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Order No. 1358 of 12.18.2012
Applicable
Publication Date: 22/12/2012
Ministry of Health

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Subsequent amendments to the Regulation

Legislation regulation concerns

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

Changes in / repeal

- Order No. 824 of 08.01.2012

Links to EU directives. See note 1

31991L0412	html	Note
32001L0020	html	Note
32001L0082	html	Note
32001L0083	html	Note
32003L0094	html	Note

Additional documents:

- Regulations which implement the EU Directive 31991L0412
- Regulations which implement the EU Directive 32001L0020
- Regulations which implement the EU Directive 32001L0082
- Regulations which implement the EU Directive 32001L0083
- Regulations which implement the EU Directive 32003L0094
- 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 manufacture and import of medicines and intermediates [1)]

Pursuant to § 39 a paragraph. 1, § 39 b, § 43a, § 57, § 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 the manufacture of pharmaceuticals and intermediates, including the manufacture for export to countries outside the EU / EEA (third countries), and the importation of drugs and intermediates from third countries.

Pcs. 2. The notice also includes the manufacture of active substances which are sterile or biological, to be used for the production of marketed drugs.

§ 2. This Order applies to companies and individuals who have received National Board of Health permission to manufacture or import of medicines or intermediates according to § 39 paragraph. 1 or paragraph. 2 of the law on drugs, and for applicants for such permits where specifically provided for in the individual provisions. The notice also applies to pharmacies, including hospital pharmacies.

Chapter 2

Definitions

§ 3. For purposes of this Order:

1) Good Manufacturing Practice (GMP): The part of quality assurance which ensures that medicinal products and intermediate products are consistently produced and controlled in accordance with the quality standards that apply to their intended use.
2) Intermediate: Mixing of raw materials (active substances and excipients) intended for further processing to a drug.
3) Magistrally drug: A drug is prepared in a pharmacy for individual patients or animals with a prescription from a doctor or a veterinarian.
4) Manufacturer: Anyone who has Board of Health permission to manufacture medicinal products or intermediates according to § 39 paragraph. 1 or paragraph. 2 of the law on medicines and pharmacies, including hospital pharmacies that perform manufacturing activities as mentioned in no. 6.
5) The maker of a drug: the company or the pharmacy, including hospital pharmacist if qualified person has made the final release of the batch.
6) Manufacturing Activities: All production processes and packaging operations, labeling, quality control and release of drugs.
7) Preparation of intermediates: Complete and partial manufacture or import of intermediate products, as well as processes of dividing up, packaging or presentation, and any negotiation of intermediates.

8) Manufacturer of the active substances: Anyone who performs activities as mentioned in no. 9th

9) Manufacture of active substances used as starting materials for the manufacture of medicinal products: Complete and partial manufacture or import of an active substance used as a raw material, and the various processes of dividing up, packaging or presentation prior to its incorporation in a medicinal product, including repackaging and nyettikering made by a distributor of raw materials.

10) Importer: Anyone who has Board of Health permission to import medicines or intermediates according to § 39 paragraph. 1 or paragraph. 2 of the Law on medicines and pharmacies, including hospital pharmacies, importers of medicinal products or intermediates.

11) Imports: Imports of products or intermediate products from a country outside the EU / EEA (third).

12) Quality Control: Procedures and documentation of sampling, inspection and qualitative and quantitative testing of raw materials, packaging materials, intermediate and finished products as well as release to ensure that drugs are not released before their quality is proven to be satisfactory in relation to both internal requirements as 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 assurance: All measures taken to ensure that a drug has a quality that corresponds to its intended use.

15) Reference test: each batch of raw material used, including packaging material, samples of the finished product, stored for subsequent documenting its contents and any labeling, etc., as well as samples of formulated bulk in respect of drugs for clinical trials .

16) Blinding: Deliberate concealment of the identity of a product for clinical trials.

17) Unblinding: Uncovering blinded product identity.

