LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

This is a translation of the Danish Medicines Act (Danish title: Lov om lægemidler). Only the Danish version has legal validity.

Danish Medicines Act[1] (Consolidated)
Danish Ministry of Health

Part I

Purpose and scope

1. The purpose of the Act is to ensure that the citizens

(i) have access to safe and effective medicinal products of a high quality,

(ii) have access to objective and adequate information about medicinal products, and

(iii) are protected against misleading advertising and other illegal marketing of medicinal products.

2. For the purpose of this Act, the following definitions apply:

(i) Medicinal product: Any product

(a) presented as having properties for treating or preventing disease in human beings or animals, or

(b) which may be used in or administered in human beings or animals with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

(ii) Intermediate product: A mixture of active substances and excipients intended for further processing into medicinal products.

(iii) Active substance: Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to making a medical diagnosis.

(iv) Excipient: Any constituent of a medicinal product other than the active substance and the packaging material.

3.-(1) The Act covers medicinal products for human beings and animals.

(2) Any provision covering medicinal products is also applicable to contraceptives that are not comprised by section 2(i) or by the Act on medical devices.

(3) To the extent that it appears from the individual provisions, the Act also applies to the following products that are not comprised by section 2(i):

(i) Intermediate products intended for further processing into medicinal products.

(ii) Active substances and excipients.

(iii) Certain substances that may be used as veterinary medicinal products.

(4) Sections 65 and 71 of the Act also cover advertisements for certain products other than medicinal products.

4.-(1) The Act does not apply to foodstuffs and dietary supplements, animal feed, cosmetics, biocides, radionuclides in the form of sealed sources, medical devices, unprocessed tissue and cells of human origin as well as whole blood, blood cells and plasma of human origin, except for plasma used as a raw material in the manufacture of medicinal products, but see subsection (2) and sections 65 and 71.

[1] Danish act no. 1180 of 12 December 2005 on medicinal products as amended by section 81 in act no. 538 of 8 June 2006, section 1 in act no. 1557 of 20 December 2006, section 1 in act no. 534 of 17 June 2008, section 1 in act no. 464 of 18 May 2011, section 46 in act no. 593 of 14 June 2011, section 1 in act no. 605 of 18 June 2012, section 1 in act no. 1258 of 18 December 2012 and section 1 in act no. 63 of 29 January 2013.

(2) Where, on the basis of an overall assessment of its characteristics, a product may be comprised both by the definition of a medicinal product and by the definition of a product within another legislative area and there is doubt as to the legislation by which the product should be governed, the Danish Medicines Agency may decide that the relevant product or product group must be governed exclusively by this Act. Following discussions with the relevant minister, the Minister for Health may lay down specific rules for such products or product groups.

4A Notwithstanding section 3(1) and section 4(2), the Act does not apply to advanced therapy medicinal products, which are prepared at a hospital in Denmark for a specific patient in compliance with the specific instructions of a doctor.

5. Pursuant to the Minister for Health's decision, specified products or product groups covered by section 2(i) may be excluded, in whole or in part, from the Act if deemed appropriate because of their characteristics. The Minister for Health lays down specific rules for such products or product groups.

6. The Minister for Health may lay down rules to the effect that the Act or parts of the Acts does not apply to medicinal products authorised or to be authorised for marketing in the European Union pursuant to rules laid down by the European Community and may lay down rules for such exceptions.

Part II

Marketing authorisation and other authorisations for sale and dispensing

Granting of marketing authorisation

7.-(1) A medicinal product may only be marketed or dispensed in Denmark when a marketing authorisation has been granted either by the Danish Medicines Agency pursuant to this Act or by the European Commission pursuant to the provisions of Community law laying down Community procedures for authorisation and pharmacovigilance of medicinal products for human and veterinary use etc. (Community marketing authorisation), but see subsection (2) and sections 11 and 29-32.

(2) A medicinal product may only be marketed online to users in other EU/EEA countries if, in addition to being covered by a marketing authorisation as mentioned in subsection (1), it is covered by a marketing authorisation applicable in the country of destination pursuant to Article 6(1) in Directive 2001/83/EC or Article 6(1) of Directive 2001/82/EC.

8.-(1) Following application, the Danish Medicines Agency grants a marketing authorisation for a medicinal product if the benefit-risk ratio is favourable and there are no grounds for refusal as specified in sections 12 and 13.

(2) In the evaluation of the benefits and risks afforded by a medicinal product, the positive therapeutic effects should be balanced against any risks relating to the quality, safety and efficacy of the product, and any risks of an undesirable environmental impact, but see section 12(2).

(3) If the application relates to a veterinary medicinal product for purposes other than the treatment or prevention of disease (zootechnical purposes), the evaluation specified in subsection (2) should particularly take into account benefits relating to animal health and welfare and consumer safety.

9.-(1) The Danish Medicines Agency may attach terms to the marketing authorisation when it is granted.

(2) Where required by special circumstances, the Danish Medicines Agency may also attach terms to the marketing authorisation after it has been granted.

(3) The Minister for Health lays down rules on the Danish Medicines Agency's review of the terms imposed pursuant to subsection (1).

10. In connection with the granting of a marketing authorisation, the Danish Medicines Agency approves a summary of product characteristics.

11. Notwithstanding the provision in section 7(1), no marketing authorisation is required for the following medicinal products:

(i) Medicinal products prepared in a pharmacy for an individual patient or animal in accordance with a prescription from a doctor or a veterinarian (the magistral formula).

(ii) Inactivated and non-inactivated immunological veterinary medicinal products manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality.

(iii) Medicinal products for non-clinical and clinical trials, see Part XI.

(iv) Medicated feedingstuffs.

Refusal as well as variation, suspension and withdrawal of a marketing authorisation

12.-(1) The Danish Medicines Agency refuses to grant a marketing authorisation for a medicinal product if

(i) the benefit-risk ratio is not favourable, but see subsection (2),

(ii) the therapeutic efficacy is lacking or is insufficiently substantiated by the applicant for the marketing authorisation, or

(iii) the qualitative or quantitative composition of the medicinal product is not as declared.

(2) For medicinal products for human use, the risk of an undesirable environmental impact is not, viewed in isolation, sufficient to justify the refusal of a marketing authorisation.

13.-(1) In addition to the cases stated in section 12, the Danish Medicines Agency can refuse to grant a marketing authorisation for a veterinary medicinal product if

(i) the labelling or package leaflet does not comply with the rules laid down under section 57,

(ii) the withdrawal period stated is insufficient to ensure that foodstuffs originating from the treated animal do not contain any residues that may jeopardise consumer health or the withdrawal period is insufficiently substantiated,

(iii) the medicinal product will be offered for sale for a purpose, which is prohibited under other Community legislation,

(iv) it is necessary for the protection of public health, consumers or animal health while Community rules on the issue are being drafted, or

(v) the medicinal product is intended for administration to one or more food-producing animal species and the pharmacologically active substances in the medicinal product are not listed in annexes I, II or III to Council Regulation laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (medicinal product residues regulation).

(2) Notwithstanding subsection (1)(v), the Danish Medicines Agency may lay down specific rules on the granting of marketing authorisations for medicinal products intended for specified animals of the equidae family.

14.-(1) The Danish Medicines Agency can vary, suspend or withdraw a marketing authorisation for a medicinal product if it turns out that

(i) the benefit-risk ratio is not favourable,

(ii) the qualitative or quantitative composition of the medicinal product is not as declared,

(iii) essential information stated by the applicant in support of the marketing authorisation application is incorrect, or

(iv) self-audit according to the rules laid down under section 39B(i)-(iii) has not been carried out.

(2) The Danish Medicines Agency may vary, suspend or withdraw a marketing authorisation for a medicinal product if

(i) the marketing authorisation holder fails to fulfil any terms attached to the authorisation under section 9(1),

(ii) the labelling or package leaflet does not comply with the rules laid down under section 57, or

(iii) the marketing authorisation holder amends the summary of product characteristics or any documents forming the basis of the marketing authorisation without authorisation from the Danish Medicines Agency to do so, see section 26(1).

15.-(1) In addition to the cases specified in section 14, the Danish Medicines Agency can vary, suspend or withdraw the marketing authorisation for a medicinal product for human use if

(i) the marketing authorisation holder has failed to take into account new information about the technical and scientific development in accordance with section 21, or

(ii) the marketing authorisation holder has failed to inform the Danish Medicines Agency of new information about the relationship between the benefits and risks afforded by the medicinal product in accordance with section 25(1).

(2) The Danish Medicines Agency may vary, suspend or withdraw a marketing authorisation for a medicinal product for human use if

(i) the medicinal product is not manufactured in compliance with the description of the manufacturing method appearing from the marketing authorisation application and any subsequent changes thereto, or

(ii) the marketing authorisation holder fails to perform the control activities pursuant to the control methods appearing from the marketing authorisation application and any subsequent changes thereto.

16.-(1) In addition to the cases specified in section 14, the Danish Medicines Agency can vary, suspend or withdraw the marketing authorisation for a veterinary medicinal product if

(i) the withdrawal period stated is insufficient to ensure that foodstuffs originating from the treated animal do not contain any residues that may jeopardise consumer health,

(ii) the medicinal product is or will be offered for sale for a purpose, which is prohibited under other Community legislation, or

(iii) the marketing authorisation holder fails to take the action required under section 26(2).

(2) The Danish Medicines Agency may vary, suspend or withdraw a marketing authorisation for a veterinary medicinal product if

(i) the marketing authorisation holder has failed to take into account new information about the technical and scientific development in accordance with section 21,

(ii) the marketing authorisation holder has failed to inform the Danish Medicines Agency of new information about the relationship between the benefits and risks afforded by the medicinal product in accordance with section 25(1), or

(iii) it is necessary for the protection of public health, consumers or animal health while Community rules on the issue are being drafted.

17.-(1) The Danish Medicines Agency notifies the European Medicines Agency, the European Commission and the national authorities responsible for medicinal products in the other EU/EEA countries when urgent action is considered necessary as a result of the evaluation of data relating to pharmacovigilance if

(i) the Danish Medicines Agency considers suspending or withdrawing a marketing authorisation for a medicinal product for human use,

(ii) the Danish Medicines Agency considers prohibiting the supply of a medicinal product for human use,

(iii) the Danish Medicines Agency considers refusing the renewal of a marketing authorisation for a medicinal product for human use,

(iv) the Danish Medicines Agency is informed by the marketing authorisation holder that, on the basis of safety concerns, he has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or that he intends to do so, or

(v) the Danish Medicines Agency considers that a new contraindication, a reduction in the recommended dose, or a restriction to the indications for a medicinal product for human use is necessary.

