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Order No. 1359 of 12.18.2012
Applicable
Publication Date: 22/12/2012
Ministry of Health

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Subsequent amendments to the Regulation

- Order No. 575 of 05.24.2013

Legislation regulation concerns

- Consolidation Act No. 506 of 04.20.2013
- Consolidation Act No. 1040 of 9/3/2014

Changes in / repeal

- Order No. 823 of 08.01.2012

Links to EU directives. See note 1

32001L0082 html | Note
32001L0083 html | Note

Additional documents:

- Regulations which implement the EU Directive 32001L0082
- Regulations which implement the EU Directive 32001L0083
- All circulars, instructions, etc. to this Order
- Decisions made under this provision
- Reports by the Ombudsman using this law

Overview (table of contents)

The full text

Order on the distribution of medicines 1)

Pursuant to § 29 paragraph. 3, § 39 a paragraph. 1, § 39 b, § 41 c, § 41 d, § 43a, § 92. 3 and § 104. 3 of Law no. 1180 of 12 December 2005 on medicinal products, as amended by Act no. 1258 of 18 December 2012 and pursuant to § 38 paragraph. 2, § 43 and § 72 paragraph. 2 of the Law on Pharmacies, cf. Consolidated Act no. 855 of 4 August 2008, as amended by Act no. 1258 of 18 December 2012, provides:

Chapter 1

Scope of the Order

§ 1. This Order includes wholesale distribution and retail distribution of medicines from the pharmacy, including storekeepers, see. However paragraph. 2nd

Pcs. 2. This Order does not apply to:

1) retail distribution of homeopathic medicines, anthroposophic medicines, herbal medicines, traditional herbal medicines, vitamin and mineral preparations and medical gases and
2) retail distribution of medicines from pharmacies OTC outlets or from retail dealers authorized to sell OTC medicines according to § 39 paragraph. 1 of the Act on drugs.

§ 2. This Order applies to companies and individuals who have received National Board of Health for wholesale distribution of pharmaceuticals in accordance with § 39 paragraph. 1 of the Act on drugs for applicants for such permission, as expressly stated in the individual provisions and pharmacies, including hospital pharmacies.

Pcs. 2. The notice shall also include, as expressly stated in the individual regulations, providers of drugs that have been registered in accordance with § 41 b paragraph. 1 of the Act on drugs.

Chapter 2

Definitions

§ 3. For purposes of this Order:

1) Good Distribution Practice (GDP): The part of quality assurance which ensures that medicinal properties do not deteriorate during distribution and that defective products can be traced and withdrawn.
2) Distribution: Any activity consisting in wholesale or retail distribution.
3) Wholesale Distributor: A company or person who makes or causes to conduct wholesale distribution.
4) Wholesale distribution: Any kind of activity that is to buy, sell, receive, hold or deliver drugs within the EU / EEA or in pharmaceutical exports to third countries, with the exception of supplying medicinal products to the users.
5) Retail Trade: A company or a person who carries out retail activities.
6) Retail distribution: Any activity which is to receive, store, sell or supply medicinal products to the users.
7) Supplier: A manufacturer, importer or wholesaler who make delivery to the next link in the distribution chain.

8) Importer: Anyone who has Board of Health authorized the importation of drugs according to § 39 paragraph. 1 of the Act on drugs and pharmacies, including hospital pharmacies, importers of medicinal products.

9) Imports: Imports of medicinal products from a country outside the EU / EEA (third).

10) The manufacturer: The company or person Board of Health permission to manufacture drugs according to § 39 paragraph. 1 of the Act on drugs, and if the qualified person has made the final release of the batch, as well as pharmacies, including hospital pharmacies, which undertakes such release.

11) Quality System: The system ensures that distributed drugs with the rules of this Order that the storage conditions to be fulfilled, including during transportation, that contamination from or of other products is avoided, that the medicines delivered to the right person and that they traceability.

12) Control Certificate: Certificate signed by the Qualified Person of the manufacturer, of the person responsible for importation or of the contract acceptor that the drug, including intermediates and active substances are manufactured in compliance with good manufacturing practice and meet the requirements underlying marketing .

