This is a translation of the Danish Medicines Act. Only the Danish version has legal validity.

Danish Medicines Act[1]
Ministry of the Interior and 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. In this Act a medicinal product means any product that

(i) is presented as a suitable product for the treatment or prevention of disease in human beings or animals, or
(ii) may be used in or administered to humans or animals to restore, change or modify physiological functions by having a pharmacological, immunological or metabolic effect or to make a medical diagnosis.

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) or by the Act on medical devices.

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

(i) Intermediate products intended for further processing into medicinal products.
(ii) Certain raw materials used in the manufacture of medicinal products.
(iii) Certain substances that may be used as veterinary medicinal products.

(4) Sections 65 and 71 of the Act further 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, cf., however, subsection (2) and sections 65 and 71.

(2) Where, on the basis of an overall assessment of 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. The Minister for the Interior and Health may, following

[1] Danish act no. 1180 of 12 December 2005 on medicinal products as amended by act no. 538 of 8 June 2006, act no. 1557 of 20 December 2006, consolidation act no. 855 of 4 August 2008 and act no. 534 of 17 June 2008.

discussions with the relevant minister, 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 the Interior and Health's decision, specified products or product groups covered by section (2) may be excluded from the Act if deemed appropriate on the basis of their characteristics. The Minister for the Interior and Health shall lay down specific rules for such products or product groups.

6. The Minister for the Interior and Health may lay down rules to the effect that the Act 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. 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), cf., however, sections 11 and 29-32.

8.-(1) Following application the Danish Medicines Agency shall grant 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, cf., however, 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) Where required by special circumstances, the Danish Medicines Agency may attach terms to the marketing authorisation.

(2) The Danish Medicines Agency annually reviews any 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, 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, cf. Part XI.
(iv) Medicated feedingstuffs.

Refusal of variation, suspension and withdrawal of a marketing authorisation

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

(i) the benefit-risk ratio is not favourable, cf., however, subsection (2),
(ii) the therapeutic efficacy is lacking or is insufficiently substantiated by the applicant for the marketing authorisation, or
(iii) the qualitative and 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 shall 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 shall 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 therapeutic efficacy is lacking,
(iii) the qualitative and quantitative composition of the medicinal product is not as declared,
(iv) essential information stated by the applicant in support of the marketing authorisation application is incorrect, or
(v) self-audit according to the rules laid down under section 40(3) 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, cf. section 26(1).

15. In addition to the cases specified in section 14, the Danish Medicines Agency shall 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).

16.-(1) In addition to the cases specified in section 14, the Danish Medicines Agency shall 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 shall notify the European Medicines Agency if the Danish Medicines Agency initiates any cases of suspension or withdrawal of a marketing authorisation.

(2) Where the Danish Medicines Agency suspends a marketing authorisation with immediate effect in order to protect the health of humans or animals, cf. section 14(1), the Agency shall no later than on the following day notify the European Commission, the European Medicines

Agency and the national authorities responsible for medicinal products in the other EU/EEA countries.

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, cf. section 18, shall 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. 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.

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 , cf. 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, either 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 must inform the Danish Medicines Agency of any significant new data about the benefit-risk ratio of the medicinal product that the Agency is not informed of according to the procedure for authorising variations of marketing authorisations or in the form of periodic safety update reports.
(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 shall, 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, cf., however, 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, cf., however, sections 14-16. However, the Danish Medicines Agency may, where this is justified by the benefit-risk ratio, decide that the marketing authorisation is renewed for a new period of five years only.

(3) Any application for renewal must be submitted to the Danish Medicines Agency by the holder of the marketing authorisation no later than six months before the expiry of the authorisation.

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

(2) The Danish Medicines Agency may in special circumstances and in consideration of the health of humans or animals 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 granted 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 the Interior and Health, authorise the use and marketing of medicinal products not covered by a marketing authorisation

in Denmark. The Minister may further lay down rules on variation, suspension and withdrawal of such authorisations.