(2) A swift assessment concerning a medicinal product covered by subsection (1) is made by the Danish Medicines Agency if the medicinal product is authorised for sale or dispensing in Denmark only. If the medicinal product is authorised for sale or dispensing in more than one EU/EEA country, the assessment of the medicinal product is processed according to a special Urgent Union Procedure.

(3) The Minister for Health may lay down specific rules on the assessment of medicinal products covered by subsection (2) second sentence.

(4) If the Danish Medicines Agency suspends a marketing authorisation for a medicinal product for human use with immediate effect in order to protect the health of humans, see section 14(1), as a result of the evaluation of pharmacovigilance data, the Danish Medicines Agency will notify the European Medicines Agency, the European Commission and the national authorities responsible for medicinal products in the other EU/EEA countries no later than the following working day of its actions.

17A.-(1) The Danish Medicines Agency will notify the European Medicines Agency if the Agency initiates any case of suspension or withdrawal of a marketing authorisation for a medicinal product for human use.

(2) The Danish Medicines Agency will inform the European Medicines Agency, the national authorities responsible for medicinal products in the other EU/EEA countries and the marketing authorisation holder in the event of new risks or risks that have changed or changes to the risk-benefit balance of a medicinal product being detected.

17B.-(1) The Danish Medicines Agency will notify the European Medicines Agency if the Agency initiates any case of suspension or withdrawal of a marketing authorisation for a veterinary medicinal product.

(2) If the Danish Medicines Agency suspends a marketing authorisation for a veterinary medicinal product with immediate effect in order to protect the health of humans and animals, see section 14(1), the Danish Medicines Agency will notify the European Medicines Agency, the European Commission and the national authorities responsible for medicinal products in the other EU/EEA countries no later than the following day of its actions.

Requirements relating to marketing authorisations

18. Applicants for and holders of marketing authorisations must be established in an EU/EEA country. The holder may designate a representative.

19.-(1) The responsibility of the marketing authorisation holder under other legislation is not affected by the granting of a marketing authorisation.

(2) The marketing authorisation holder is responsible for the marketing of the medicinal product. The designation of a representative, see section 18, does not relieve the marketing authorisation holder of his responsibility.

20. The applicant for or holder of a marketing authorisation must ensure that any documents and data submitted to the Danish Medicines Agency are adequate and true.

21.-(1) The marketing authorisation holder must take into account the technical and scientific development and make any changes necessary for the medicinal product to be manufactured and controlled in accordance with generally recognised scientific methods.

(2) The marketing authorisation holder of a medicinal product for human use must ensure that the information in the medicinal product's summary of product characteristics, package leaflet and labelling is kept up to date with the current knowledge, including the conclusions of the

assessments and recommendations published on the European Medicines Agency's medicines web-portal.

22.-(1) The marketing authorisation holder must inform the Danish Medicines Agency of when the actual marketing of the medicinal product commences and when the marketing ceases, either temporarily or permanently.

(2) Notification to Medicinpriser, see section 82, and notification in accordance with rules laid down in pursuance of section 78 are deemed to constitute notification in accordance with subsection (1).

23. A marketing authorisation holder must inform the Danish Medicines Agency of the reason if the holder decides to withdraw a marketing authorisation and to withdraw any surplus stock and if the marketing ceases, temporarily or permanently, on grounds of the quality, safety or efficacy of the medicinal product.

24. The marketing authorisation holder must inform the Danish Medicines Agency immediately if an error is found in the manufacture of a medicinal product, which may have an impact on the quality, safety or efficacy of the product.

25.-(1) The marketing authorisation holder of a medicinal product must immediately inform the Danish Medicines Agency of any significant new data about the benefit-risk ratio of the medicinal product that the Danish Medicines Agency is not informed of according to the procedure for authorising variations of marketing authorisations or in the form of periodic safety update reports. If this information concerns a medicinal product for human use, the European Medicines Agency must also be informed.

(2) The Danish Medicines Agency may at any time order the marketing authorisation holder to substantiate that the benefit-risk ratio remains favourable.

(3) The Danish Medicines Agency monitors compliance with the requirement stipulated in subsection (1), and the representatives of the Agency must, on the presentation of appropriate identification and without a court order, have access to companies in order to conduct inspection in this connection.

26.-(1) A holder of a marketing authorisation granted by the Danish Medicines Agency must apply to the Agency for authorisation of any variation of the summary of product characteristics and of the documents forming the basis of the marketing authorisation (variation application).

(2) In the event that amendments are made to the annexes to the medicinal product residues regulation, the holder of a marketing authorisation for a veterinary medicinal product must no later than 60 days after the publication of such amendments apply to the Danish Medicines Agency for permission to make the changes required or withdraw the marketing authorisation himself.

Period of validity, renewal and cessation of validity of marketing authorisations

27.-(1) A marketing authorisation for a medicinal product is valid for five years, but see subsection (2) and sections 14-16.

(2) The Danish Medicines Agency may renew the marketing authorisation if the benefit-risk ratio remains favourable. A marketing authorisation that has been renewed is valid for an unlimited period, but see subsection (3) and sections 14-16.

(3) The Danish Medicines Agency may decide that the marketing authorisation is renewed only for five years on grounds justified by the benefit-risk ratio, including as a result of assessments of pharmacovigilance data.

(4) An application to renew a marketing authorisation for a medicinal product for human use must be submitted to the Danish Medicines Agency by the marketing authorisation holder no later than nine months before the authorisation expires.

(5) An application to renew a marketing authorisation for a veterinary medicinal product must be submitted to the Danish Medicines Agency by the marketing authorisation holder no later than six months before the authorisation expires.

28.-(1) A marketing authorisation ceases to be valid if the medicinal product has not been marketed for three consecutive years.

(2) In special circumstances and in consideration of the health of humans or animals, the Danish Medicines Agency may derogate from the provision in subsection 1.

Other authorisations for sale or dispensing of medicinal products

29.-(1) In special circumstances, following application, the Danish Medicines Agency may authorise the sale or dispensing in limited amounts of medicinal products, which are not covered by a marketing authorisation or not marketed in Denmark (compassionate use permit).

(2) The Danish Medicines Agency may attach terms to the compassionate use permit and may withdraw the permit if such terms are not fulfilled or if serious problems occur relating to the quality, safety or efficacy of the medicinal product, including serious adverse reactions.

(3) The Danish Medicines Agency may lay down rules on the distribution of medicinal products covered by an authorisation under subsection (1).

30. Upon request, Statens Serum Institut and the National Veterinary Institute DTU may in special cases and in limited quantities sell or dispense sera, vaccines, specific immune globulins and other immunological investigational medicinal products not covered by a marketing authorisation. The Danish Medicines Agency must be informed of every sale or dispensing.

31.-(1) Where required by health considerations or other special considerations, the Danish Medicines Agency may, pursuant to rules laid down by the Minister for Health, authorise the use and marketing of medicinal products not covered by a marketing authorisation in Denmark. The Minister may also lay down rules on variation, suspension and withdrawal of such authorisations.

(2) The Danish Medicines Agency will notify the European Commission of any authorisations granted pursuant to subsection (1).

32.-(1) In the event of suspicion or confirmation of the spreading of pathogenic agents, toxins, chemical agents or nuclear radiation, the Danish Medicines Agency may temporarily authorise the dispensing of a medicinal product notwithstanding that the medicinal product is not covered by a marketing authorisation.

(2) The Minister for Health may lay down rules to the effect that in the situations specified in subsection (1) marketing authorisation holders, manufacturers and healthcare professionals will not be held liable for any consequences of the use of

(i) a medicinal product outside its approved indications, or

(ii) a medicinal product not covered by a marketing authorisation.

(3) No person can be relieved of any responsibility under the Act on product liability by virtue of any rules laid down pursuant to subsection (2).

The Danish Medicines Agency's handling of cases concerning marketing authorisations and other authorisations for sale or dispensing of medicinal products

33. In Denmark, the Danish Medicines Agency is in charge of the work relating to the processing of applications for marketing authorisation in accordance with the mutual recognition procedure and the decentralised procedure resulting from the rules in the directives of the European Parliament and the Council on the establishment of a Community code relating to medicinal products for human and veterinary use.

34. The Minister for Health lays down rules on:

(i) The information which must accompany an application for the granting or renewal of a marketing authorisation, including information on the quality, safety and efficacy of a

medicinal product and its possible environmental impact as well as any requirements to be met by an application for granting or renewal of a marketing authorisation.

(ii) Special conditions for the granting of a marketing authorisation for
  (a) natural medicinal products,
  (b) vitamin and mineral products, and
  (c) homeopathic medicinal products.

(iii) Special conditions for registration of homeopathic medicinal products and traditional herbal medicinal products.

(iv) The special conditions to be fulfilled for a radiopharmaceutical to be given a marketing authorisation.

(v) The Danish Medicines Agency's assessment of marketing authorisation cases and notification to the European Medicines Agency about the Agency's established terms for assessment.

(vi) The Danish Medicines Agency's processing of the cases specified in section 33 and cases relating to Community marketing authorisations.

35. For the purposes of the Danish Medicines Agency's processing of applications for marketing authorisations and cases relating to granting, renewal, variation, suspension or withdrawal of a marketing authorisation, the Danish Medicines Agency is entitled to order the applicant for or the holder of a marketing authorisation to hand over or disclose information, including written material, samples of the medicinal product, including its packaging, and samples of intermediate products, active substances and excipients.

36. The Danish Medicines Agency may lay down specific rules on which information should be included in applications and notifications pursuant to sections 22-27, 29 and 30 as well as any deadlines set for submission of such applications and notifications.

37. The Danish Medicines Agency may lay down formal requirements for submission of applications and notifications pursuant to the provisions of this Part, including a requirement for electronic submission.

38. The Danish Medicines Agency maintains a register of the medicinal products for which authorisation is applied and which are authorised by way of a marketing authorisation pursuant to the provisions of this Part.

Part III

Manufacturing, import, distribution, brokering, etc. of medicinal products and intermediate products

38A.-(1) Any manufacture, import, export, storage, distribution, brokering or dispensing of falsified medicinal products will be prohibited, but see subsection (2).

(2) A person holding an authorisation under section 7(1) may in limited quantities import, export and store medicinal products that have been purchased to detect a possible occurrence of falsified medicinal products among the medicinal products covered by the authorisation.

39.-(1) Any manufacture, import, export, storage, distribution, providing, dispensing, splitting and packaging of medicinal products is subject to authorisation from the Danish Medicines Agency.

(2) Any manufacture, import, export, storage, distribution and providing of intermediate products intended for further processing into medicinal products is subject to authorisation from the Danish Medicines Agency.