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 content of these components

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

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

Chapter 3

Permission for the manufacture or import of medicines and intermediates

§ 4. In order to obtain a license to manufacture or import medicines or intermediates according to § 39 paragraph. 1 or paragraph. 2 of the law on medicinal products, the applicant must:

1) specify which drugs, including drug forms, or intermediate products to be manufactured or imported and also inform the property of their production, including production and analytical control

2) have premises, technical equipment and control facilities that meet the requirements of this Order and the requirements of any marketing and

3) have at least one qualified person available.

Pcs. 2. The applicant must apply the Health Protection Agency preprinted application form and provide the application with evidence that he meets the requirements listed in paragraph. 1 pt. 2 and 3, including supplying a detailed description of the company, for example in the form of a site master file.

§ 5. The Board of Health may require from the applicant additional information on the factors listed in § 4th

Pcs. 2. If the Board of Health requires additional information in accordance with paragraph. 1, suspended the deadlines specified in § 6 until that information is provided.

§ 6. An application or reapplication for a license to manufacture or import medicines or intermediates processed within 90 days from the submission of a complete application.

Pcs. 2. If the holder of a permit to manufacture or import medicines or intermediates applicant for a change in the consent information listed application will be processed within 30 days. This period may be extended to 90 days.

§ 7. Health Agency issues first license to produce or import medicines or intermediates having secured by a study carried out by its representatives that the information in the application corresponds to the facts.

Pcs. 2. Health introduces information on authorizations granted under this Order in the Union database as the European Medicines Agency administers on behalf of the EU.

§ 8. The holder of a permit to manufacture or import medicines or intermediates may not without the National Board of Health permission to change the conditions that led to the authorization referred. § 4, paragraph. First

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

Chapter 4

Manufacturing

§ 10. A manufacturer must ensure the following:

1) That the drugs covered by a marketing follows the manufacturing processes that underlie marketing.
2) That all manufacturing processes are carried out in accordance with good manufacturing practices for pharmaceuticals and intermediates in accordance with the license to produce or import medicines or intermediates.
3) The active substances used as starting materials in the manufacture of pharmaceuticals and intermediates, manufactured in compliance with good manufacturing practices for active substances and distributed in accordance with good distribution practices for active substances referred to. However paragraph. 2. The manufacturer of a drug should also make sure that the manufacturer and the distributor of the active substances with good practices for distribution and manufacturing of active substances by conducting audits at the manufacturing and distribution sites of the active substances. The manufacturer must also verify that the manufacturers, importers or distributors from whom the manufacturer decreases active substances are registered with the competent authority in the EU / EEA country where they are established. The manufacturer shall finally check the active component of authenticity and quality.
4) The fact that the excipients are suitable for use in medicinal products by ascertaining what the appropriate good manufacturing practices for excipients. This will be determined on the basis of a formalized risk assessment taking into account the requirements for other suitable quality systems excipients origin, their intended use and history of quality defects. The manufacturer shall ensure that the established appropriate good manufacturing practice and document the measures taken accordingly. The manufacturer must also check the excipients authenticity and quality.

Pcs. 2. The provisions of paragraph. 1 pt. 3 and 4 shall not apply to:

1) Extemporaneous drugs.
2) Drugs sold or delivered pursuant to § 29 paragraph. 1, or § 30 of the Law on medicines, which are not covered by a marketing authorization in Denmark.
3) Drugs for use in clinical trials that are not covered by marketing.

Pcs. 3. In the manufacture of pharmaceuticals for clinical trials, the manufacturer shall, in addition to comply with the paragraph. 1 said requirements ensure that drugs manufactured in accordance with the data underlying the authorization of the clinical trial.

§ 11. Detailed guidelines for good manufacturing practices concerning drugs, intermediates and active substances published by the European Commission in the 'Rules Governing Medicinal Products in the European Community, Volume 4'.