(2) The Danish Medicines Agency shall 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 the Interior and Health may lay down rules to the effect that in the situations specified in subsection (1) marketing authorisation holders, manufacturers and health 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 shall 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 the Interior and Health shall lay 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) herbal medicinal products,
  (b) vitamins and minerals, 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 processing of applications for marketing authorisation.

(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 and raw materials used in the manufacture of the medicinal product.

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 shall maintain 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

Authorisation for sale, manufacture and import etc.

Authorisation of companies, etc.

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

(2) Any manufacture, import, export, storage, resale and distribution 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 distribution, splitting and dispensing by hospitals and other healthcare institutions of medicinal products to be used in treatment.

(ii) The distribution, 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 distribution, 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.

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

40.-(1) The Minister for the Interior and Health shall lay 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) The Danish Medicines Agency's processing of applications for authorisation pursuant to section 39(1) and (2).

(2) To ensure compliance with the conditions laid down under subsection (1)(i), the Danish Medicines Agency may attach specific terms to the authorisation, including granting the authorisation for a limited period of time.

(3) The Danish Medicines Agency shall lay down rules on technical management, specialist knowledge, organisation and operation of companies with authorisation under section 39(1) and (2) and rules on the manufacture and other handling of certain raw materials used in the manufacture of medicinal products.

(4) The Danish Medicines Agency may disclose relevant information on authorisations under section 39(1) and (2), on variation, suspension and withdrawal of authorisations pursuant to section 41 and on its control activity pursuant to section 44(1) and (2) to the European Medicines Agency, the European Commission and the national authorities responsible for medicinal products in the other EU/EEA countries. The Minister for the Interior and Health shall lay down specific rules to this effect.

40A.-(1) Anyone authorised under section 39(1) to sell medicinal products for production animals to consumers, shall have the right to sell and dispense all non-prescription medicinal products intended for production animals.

(2) Anyone authorised under section 39(1) to sell medicinal products for production animals to consumers must not sell or dispense other products than medicinal products for production animals and may only in special cases and subject to the approval of the Minister for the Interior and Health carry on activities other than those set out in subsection (1) and rules issued pursuant to section 40B.

(3) Anyone authorised under section 39(1) to sell medicinal products for production animals to consumers must not without the approval of the Danish Medicines Agency operate or be affiliated to another company whose authorisation issued in pursuant to 39(1) or (2) is not limited to the sale of medicinal products for production animals to consumers.

40B. The Minister for the Interior and Health shall lay down specific rules on the additional, special obligations imposed on the holder of an authorisation under section 39(1) to sell medicinal products for production animals, including rules on

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

41. 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, if the holder of the authorisation has violated any rules laid down pursuant to section 40(3) or section 40B or refuses to participate in the Danish Medicines Agency's control under section 44.

42. The holder of an authorisation granted under section 39(1) to manufacture and 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.

43. The holder of an authorisation granted under section 39(1) and pharmacies must keep records of the handling etc. of medicinal products. The Danish Medicines Agency shall lay down specific rules to this effect.

43A.-(1) The holder of an authorisation granted under section 7 or section 39(1) shall notify the Danish Medicines Agency of any doctors, dentists and pharmacists associated with the company.

(2) The Minister for Health and Prevention shall lay down rules on the obligation to report, including a requirement for electronic notification.

Counterfeit medicinal products

43B.-(1) Any manufacture, import, export, storage, distribution or dispensing of counterfeit medicinal products shall be prohibited.

(2) The holder of an authorisation granted under section 7 and section 39(1) shall immediately report any discovery of counterfeit medicines in the company to the Danish Medicines Agency. For holders of an authorisation granted under section 7 and holders authorised to manufacture medicinal products, such reporting duty shall also apply to any findings outside their company that come to their awareness.

43C. If the Danish Medicines Agency suspects to have found a counterfeit medicinal product, it may disclose all information about the finding of a counterfeit medicinal product to the marketing authorisation holder of the concerned, named medicinal product which the counterfeit version appears to be identical with.