(3) The provision of subsection (1) does not apply to:

(i) the providing, splitting and dispensing by hospitals and other healthcare institutions of medicinal products to be used in treatment,

(ii) the providing, splitting and dispensing by doctors, veterinarians and dentists of medicinal products for use in practice,

(iii) the import and export by private individuals for personal use of medicinal products for human use,

(iv) the providing, splitting and dispensing of medicinal products for human use by shipmasters and -owners for use on board and the import of such medicinal products when calling at ports in foreign countries,

(v) companies' import, export and storage of medicinal products as mentioned in section 38A(2).

(4) The Danish Medicines Agency may lay down rules on the handling of medicinal products mentioned in subsection (3)(i)-(v).

39A.-(1) The Minister for Health lays down rules on:

(i) any information to accompany an application for authorisation under section 39(1) and (2) and on the conditions for authorisation,

(ii) format requirements for the applications mentioned in (i), including that the application must be submitted electronically,

(iii) the Danish Medicines Agency's processing of applications for authorisation pursuant to section 39(1) and (2),

(iv) the Danish Medicines Agency's disclosure of information on authorisations granted pursuant to section 39(1) and (2), on variation, suspension and withdrawal of such authorisations and on control activities carried out pursuant to section 44 to the European Medicines Agency, the European Commission and the national authorities responsible for medicinal products in the other EU/EEA countries.

(2) To ensure compliance with the conditions laid down under subsection (1)(i), the Danish Medicines Agency may attach terms to the authorisation, including restrict the duration of authorisation.

39B. The Danish Medicines Agency lays down rules on:

(i) requirements for technical management, specialist knowledge, organisation and operation of persons holding an authorisation under section 39(1) and (2),

(ii) requirements for the active substances and excipients which persons holding an authorisation under section 39(1) or (2) use in the manufacture of medicinal products or intermediate products,

(iii) the actions which persons holding an authorisation under section 39(1) or (2) to manufacture medicinal products or intermediate products must undertake to ensure that the active substances and excipients used in the manufacture of medicinal products or intermediate products comply with the requirements laid down pursuant to (ii),

(iv) the dispatch of medicinal products to users for persons holding an authorisation under section 39(1), including rules on obligatory information to be placed on the medicinal product parcel.

40. The Danish Medicines Agency may vary, suspend or withdraw an authorisation granted under section 39(1) and (2) if the conditions for the authorisation or the terms attached to it are not being met, or if the holder of the authorisation grossly or repeatedly has violated any of the rules issued pursuant to section 39B(i)-(iii) or section 40B or refuses to participate in the Danish Medicines Agency's control under section 44.

Distribution of medicinal products for production animals

40A.-(1) Persons holding an authorisation under section 39(1) to sell medicinal products for production animals to users of such products, have the right to sell and dispense all non-prescription medicinal products intended for production animals.

(2) Persons holding an authorisation under section 39(1) to sell medicinal products for production animals to users of such products can sell or dispense no other products than medicinal products for production animals and may only in special cases and subject to the approval of the Minister

for Health carry on activities other than those set out in subsection (1) and rules issued pursuant to section 40B.

(3) Persons holding an authorisation under section 39(1) to sell medicinal products for production animals must not without the approval of the Danish Medicines Agency operate or be affiliated to another company whose authorisation issued under section 39(1) or (2) is not limited to the sale of medicinal products for production animals to users of such products.

40B. The Minister for Health lays down specific rules on the additional, special obligations imposed on persons holding an authorisation under section 39(1) to sell medicinal products for production animals to users of such products, including rules on

(i) provision, sale and dispensing of prescription-only medicinal products to users,
(ii) information and advice to users,
(iii) service targets,
(iv) collection of medicinal product residues,
(v) compliance with risk management programmes, see section 62,
(vi) presentation of accounts.

Online sale of medicinal products

41.-(1) Persons holding an authorisation under section 39(1) who within the scope of such authorisation intend to sell medicinal products online to users must notify the Danish Medicines Agency thereof no later than at the same time as the online sale begins.

(2) The Danish Medicines Agency maintains and publishes on its website a list of distributors having submitted a notification under subsection (1) and proprietary pharmacists having submitted a notification under section 43A(1) of the Danish act on pharmacy practice.

(3) The Danish Medicines Agency must make available on its website information about online sale of medicinal products, including the potential risks associated with buying medicinal products from internet domains that are not subject to regulatory control. The Minister for Health lays down specific rules to that effect.

41A. The Danish Medicines Agency lays down rules on the additional, special obligations imposed on persons having submitted a notification under 41(1), including rules on:

(i) The information to accompany the notification, and on the obligation to notify the Danish Medicines Agency about any changes to this information,
(ii) The format requirements for the notification, including that the notification must be submitted electronically,
(iii) The requirements for the internet domain offering medicinal products for sale, including rules on the information that must appear from the domain, requirements for its technical set-up and the obligation to display a common European safety logo.

Brokering of medicinal products

41B.-(1) Brokering of medicinal products is only permitted for persons having registered their activities with the Danish Medicines Agency and who appear from the list mentioned in subsection (2).

(2) The Danish Medicines Agency maintains and publishes on its website a list of brokers having registered with the Danish Medicines Agency according to subsection (1).

(3) The Danish Medicines Agency may delete a broker from the list mentioned in subsection (2) if the broker grossly or repeatedly infringes the rules issued pursuant to section 41D or refuses to participate in the Danish Medicines Agency's control activities under section 44.

41C. The Minister for Health lays down rules on:

(i) The information to accompany the registration notification under section 41B(1), and on the obligation to notify the Danish Medicines Agency about any changes to this information.

(ii) The format requirements for the notifications mentioned in section 41B(1), including that the notification must be submitted electronically.

(iii) The Danish Medicines Agency's processing of notifications under section 41B(1).

41D. The Danish Medicines Agency lays down rules on the requirements for technical management, specialist knowledge, organisation and operation of brokers of medicinal products. The Danish Medicines Agency also lays down rules on the types of medicinal products that persons registered according to section 41B(1) are allowed to broker.

Notification of falsified medicinal products and intermediate products

42.-(1) Any person holding an authorisation under section 39(1) or (2) to manufacture medicinal products and intermediate products must immediately notify the Danish Medicines Agency and the marketing authorisation holder of the product in question if he obtains information that a medicinal product or intermediate product that he manufactures is, or may have been, falsified.

(2) Any person holding an authorisation under section 39(1) to distribute medicinal products, and any person registered under section 41B(1), must immediately notify the Danish Medicines Agency and, where applicable, the marketing authorisation holder of the product in question, if he receives or is offered to buy medicinal products which are or may be falsified.

(3) The Danish Medicines Agency may lay down rules on the content of and format requirements for the notifications mentioned in subsections (1) and (2), including that notifications must be submitted electronically.

(4) The Danish Medicines Agency may lay down rules providing that holders of an authorisation under section 7(1) must notify the Danish Medicines Agency on the discovery of falsified medicinal products.

42A. If the Danish Medicines Agency discovers or suspects to have discovered falsified medicinal products or intermediate products, it may disclose all information thereon to the marketing authorisation holder or the manufacturer for the medicinal product or intermediate product in question.

Information about failure to apply for marketing authorisation

43. Persons holding an authorisation under section 39(1) to manufacture or export medicinal products must upon request inform the Danish Medicines Agency of the reason why an application for a marketing authorisation for one or more of the medicinal products has not been submitted in Denmark.

Records

43A. Persons holding an authorisation under section 39(1) and proprietary pharmacists must keep records of the handling etc. of medicinal products. The Danish Medicines Agency lays down specific rules to this effect.

Association

43B.-(1) Persons holding an authorisation under section 7(1) or section 39(1) must notify the Danish Medicines Agency of any doctors, dentists and proprietary pharmacists associated with the company. This, however, does not apply to public hospitals.

(2) The Minister for Health lays down rules on the notification duty, including rules stipulating that notification must be submitted electronically.

Regulatory control

44.-(1) The Danish Medicines Agency monitors compliance with the requirements imposed by this Act and rules issued thereunder in relation to medicinal products and intermediate products and in relation to persons handling medicinal products or intermediate products.

(2) In order to conduct inspection relating to the monitoring specified in subsection (1) or to accommodate a request from another EU/ EEA country, the European Commission or the

European Medicines Agency, representatives of the Danish Medicines Agency must, on the presentation of appropriate identification and without a court order, have access to:

(i) Companies with an authorisation under section 7(1).

(ii) Companies with an authorisation under section 39(1) or (2).

(iii) Companies registered under section 41B(1).

(iv) Companies registered under section 50A(1).

(v) Companies manufacturing or importing excipients.

(3) The Danish Medicines Agency's control tasks are carried out in collaboration with the European Medicines Agency. As part of this collaboration, the Danish Medicines Agency exchanges information with the European Medicines Agency on planned and completed inspection visits.

(4) The Danish Medicines Agency prepares a report on every completed inspection visit pursuant to subsection (2).

(5) Notwithstanding the provisions of subsection (2)(v), the Danish Medicines Agency may carry out inspection visits at a company which manufactures or imports excipients if the company so requests.

44A. In order to carry out its control activities under section 44(1), the Danish Medicines Agency may free of charge against receipt take or demand to receive samples of medicinal products and products assumed to be medicinal products, including packaging and package leaflet, intermediate products, active substances and excipients. Furthermore, the Agency may demand all information and material necessary for the control function.

44B. The Danish Medicines Agency may order the holder of an authorisation under section 39(1) or (2), and any person registered according to section 41B(1), to change the execution of tasks, organisation, design or operation and may impose a deadline for the implementation of such changes to ensure compliance with the rules issued pursuant to section 39B, section 40B, section 41A(iii), or section 41D.

44C.-(1) The Danish Medicines Agency may confiscate any medicinal products and products assumed to be medicinal products, which are distributed to users in violation of section 7(1), section 39(1) or section 60(1). Furthermore, the Danish Medicines Agency may confiscate medicinal products and products assumed to be medicinal products, which in violation of the rules on private individuals' import of medicinal products for personal use are being imported from countries other than EU or EEA countries.

(2) Confiscation carried out pursuant to subsection (1) must take place subject to the confiscation provisions of Part 74 of the Danish Administration of Justice Act.

44D. The representatives of the Danish Veterinary and Food Administration must, on the presentation of appropriate identification and without a court order, have access to companies authorised under section 39(1) to sell medicated feedingstuffs for animals or fish. The representatives of the Danish Veterinary and Food Administration may demand to have presented and receive copies of order slips for medicated feedingstuffs prescribed by a veterinarian.

45. The Minister for Health may upon negotiation with the competent minister lay down rules to the effect that representatives from authorities sorting under the concerned competent ministers may carry out control activities on behalf of the Danish Medicines Agency and exercise the authorities which pursuant to section 44A and section 44C(1) first sentence of this Act have been assigned to the Danish Medicines Agency, for the purpose of ensuring the lawful distribution of medicinal products.