§ 12. The manufacturer shall periodically conduct a review of the manufacturing methods in the light of scientific and technical progress.

Quality assurance

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

Organisation and staff

§ 14. The manufacturer shall have competent and appropriately qualified personnel, which is large enough that the objectives of the quality assurance of drugs and intermediates can be met.

Pcs. 2. The responsibilities of the managerial and supervisory staff, including the person or qualified persons, responsible for implementing and operating good manufacturing practice shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organizational chart.

Pcs. 3. The job descriptions and the organizational chart, as referred to in paragraph. 2, must be approved in accordance with the manufacturer's system of quality assurance.

§ 15. The personnel mentioned in § 14 paragraph. 1 must undergo initial and continuing training including the theory and practical application of the concepts of quality assurance and good manufacturing practice. In the manufacture of pharmaceuticals for clinical trials, the training also include the special circumstances prevailing in the manufacture of this type of drugs.

§ 16. The personnel mentioned in § 14 paragraph. 2 shall be given sufficient authority to that it can discharge its responsibilities properly.

§ 17. The manufacturer shall establish and comply with hygiene instructions that are adapted to the activities to be carried out.

Pcs. 2. The instructions shall include procedures relating to health, hygiene and attire.

Premises and equipment

§ 18. The manufacturer shall ensure that facilities and equipment are designed, dimensioned, used and maintained so that they are fit for their purpose, and so that effective cleaning can be made.

Pcs. 2. Accommodation and design of premises and equipment and working operations should be conducted in such a way that the risk of error is as small as possible and so that confusion, contamination, cross-contamination and any other action that may have an adverse effect on product quality can be avoided.

§ 19. The manufacturer shall ensure that the equipment and premises to be used for manufacturing operations with a decisive influence on the quality of products, subject to appropriate qualification and validation.

Documentation

§ 20. The manufacturer shall establish and maintain a documentation system. The system must be based on specifications for raw materials, intermediate products and the finished product, the main regulations regarding the composition, production and control of the finished product as well as on general instructions on procedures relating to the equipment, hygiene, production and control.

Pcs. 2. There shall be the main requirements for each batch sizes produced.

Pcs. 3. Documents shall be clear, flawless and updated.

§ 21. The manufacturer shall be in possession of documentation for the manufacture of each batch, which makes it possible to follow the production process.

Pcs. 2. All documentation relating to the manufactured batch should be kept at least one year longer than the expiry date of the batch or at least 5 years after the drug release for sale or distribution, whichever period is longer.

Pcs. 3. In the manufacture of pharmaceuticals for clinical trials, the documentation must be kept for at least 5 years after the formal completion or discontinuation of the trial in which the batch entered.

§ 22. Use electronic, photographic or other data processing systems, the manufacturer shall validate the system and demonstrate that the data will be appropriately stored, that data is protected against loss or damage during the anticipated period of storage, as well as changes in the data documented.

Pcs. 2. Data stored in these systems must immediately be handed to the Health Protection Agency in legible form.

Production

§ 23. The manufacturer shall ensure that manufacturing operations are carried out in accordance with established instructions and procedures. There must be suitable and sufficient resources are available for process control.

Pcs. 2. Measures must be taken to avoid cross contamination and mix, and the manufacture of pharmaceuticals for clinical trials should be approached with particular caution when handling during and after blinding.

Pcs. 3. Any new manufacture or important modification of a manufacturing process shall be validated. Critical phases of any manufacturing process must be periodically validated.

Pcs. 4. In the production of drugs for clinical trials, validated the whole production process, to the extent applicable, taking into account the stage of product. At least the critical process steps (eg. Sterilization) validated. All steps in the design and development of the manufacturing process shall be fully documented.

Pcs. 5. Any process deviation or defect of a drug or an intermediate should be documented and explained thoroughly.

Quality control

§ 24. The manufacturer shall establish and maintain a system of quality control, which is headed by a person who has the requisite qualifications and is independent of production.