13) Qualified person: A person who meets the requirements for scientific and technical qualifications laid down in Article 49. 2-3 of Directive 2001/83 / EC or Article 53. 2-3 of Directive 2001/82 / EC and if appropriate Article 13. 2 of Directive 2001/20 / EC.

14) Quality Responsible person: A person designated by the company to ensure that the company complies with the applicable rules of good distribution practices.

15) Receive Control: Ensuring that the drug storage conditions have been complied with in transit to the documentation required by this Order, supplied and that the medicinal products supplied corresponds to the ordered.

16) Mediator of drugs: A company or person making distribution of drugs.

17) Dissemination of medicines: Any kind of business related to the purchase and sale of drugs, except for wholesale distribution, that do not include physical handling, but consist of negotiating independently and on behalf of another legal or natural person.

18) Falsified medicinal product: Any medicinal product with a false representation of:

a) its identity, including its packaging and labeling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients,

b) its source, including its manufacturer, its country of manufacture, its country of origin or the holder of the marketing authorization for them or

c) its history, including the records and documents relating to the distribution channels.

Chapter 3

Permission for wholesale distribution

§ 4. In order to obtain authorization for wholesale distribution of pharmaceuticals in accordance with § 39 paragraph. 1 of the Act on drugs, the applicant must:

1) have sufficient staff to meet the requirements of §§ 15-16, and

2) have premises and equipment that meets the requirements of §§ 17-20.

Pcs. 2. When applying for authorization for wholesale distribution of medicinal products, the applicant must apply Board of Health preprinted application form.

§ 5. An application or reapplication for a license for wholesale distribution under § 39 paragraph. 1 of the Act on drugs are processed within 90 days from the submission of a complete application.

Pcs. 2. If the holder of a license for wholesale distribution requests a change in the consent information listed application will be processed within 30 days. This period may be extended to 90 days.

§ 6 Board of Health may require from the applicant further information as regards the matters referred to in § 4, paragraph. First

Pcs. 2. If the Board of Health requires additional information in accordance with paragraph. 1, suspended the deadlines specified in § 5 until the information is provided.

§ 7 Board of Health shall issue the authorization for distribution, after having secured by a study carried out by its representatives that information in the application corresponds to the facts.

§ 8. The holder of a license for the wholesale distribution of medicinal products may not, without Board of Health permission to change the conditions mentioned in § 4, paragraph. First

§ 9. Possession of a permit to manufacture or import medicines under the see. § 39 paragraph. 1 of the Act on drugs, shall include authorization to wholesale distribute the drugs.

Pcs. 2. Possession of an authorization for wholesale distribution of medicines do not allow you to import or produce drugs, including produce multipacks or drugs for clinical trials, change the drug's labeling or packaging, or to break the finished product packs.

§ 10. Health introduces the information received for registration in accordance with § 4, in the Union database as the European Medicines Agency administers on behalf of the EU.

Chapter 4

Registering dissemination of drugs

§ 11. To obtain registration as a provider of pharmaceuticals in accordance with § 41 c paragraph. 1 of the Act on drugs, the applicant must:

Apply the electronic form, as Board of Health has made available

The following details in the form: name, corporate name and permanent address

Pcs. 2. An intermediary must have a permanent address and contact information in Denmark.

Pcs. 3. Any alteration of the information under paragraph. 1, the intermediary, without undue delay of Health.

Chapter 5

Good Distribution Practice

§ 12. Al wholesale and retail activities must be conducted in accordance with good distribution practices.

§ 13. Detailed guidelines on good distribution practice published by the European Commission in the 'Guide to good distribution practice for medicinal products for human use', which is also used for medicinal products for animals.

Quality Assurance System

§ 14. Every wholesale dealer must establish and operate an effective quality assurance system that actively involving management and staff in the affected departments within the company. Wholesale dealer must document in writing quality management system, including describe responsibilities, processes and risk management measures related to the company.