Part IIIA

Prohibition, warning, withdrawal, etc.

46.-(1) The Danish Medicines Agency may prohibit the sale and dispensing of a medicinal product and may order that the product should be withdrawn from the market if

(i) the benefit-risk ratio of the medicinal product is not favourable,

(ii) the therapeutic efficacy of the medicinal product is lacking,

(iii) the qualitative or quantitative composition of the medicinal product is not as declared,

(iv) self-audit relating to the medicinal product, its intermediate products, active substances or excipients in accordance with rules laid down under section 39B(i)-(iii) has not been carried out or any other requirement attaching to the grant of the authorisation under section 39(1) or (2) has not been fulfilled,

(v) the medicinal product originates from a company that has not been authorised by the Danish Medicines Agency under section 39(1) or (2) or that refuses to participate in the Danish Medicines Agency's control under section 44,

(vi) the medicinal product is not manufactured in compliance with the description of the manufacturing method appearing from the marketing authorisation and any subsequent changes thereto, or if the control activities performed do not comply with the control methods appearing from the marketing authorisation and any subsequent changes thereto,

(vii) there is reason to believe that the medicinal product presents a serious risk to public health,

(viii) the marketing authorisation for the medicinal product is suspended or withdrawn pursuant to sections 14-16, or

(ix) an order to comply with existing rules on labelling of medicinal products has not been complied with.

(2) The Danish Medicines Agency must inform the European Medicines Agency immediately about any decisions pursuant to subsection (1) and the grounds for such decisions.

(3) The Danish Medicines Agency may in special circumstances for a transitional period authorise the dispensing of a medicinal product pursuant to section 29 to patients who receive treatment with the medicinal product concerned even though the medicinal product has been imposed a prohibition or requirement according to subsection (1).

(4) The Minister for Health may lay down rules on the Danish Medicines Agency's handling of cases pursuant to subsection (1).

46A. The Danish Medicines Agency may require that the marketing and dispensing of a medicinal product not covered by a marketing authorisation, see section 7, or other authorisation for sale or dispensing of medicinal products, see sections 29-32, be stopped and may order the medicinal product to be withdrawn from the market.

Prohibition against manufacture and import

47. The Danish Medicines Agency may prohibit the manufacture or import of a medicinal product from a third country if a company with authorisation under section 39(1) is violating any rules on the manufacture or import of medicinal products laid down under section 39B(i)-(iii).

Monitoring and warnings

47A. The Danish Medicines Agency sets up a system, which is to prevent medicinal products suspected to present a danger to health from reaching the consumers. The Minister for Health lays down specific rules to that effect.

47B. If the Danish Medicines Agency assesses that a medicinal product which is sold or dispensed in Denmark poses a serious risk to public health, it must without any delay transmit a rapid alert notification to the competent authorities in the other EU/EEA countries and to all relevant actors in the supply chain in Denmark in accordance with rules laid down by the Minister for Health. If the Danish Medicines Agency assesses that any such medicinal products may have reached consumers, it must immediately issue a public warning against using the medicinal product.

Import of medicated feedingstuffs

48. The Danish Medicines Agency may lay down rules on import of medicated feedingstuffs prepared from pre-mix authorised in another EU/EEA country if, in terms of quantity and quality, the pre-mix corresponds to a pre-mix authorised by the Danish Medicines Agency.

The right of healthcare professionals to bring along medicinal products

49. Healthcare professionals and other staff, including ambulance drivers, established or working in another EU/EEA country who are requested to provide assistance in case of accidents and catastrophes in Denmark, by virtue of bilateral agreements with neighbouring countries or by virtue of an agreement between the Nordic countries to provide assistance in acute situations, may to a limited extent bring along medicinal products from their country of residence for the pre-hospital treatment. Such medicinal products may be brought along notwithstanding that the individual medicinal product is not covered by a marketing authorisation in Denmark, if the medicinal product has been authorised in the country in which the healthcare professional, etc. is established or working.

50.-(1) Pursuant to rules laid down by the Danish Medicines Agency, a veterinarian established in another EU/EEA country may to a limited extent bring along veterinary medicinal products for his treatment of animals in Denmark. Such medicinal products may be brought along notwithstanding that the individual medicinal product is not covered by a marketing authorisation in Denmark.

(2) A medicinal product brought along under subsection (1) must have been authorised in the country in which the veterinarian is established, and the composition of the medicinal product must correspond in terms of quantity and quality to a medicinal product authorised by the Danish Medicines Agency.

(3) Notwithstanding subsections (1) and (2), sera and vaccines for veterinary purposes must not be brought along.

Part IIIB

Manufacturing, import and distribution, etc. of active substances

50A.-(1) The manufacturing, import and distribution of active substances intended for use in the manufacture of medicinal products for human use, and which are covered by a marketing authorisation, must only be permitted for persons having registered their company with the Danish Medicines Agency and who appear from the list mentioned in subsection (2).

(2) The Danish Medicines Agency maintains and publishes on its website a list of manufacturers, importers and distributors having registered their company according to subsection (1).

(3) The Danish Medicines Agency may delete a company from the list mentioned in subsection (2) if the company grossly or repeatedly infringes the rules issued pursuant to section 50C or refuses to participate in the Danish Medicines Agency's control activities under section 50E.

50B. The Minister for Health lays down rules on:

(i) The information to accompany the registration notification under section 50A(1), and on the obligation to notify the Danish Medicines Agency about any changes to this information.

(ii) The time when the manufacture, import and distribution activities may begin after a registration notification has been submitted.

(iii) The format requirements for the notifications mentioned in (i), including the deadlines applicable to registration notifications and whether such notifications must be submitted electronically.

(iv) The Danish Medicines Agency's processing of the notifications mentioned in (i), including on any potential company visits.

(v) The Danish Medicines Agency's disclosure of the information which according to rules issued pursuant to (i) must accompany a registration notification under section 50A(1) to the European Medicines Agency.

50C. The Danish Medicines Agency lays down rules on technical management, specialist knowledge, organisation and operation of companies registered under section 50A(1), including rules on the conditions for the legal import of active substances, e.g. in the form of

(i) requirements for the manufacture of substances in the exporting country and

(ii) requirements for the exporting country's control and enforcement of good manufacturing practice for active substances and procedures in the event of findings relating to non-compliance with good manufacturing practice, unless the exporting country is included in the list referred to in Article 111b of Directive 2001/83/EC.

Notification about falsified active substances

50D. Any person registered under section 50A(1) and any person holding an authorisation under section 39(1) or (2) to manufacture medicinal products or intermediate products must immediately notify the Danish Medicines Agency if they receive or are offered to buy active substances, which are or may be falsified.

Regulatory control

50E.-(1) The Danish Medicines Agency monitors compliance with the requirements established in this Part and in rules established pursuant to section 50C.

(2) In order to monitor compliance under subsection (1) or to accommodate a request from another EU/EEA country, the European Commission or the European Medicines Agency, representatives of the Danish Medicines Agency must, on the presentation of appropriate identification and without a court order, have access to companies having registered under section 50A(1).

(3) The Danish Medicines Agency will prepare a report on every inspection visit completed pursuant to subsection (2).

50F. In order to monitor compliance under section 50E(1), the Danish Medicines Agency may free of charge against receipt take or demand to receive samples of active substances. Furthermore, the Danish Medicines Agency may demand all information and material necessary for the control function.

50G. The Danish Medicines Agency may order a company registered under section 50A(1) to change the execution of tasks, organisation, design or operation and may impose a deadline for the implementation of such changes to ensure compliance with the rules issued pursuant to section 50C.

Part IV

The quality of medicinal products

51.-(1) A medicinal product, including its packaging, and intermediate products, active substances and excipients must be of a satisfactory quality.

(2) The documentation for determining the quality must include information on

(i) the qualitative and quantitative constituents of the medicinal product,

(ii) the manufacturing method,

(iii) control methods with related acceptance criteria (specifications), and

(iv) shelf life.

(3) The methods specified in subsection (2)(ii) and (iii) must be described in such detail that they can be repeated in control analyses instigated by the Danish Medicines Agency.

52. The Danish Medicines Agency may lay down rules on the quality of medicinal products, including the quality of packaging, and the quality of intermediate products, active substances and excipients. The Danish Medicines Agency may establish such requirements as to quality in the form of standards in a pharmacopoeia or the like.

Part V

Adverse reactions to medicinal products

53.-(1) The holder of a marketing authorisation for a medicinal product must

(i) operate a pharmacovigilance system to monitor the safety of the medicinal product, assess the possibilities for risk minimisation and if necessary take appropriate measures,

(ii) keep a detailed description of the pharmacovigilance system applied and on request make a copy of such description available to the Danish Medicines Agency, but see subsection (2),

(iii) keep records of suspected adverse reactions,

(iv) make such records available to the Danish Medicines Agency,

(v) report information on suspected adverse reactions to the Danish Medicines Agency or the European Medicines Agency,

(vi) prepare and submit periodic safety update reports to the Danish Medicines Agency, and

(vii) have at his disposal a qualified person for pharmacovigilance residing in the EU.

(2) Subsection (1)(ii) does not apply to veterinary medicinal products.

(3) Where required by pharmacovigilance, the Danish Medicines Agency may require the marketing authorisation holder of a medicinal product for human use to nominate a contact person in Denmark to represent the qualified person referred to in subsection (1)(vii).

(4) The Minister for Health lays down rules on the marketing authorisation holder's obligations referred to in subsection (1), including on the reporting of suspected adverse reactions occurring in Denmark or a country outside the EU and the EEA respectively, and on the professional expertise, activity area and contact person for qualified persons for pharmacovigilance.

(5) The Danish Medicines Agency monitors compliance with the requirements in subsection (1) and in rules laid down under subsection (4). The Danish Medicines Agency also monitors compliance with the pharmacovigilance requirements in provisions of Community law laying down Community procedures for authorisation and pharmacovigilance of medicinal products for human and veterinary use etc.

(6) The representatives of the Danish Medicines Agency must, on the presentation of appropriate identification and without a court order, have access to companies in order to monitor compliance as specified in subsection (5). The Danish Medicines Agency may order companies to hand over or disclose all information, including written material, necessary for the control function.

(7) The Danish Medicines Agency will notify the European Medicines Agency, the European Commission, the national authorities responsible for medicinal products in the other EU/EEA countries and the marketing authorisation holder if the Danish Medicines Agency based on the outcome of an inspection visit concludes that the marketing authorisation holder does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file, see subsection (1)(ii).

54.-(1) The marketing authorisation holder of a medicinal product for human use must not publish information about the safety of the medicinal product on the basis of pharmacovigilance data without giving prior or simultaneous notification to the Danish Medicines Agency, the European Medicines Agency and the European Commission.

