LÆGEMIDDEL STYRELSEN

DANISH MEDICINES AGENCY

Guidelines on applications for authorisation to manufacture and import medicines and intermediates

These guidelines offer guidance on how to complete the application form for authorisation to manufacture and import medicines and intermediates.

In the following, an authorisation to manufacture and import medicines and intermediates will be referred to as an MIA (**m**anufacturer's and **i**mporter's **a**uthorisation). In the following, an authorisation for wholesale distribution of medicines within the EU/EEA will be referred to as a wholesale dealer's authorisation.

For information on general requirements and guidelines for application for a company authorisation, please see Guidelines on requirements and deadlines for applications for company authorisations. For information about which activities require a company authorisation pursuant to section 39 of the Danish Medicines Act, please refer to Guidelines on activities subject to a section 39 authorisation.

For information on the requirements for manufacture and importation of medicines, see the Danish executive order on the manufacture and import of medicinal products and intermediate products (Danish title: *"Bekendtgørelse om fremstilling og indførsel af lægemidler og mellemprodukter"*), in the following referred to as the GMP executive order.

For information on the requirements for distribution of medicinal products, see the Danish executive order on the distribution of medicinal products (Danish title: *"Bekendtgørelse om distribution af lægemidler"*), in the following referred to as the GDP executive order.

For information on the specific requirements for batch release by the Qualified Person, see Annex 16 of the EU GMP guidelines, Certification by a Qualified Person and Batch Release, as well as The Danish Medicines Agency's guidelines on requirements and expectations for the qualified person in a pharmaceutical company.

These guidelines firstly provide general guidance on the form to apply for an MIA and then offer guidance on how to complete each of the application form's Annexes.

The application must be submitted with a detailed cover letter or cover email, describing the reason for the application, and must contain relevant additional material.

General guidance on the application form

The MIA application form is divided into 6 Annexes, of which Annex 1 and Annex 2 fall in two parts each.

Annex 1, Part 1:	Manufacturing of medicines
Annex 1, Part 2:	Importation of medicines
Annex 2, Part 1:	Manufacturing of medicines for use in clinical trials
Annex 2, Part 2:	Importation of medicines for use in clinical trials
Annex 3:	Manufacturing activities contracted out
Annex 4:	Quality control (testing) contracted out
Annex 5:	Qualified Persons
Annex 6:	Responsible manager

Annex 3 and Annex 4 should no longer be completed, but the application must instead be accompanied by a list of contract acceptors, please see "Annex 3 and Annex 4" later in these guidelines.

In the following sections, you can find information on how to complete the application form.

1. Annex 1 and Annex 2 – (Manufacture and importation at own address)
Annex 1 and Annex 2 are site-specific, and Annex 1 and Annex 2 must therefore be completed for each site that carries out manufacturing and/or importation activities. If no GMP activities take place at the main address, Annex 1 or Annex 2 should not be completed for the main address.

In Annex 1 and Annex 2, only the manufacturing activities carried out at the company's own address are indicated. Activities that are carried out only by contract acceptor are not to be indicated in Annex 1 and Annex 2.

2. The difference between Annex 1 and Annex 2
Annex 1 and Annex 2 are structured in the same way and include the same activities. The difference is that Annex 1 concerns authorised medicines for sale at pharmacies and retail outlets, whereas Annex 2 concerns medicines for use in clinical trials.

3. Annex 1 and Annex 2 – difference between human and veterinary
Annex 1 and Annex 2 are similar for manufacture and importation of medicines for respectively human and veterinary use. The only difference is that the application form for veterinary use includes more activities (1.2.1.15, 1.2.1.16, 1.4.1.4.2, 1.4.1.4.3, 1.4.1.4.4, 1.5.1.15, 1.5.1.16 and sub-items under 2.2.4.6), which are not used in the form for human use. An application form must be completed separately for manufacture and/or importation of medicines for human and veterinary use, respectively.