Control and inspection

44.-(1) The Danish Medicines Agency shall monitor compliance with requirements established pursuant to this Act and to rules laid down under the Act for content, quality and manufacture and other handling pursuant to section 39(1) and (2) of medicinal products and intermediate products. The Danish Medicines Agency shall also check that the medicinal products distributed or dispensed by a company authorised pursuant to section 39(1) are covered by a marketing authorisation, cf. section 7, or an authorisation pursuant to sections 29, 31 or 32. The Danish Medicines Agency shall also monitor compliance with section 40A(3) and 43B.

(2) In order to conduct inspection relating to the monitoring specified in subsection (1) the representatives of the Danish Medicines Agency shall, on the presentation of appropriate identification and without a court order, have access to companies with authorisation under section 39(1) and (2), marketing authorisation holders and manufacturers of raw materials, to the extent that the raw material is covered by rules laid down pursuant to section 40(3). The Danish Medicines Agency may take or demand to receive samples of medicinal products, including packaging, intermediate products and raw materials used in the manufacture of the medicinal products. The Agency may require all information and material necessary for the control function. The Danish Medicines Agency can require changes in the execution of tasks, organisation, design and operation and set deadlines for the implementation of the changes with a view to ensuring compliance with rules laid down pursuant to section 40(3) and 40B.

(3) The inspections referred to in subsection (2) may also be carried out at the request of another EU/EEA country, the European Commission or the European Medicines Agency.

(4) Notwithstanding the provisions in subsections (2) and (3), the Danish Medicines Agency may carry out unannounced inspections at holders of marketing authorisations and manufacturers of raw materials only if the Agency has grounds for assuming that rules

governing the manufacture of medicinal products, intermediate products and certain raw materials laid down pursuant to section 40(3) are being violated.

(5) The Danish Medicines Agency may also make inspection visits at a manufacturer of raw materials at the request of such manufacturer.

45. The representatives of the Danish Veterinary and Food Administration shall, 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.

45A. The Minister for Health and Prevention 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 for the purpose of ensuring the lawful distribution of medicinal products.

Prohibition against sale and dispensing

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 and quantitative composition of the medicinal product is not as declared,
(iv) self-audit relating to the medicinal product, its intermediate products or raw materials in accordance with rules laid down under section 40(3) 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 marketing authorisation for the medicinal product is suspended or withdrawn pursuant to sections 14-16, or
(vii) an order to comply with existing rules on labelling of medicinal products has not been complied with.

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

(3) The Minister for the Interior and Health may lay down rules on the Danish Medicines Agency's handling of cases in pursuance of subsection (1).

46A. The Danish Medicines Agency may require that the distribution and dispensing of a medicinal product not covered by a marketing authorisation, cf. section 7, or other authorisation for sale or dispensing of medicinal products, cf. 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 40(3).

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, provided that 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 Board.

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

PART IV

The quality of medicinal products

51.-(1) A medicinal product, including its packaging, and intermediate products and raw materials used in the manufacture of the medicinal product 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 and raw materials used in the manufacture of medicinal products. 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) Pursuant to rules laid down by the Minister for the Interior and Health the holder of a marketing authorisation must

(i) keep records of suspected adverse reactions,
(ii) make such records available to the Danish Medicines Agency,
(iii) report information on adverse reactions to the Danish Medicines Agency, and
(iv) prepare and submit periodic safety update reports to the Danish Medicines Agency.

(2) The Minister for the Interior and Health may lay down rules to the effect that the holder of a marketing authorisation must report information on suspected adverse reactions to the European Medicines Agency and the national authorities responsible for medicinal products in the other EU/EEA countries.

(3) The Minister for the Interior and Health may lay down rules on companies' obligation to have at their disposal an appropriately qualified person responsible for pharmacovigilance , including requirements as to the specialist knowledge and area of activity of such qualified person.