Organisation and staff

§ 15. Wholesalers and pharmacies, including hospital pharmacies must have competent and appropriately qualified personnel. It must be designated a quality responsible person who is responsible for the activity exercised in accordance with the provisions of this Order. The responsible person must have its time in the company of a sufficiently taking into account the activity of the company or pharmacist.

Pcs. 2. Wholesale dealers must appoint a management representative who possesses the necessary qualifications, and who have the authority and responsibility to implement and maintain a quality assurance system.

§ 16. The hierarchical relationships shall be defined in an organizational chart. The duties of the staff who handle drugs must be provided in job descriptions.

Pcs. 2. The staff must be familiar with the principles and guidelines governing good distribution practices.

Premises and equipment

§ 17. Premises and equipment must be designed, dimensioned, used and maintained so that they are fit for their purpose, and so that effective cleaning can be made.

§ 18. Storage facilities must be sufficiently large to allow the maintenance of good order and compliance with appropriate product flow, for example. first in first out basis. A special area should be designed items for destruction.

§ 19. Warehousing be done by the storage conditions specified in any marketing or by the manufacturer. The temperature in the storage rooms and refrigeration equipment must be checked and documented.

§ 20. Medicines should be stored out of reach of unauthorized persons.

Receipt and Delivery

§ 21. Wholesalers and pharmacies must ensure that they only receive supplies of drugs from the companies or persons within the EU / EEA have a license to manufacture, import or wholesale distribution of medicinal products or a pharmacy.

Pcs. 2. If the product has been received from another wholesaler, the wholesaler must ensure that the supplier wholesale distributor complies with the principles and guidelines of good distribution practices. This includes verifying whether the supplying wholesale distributor holds a license for wholesale distribution.

Pcs. 3. Where the product is obtained from the manufacturer or importer, wholesaler verify that the manufacturer or importer holds a manufacturing authorization.

Pcs. 4. Where the product is obtained through brokering, the wholesale distributor check that the intermediary meets the requirements laid down for intermediaries.

§ 22. Wholesale Retailers must ensure that performed acceptance testing for all supplies of medicinal products they receive from companies or persons within the EU / EEA are permitted to manufacture, import or wholesale distribution of medicinal products or a pharmacy. Acceptance testing can only be carried out in Denmark.

§ 23. Wholesale Distributors must ensure that they know delivery within the EU / EEA of other drugs than those mentioned in § 1. 2, no. 1, only delivers to companies or individuals who have a license to manufacture, import, wholesale or retail distribution of drugs, or who is a pharmacist referred to. However paragraph. 2-6.

Pcs. 2. In addition to in paragraph. 1 recipients referred to drugs for clinical trials is provided to the physician, dentist or veterinarian who is responsible for the trial implementation, when the trial is approved in accordance with § 88 paragraph. 1 of the Act on drugs.

Pcs. 3. In addition to in paragraph. 1 said receivers can serums and medicines made from blood, vaccines and immunological test substances from Statens Serum Institute and Veterinary Institute delivered to doctors, dentists and veterinarians see. § 30 of the Law on medicines Order on preparations and studies mm at Statens Serum Institut and Order preparations and studies at Technical University of Denmark.

Pcs. 4. In addition to in paragraph. 1 recipients referred to drug tests Health's permission, the marketing authorization holder or his representative, distributed to doctors, dentists and veterinarians, cf. Order the extradition of drug samples. Health can set conditions for authorization.

Pcs. 5. In addition to in paragraph. 1 said receivers can radiopharmaceuticals comes to nuclear medicine departments in hospitals, see. Order on radiopharmaceuticals and Order Handling, etc. of radiopharmaceuticals in hospitals.

Pcs. 6. The institutions, companies, etc. may be technical, analytiske- and educational purposes (non-medicinal purposes) supplied drugs by written order signed by the head of the institution or by a person authorized to do so.

Control Proof

§ 24. Upon delivery of goods from other EU / EEA countries, the receiving company or the receiving pharmacy to ensure that the delivery is accompanied by an inspection certificate in accordance with. Subject to paragraph. 2nd

Pcs. 2. Upon delivery of drugs for clinical trials or medicines sold or dispensed pursuant to § 29 paragraph. 1, or § 30 of the Law on medicines, which are not covered by a marketing can inspection certificate is replaced by the corresponding documentation.