4. Annex 1 and Annex 2 – difference between Part 1 and Part 2
Both Annex 1 and Annex 2 are split up in two parts. In Part 1, the applicant must indicate the company's manufacturing activities, in Part 2, the company's importation activities. Part 2 must always be ticked as relevant if the company imports medicines or intermediates.
If the company imports an intermediate for further processing, the relevant manufacturing activities in Part 1 as well as the relevant importation activities in Part 2 must be ticked.

5. Annex 1 and Annex 2 – a quick overview of the manufacturing activities
Items 1.1 and 1.2:
Concern manufacturing activities of sterile and non-sterile intermediate products and medicinal products.
Item 1.3.:
Concerns manufacturing activities of biological intermediate products and medicinal products. When filling out item 1.3, it must also be indicated whether the activities under 1.3 relate to sterile or non-sterile medicines under 1.1. or 1.2.
Item 1.4.:
Concerns other medicines and other manufacturing activities. When filling out item 1.4, it must also be indicated whether the activities under 1.4 relate to sterile or non-sterile medicines under 1.1. or 1.2.
Item 1.5
Concerns packaging activities. This item is to be completed if the company handles products in relation to packaging only, i.e. products manufactured by another manufacturer. Release of the package is included in the activities, but the activities do not include the overall batch release of the finished product, unless this is explicitly stated.
Item 1.6.:
Concerns quality control testing of manufactured medicines. This activity is not included in other items, and 1.6 must therefore always be completed if the company performs testing of finished medicinal products. Batch release is not included in these activities.
Item 2.1.:
Concerns quality control testing of imported medicines. This activity is not included in any other items, and 2.1 must therefore always be completed if the company performs testing of imported medicines. Batch release is not included in these activities.
Item 2.2.:
Concerns batch release of imported medicines. A distinction is made between sterile, non-sterile, biological and special product types, and the items are to be used if the company imports medicines from third countries.

If a company only carries out some elements of a manufacturing activity, this should be indicated as a comment in the application form.

6. Annex 3 and Annex 4 (Contract work)
Under contract work, the contract giver (the company) outsources GMP activities to a contract acceptor (another company holding an MIA). The contract between the two parties is called a technical agreement. Under contract work, the contract giver has overall responsibility for compliance with the GMP and GDP rules, also for the activities carried out by the contract acceptor. The outsourcing of activities not included on the application form (e.g. cleaning) is not contract work in the meaning of section 39. Likewise, if a MAH pays a manufacturer to manufacture and batch release a product, and the MAH does not have responsibilities in relation to the GMP and GDP rules, this is not contract work in the meaning of section 39, but instead a commercial agreement.

Only manufacturing or testing activities can be contracted out. Activities related to batch release cannot be outsourced pursuant section 28 of the GMP executive order.

The conditions based on which manufacturing and testing activities can be outsourced to a contract acceptor are described in section 28 of the GMP executive order. The obligation to audit contract acceptors is described in section 31(3) of the GMP executive order. The following must therefore be in place before a company is permitted to use a new contract acceptor:

- The contract giver must ensure that the contract acceptor holds a valid regulatory approval (MIA or GMP certificate). The contract giver must therefore not release medicines where a new contract acceptor has partaken before it is ensured that the contract acceptor has a valid regulatory approval.
- The contract giver must as part of the self-inspection programme audit its contract acceptors on a regular basis. The contract giver must therefore not release medicines where a new contract acceptor has partaken before the contract acceptor has been audited in pursuance of the EU GMP rules with a satisfactory result.
- There must be a contract between contract giver and contract acceptor according to the provisions of section 28 of the GMP executive order. The contract giver must therefore not release medicines where a new contract acceptor has partaken before the contract between contract giver and contract acceptor has been signed.

The Danish Medicines Agency is not obliged to pre-approve contract acceptors that carry out manufacturing or testing activities. As a result, Annex 3 and Annex 4 should therefore not be completed, but a list of contract acceptors must be submitted with the application instead. An updated list of contract acceptors must be available at the company at all times. We prefer companies to use our template for the list of contract acceptors, which can be downloaded at Application for manufacture and import of medicines and intermediates under Forms.