(2) The marketing authorisation holder of a veterinary medicinal product must not publish information about the safety of the medicinal product on the basis of pharmacovigilance data without giving prior or simultaneous notification to the Danish Medicines Agency.

(3) The information referred to in subsections (1) and (2) must be presented in an objective manner and must not be misleading.

54A.-(1) The Danish Medicines Agency may require that the holder of a marketing authorisation for a medicinal product publishes, or to a defined group of healthcare professionals or hospitals dispatches

information about the medicinal product which serves patient safety purposes, including information about suspected adverse reactions.

(2) The Danish Medicines Agency may impose requirements on the format and content of the information mentioned in subsection (1). Furthermore, the Danish Medicines Agency may impose a deadline on the publication or dispatch of such information.

55.-(1) The Minister for Health lays down rules on the obligation of healthcare professionals to report information on suspected adverse reactions, including information from patient records and post-mortem reports, to the Danish Medicines Agency.

(2) The Minister for Health lays down rules on the right of patients, relatives and animal owners to report information on suspected adverse reactions directly to the Danish Medicines Agency.

56.-(1) The Danish Medicines Agency operates a pharmacovigilance system to monitor the safety of medicinal products and maintains a register of reported adverse reactions. The Minister for Health lays down specific rules on the Danish Medicines Agency's assessment of the reported information and assessment of the periodic safety update reports.

(2) The Danish Medicines Agency may disclose information on reported adverse reactions to the European Medicines Agency, the European Commission, the national authorities responsible for medicinal products in the other EU/EEA countries, the Patient Complaints Centre and the marketing authorisation holder. The Minister for Health lays down specific rules to that effect.

56A. The Minister for Health may lay down rules on format requirements for reports and periodic safety update reports prepared by the marketing authorisation holders under this Part, including that reporting must be done electronically.

Part VI

Labelling, pharmacy restriction and dispensing status

57. The Danish Medicines Agency may lay down rules on and make requirements to medicinal products' package leaflet, labelling, packaging and package size. Such requirements may be impressed on the holder of the marketing authorisation and other persons or companies placing a medicinal product on the market.

58.-(1) A medicinal product covered by a marketing authorisation granted by the Danish Medicines Agency may only be sold and dispensed under a name authorised by the Danish Medicines Agency.

(2) The name must be

(i) an invented name, not liable to confusion with the common name,

(ii) a common name in connection with a trademark or the name of the holder of the marketing authorisation, or

(iii) a scientific name in connection with a trade mark or the name of the holder of the marketing authorisation.

(3) The name must not be misleading in relation to the composition, efficacy or characteristics of the product and must not be suitable to cause confusion with other medicinal products.

(4) The Minister for Health may lay down rules on the naming of parallel imported medicinal products.

59.-(1) Anyone who places a medicinal product on the Danish market must submit the package leaflet applicable from time to time for the medicinal product to the Danish Medicines Agency.

(2) The Danish Medicines Agency may lay down deadlines and formal requirements for the submission of package leaflets under subsection (1), including a requirement for electronic submission.

60.-(1) The sale of medicinal products to consumers is allowed only through pharmacies (pharmacy restriction), unless otherwise provided by other statutory rules or by provisions laid down by the Minister for Health, but see subsections (2) and (3).

(2) Where it is justifiable in terms of health, the Danish Medicines Agency may decide that a non-prescription medicinal product, including specific package sizes, pharmaceutical forms or strengths of the medicinal product, may be sold to users outside pharmacies. The Danish Medicines Agency may lay down restrictions on the number of packages of a medicinal product to be sold to one user.

(3) Prescription-only and non-prescription medicinal products for production animals may be sold in outlets other than pharmacies as the Danish Medicines Agency may decide.

(4) The Danish Medicines Agency may lay down rules to the effect that medicinal products not comprised by the pharmacy restriction in subsection (1) can only be dispensed based on ordering from doctors, dentists or veterinarians. Furthermore, the Danish Medicines Agency may lay down rules on the wording, etc. of such orders as well as rules on dispensing of such medicinal products.

61.-(1) In connection with the granting of the marketing authorisation, the renewal of the marketing authorisation and where otherwise required, the Danish Medicines Agency decides whether a medicinal product is subject to a prescription.

(2) The Danish Medicines Agency lays down rules on the medicinal products to be dispensed subject to a prescription, and on the division of medicinal products into dispensing groups.

(3) The Danish Medicines Agency lays down rules on the wording of prescriptions, etc. and on dispensing and substitution of prescription-only medicinal products and non-prescription medicinal products ordered on prescription. The Danish Medicines Agency also lays down rules on the dispensing of medicinal products in special cases without guarantee for payment.

62.-(1) The Danish Medicines Agency may lay down rules on the conditions for prescription and dispensing of medicinal products to which a special programme on management, organisation and assessment of risk (risk management programme) is attached.

(2) In specific cases, the Danish Medicines Agency may decide that specific restrictions apply in connection with prescription and dispensing of a medicinal product to which a risk management programme as specified in subsection (1) is attached.

Part VII

Advertising, bonuses, discounts, etc.

63. Advertising of a medicinal product must be adequate and objective, and it must not mislead or exaggerate the characteristics of the medicinal product. The advertising information must be in accordance with the authorised summary of product characteristics.

64. Advertising is not allowed for

(i) medicinal products that are not legally sold or dispensed in Denmark, and

(ii) medicinal products prepared in accordance with a magistral formula.

65. The word pharmacy must not be used in advertising for non-pharmacy-restricted medicinal products, see section 60(1), or for products other than medicinal products, unless the person responsible for the advertising can document that the product is generally sold at pharmacies in Denmark.

66.-(1) Advertising to the general public is not allowed of medicinal products that

(i) are available only on prescription,

(ii) are inappropriate for use unless the patient has first consulted a doctor with a view to diagnosis or monitoring of the treatment, or

(iii) are comprised by the Act on Euphoriant Substances.

(2) The general public means anyone who is not a doctor, dentist, veterinarian, pharmacist, nurse, veterinary nurse, pharmaconomist, midwife, bioanalyst, clinical dietitian, radiographer or a student within one of these fields.

(3) The Danish Medicines Agency may give professional journals for healthcare professionals other than those specified in subsection (2) permission to advertise for the medicinal products specified in subsection (1) if the professional group has a special interest in the use of medicinal products.

(4) The prohibition in subsection (1) does not apply to vaccination campaigns approved by the Danish Medicines Agency.

67.-(1) Distribution of free medicinal products to the general public is prohibited. However, the Danish Medicines Agency may give permission to free distribution of medicinal products to the general public if such distribution is not for promotional ends.

(2) The Minister for Health lays down rules on the extent to which medicinal products can be distributed for free to the healthcare professionals specified under section 66(2).

(3) The Minister for Health lays down rules on the function carried out by medical sales representatives.

68.-(1) The holder of a marketing authorisation must keep a copy of or other documentation for all advertising of the medicinal product concerned. The Minister for Health lays down rules on what information to keep, including information on the target group, contents, use, form of publication and way of distribution of the advertising.

(2) The material specified in subsection (1) must be kept for two years. Upon request, the material must be made available to the Danish Medicines Agency.

(3) If a person other than the holder of the marketing authorisation advertises a medicinal product, the obligation under subsections (1) and (2) rests with the person responsible for the advertising.

(4) The Danish Medicines Agency may order disclosure of all necessary information with a view to monitoring compliance of advertising of medicinal products, discounts and other inducements or methods of a similar effect with the provisions of this Part, including rules laid down pursuant to section 67(2) and (3) or section 70(1).

69.-(1) The Danish Medicines Agency may require that advertising which is in conflict with sections 63-68 or with rules laid down pursuant to section 67(2) and section 70(1) must be stopped.

(2) The Danish Medicines Agency may require that any person responsible for illegal advertising publishes a decision made under subsection (1) or a correction of the advertising. The Danish Medicines Agency may decide the form, contents and place of the publication.

70.-(1) The Minister for Health may lay down specific rules on advertising of medicinal products, discounts and other inducements or methods of a similar effect.

(2) The Minister for Health may lay down rules to the effect that the Danish Medicines Agency, upon request from companies, must issue an opinion on its view on the legality of intended advertising measures.

71. The Danish Medicines Agency may lay down rules to the effect that, in special cases, it is permitted to advertise dental products not comprised by section 2 as suitable for the prevention of certain diseases in humans.

71A. Bonuses or other economic advantage may not be paid or offered to users of medicinal products in connection with the sale of a pharmacy-only medicinal product, see section 60(1). However, bonuses may be paid to hospital owners in connection with the sale of pharmacy-only medicinal products to hospitals.

71B.-(1) In connection with the sale of a pharmacy-only medicinal product, see section 60(1), to a proprietary pharmacist, the holder of an authorisation under section 39(1) (the discount provider) may grant discounts provided only they reflect cost savings for the discount provider. Such discounts must be commensurate with the cost savings and must be in the form of a price reduction.

(2) The discount provider must prepare and publish information about the access to obtaining the discounts mentioned in subsection (1) which the discount provider offers as part of the sale of pharmacy-only medicinal products (duty to display information).

(3) The Minister for Health lays down specific rules on the provision of the discounts mentioned in subsection (1) and the duty to display information mentioned in subsection (2) and on accounting related matters, management statement and auditing of discounts granted.

(4) Proprietary pharmacists are not permitted as part of the sale of medicinal products mentioned in subsection (1) to request or receive discounts that are not compliant with the information that the discount provider has prepared and published pursuant to his duty to display information.

(5) Discount providers and proprietary pharmacists must, for a period of three years, keep documentary evidence of any discounts mentioned in subsection (1) granted or earned as part of the sale of pharmacy-only medicinal products. The Minister for Health may lay down rules detailing what documentary evidence must be kept.

(6) The Danish Medicines Agency may order discount providers and pharmacies to hand over all information necessary to check whether discounts have been granted and received in compliance with subsections (1) and (4) and rules issued in pursuance of subsection (3).

71C. Based on appropriate identification and without a court order, representatives of the Danish Medicines Agency must have access to pharmacies and companies holding an authorisation under section 39(1) in order to monitor compliance with the provisions of sections 71A and 71B(1), (2) and (4) and (5) first sentence, and of rules issued in pursuance of section 71B(3) and (5) second sentence.

Part VIII

Information on medicinal products

72.-(1) The Danish Medicines Agency makes the following information available to the general public on the website of the Danish Medicines Agency, but see subsection (2):

(i) The Danish Medicines Agency's decisions on granting, suspension and revocation of marketing authorisations.