(4) The Danish Medicines Agency monitors compliance with the requirements stated in subsection (1) and in rules laid down under subsections (1)-(3). The Danish Medicines Agency further 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.

(5) The representatives of the Danish Medicines Agency shall, on the presentation of appropriate identification and without a court order, have access to companies in order to conduct inspection relating to the monitoring specified in subsection (4). The Danish Medicines Agency may order companies to hand over or disclose all information, including written material necessary for the control function.

54. The holder of a marketing authorisation must not without the prior or simultaneous notification of the Danish Medicines Agency publish new information of importance for the evaluation of the benefits and risks afforded by the medicinal product deriving from pharmacovigilance. Such information must be presented in an objective and non-misleading manner.

55.-(1) The Minister for the Interior and Health shall lay down rules on the obligation of health-care 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 the Interior and Health shall lay 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 shall maintain a register of reported adverse reactions. The Minister for the Interior and Health shall lay down specific rules on the handling of reported information by the Danish Medicines Agency.

(2) The Danish Medicines Agency is entitled to disclose all 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 and the holder of the marketing authorisation. The Minister for the Interior and Health shall lay down specific rules to this effect.

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 marketing authorisation.

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

(4) The Minister for the Interior and Health may lay down rules on 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 shall be allowed only through pharmacies (pharmacy restriction), unless otherwise provided by other statutory rules or by provisions laid down by the Minister for the Interior and Health, cf. however, 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), shall 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 shall decide whether a medicinal product shall be subject to a prescription.

(2) The Danish Medicines Agency shall lay 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 shall lay 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 shall furthermore lay 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 covered by a Community marketing authorisation 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 shall 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 shall be adequate and objective, and it shall 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 shall not be 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, cf. 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 shall not be 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 Act on Euphoriant Substances.
(2) The general public means anyone who is not a doctor, dentist, veterinarian, pharmacist, nurse, veterinary nurse, pharmaconomist or a student within one of these fields.
(3) The Danish Medicines Agency may give professional journals for health 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) shall not apply to vaccination campaigns approved by the Danish Medicines Agency.

67.-(1) Distribution of free medicinal products to the general public shall be 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) (2) The Minister for the Interior and Health shall lay down rules on the extent to which medicinal products can be distributed for free to the health professionals specified under section 66(2).
(3) The Minister for the Interior and Health shall lay down rules on the function carried out by medical sales representatives.

68.-(1) The holder of a marketing authorisation shall keep a copy of or other documentation for all advertising of the medicinal product concerned. The Minister for the Interior and Health shall lay 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) shall rest 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 the Interior and 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 the Interior and 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, cf. 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, cf. section 60(1), to a 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 shall be commensurate with the cost savings note5 and must be in the form of a price reduction

(2) The discount provider shall 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 the Interior and Health shall lay 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) 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 pharmacists shall, 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 the Interior and 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 from the Danish Medicines Agency shall 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 shall make the following information available to the general public, cf., however, subsection (2):

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

(ii) The product characteristics for medicinal products authorised by the Danish Medicines Agency.

(iii) An assessment in Danish or English of the material which forms the basis for the marketing authorisation granted by the Danish Medicines Agency (assessment report).
(iv) Package leaflets for any medicinal product marketed in Denmark.
(v) 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 shall not make available to the general public information exempted from publication under the Danish Act on Public Access.

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 the Interior and Health, the information specified in subsection (2) may be distributed to associations of doctors, dentists, veterinarians, pharmacists and dispensing pharmacists as well as to companies with the purpose of offering health-care 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.

74. The Minister for the Interior and Health may instruct the Danish Medicines Agency to inform health 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 shall ensure appropriate and continuous supply of the medicinal product concerned, if it is:
(i) A medicinal product comprised by pharmacy restriction, cf. 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, cf. section 60(2).

76.-(1) The Minister for the Interior and 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) causes financial loss for a company the Danish State shall be liable in damages under the general rules of Danish law.