When an application for a new MIA or renewal of an existing MIA is submitted to the Danish Medicines Agency, the list of contract acceptors must be resubmitted. We review the list before we issue an MIA.

After 1 June 2011, the Danish Medicines Agency no longer indicates contract acceptors in Annex 3 or Annex 4.

An activity can appear in Annex 1 or Annex 2 and in the List of contract acceptors if the activity takes place both at the company's own address and at the contract acceptor.

7. An MIA also permits wholesale dealing of own manufactured medicines
The MIA also allows the holder to wholesale deal medicines manufactured and batch released at the company's own address. In these guidelines, these medicines are referred to as own manufactured medicines. Wholesale distribution of medicines batch released by another manufacturer (also other EU/EEA company within the same organisation) requires a wholesale dealer's authorisation.

8. Importation of medicines

Importation of medicines means importation of medicines from a third country (countries outside the EU/EEA). Please note that the MRA countries Australia, Canada, Japan, New Zealand and Switzerland are also third countries. The company physically receiving medicines from a third countries is called the importer. It is the importer's obligation to release imported medicines pursuant to section 34 of the Danish GMP executive order before they are redistributed within the EU/EEA. The responsibility for batch release of imported medicines cannot be contracted out pursuant to section 28 of the GMP executive order.

9. Wholesale distribution of medicines
Wholesale distribution of medicines means the receipt, storage and delivery of finished medicines within the EU/EEA. A wholesale dealer must not handle intermediates or bulk products and must not import medicines from third countries.
A manufacturer must hold a wholesale dealer's authorisation if it wholesale deals medicines that are not manufactured at an address approved on the MIA, or if the manufacturer chooses to wholesale deal own manufactured medicines from other addresses than those authorised on the MIA (e.g. separate storage addresses).

10. Site Master File
The Site Master File (SMF) is a brief description /overview of the manufacturing sites that manufacture marketed products. The SMF can be prepared according to the Explanatory Notes on the preparation of a Site Master File, EudraLex, Vol. 4 2010.

11. Name or address changes
If a company changes name or address, an application to change the MIA must be submitted, see Guidelines on requirements and deadlines for applications for company authorisations.

12. Special requirements for application to change an MIA.
For application to change activities in Annex 1 and Annex 2, the entire Annex for the site concerned must be completed (all tick marks must be put). If changes only involve one site, it is enough to complete the relevant Annex for the site in question. The front page must also be completed.
If a company applies to change authorised Qualified Persons or the responsible manager, it is sufficient to submit the front page of the application form as well as the relevant Annex of the form. All persons must be indicated in the relevant annex. If a company wishes to delete a person from the Annex, all other remaining persons must be stated in the relevant annex.

13. Special requirements for application to renew an MIA.
For renewal applications, the company must submit a fully completed application form with completed front page and all required information (however, not the CVs of already approved Qualified Persons). Annex 1 and/or Annex 2 must be completed for all relevant sites, and all Qualified Persons and the responsible manager must be indicated in the relevant annexes.

14. Manufacturing of intermediate products and bulk products
An intermediate product (or intermediate) is a partly processed product that must undergo further manufacturing steps before it becomes a bulk product. A bulk product is a product that has completed all processing stages up to, but not including, final packaging. The manufacturing of intermediate products and bulk products is included in the individual manufacturing activities of the application form.
If a company exclusively manufactures intermediates that contain one or more active substances, the company must apply for authorisation of item "1.4.1.4 Other" and indicate the formulations (e.g granules, powder, fluid, etc.) that are manufactured.
If the company itself carries out the further processing of the intermediate product to become a bulk product, the formulation type concerned, which the bulk product ends up becoming, must be ticked under 1.1. or 1.2 (and if relevant 1.3. and 1.4).