Pcs. 3. If a delivery is not accompanied by paragraph. 1 or 2 above documentation, the receiving company or the receiving pharmacy before further distribution or disclosure ensure that every batch is checked according to § 35 of the Ordinance on the production and import of medicines and intermediates.

Evidence received and supplied drugs

§ 25. The holder of an authorization for wholesale distribution of medicinal products must retain documentation of all received drugs in the form of information on:

1) The date of receipt,

2) precise indication of the name,

3) received quantity

4) pharmaceutical form, strength and package size,

5) the name and address and

6) the name and address.

Pcs. 2. Upon receipt of medicines from the manufacturer, importer or other wholesale dealer, the documentation in

addition to in paragraph. 1 shall also include information on the batch number and expiration date.

§ 26. The holder of an authorization for wholesale distribution of medicinal products must store and attach documentation for all medicinal products supplied to pharmacies as well as for businesses and individuals, according to Danish or foreign legislation to supply medicinal products to users, including medicines exported to countries outside the EU / EEA (third countries), in the form of information on:

1) date of delivery,

2) precise indication of the name,

3) quantity supplied,

4) pharmaceutical form, strength and package size,

5) the name and address and

6) the name and address.

Pcs. 2. For deliveries of drugs to another wholesale dealer, the documentation in addition to in paragraph. 1 shall also include information on the batch number and expiration date.

Pcs. 3. For supplies of drugs for animals, the documentation in addition to in paragraph. 1 shall also include information on the batch number and expiration date.

§ 27. Pharmacies, including hospital pharmacies must for all received drugs keep documentation in the form of information on:

1) The date of receipt,

2) precise indication of the name,

3) received quantity

4) pharmaceutical form, strength and package size,

5) the name and address and

6) the name and address.

Pcs. 2. Upon receipt of prescription drugs for animals, the documentation in addition to in paragraph. 1 shall also include information on the batch number.

§ 28. Pharmacies must keep documentation of all dispensed prescription drugs to animals in the form of information on:

1) surrender date,

2) precise indication of the name,

3) delivered quantity

4) pharmaceutical form, strength and package size,

5) the name and address

6) the name and address,

7) batch number and

8) the prescribing veterinarian's name and address and a copy of the prescription.

§ 29. The §§ 25-28 above documentation must be in the form of purchase or sales invoices, accompanying papers, etc., and wholesalers and pharmacies, including hospital pharmacies must ensure it is available to the Board of Health for 5 years.

§ 30. Wholesalers of veterinary medicines and pharmacies should at least annually conduct a documented detailed audit a record of received, delivered and dispensed drugs for animals to be compared with the stock, and a report should be prepared of any discrepancies. For pharmacies, the requirement concerns only prescription medicines for animals.

Pcs. 2. Wholesale Merchants must leave it in paragraphs. 1 that report be available to Health for 3 years.

Pcs. 3. Pharmacies must leave it in paragraphs. 1 that report be available to Health for 5 years.

Complaints and withdrawals

§ 31. There must introduce an effective system for handling the case of complaints and shortcomings, demonstrating how they were treated, and which makes it possible to withdraw drugs in the distribution grid immediately and at any time after orders from the Board of Health or in cooperation with the manufacturer, importer or marketing authorization holder for the medicinal product.

Counterfeit medicines

§ 32. Wholesalers and pharmacies must ensure that the drugs that are or may be counterfeit, kept separate from other drugs. The drugs must also be labeled, so it is clear that they are not for sale or distribution.

Storage, distribution and reception control by contract

§ 33. Wholesale dealer (contract offers) can leave to others (contract makers) to perform reception (including acceptance testing), supply and distribution, if:

1) contract takes has a nationwide license pursuant to § 39 paragraph. 1 of the Act on drugs or other relevant authorized by the law of another EU / EEA country
2) there is a written contract between the contract giver and contract takes for each task,
3) kontraktgivers and contract's responsibility is clear from the contract,
4) it appears from contract to contract takes an obligation to comply with good distribution practices,
5) it appears from the contract, the contract does not confer upon the performance of tasks to third parties without the consent of contract offers, and
6) it appears from the contract, the contract takes, if this has a permit under the law of another EU / EEA country, see. no. 1, agrees that the National Board of Health controls the company.