(ii) The terms attached to marketing authorisations pursuant to section 9(1) and (2), and information on any deadlines for the fulfilment of the terms.

(iii) The summaries of product characteristics for medicinal products authorised by the Danish Medicines Agency.

(iv) An assessment in Danish or English of the material which forms the basis for the marketing authorisations granted by the Danish Medicines Agency, in the form of a public assessment report. Concerning marketing authorisations for medicinal products for human use, a summary in Danish or English of the assessment report must also be published.

(v) Package leaflets for medicinal products comprised by a marketing authorisation in Denmark.

(vi) Summaries of risk management plans and programmes for medicinal products for human use.

(vii) The list of medicinal products subject to additional monitoring provided for in Article 23 of Regulation (EC) No 726/2004 published on the European Medicines Agency's medicines web portal.

(viii) Information detailing how healthcare professionals and patients can report suspected adverse reactions to the Danish Medicines Agency, including information on electronic reporting.

(ix) Rules of procedure, agendas and minutes of meetings accompanied by the decisions made, details of votes and explanation of votes, including minority opinions, of the councils and committees specified in Part XIII.

(2) Notwithstanding subsection (1), the Danish Medicines Agency will not make available to the general public information exempted from publication under the Danish Act on Public Access.

(3) Furthermore, the Danish Medicines Agency must inform the public when otherwise necessitated by special health circumstances. Notwithstanding the provisions of subsection (2), the Danish Medicines Agency may publish the name of the legal or natural person having committed a criminal offence.

72A. The Danish Medicines Agency organises meetings involving patient and consumer organisations in order to communicate public information about the actions undertaken to prevent and combat the falsification of medicinal products.

73.-(1) The Danish Medicines Agency may provide information on medicinal products and on the relevant use of medicinal products.

(2) As the basis for its information activities, the Danish Medicines Agency may use all necessary information, which the Agency has at its disposal as part of its function.

(3) Following the decision by the Minister for Health, the information specified in subsection (2) may be distributed to associations of doctors, dentists, veterinarians, pharmacists and proprietary pharmacists as well as to companies with the purpose of offering healthcare information on medicinal products, but not information regarding individual persons.

(4) The Danish Medicines Agency may publish information on adverse reactions caused by medicinal products, but not information regarding individual persons.

(5) When the Danish Medicines Agency on the basis of pharmacovigilance data provides information about safety concerns related to a medicinal product for human use pursuant to subsection (1) or (4), the Danish Medicines Agency must inform the European Medicines Agency, the European Commission and the national authorities responsible for medicinal products in other EU/EEA countries not less than 24 hours prior to such publication. The deadline may, however, be waived if urgent public announcements are required for the protection of public health.

74. The Minister for Health may instruct the Danish Medicines Agency to inform healthcare professionals of medicinal products according to specific rules.

Part IX

Supply of medicinal products

75. Under the rules laid down by the Danish Medicines Agency, anyone who places a medicinal product for humans on the market and wholesalers of such medicinal product must ensure appropriate and continuous supply of the medicinal product concerned, if it is:

(i) A medicinal product comprised by pharmacy restriction, see section 60(1).

(ii) A serum, a vaccine, an immunological investigational medicinal product or a medicinal product derived from plasma.

(iii) A radiopharmaceutical.

(iv) A medicinal product, including specific package sizes, pharmaceutical forms and strengths of the medicinal product which as specified by the Danish Medicines Agency may be sold to users outside the pharmacies, see section 60(2).

76.-(1) The Minister for Health may lay down rules on the obligation for companies authorised by the Danish Medicines Agency under section 39(1) to take action with a view to maintaining the supply of medicinal products in supply emergencies and in case of accidents and catastrophes, including acts of war.

(2) The rules laid down pursuant to subsection (1) may include provisions on:

(i) The companies' obligation to take action with a view to moving and distributing stocks that are used, manufactured or sold in connection with their usual operations.

(ii) Payment and delivery terms concerning medicinal products that are moved or distributed in accordance with the rules laid down.

(iii) Pharmacies' and hospital pharmacies' access to supply medicinal products to pharmacies and hospital pharmacies.

(iv) The right of the Danish Medicines Agency to give the companies concerned specific instructions on taking measures that deviate from the rules laid down.

(3) If the rules laid down under subsection (1) or an instruction issued by the Danish Medicines Agency pursuant to the rules laid down under subsection (1) cause a financial loss for a company, the Danish State will be liable in damages under the general rules of Danish law.

(4) In the absence of amicable settlement, the damages will be fixed in accordance with rules laid down by the Minister for Health.

Part X

Prices, product range, product numbers and statistics

Prices and product range

77.-(1) Anyone who places a pharmacy-restricted medicinal product on the Danish market must notify the Danish Medicines Agency of the pharmacy cost price and of any changes of such price of the concerned medicinal product made up per package size no later than 14 days prior to the price coming into force. However, the notification requirement does not apply to medicinal products exempted from the marketing authorisation requirement under section 11.

(2) The Minister for Health may lay down rules on notification pursuant to subsection (1), including a minimum threshold for changes of pharmacy cost prices of medicinal products for human use and formal requirements for notification, including a requirement for electronic submission.

78.-(1) The Minister for Health may lay down rules to the effect that anyone who places a medicinal product exempted from a pharmacy restriction on the Danish market must notify the Danish Medicines Agency of the package sizes in which the medicinal product is marketed, including notification of any change of the product range.

(2) The Minister for Health may lay down rules to the effect that for certain medicinal products exempted from a pharmacy restriction, anyone who places the medicinal product on the Danish market must notify the Danish Medicines Agency of the pharmacy cost price prepared per package size.

(3) The notification under subsections (1) and (2) must reach the Danish Medicines Agency no later than 14 days prior to the price coming into force or a package being placed on the market, changed or withdrawn from the market.

(4) The Minister for Health may lay down specific rules on the notification to the Danish Medicines Agency pursuant to subsections (1)-(3), including a minimum threshold for changes of pharmacy cost prices of medicinal products, and formal requirements for notification, including a requirement for electronic submission.

79. The Danish Medicines Agency's processing of the pharmacy cost prices referred to in section 77 and in rules laid down pursuant to section 78 does not imply approval.

80.-(1) Upon request from the Danish Medicines Agency, anyone who places a medicinal product on the Danish market must inform how big a volume of a given medicinal product the company will be able to deliver to the market.

(2) The Minister for Health may lay down rules to the effect that anyone who places a medicinal product for human use on the market, and wholesalers, must notify the Danish Medicines Agency of expected and actual supply failure.

(3) The Minister for Health may lay down specific rules on the obligation to inform and notify under subsections (1) and (2).

(4) The Danish Medicines Agency may lay down formal requirements for the submission of notification under subsection (2), including a requirement for electronic submission.

81.-(1) The Danish Medicines Agency must inform the pharmacies of the package sizes to use for marketing the medicinal products, and of any change of the product range as well as of the medicinal product retail price. The information is published in Medicinpriser, see section 82.

(2) However, based on information received under section 80(1), the Danish Medicines Agency may refrain from informing the pharmacies of the retail price of a medicinal product.

(3) The Minister for Health may lay down rules to the effect that information on medicinal products, which cannot be supplied, is not included in Medicinpriser. In this connection, the Minister may lay down rules to the effect that the Danish Medicines Agency's information to the pharmacies on changes of the reimbursement price, see Act on National Health Service, if the medicinal product forming the basis for fixing the reimbursement price in a reimbursement group cannot be supplied.

82.-(1) For medicinal products comprised by section 77 and rules laid down pursuant to section 78, the Danish Medicines Agency publishes in Medicinpriser information on

(i) dispensing group,

(ii) limitation of the number of packages to be dispensed per purchase outside the pharmacy,

(iii) medical specialists authorised to prescribe the medicinal product, and

(iv) reimbursement price, including any unit reimbursement price.

(2) The Minister for Health may lay down specific rules on Medicinpriser, including

(i) the information that may or must appear from Medicinpriser apart from the information specified in subsection (1),

(ii) the Danish Medicines Agency's disclosure of certain information in Medicinpriser prior to publication, including the exact date of such disclosure, and

(iii) the Danish Medicines Agency's publication of information in Medicinpriser, including the exact date of such publication.

(3) Medicinpriser is not published in the Danish Law Gazette (Lovtidende).

Product numbers

83.-(1) Each individual package of medicinal product must be provided with a unique product number. Product numbers are allocated by the Danish Medicines Agency upon request from anyone who places the medicinal product on the Danish market.

(2) The Danish Medicines Agency may lay down specific rules on product numbers, including rules to the effect that immediate packaging from medicinal products for veterinary use must have a separate product number, that the use of an allocated product number must be reported to the Danish Medicines Agency, and that certain medicinal product groups are exempt from the requirement in subsection (1) first sentence.

(3) For an agreed period, the task specified in subsection (1) second sentence may be transferred to a private institution, etc., on terms laid down by the Danish Medicines Agency. If the terms are violated, the Danish Medicines Agency may relieve the institution of the allocated task.

(4) The Danish Medicines Agency may lay down formal requirements for the reporting of product numbers to the Danish Medicines Agency, see subsection (2), including that reporting must be done electronically.

Statistics

84.-(1) According to rules laid down by the Minister for Health, companies producing, importing, exporting, storing, reselling, distributing, dispensing, splitting or packaging medicinal products as well as the associations and industry organisations of such companies must inform the Minister or the authority appointed by the Minister to receive such information, electronically of turnover etc. of medicinal products.

(2) The Minister for Health or the authority appointed by the Minister to receive the information may pass on the information comprised by rules laid down pursuant to subsection (1) to the

general public, including the publication of statistics on turnover of all medicinal products and medicinal product packages.

(3) From the authority appointed by the Minister for Health to receive the information, the Minister may receive the same information and disclose such information to the same extent as the mentioned authority.

(4) Upon the request of the Danish Medicines Agency, the companies and associations, etc., specified in subsection (1) must furthermore give information in electronic form on turnover, etc. of medicinal products. Such information may be disclosed in accordance with subsection (2). The Danish Medicines Agency lays down specific rules to this effect.

84A. The Minister for Health may lay down rules on which information about medicinal products, including confidential information, the Danish Medicines Agency must disclose to the authority appointed by the Minister to prepare and publish statistics on the sales volume of medicinal products. The appointed authority must only use the confidential information in connection with the preparation of medicinal product statistics.

Part XI

Trials

Non-clinical trials of medicinal products

85.-(1) Conducting toxicological and pharmacological trials (non-clinical trials) with a view to assessing the safety of medicinal products for the purposes of applying for clinical trials, applying for marketing authorisation or maintaining the marketing authorisation may take place only following the authorisation of the Danish Medicines Agency.