Pcs. 2. The paragraphs. 1 mentioned person must possess or have access to one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of raw materials, intermediate products, finished products and all parts of the packaging.

Pcs. 3. Laboratories outside the company can be used in accordance with this notice rules for production or analysis by contract.

§ 25. The final quality control of the finished product before release for sale or distribution or use in clinical trials must be the maker of a drug ensure that an assessment of all material information in batch documentation such as production process, results from the process control, analytical results , product line with the finished product specification and the finished pack.

§ 26. The maker of a drug to ensure that reference samples of each batch of the finished product stored for at least one year after the expiry date.

Pcs. 2. Samples of raw materials used, the manufacturer must keep at least two years after the release of the product. This period may be shortened if their shelf life is shorter. For some volatile solvents, gases, water and other raw materials, which are essential conditions warrant it, the storage of reference samples omitted.

Pcs. 3. In the preparation of drugs for clinical trials should be stored reference samples from each batch of the formulated product in bulk as well as the reference sample of the essential parts of the packing material which is used for the finished product. Samples must be kept for at least two years after the formal completion or discontinuation of the clinical trial in which the batch was used.

Pcs. 4. in paragraph. 1-3 mentioned tests should be available to Health.

§ 27. In the manufacture of extemporaneous drugs in a single or a few packs can sampling, testing and storage of reference samples of the finished product may be omitted.

Pcs. 2. Board of Health may allow for other medicinal products manufactured individually or in small quantities, or when that may occur specific issues during their storage, specific conditions for sampling, testing and storage of reference samples of the finished product.

Production or analysis after contact

§ 28. The manufacturer (contract offers) can leave to others (contract holders) to carry out the production or analysis, provided that:

1) contract takes has a nationwide license under § 39 paragraph. 1 or paragraph. 2 of the Act on drugs, or other relevant authorized by the law of another EU / EEA country or third country,
2) there is a written contract between the contract giver and contract takes for each manufacturing process, including analysis task or operation linked with the manufacture,
3) kontraktgivers and contract acceptor responsibility is clear from the contract,
4) it appears from contract to contract takes an obligation to comply with good manufacturing practice
5) the contract contains a description of the manner in which the qualified person responsible for the proper implementation of the given task to perform his duties,
6) it is clear from the contract that the contract does not confer upon the performance of tasks to third parties without the consent of contract offers, and
7) it appears from contract to contract out if this has a permit under the law of another EU / EEA country or third country referred. no. 1, agrees that the National Board of Health controls the company.

Pcs. 2. Analysis Laboratories in other EU / EEA countries or in third countries not subject to permit requirements as referred to in paragraph. 1 pt. 1 Notwithstanding this provision perform tasks for contract offers, if the contract states that they agree that the performance of these analyzes can be controlled according to the rules of good manufacturing practice.

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

Release

§ 29. The qualified person must before the release of each batch attest that the batch is made pursuant to this notice. Upon release of the drugs covered by the authorization must be an expert also certify that they meet the requirements underlying the permit. Upon release of drugs for clinical trials, the qualified person also certify that they meet the

requirements underlying the Board of Health approval to begin the trial, see. § 88. 1 of the Act on drugs.

Pcs. 2. The certificate must be in a register or the like which are created for this purpose and which continually updated. The register shall be kept for at least five years and be available to the Board of Health during this period.

Complaints, recalls and unblinding

§ 30. The manufacturer shall implement a system for recording and reviewing complaints together a system that makes it possible to withdraw products or intermediates in the distribution grid immediately and at any time.

Pcs. 2. In the manufacture of drugs for clinical trials introduced the systems referred to in paragraph. 1, in cooperation with the sponsor of the study.

Pcs. 3. The manufacturer shall record and investigate any complaint concerning defects or deficiencies and inform the Board of Health of any defect that could result in a recall or abnormal restriction on supply in the distribution network.