15. Storage of intermediate products and bulk products
The storage of intermediate products and bulk products requires an MIA. Storage of own manufactured intermediate products and bulk products is included in the manufacturing activities on the company's MIA.

If a company wishes to store own manufactured intermediate products and bulk products at other addresses than those covered by the MIA, the company must apply to have the concerned address(es) approved as a site on the MIA.
There are two situations in which companies must specifically apply for authorisation for storage of intermediate products and bulk products: 1) Storage of own manufactured intermediate products and bulk products at other addresses than the actual place of manufacturing and 2) Storage of intermediate products and bulk products that are not manufactured or processed further by the manufacturer itself.

For intermediate products, the company must apply for authorisation of item "1.4.3 Other" and indicate the formulations (e.g granules, powder, fluid, etc.) that are stored. For bulk products, the company must apply for authorisation of the relevant manufacturing activity (e.g. tablets, capsules, etc.), stating at the end of Annex 1 or Annex 2 that the selected type of formulation is exclusively stored as a bulk product.

16. Manufacturing of API
According to the Guidelines on activities subject to a section 39 authorisation, the manufacturing of a chemical non-sterile API does not require an MIA. However, the manufacturing of a biological and/or sterile API does require an MIA. If the company manufactures a biological API, item 1.4.1.3 must be ticked. If the company manufactures a sterile API, the relevant item under item 1.4.2 must be ticked.

17. Termination of authorisation
When a company is to terminate an MIA, the company will normally be contacted by an inspector to schedule a close-down inspection to ensure that the handling of complaints, withdrawals, storage of reference and retention samples, etc. are adequately dealt with.

If the company continues to have GMP and GDP responsibilities for medicines, it must still hold a section 39 authorisation for a given time frame.

The termination of an MIA cannot be effected until the day the company no longer carries out GMP activities, including has responsibilities for storage of reference and retention samples. Pursuant to Annex 19 of the EU GMP rules, reference and retention samples must be stored at the original site of manufacture. Section 26 of the GMP executive order further specifies that reference samples of medicines must be stored for at least one year after the expiry date. Reference samples of an API used in the finished product must be stored for at least two years after batch manufacture.

A company wishing to terminate its MIA must therefore first submit an application to change the authorisation, notifying the Danish Medicines Agency that all manufacturing activities are being stopped. The Danish Medicines Agency will then issue an altered MIA from which it appears that the company exclusively stores reference and retention samples at the address. As soon as the company is no longer obliged to comply with the rules above, the company must inform the Danish Medicines Agency to effect an absolute termination of the MIA.

The application form step by step
The following sections describe how to complete Annex 1 through Annex 6 of the application form. Please be aware that Annex 1 and Annex 2 apply to the manufacture and importation of both intermediate products and finished products, and that no distinction is made according to whether the company manufactures/imports intermediate products or finished products.

General remarks on Annex 1 and Annex 2
Please be aware that Annex 1 and Annex 2 are site-specific. Therefore, one Annex 1 and/or Annex 2 must be completed for each site that manufactures or imports medicines or intermediates. Specify the address of the relevant site at the top of Annex 1 or Annex 2. In Annex 1 and Annex 2, the applicant is only to indicate the manufacturing activities carried out at the company's own address. Activities that are exclusively carried out through outsourcing to a contract acceptor, must only be indicated in the list of contract acceptors.

Annex 1 and Annex 2, Part 1

1.1: Manufacturing of sterile medicines (Packaging and batch release included)
Guidance: Here, it is indicated if the company manufactures sterile medicines. The section is divided into three subsections. For aseptically prepared sterile products, the relevant activity under 1.1.1 must be ticked. If the company manufactures terminally sterilised products, the relevant activity under 1.1.2 must be ticked. If the company only carries out batch release of sterile medicines (whether aseptically prepared or terminally sterilised), 1.1.3 must be ticked.
Validation rule: 1.1.3 excludes using 1.1.1.x and 1.1.2.x at the same time, whereas 1.1.1.1 and/or 1.1.2.1 excludes using 1.1.3 at the same time.
Special situations: If the company manufactures a sterile product and only carries out batch release of another sterile product (same product type as the first product), please tick as if both sterile products are being manufactured (1.1.3 cannot be ticked at the same time, because 1.1.3 excludes ticking 1.1.1 and 1.1.2). In this case, a comment must be added at the end of the relevant Annex, indicating that batch release is only carried out for the one type of sterile medicines.