Pcs. 2. The final acceptance testing by deliveries from other EU / EEA countries can only be made in Denmark.

Pcs. 3. Contract Takes can only transfer the execution of tasks to third parties by following the provisions of this Order.

Pcs. 4. The provision of paragraph. 1 shall also apply to delivery of drug samples to doctors, dentists and veterinarians, is happening on behalf of the MAH see. § 23 paragraph. 4th

Self-inspection

§ 34. Wholesale dealer must regularly self-inspections as part of the quality assurance system to verify the implementation of and compliance with the principles of good distribution practice and to propose any changes that may be necessary.

Pcs. 2. There must be records of self-inspections and corrective actions.

Pcs. 3. Self-inspection program will include audits of any contract makers.

Miscellaneous

§ 35. Multi-packs may only be broken by hospital pharmacies, drug stores and distributing veterinarians. Multi-packs consisting of individual packages of a veterinary medicinal product may be broken by pharmacies, Technical University of Denmark, holders of Board of Health authorization for retail sale of drugs for animals recorded in dispensing group 'HV' National Board of Health's register of approved drugs and holders a permit under § 39 paragraph. 1 of the Act on drugs for distribution to users of medicines for production.

Pcs. 2. Pharmacies and hospital pharmacies must also break the drug packs in accordance with executive order on the division of medicine packages to animals and Order on dose dispensing of medicines.

§ 36. Medicinal products whose shelf life has expired, or which otherwise can not be assumed to be equal to the applicable quality requirements, may not be distributed. Such drugs should be returned to the manufacturer or supplier or disposed of properly.

Chapter 6

Good distribution practices for dissemination

§ 37. It is for the intermediary to carry out communication in accordance with good distribution practices for intermediaries.

§ 38. If the drug is mediated through a wholesaler, the retailer verify that the supplier wholesaler complies with the principles and guidelines of good distribution practices. This includes verifying whether the supplying wholesale distributor holds a license for wholesale distribution.

Pcs. 2. If the drug is mediated by the manufacturer or importer, retailer verify that the manufacturer or importer holds a license to manufacture or import of medicines or intermediates.

Pcs. 3. If the drug is mediated through another intermediary, the intermediary check that the intermediary meets the specified requirements for intermediaries.

Pcs. 4. The intermediary shall ensure that the recipient has appropriate authorization.

Quality Assurance System

§ 39. An intermediary shall establish and operate an effective quality assurance system that actively involving management and staff in the affected departments within the company. The intermediary shall document in writing quality management system, including describe responsibilities, processes and risk management measures related to the company.

Incoming and outgoing drugs

§ 40. An intermediary must ensure that the brokered medicinal products are covered by a marketing authorization in an EU or EEA country.

§ 41. An intermediary must keep documentation of all incoming and outgoing brokered medicinal products in the form of information on:

1) the date of the communication,

2) precise indication of the name,

3) conveyed amount,

4) pharmaceutical form, strength and package size and

5) the supplier and the recipient's name and address

Withdrawal

§ 42. An intermediary must have an effective system to ensure the implementation of the withdrawal from the market under the orders of Health or in cooperation with the manufacturer, the supplier of the medicinal product or marketing authorization holder for the medicinal product.

Removal from the list of registered agents

§ 43. If the Board of Health delete an intermediary from the list according to § 41 c paragraph. 3 of the Act on drugs shall Sundhedsstyrelsen the person concerned.

Chapter 7

Inspection, disclosure of information, etc.

§ 44. After any inspection according to § 44 paragraph. 1 of the Act on drugs, prepares Board of Health a report on whether the principles and guidelines of good distribution practices observed. The content of these inspection reports shall be communicated to the affected wholesale dealer or retailer, who must keep the report on the company. Before adopting the report, the Board of Health the affected inspected the company the opportunity to submit comments.

