern Finland Pharmacy

University of Oulu, Faculty of Medicine

University of Tampere, Faculty of Medicine

University of Turku, Faculty of Medicine

Åbo Akademi University, Department of Biochemistry and Pharmacy

The Association of Finnish Pharmacies

The Finnish Veterinary Association

The Finnish Pharmacists' Association

Finnish Dental Association

The Finnish Medical Association

The Finnish Pharmacists' Society

The Association of Finnish Local and Regional Authorities

University Pharmacy

The Association of Finnish Homeopaths

The Finnish Association for Anthroposophic Medicine

Regulation
ISSN-L 1798-6567
ISSN 1798-6567