1.2: Manufacturing of non-sterile medicines (Packaging and batch release included)
Guidance: Here, it is indicated if the company manufactures non-sterile medicines. If the company manufactures non-sterile medicines, the relevant activities under 1.2.1 must be ticked. Please note that the application form for manufacturing of medicines for veterinary use contains two more items than the form for human use; 1.2.1.15 and 1.2.1.16. If the company only carries out batch release of non-sterile medicines, 1.2.2 must be ticked.
Validation rule: 1.2.2 excludes using 1.2.1.x at the same time, whereas 1.2.1.x excludes using 1.2.2 at the same time. Furthermore, primary packaging of non-sterile products (1.5.1) cannot be selected at the same time as the associated manufacturing activity of non-sterile products (1.2.1). If the company manufactures a product under 1.2.1 at the same time as it packages the same product under 1.5.1, the activity is only to be ticked under 1.2.1.
Special situations: If the company manufactures a non-sterile product type and only carries out batch release of another non-sterile product type, please tick as if both non-sterile product types are being manufactured (1.2.2 cannot be ticked at the same time as 1.2.1.x). In this case, a comment must be added at the end of the relevant Annex, indicating that batch release is only carried out for the one type of non-sterile medicines.

1.3: Manufacturing of biological medicines (Packaging and batch release included)
Guidance: Here, it is indicated if the company manufactures biological medicines. The section is divided into two subsections. If the company manufactures biological medicines, the relevant activities under 1.3.1 must be ticked. If the company only carries out batch release of biological medicines, the relevant activities under 1.3.2 must be ticked.
Validation rule: Corresponding items under 1.3.1 and 1.3.2 exclude each other and cannot be selected at the same time. If the company both manufactures a biological product and exclusively releases the same type of biological product, only manufacturing of the biological product must be ticked (under 1.3.1). In this case, a comment must be added at the end of the relevant Annex, indicating that also batch release of the concerned biological medicine is exclusively taking place.
Special situations: With regard to the manufacturing of biological medicines, the relevant activity under 1.1 or 1.2, which describe the formulation type of the biological medicine (sterile or non-sterile), must be ticked at the same time.

1.4: The manufacturing of other medicines or other manufacturing activities (Packaging and batch release are included in the activities under 1.4.1.x).
Guidance: Here, it is indicated if the company manufactures special medicines or carries out special manufacturing activities. The section is divided into three subsections. If the company manufactures herbal medicines, homeopathic medicines, biological APIs or other types of medicines, e.g. strong vitamins and minerals or medicated feed, the relevant activities under 1.4.1 must be ticked. If sterilisation of APIs, excipients or finished products takes place, the relevant activities under 1.4.2 must be ticked. If other manufacturing activities are carried out (excluding packaging and quality control testing, which are described in 1.5 and 1.6, respectively) that are not described in 1.1, 1.2, 1.3 or 1.4.1 and 1.4.2, please indicate these activities under 1.4.3, e.g. storage of intermediates only.

If the company manufactures an intermediate that can be used in different product types (e.g. granules), 1.4.3 should be ticked while adding a comment at the end of the Annex, stating the intermediate concerned and its intended use.
Special situations: Under 1.4, there is no activity to indicate batch release only. If the company only carries out batch release of products under 1.4, the relevant manufacturing activity under 1.4 should be ticked and a comment should be added at the end of the Annex, stating that only batch release for this type of medicine is carried out.
Special situations: With regard to the manufacturing of special medicines, the relevant activity under 1.1 or 1.2, which describe the formulation type of the medicine (sterile or non-sterile), must be ticked.