(4) In the absence of amicable settlement, the damages shall be fixed in accordance with rules laid down by the Minister for the Interior and 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 shall 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 and Prevention 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 the Interior and Health may lay down rules to the effect that anyone who places a medicinal product on the Danish market exempted from a pharmacy restriction shall 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 the Interior and Health may lay down rules to the effect that for certain medicinal products exempted from pharmacy restriction, anyone who places the medicinal product on the Danish market shall 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 and Prevention 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 the Interior and Health may lay down rules to the effect that anyone who places a medicinal product for human use on the market, and wholesalers, shall notify the Danish Medicines Agency of expected and actual supply failure.

(3) The Minister for the Interior and 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 shall 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 , cf. 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 the Interior and 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, cf. 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 the Interior and 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 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 and rules on exception of certain medicinal product groups from the requirement in subsection (1).

(3) For an agreed period of time the task specified in subsection (1) 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.

Statistics

84.-(1) According to rules laid down by the Minister for the Interior and 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 the Interior and 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 the Interior and 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 shall lay down specific rules to this effect.

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 the Interior and Health shall lay 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)(i), the Danish Medicines Agency may attach specific terms to the authorisation, including granting the authorisation with a time limit.

(4) The Danish Medicines Agency shall lay 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 shall control companies, etc., with authorisations under section 85(1). The control shall comprise the planning, execution, monitoring, registration, reporting and filing of the trials. The Minister for the Interior and Health shall lay down specific rules on this control activity.

(2) Based on appropriate identification and without a court order, representatives from the Danish Medicines Agency shall 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 can only be conducted if the Danish Medicines Agency has given an authorisation for the trial. However, non-interventional trials may be implemented without the authorisation of the Danish Medicines Agency. Furthermore, trials on humans must be approved by a scientific ethical committee, cf. 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 shall lay 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, cf. 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 the Interior and Health shall lay 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 the Interior and Health.

(2) The sponsor shall

(i) immediately inform the Danish Medicines Agency if presumed 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 the Interior and Health shall lay down rules on information specified in subsection (2).

(4) The Minister for the Interior and Health shall lay 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 is entitled to inspect any company, etc. that is or has been carrying out clinical trials of medicinal products, and the Agency is entitled to demand all information necessary, including written material, for its control activity. As part of the control, the Danish Medicines Agency's representatives shall:

(i) on the presentation of appropriate identification and without a court order, have access to companies, hospitals, medical practices and other places affected by the implementation of the trial and .

(ii) have access to patient records, etc., provided that the trial subject, his or her relatives or guardian has consented to or authorised this.

(3) For trials of medicinal products for humans, the Danish Medicines Agency's control pursuant to subsection (2) shall comprise observation of good clinical practice. The Minister for the Interior and Health shall lay down specific rules on this control activity.

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

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

(6) In deciding to stop or prohibit a trial of medicinal products for humans, the Danish Medicines Agency shall immediately notify its decision and the grounds for it to the scientific ethical 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 the Interior and Health shall lay 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 the Interior and Health shall lay down specific rules to this 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 scientific ethical committee concerned.

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

PART XII

Certain substances that may be used as veterinary medicinal products

93.-(1) Manufacture, import, export, storage, resale, distribution, 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 shall only be permitted provided prior notification has been submitted to the Danish Medicines Agency and the company has obtained a receipt from the Agency. The Danish Medicines Agency shall lay down specific rules on the notification procedure, etc.

(2) The provision in subsection (1) shall also apply 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, cf. 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 shall lay 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 may 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.

94.-(1) The Danish Medicines Agency shall establish 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 shall lay down specific rules to this effect.

95.-(1) The Danish Medicines Agency shall inspect 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 the Interior and 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 from the regulatory authority may at any time have access 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. In cases of application for, amendments to and withdrawal of marketing authorisations for medicinal products and for clinical trials of medicinal products the Danish Medicines Agency may consult the Licensing Committee. The Licensing Committee consists of maximum 13 members.