Pcs. 4. Notification of the Board of Health in accordance with paragraph. 3 shall contain information on all the countries of destination and any test sites.

Pcs. 5. If a product covered by a marketing manufactured for use in a clinical trial, the manufacturer shall, in cooperation with the sponsor to inform the marketing authorization holder of any defect that can be attributed to the drug.

Pcs. 6. The sponsor shall establish a procedure for the rapid unblinding of blinded products that make it possible to implement an immediate recall. The sponsor must accordingly ensure that the blinded product identity is revealed only if necessary.

Counterfeit medicines

§ 31. The manufacturer shall ensure that 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.

Self-inspection

§ 32. The manufacturer shall regularly conduct self-inspections as part of the quality assurance system to monitor the implementation and compliance with the principles of good manufacturing 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.

The labeling of drugs for clinical trials

§ 33. Marking of drugs for clinical trials to ensure protection of the subject, traceability identification of trials and drug and proper use of the drug.

Chapter 5

Importation

§ 34. The provisions of §§ 13-19, §§ 24-28 and §§ 30-32 shall apply to imports of medicines.

Release

§ 35. The qualified person of the importer must before release of any batch of medicinal products and intermediate products imported, ensure

1) the drug and the product is made by duly authorized to do so,
2) the drug, between the product and the active substances used in their manufacture, are manufactured in accordance with standards of good manufacturing practices for drugs, intermediates and active ingredients, at least equivalent to the requirements of this Order,
3) the drug, between the product and the active substances used in their manufacture, comply with any marketing, and
4) that the importer stored copy of the manufacturing authorization if, in the country where production took place, requiring such authorization.

Pcs. 2. During the checks in accordance with paragraph. 1, the qualified person, regardless of whether the drug or the product was originally manufactured in the EU / EEA, ensure that within the EU / EEA made a full qualitative analysis and a quantitative analysis of at least all the active constituents and all the other tests or control that is necessary to ensure the

quality of the product or intermediate product. The qualified person must check that the medicine's label (labels, etc.) are in compliance with applicable regulations.

Pcs. 3. The qualified person shall, prior to release of each batch of medicinal products and intermediate products imported, in addition to in paragraph. 1 and 2 above, ensure that there are representative samples of each batch and to certify that the batch is made pursuant to this notice and meets the requirements underlying any marketing. The certificate must be in a register or the like which are created for this purpose and which continually updated.

Pcs. 4. The checks referred to in paragraph. 2, may be omitted for the import of medicines and intermediates for clinical trials, or when the exporting country is taken adequate arrangements such. in the form of agreements on mutual recognition of other countries' regulatory authority (MRA) covering the specific types of drugs and intermediates, and ensuring that this has been adequately addressed in this country.

Pcs. 5. The importation of drugs or between products intended for clinical trials, the qualified person, in addition to in paragraph. 1 and 3 above, ensure that every batch of medicines and any batch of intermediate products imported, is controlled in accordance with the data underlying the authorization to conduct the clinical trial.

Pcs. 6. Imports of drugs to be sold or delivered pursuant to § 29 paragraph. 1 of the Act on drugs and which are not covered by a marketing paragraph. 1-3 does not apply. The qualified person shall import of such products ensure that they are released in accordance with the requirements in force in the country of manufacture (Declaration from the manufacturer), unless stricter requirements are set out in the authorization granted in accordance with § 29 paragraph. 1 of the Act on drugs. The qualified person must also ensure that medicinal products meet the conditions as stipulated in the relevant permit. The same applies to the import of drugs sold or delivered in accordance with § 30 of the law on drugs.

Pcs. 7. When checking after paragraph. 2 of a drug that is covered by a marketing authorization in the EU / EEA or in a third country, the qualitative and quantitative analysis carried out in accordance with the method of analysis approved by the relevant drug authorities in connection with the issuance of the marketing authorization for the medicinal product concerned.