1.5: Packaging only (Batch release of the package is included)
Guidance: Here, indicate if the company packages medicines that it has not manufactured itself. The section is divided into two subsections. If non-sterile medicines are packaged in their primary packaging (blister cards, tablet bottles, etc.), tick the relevant activities under 1.5.1. Please note that the application form for manufacturing of medicines for veterinary use contains two more items than the form for human use; 1.5.1.15 and 1.5.1.16. If the company only packages medicines in their secondary packaging, (packages blister cards in boxes, labels, replaces package leaflet, etc.), 1.5.2 must be ticked. Only tick 1.5 if the company only handles products through packaging activities, i.e. products which are not manufactured at the company's own address.
Validation rule: Primary packaging of non-sterile products (1.5.1) cannot be selected at the same time as the associated manufacturing activity of non-sterile products (1.2.1). If the company manufactures a product under 1.2.1 and at the same time it packages another product of the same type under 1.5.1, the item in 1.2.1 is only to be selected while at the same time adding a comment at the end of the relevant Annex.
Secondary packaging is included under the activities in 1.5.1, and 1.5.2 is therefore only to be used if the company only packages/re-packages medicines, of which it is not the manufacturer or primary packager, in secondary packaging. Consequently, there may be activities in both 1.5.2 as well as items in 1.5.1 if the company packages some medicines in primary packaging (and possibly also secondary packaging) at the same time as it packages other medicines in secondary packaging.
Special situations: 1.5.1.x only concerns primary packaging of non-sterile medicines. Activities associated with the packaging of sterile products in primary packaging do not fall under 1.5.1 ”Primary packaging”, but are instead considered as part of the manufacturing process of sterile products (1.1.1.1 – 1.1.2.5). As regards 1.5.2, no distinction is made between sterile and non-sterile medicines.

1.6: Quality control testing of medicines.
Guidance: Here, it is indicated if the company performs quality control testing of finished products. The item has four activities to be ticked as appropriate. There are no other manufacturing activities contained in this activity. If, at the same time, the company also carries out batch release of the tested medicines, the relevant item under 1.1.3, 1.2.2, 1.3.2.x or 1.4.1 must also be ticked.
Special situations: Quality control testing of APIs and intermediates is included in the individual manufacturing activities under 1.1.-1.4.

Special requirements
Guidance: Here, it is indicated if some of the products which the company manufactures, packages, tests or batch releases contain active substances subject to special requirements. The relevant special requirements must be ticked, and it must be indicated which items in the application form (e.g. 1.1.1.4 or 1.2.1.13) the special requirements apply to.

Comment
At the end of Part 1, Annex 1 and Annex 2, it is possible to add comments as necessary. Use this field if some of the selected activities need further elaboration.

Annex 1 and Annex 2, Part 2:
An authorisation pursuant to Part 2 in either Annex 1 or Annex 2 is mandatory if the company imports medicines and intermediates from third countries. Part 2 is split in two sections: Quality control testing and batch release.
Only the activities under item 2.2. of Part 2 (Batch release) give the company the possibility to physically receive medicines from a third country, as imported medicines must be released by the receiving

company. The activities under item 2.1 of Part 2 (Quality control testing) do not authorise importation of medicines.

2.1: Quality control testing of imported medicines
Guidance: Here, it is indicated if the company performs quality control testing of imported medicines. The item has four activities to be ticked as appropriate. There are no other manufacturing activities contained in this activity. If, for example, the company also carries out batch release of the imported, tested medicines, the relevant items under 2.2 must also be ticked.