(2) The Minister for Health lays down rules on the conditions for achieving an authorisation for performing trials under subsection (1), on information to accompany the application, and on the Danish Medicines Agency's processing of the application.

(3) To ensure compliance with the conditions laid down under subsection (2), the Danish Medicines Agency may attach specific terms to the authorisation, including restrict the duration of authorisation.

(4) The Danish Medicines Agency lays down rules on technical management, specialist knowledge, organisation and operation of companies with an authorisation under subsection (1).

86. The Danish Medicines Agency may withdraw or suspend an authorisation under section 85(1) if the conditions of the authorisation or the associated terms are not met, if the company is violating rules laid down by the Danish Medicines Agency pursuant to section 85(4), or if the company refuses to participate in the Danish Medicines Agency's control under section 87.

87.-(1) The Danish Medicines Agency controls companies, etc., with authorisations under section 85(1). The control comprises the planning, execution, monitoring, registration, reporting and filing of the trials. The Minister for Health lays down specific rules on this control activity.

(2) Based on appropriate identification and without a court order, representatives of the Danish Medicines Agency must have access to companies, etc., having been granted authorisations under section 85(1) in order to carry out the control stated in subsection (1). The Danish Medicines Agency may sample or order the company, etc., to supply samples of the subject matter or substance to be examined (test substance). The Agency may demand all information, including written material necessary for the control function. The Danish Medicines Agency may demand changes and set deadlines for the implementation of the changes with a view to complying with the rules laid down pursuant to section 85(4).

(3) The Danish Medicines Agency may disclose relevant information on authorisations issued under section 85(1) and on the control function under subsection (2) to the European Commission and the national authorities responsible for medicinal products in the other EU/EEA countries and non-member countries.

Clinical trials of medicinal products, etc.

88.-(1) A clinical trial of medicinal products must only be conducted if the Danish Medicines Agency has authorised the trial. Furthermore, a scientific ethical committee must approve trials on humans, see Act on a Scientific Ethical Committee System and the Processing of Biomedical Research Projects.

(2) Trials of medicinal products on humans must be conducted in accordance with Good Clinical Practice. The Danish Medicines Agency lays down rules on Good Clinical Practice, including quality standards for the planning, conducting and reporting of clinical trials.

(3) Application for authorisation of a clinical trial must be submitted to the Danish Medicines Agency by the person, company or institution undertaking the responsibility for the initiation, management and possibly the financing of a clinical trial (sponsor).

(4) If the Danish Medicines Agency has a reasoned objection, the sponsor may amend the application once to allow for the objection. If the application is not amended according to the objection, the application is rejected.

(5) The sponsor must inform the manufacturer of the medicinal product or the manufacturer's representative of the application at the same time as the application is submitted to the Danish Medicines Agency.

(6) In connection with applications for trials of medicinal products on humans, the Danish Medicines Agency must make its decision of authorisation under subsection (1) or of rejection of application for authorisation known to the scientific ethical committee concerned, see Act on a Scientific Ethical Committee System and the Processing of Biomedical Research Projects.

(7) The sponsor or sponsor's representative must have a permanent address in an EU/EEA country.

(8) The Minister for Health lays down specific rules on which information should be included in applications for authorisation of clinical trials and on the Danish Medicines Agency's processing of such applications.

89.-(1) When a trial has been initiated, sponsor can only amend the trial protocol according to rules laid down by the Minister for Health.

(2) The sponsor must

(i) immediately inform the Danish Medicines Agency if suspected unexpected and serious adverse reactions occur during the trial,

(ii) inform the Danish Medicines Agency within 15 days if a trial needs to be interrupted earlier than planned and give the Agency a clear reason for the interruption,

(iii) once a year throughout the entire trial period draw up a list of all serious suspected adverse reactions which have occurred during the trial period, and a report on the safety of the trial subjects and submit the list and the report to the Danish Medicines Agency, and

(iv) no later than 90 days after the end of the trial, inform the Danish Medicines Agency that the trial has been completed and as soon as possible and no later than one year after submit the result of the trial to the Agency.

(3) The Minister for Health lays down rules on the information specified in subsection (2).

(4) The Minister for Health lays down rules on sponsor's obligation to inform others, including those responsible for clinical trials and the national authorities responsible for medicinal products in the other EU/EEA countries of the information submitted under subsection (2).

90.-(1) The Danish Medicines Agency is entitled to set terms for the trial to the sponsor and the doctor, dentist or veterinarian responsible for the practical conduct of the trial (investigator).

(2) The Danish Medicines Agency may before, during and after the conduct of a clinical trial of medicinal products, including as part of the processing of a marketing authorisation application and as follow-up on a granted marketing authorisation, inspect any company, etc. that is or has been carrying out clinical trials of medicinal products. The Danish Medicines Agency may order the handing over of all information, including written material, necessary for the inspection.

(3) The Danish Medicines Agency may on the basis of a request for assistance from a competent authority in another EU/EEA country inspect any company, etc. that is or has been carrying out

clinical trials of medicinal products. The Danish Medicines Agency may order the handing over of all information, including written material, necessary for the inspection.

(4) As part of the Danish Medicines Agency's inspection referred to in subsections (2) and (3), the Agency's representatives must, upon the presentation of appropriate identification and without a court order, have access to companies, hospitals, medical practices and other places affected by the conduct of the trial.

(5) Disclosure and processing of information about the trial subjects' health status and other purely personal matters and otherwise confidential information may take place without the consent of the trial subject as part of the Danish Medicines Agency's inspection pursuant to subsections (2)-(4).

(6) As regards trials of medicinal products for human use, the Danish Medicines Agency's inspection pursuant to subsections (2) and (3) must comprise compliance with good clinical practice. The Minister for Health lays down specific rules on this inspection.

(7) If an investigator or any other party involved in the trial fails to comply with the established obligations for a trial of medicinal products in humans, the Danish Medicines Agency presents such parties with suggestions for remedying the problem and submits the proposal to the ethics committee concerned, the European Commission and the national authorities responsible for medicinal products in the other EU/EEA countries.

(8) During the trial, the Danish Medicines Agency is entitled to demand from the sponsor and the investigator that the trial should be altered or temporarily suspended, or the Agency is entitled to prohibit the trial. The Minister for Health lays down specific rules to that effect.

(9) In deciding to stop or prohibit a trial of medicinal products for humans, the Danish Medicines Agency must immediately notify its decision and the grounds for it to the ethics committee concerned, the European Medicines Agency, the European Commission and the national authorities responsible for medicinal products in the other EU/EEA countries.

91.-(1) The Danish Medicines Agency must enter information on all clinical trials of medicinal products for humans, which the Agency has authorised in a European database. The Minister for Health lays down specific rules on what information the Danish Medicines Agency must report and on the Agency's processing of the information.

(2) The Danish Medicines Agency is entitled to disclose relevant information on clinical trials to the European Medicines Agency, the European Commission, the national authorities responsible for medicinal products in the other EU/EEA countries and the scientific ethical committee concerned. The Minister for Health lays down specific rules to that effect.

92.-(1) The medicinal products for clinical trials must comply with the current standards for good manufacturing practice. Compliance in this respect is comprised by the Danish Medicines Agency's monitoring of clinical trials under section 90(2).

(2) In response to a reasoned request, the Danish Medicines Agency is entitled to disclose information from the monitoring under section 90(2) to the European Medicines Agency, the national authorities responsible for medicinal products in the other EU/EEA countries and the scientific ethical committee concerned.

(3) The Danish Medicines Agency lays down specific rules on the manufacture, import, labelling, distribution and monitoring of medicinal products for clinical trials.

Format requirements

92A. The Minister for Health may lay down rules on the format requirements for applications and notifications under this Part, including that applications and notification must be done electronically.

Non-interventional safety studies

92B.-(1) A non-interventional safety study of a medicinal product for human use which is a term for a marketing authorisation, and which has been imposed after granting of the marketing authorisation, see section 9(2), must not be initiated before the Danish Medicines Agency has authorised the study. Such

authorisation from the Danish Medicines Agency must be obtained when the study is to take place in Denmark only.

(2) The Minister for Health lays down specific rules on the information to be included in applications for authorisation under subsection (1) and on the processing of such applications.

(3) When a non-interventional safety study authorised pursuant to subsection (1) has been initiated, the marketing authorisation holder can only make substantial changes to the trial protocol according to rules laid down by the Minister for Health.

92C.-(1) The marketing authorisation holder must send a report on the results of a non-interventional safety study to the Danish Medicines Agency. If the study has also been conducted in other EU/EEA countries, the report must also be submitted to the countries in question. Submission must take place within 12 months of the end of data collection unless a written waiver has been granted by the Danish Medicines Agency.

(2) The Minister for Health lays down rules on the content and submission of the reports referred to in subsection (1), including separate requirements for reports from a non-interventional safety study which is a term for the marketing authorisation.

92D.-(1) Non-interventional safety studies of authorised medicinal products must not be performed if the act of conducting the study promotes the use of a medicinal product.

(2) Payments to healthcare professionals for participating in non-interventional safety studies of an authorised medicinal product must be restricted to the compensation for time and expenses incurred.

Part XII

Certain substances that may be used as veterinary medicinal products

93.-(1) Manufacture, import, export, storage, distribution, providing, dispensing, splitting, packaging, possession or disposal of substances to be used as veterinary medicinal products and which comprise characteristics detailed by the Danish Medicines Agency must only be permitted if prior notification has been submitted to the Danish Medicines Agency and the company has obtained a receipt from the Agency. The Danish Medicines Agency lays down specific rules on the notification procedure, etc.

(2) The provision in subsection (1) also applies to products of which one or more of the substances concerned form part.

(3) Likewise, private individuals are not permitted to acquire, possess or have at their disposal substances and products under subsections (1) and (2), unless the substance or product is acquired from a company that has submitted notification to the Danish Medicines Agency and obtained a receipt for such notification, see subsection (1). The substances and products are not to be administered to animals, used on animals, transferred or resold, unless it is authorised by the Danish Medicines Agency in specific cases. The Danish Medicines Agency lays down specific rules to this effect.

(4) The Danish Medicines Agency may lay down rules on sale and dispensing of substances and products that fall under subsections (1) and (2), including that dispensing can only take place following a requisition signed by the local commissioner of police. The Danish Medicines Agency may lay down specific rules on the wording and contents of the requisition as well as on private individuals' obligation to file a copy of the requisition.

(5) The Danish Medicines Agency may lay down rules on the format requirements for notifications and applications under subsections (1) and (3), including that notification and application must be done electronically.

94.-(1) The Danish Medicines Agency establishes a register of companies and pharmacies that give notification pursuant to section 93(1).

(2) The companies and pharmacies specified under subsection (1) must have detailed records of all transactions with the substances and products concerned. The Danish Medicines Agency lays down specific rules to this effect.