Pcs. 2. Following a reasoned request from an authority in another EU / EEA country or from the European Medicines Agency sends Health Agency electronically in paragraph. 1, said reports that concerns wholesale distributors of medicinal or active substances for medicinal purposes to the relevant authority in another EU / EEA country or to the European Medicines Agency.

Pcs. 3. Health introduces information on authorizations granted under this Order in the Union database managed by the Agency on behalf of the EU.

§ 45. Within 90 days after an inspection as specified in § 44 issue of Health a certificate of good distribution practices for wholesale distributor if the outcome after an inspection, that the person complies with the principles and guidelines of good distribution practices.

Pcs. 2. Health leaves in paragraph. 1 certificates referred to in a Community database, as the European Medicines Agency administers on behalf of the EU.

Pcs. 3. If the outcome of an inspection referred to in paragraph. 1 is that the wholesaler does not comply with the principles and guidelines of good distribution practices, the information shall be in the paragraph. 2 Community database referred.

§ 46. The Board of Health should have a monitoring system that includes inspections at an appropriate frequency based on risk with importers and distributors are based in Denmark, and an effective follow-up.

§ 47. At the request of the European Commission or another EU / EEA country must Health to submit all relevant information concerning the individual authorization for wholesale distribution, issued according to § 39 paragraph. 1 of the Act on drugs.

§ 48. If the Board of Health shall suspend or revoke an authorization for wholesale distribution of pharmaceuticals in accordance with § 41 of the law on medicinal products, shall inform the National Board of Health immediately the other EU / EEA countries and the European Commission.

§ 49. If a competent authority in another EU / EEA country estimates that the holder of an authorization for wholesale distribution of medicines no longer fulfills the conditions of authorization and shall inform the Board of Health thereof, shall Sundhedsstyrelsen the necessary measures and inform the Member State and the European Commission of the decisions taken and the reasons therefor.

§ 50. If a medicinal product in the context of an action for revocation is suspected of posing a serious risk to public health, and was first identified in Denmark, ensuring Health immediately that emitted a quick warning to all EU / EEA countries' competent authorities and all relevant actors in the supply chain in Denmark.

Pcs. 2. In the event that products referred to in paragraph. 1 is assumed to be reached patients, emits Health or wholesale dealer within 24 hours of a message to the public about the suspected quality defect or falsification, the potential risks and recommendations to patients.

§ 51. Board of Health may grant an exemption from one or more of the provisions of this Order, if exceptional circumstances so require.

Criminal and entry into force

§ 52. Unless a higher penalty is warranted under other legislation penalized with a fine that violate § 8, § 12, §§ 14-22, § 23 paragraph. 1, § 24 paragraph. 1 and 3, §§ 25-34, § 35 paragraph. 1, and §§ 36-42.

Pcs. 2. There may be imposed on companies etc. (legal persons) under the rules of the Penal Code Chapter 5.

§ 53. This Order shall enter into force on 1 January 2013.

Pcs. 2. Order no. 823 of 1 August 2012 on the distribution of pharmaceuticals repealed.

Pcs. 3. Individuals and companies that administer drugs and who began their activity before 1 January 2013 must register with the Board of Health by 1 March 2013.

Ministry of Health, December 18, 2012

Astrid Krag

/ Kirstine F. Hindsberger

Official notes

1) The Order contains provisions implementing parts of European Parliament and Council Directive 2001/82 / EC of 6 November 2001 on the Community code relating to veterinary medicinal products Official 2001 no. L 311, p. 1, as amended the European Parliament and Council Regulation (EC) 596/2009 of 18 June 2009, Official Journal 2009 No. L 188, p. 14, and parts of the European Parliament and Council Directive 2001/83 / EC of the sixth November 2001 on the Community code relating to medicinal products, Official Journal 2001, No. L 311, p. 67, as amended by the European Parliament and Council Directive 2010/84 / EU of 15 December 2010, Official Journal 2010, no. L 348, p. 74, and the European Parliament and Council Directive 2011/62 / EU of 8 June 2011, Official Journal 2011, no. L 174, p. 74.