97. In cases relating to requirements for the quality of medicinal products, cf. section 52, the Danish Medicines Agency may consult the Danish Pharmacopoeia Commission. The Pharmacopoeia Commission consists of maximum 6 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 the Interior and Health on the recommendation of the Danish Medicines Agency. The Minister appoints the chairman and the vice-chairman from among the members of the individual committee or council.

(2) The Minister for the Interior and 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 the Interior and 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 the Interior and Health shall lay down the rules of procedure for the committees specified in sections 96 and 97.

100. Pursuant to section 152 of the civil penal 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 that they obtain in connection with their office or function if such information is confidential.

101.-(1) The Danish Medicines Agency shall appoint a Council for Adverse Drug Reactions to advise on questions regarding adverse reactions of medicinal products, and the Agency shall lay down the rules of procedure for the Council.

(2) The Council consists of maximum 9 members. The members should include representatives of doctors and dentists working in a clinical capacity with medicinal product treatment, pharmacists and consumers.

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 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 the Interior and 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, pharmaceutical companies and manufacturers of raw materials used in the manufacture of medicinal products,
(ii) payment for allocation, etc., of product numbers for medicinal products,
(iii) 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,
(iv) fee for notification of prices and information to the pharmacies about prices of pharmacy-restricted medicinal products,
(v) fee for notification of package sizes on non-pharmacy-restricted medicinal products, and
(vi) fee for application 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. Anyone authorised under section 39(1) to sell medicinal products for production animals to consumers shall be charged an aggregate fee determined by the Danish Finance Act for the financing of food safety and animal welfare measures.. Such fee shall be distributed on a pro rata basis according to the sales volume of medicinal products for production animals. The Minister for the Interior and Health shall lay down specific rules to this effect.

PART XV

Penalty etc.

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

(i) infringes sections 20, 21, 26, section 40A, (2) or (3), section 43, section 43A(1), and section 43B(2), section 50(3), section 53(1), section 54, section 58(3), section 59(1), section 60(1), section 62(2), sections 63-65, section 66(1), section 67(1) first sentence, section 68(1) first sentence, (2) first sentence, or (3), sections 71A, 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 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(5),

(iv) fails to comply with an order or a duty to inform in pursuance of section 22(1), sections 23- 24, section 25(1) or (2), sections 35, 42, section 44(2) second to fourth sentence, section 45, second sentence, section 46(1), section 53(1) or (5) second sentence, section 68(2) second sentence, or (4), section 69, section 71B(6), section 80(1), section 84(1) or (4) first sentence, section 87(2), second to fourth sentence, section 89(2), section 90(2) first sentence, or (5), or section 95(3) second sentence, or

(v) denies access to representatives from the regulatory authority pursuant to section 25(3), section 44(2) first sentence, section 45, first sentence, section 53(5) first sentence, section 71C, section 87(2) first sentence, section 90(2) second sentence, or section 95(3) first sentence

shall 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, section 39(1) or (2), or section 43B(1), or fails to comply with an order issued pursuant to section 46A, shall 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) shall be held criminally liable under the provisions of Part V of the Danish Criminal Code.

104A.-(1) The Minister for the Interior and 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.

(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 shall apply correspondingly.

(3) If the fine is accepted, there shall 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 shall be laid down by the Minister for the Interior and Health.

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

(3) The provisions laid down in pursuance of the Medicines Act, cf. Consolidated Act No. 656 of 28 July 1995 shall 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" shall be 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 shall be maintained until they are amended or withdrawn in pursuance of the provisions of the Act.

(2) A marketing authorisation for a medicinal product may not become valid for an unlimited period, cf. 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, provided 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 shall count from the commencement of the Act.

108. (Omitted. Amendment of certain provisions of the Danish Pharmacy Act).

109. (Omitted. Amendment of a provision of the Danish Act on Medical Devices).

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

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