95.-(1) The Danish Medicines Agency inspects companies and pharmacies that fall under section 93(1) and the specified records under section 94(2).

(2) Following discussions with the relevant minister, the Minister for Health may lay down rules on the participation by other authorities or institutions in the performance of control activities under subsection (1).

(3) On presentation of appropriate identification and without a court order, representatives of the regulatory authority may have access at any time to public and private premises and facilities as well as access to obtain samples of substances and products, etc. The regulatory authority may require all information, including written material, necessary for the control activity.

Part XIII

Committees and councils, etc.

96.-(1) The Danish Medicines Agency may consult the Medicinal Products Committee in cases involving:

(i) Granting, variation, suspension or withdrawal of marketing authorisations for medicinal products.

(ii) Monitoring of adverse reactions and other risks involving medicinal products.

(iii) Evaluation of the risk-benefit balance of the medicinal products.

(iv) Clinical trials of medicinal products.

(2) The Medicinal Products Committee consists of a maximum of 15 members, two of which represent patient and consumer interests.

97. In cases relating to requirements for the quality of medicinal products, see section 52, the Danish Medicines Agency may consult the Danish Pharmacopoeia Commission. The Pharmacopoeia Commission consists of a maximum of six members.

98.-(1) The members of the committees and commissions referred to in sections 96 and 97 are appointed for four years at a time by the Minister for Health on the recommendation of the Danish Medicines Agency. The Minister appoints the chairperson and the vice-chairperson from among the members of the individual committee or council.

(2) The Minister for Health may assign additional tasks to the committees.

(3) The committees may obtain expert opinions from specialists.

(4) With the approval of the Minister for Health, standing committees may be set up within the committees. The Minister may appoint as members of such committees individuals that are not members of the committees.

99. The Minister for Health lays down the rules of procedure for the committees specified in sections 96 and 97.

100. Pursuant to section 152 of the Danish Criminal Code, members of the committees specified in sections 96 and 97 and experts providing the committees with expert opinion are obliged to keep secret from unauthorised persons any information they obtain in connection with their office or function if such information is confidential.

101.-(1) In questions regarding adverse reactions and other risks involving medicinal products, the Danish Medicines Agency may consult the Danish Pharmacovigilance Council.

(2) The Danish Pharmacovigilance Council consists of a maximum of 11 members. The members must include representatives of healthcare professionals, pharmaceutical companies, proprietary pharmacists and other retail distributors of medicinal products, patients and consumers.

(3) The Danish Pharmacovigilance Council is established by the Danish Medicines Agency upon public notice. The Danish Medicines Agency appoints a chairperson from among the members of the council.

(4) The Danish Medicines Agency lays down the rules of procedure for the Danish Pharmacovigilance Council.

Independence of the Danish Medicines Agency

102.-(1) Employees of the Danish Medicines Agency, members of councils, committees and commissions appointed pursuant to this Act and other persons giving advice to the Danish Medicines Agency and participating in the processing of decisions on authorisation, control and monitoring of adverse reactions of medicinal products are not permitted to have any financial or other interest in the pharmaceutical industry that may influence their impartiality.

(2) The persons specified in subsection (1) must each year make a statement of their financial interests in the pharmaceutical industry.

Part XIV

Fees

103.-(1) The Minister for Health may lay down rules on payment of the functions of the Danish Medicines Agency pursuant to this Act and pursuant to rules laid down under the Act, including

(i) fees for medicinal products and pharmaceutical companies as well as manufacturers, importers and distributors of active substances,

(ii) fee for registration as a broker of medicinal products,

(iii) payment for allocation, etc., of product numbers for medicinal products,

(iv) payment of the Danish Medicines Agency's travel and accommodation expenses if processing of an application or monitoring of the authorised medicinal product makes it necessary that the Danish Medicines Agency inspects a company in a third country,

(v) fee for notification of prices and information to the pharmacies about prices of pharmacy-restricted medicinal products,

(vi) fee for notification of package sizes on non-pharmacy-restricted medicinal products, and

(vii) fee for applications for authorisation of clinical trials and fee for monitoring of clinical trials.

(2) Payment pursuant to rules laid down under subsection (1) may be recovered by statutory debt collection.

103A.-(1) Anyone authorised under section 39(1) to sell medicinal products for production animals to users of such products will be charged a fee by the Danish Medicines Agency as indicated in subsections (2)-(5) for the financing of food safety and animal welfare measures.

(2) The fee amounts to 0.77 percent of the distributor's turnover of natural narrow-spectrum penicillin for production animals.

(3) The fee amounts to 10.77 percent of the distributor's turnover of critically important antibiotics for production animals.

(4) The fee amounts to 5.44 percent of the distributor's turnover of other antibiotics for production animals.

(5) The fee amounts to 0.77 of the distributor's turnover of other medicinal products for production animals, however, discarding the distributor's turnover of vaccines for production animals.

Part XIVA

Publication

103B.-(1) The Minister for Health may lay down rules providing that standards for the quality of medicinal products and for manufacturing, control and storage of medicinal products referred to in rules laid down by the Danish Medicines Agency pursuant to this Act are not to be published in the Danish Law Gazette (Lovtidende).

(2) The Minister for Health may lay down rules establishing how the Danish Medicines Agency is to communicate the content of the rules issued by the Agency, see subsection (1).

(3) The Minister for Health may lay down rules stipulating that provisions of executive orders and technical specifications, which are not published in the Danish Law Gazette (Lovtidende), see subsection (1), apply even though they are not available in Danish.

Part XIVB

Complaints

103C. The Minister for Health may lay down rules on complaints about the decisions made by the Danish Medicines Agency, including rules on time limits for complaints.

Part XV

Penalty etc.

104.-(1) Unless the offence carries a more severe penalty under any other legislation, anyone who

(i) infringes section 7(2), sections 20, 21, 26, section 40A(2) or (3), section 41(1), section 41B(1), section 42(1) or (2), section 43A, section 50(3), section 50A(1), section 50D, section 53(1), section 54, section 58(3), section 59(1), section 60(1), section 62(2), section 63, section 64, section 65, section 66(1), section 67(1) first sentence, section 68(1) first sentence, (2) first sentence, or (3), section 71A, section 71B(1), (2), (4) or (5) first sentence, section 83(1) first sentence, section 85(1), section 88(1) first sentence, (2) first sentence or (5), section 92(1) first sentence, section 92B(1) and (3), section 92C(1), section 92D, section 93(1) first sentence, or (2) or (3), section 94(2) first sentence, or EU regulations on medicinal products and pharmaceutical companies,

(ii) ignores any terms laid down in an authorisation or approval pursuant to the Act or to provisions laid down under the Act,

(iii) violates any prohibitions issued under section 46(1), section 47 or section 90(8),

(iv) fails to comply with an order or a duty to inform in pursuance of section 22(1), section 23, section 24, section 25(1) or (2), section 35, section 43, section 43B(1) first sentence, section 44A, section 44B, section 44D, second sentence, section 46(1), section 50F, section 50G, section 53(1), (3) or (5) second sentence, section 54A, section 68(2) second sentence, or (4), section 69, section 70B(6), section 80(1), section 84(1) or (4) first sentence, section 87(2), second to fourth sentence, section 89(2), section 90(2) second sentence, (3) second sentence, or (8) or section 95(3) second sentence, or

(v) denies access to representatives of the regulatory authority pursuant to section 25(3), section 44(2), section 44D first sentence, section 50E(2), section 53(5) first sentence, section 71C, section 87(2) first sentence, section 90(4), or section 95(3) first sentence

will be liable to a fine or imprisonment for up to four months.

(2) Unless the offence carries a more severe penalty under any other legislation, anyone who infringes section 7(1), section 38A(1), or section 39(1) or (2), or fails to comply with an order issued pursuant to section 46A, will be liable to a fine or imprisonment for up to 18 months.

(3) Rules laid down under the Act may provide for the imposition of a fine.

(4) Companies, etc. (legal entities) will be held criminally liable under the provisions of Part V of the Danish Criminal Code.

104A.-(1) The Minister for Health may lay down rules to the effect that where the penalty for a violation in cases under section 104(1) or defined in rules issued pursuance of the Act is not deemed to be more severe than a fine, the Danish Medicines Agency may declare that the case can be settled without instituting legal proceedings, if the person who has committed the violation pleads guilty of such violation and accepts to pay the fine stated in the declaration within a specific time-limit, which may be extended on request. The Minister for Health may furthermore lay down rules to the effect that requirements for the confiscation of medicinal products confiscated under section 44C may be adopted in the same way without legal proceedings.

(2) The provisions of the Danish Administration of Justice Act on the requirements for the contents of an indictment and on an accused person not being under an obligation to make a statement apply correspondingly.

(3) If the fine is accepted, there will be no further proceedings.

105. The Danish Medicines Agency may impose a charge on anyone who fails to comply with an order to submit information under section 84(4) first sentence, and companies that fail to comply with the duty to inform under section 84(1). The charge amounts to DKK 500 per week started until the information is submitted correctly. A right of distraint applies in respect of such charge, which reverts to the Treasury.

Part XVI

Commencement, amendment and transitional provisions

106.-(1) The date of commencement of the Act or parts of the Act will be laid down by the Minister for Health.

(2) The Minister for Health may repeal the Medicines Act, see Consolidated Act No. 656 of 28 July 1995.

(3) The provisions laid down in pursuance of the Medicines Act, see Consolidated Act No. 656 of 28 July 1995 remain in force until replaced or repealed by provisions laid down in pursuance of this Act.

(4) On 1 January 2007, in section 81(3) second sentence "Act on National Health Service" is amended to "the Health Care Act".

107.-(1) All authorisations and approvals issued in pursuance of the Medicines Act No. 327 of 26 June 1975 as amended in force at the date of commencement of the Act will be maintained until they are amended or terminated in pursuance of the provisions of the Act.

(2) A marketing authorisation for a medicinal product may not become valid for an unlimited period, see section 27(2), until the marketing authorisation has been renewed under this Act. If a holder of a marketing authorisation has submitted an application for renewal of the marketing authorisation prior to the commencement of this Act, the Danish Medicines Agency can require additional information if the application does not comply with the requirements of this Act. The Danish Medicines Agency may grant an exemption from the application deadline in section 27(3) regarding medicinal products if the marketing authorisation expires within six months of the commencement of the Act.

(3) Regarding medicinal products comprised by a marketing authorisation on the date of the commencement of the Act, the three-year limit under section 28 counts from the commencement of the Act.

108. (Omitted)

109. (Omitted)

110. This Act does not apply to Greenland and the Faroe Islands.

Ministry of Health, 20 April 2013

ASTRID KRAG

/ Nina Moss