Documentation

§ 36. The importer must be in possession of documentation for all imported medicines and intermediates. This should include the date, precise identity of the product name or the product name, introduced quantity, form, strength and pack size, batch number, expiration date and the supplier and the recipient's name and address.

§ 37. The documentation referred to in § 35 paragraph. 3 and § 36 shall be kept by the importer at least one year longer than the expiry date for the batch, or at least 5 years after the release for sale or distribution, whichever period is longer.

Pcs. 2. Use electronic, photographic or other data processing systems, the importer must validate the system and demonstrate that the data will be appropriately stored, that data is protected against loss or damage during the anticipated period of storage, and that changes in data documented.

Pcs. 3. Data stored in these systems must immediately be handed to the Health Protection Agency in legible form.

Chapter 6

Inspection, disclosure of information, etc..

§ 38. 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 manufacturing practice. The content of these inspection reports shall be communicated to the inspection visit to the manufacturer, importer, manufacturer of active substances or marketing authorization holder.

Pcs. 2. Before the report is completed, the Board of Health inspected entity concerned the opportunity to submit comments.

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

§ 40. Within 90 days after an inspection as mentioned in § 38 issue of Health a certificate of good manufacturing practice to the manufacturer, importer or manufacturer of the active substances if the outcome of the inspection shows that the person complies with the principles and guidelines of good manufacturing practice.

Pcs. 2. Health Authority shall enter the certificates mentioned in paragraph. 1, 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 manufacturer or importer does not comply with the principles and guidelines of good manufacturing practice, the information shall be in the paragraph. 2 Community database referred.

§ 41. Board of Health, after a reasoned request from an authority in another EU / EEA country or a country with which it has taken the appropriate arrangements for mutual recognition of other countries' regulatory supervision (MRA) or from the European Medicines Agency, pass the in § 38 the inspection reports electronically.

§ 42. At the request of the European Commission, an EU / EEA country or a third country which has taken the appropriate arrangements for mutual recognition of other countries' regulatory supervision (MRA), the Health Protection Agency disclose information on the authorization of the manufacture or importation of drugs or intermediates that are issued pursuant to § 39 paragraph. 1 or paragraph. 2 of the law on medicinal products.

§ 43. If the Board of Health because of the overriding reasons of human or animal health do not agree with the conclusions of an inspection carried out in another EU / EEA country, inform Health immediately the European Commission and the European Medicines Agency thereof.

§ 44. 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 country 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 Board of Health or the manufacturer within 24 hours of a message to the public about the suspected quality defect or falsification, the potential risks and recommendations to patients.

§ 45. 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

§ 46. Unless a higher penalty is warranted under other legislation penalized with a fine that violate § 8, § 10 paragraph. 1 and 3, §§ 12-23, § 24 paragraph. 1-2, § 25, § 26 paragraph. 1 piece. 2, first sentence. And paragraph. 3-4, § 28 para. 1 and 3, §§ 29-33, § 35 paragraph. 1-3, paragraph. 5 pieces. 6, 2nd and 3rd clauses., And paragraphs. 7 and §§ 36-37.

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

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

Pcs. 2. Order no. 824 of 1 August 2012 on the manufacture and import of medicines and intermediates repealed.

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, parts of the European Parliament and Council Directive 2001/83 / EC of 6 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, parts of the European Parliament and Council Directive 2001 / 20 / EC of 4 April 2001 on the approximation of laws, regulations and administrative provisions relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use Official Journal 2001, no. L 121, p. 34, Commission Directive 2003/94 / EC of 8 October 2003 on the principles and guidelines of good manufacturing practice for medicinal products and investigational medicinal products for human use Official 2003 no. L 262, p. 22, and Commission Directive 91/412 / EEC of 23 . July 1991 on principles and guidelines of good manufacturing practice for veterinary medicinal products Official 1991 no. L 228, p. 70.