2.2: Batch release of imported medicines
Guidance: Here, it is indicated if the company carries out batch release of medicines imported from a third country. The item is divided into four sub-items, which are similar to 1.1, 1.2, 1.3 and 1.4 of Part 1. Under item 2.2, the type of product to be imported and subsequently released is indicated. If biological products (2.2.3.x) or special product types (2.2.4.x) are to be imported, it should also be indicated whether these products are sterile or non-sterile under 2.1 or 2.2.

Special requirements
Guidance: Here, it is indicated if some of the products which the company manufactures, packages, tests or batch releases contain active substances subject to special requirements. The relevant special requirements must be ticked, and it must be indicated which items in the application form (e.g. 2.1.3 or 2.2.2) the special requirements apply to.

Comment
At the end of Part 2, Annex 1 and Annex 2, it is possible to add comments as necessary. Use this field if some of the selected activities need further elaboration.

Annex 3 and Annex 4
The Danish Medicines Agency does not pre-approve contract acceptors, and contract acceptors do not appear on the issued manufacturing authorisation. Whenever a new or renewal application for an MIA is submitted, the applicant must instead submit a list of all contract acceptors (contract acceptors as well as contract laboratories) with the application. The list must include the following details about each contract acceptor:

- Name and precise address of the contract acceptor (the same address as the one the regulatory approval)
- Which activities (items from the application form) have been contracted out
- The date of the latest audit of the contract acceptor
- The date of the next scheduled audit of the contract acceptor
- The expiry date of the contract acceptor's regulatory approval
- The date when the contract between the contract giver and contract acceptor was concluded (date of signatures)
- The date when the first batch was released, in which the contract acceptor was used for manufacturing or testing activities
- Medicines in which the contract acceptor is involved in manufacturing or testing activities

The Danish Medicines Agency prefers companies to use the Template for the List of contract acceptors. Guidance on how to fill out the list is given in the tab "Guidelines".

This list will replace Annex 3 and Annex 4. The list must be updated on a current basis and should be readily available at inspections.

Please remember that activities outsourced to a third party (contract acceptor) are not to be indicated in Annex 1 or Annex 2. However, any activities which the company carries out itself and also outsources to a contract acceptor must be indicated in Annex 1 and/or Annex 2 as well as in the list of contract acceptors.

Special situations: Batch release cannot be outsourced to a contract acceptor.

Annex 5
Here, the company's Qualified Persons are indicated. If a Qualified Person has not been authorised internally to carry out batch release activities for all types of formulations released by the company, the Qualified person's areas of responsibility are indicted here. State the title of the Qualified Person in Danish and English.
When new Qualified Persons are to be authorised, their CVs must be submitted with the application, including a list of their qualifications, relevant practical experience, relevant courses, etc. Qualified Persons must, as a minimum, meet the criteria of applicable law, see the Danish Medicines Agency's Guidelines on requirements and expectations for the Qualified Person in a pharmaceutical company. A Qualified Person is not required for analytical laboratories and manufacturers of medicated feed.

Annex 6
Here, the name of the company's responsible manager is indicated. The title of the responsible manager must be provided in Danish and English.
Please be aware that doctors, dentists and proprietary pharmacists are legally bound to apply to the Danish Medicines Agency for permission to establish a relationship with or run a pharmaceutical company, cf. section 3(2) of the Danish Pharmacy Act., see Doctors, dentists and proprietary pharmacists associated with a pharmaceutical company.
Also note that according to section 8A of the Danish Veterinarian Act, veterinarians are not permitted to be associated with a company handling veterinary medicines, unless the Danish Veterinary and Food Administration has granted an exemption. Further information in Danish is available here: Veterinarians' financial independence of pharmaceutical companies.

Additional material to the application
When an application for a new MIA is submitted, an organisation chart and SMF must be submitted with the application. When an application to change or renew an existing authorisation is submitted, it is only necessary to attach an organisation chart and SMF if these documents have changed significantly.

EudraGMP
MIAs are transferred to EudraGMP, see http://eudragmp.eudra.org/.

Exemptions from applying for a company authorisation
Exemption from section 39(1) and (2) of the Danish Medicines Act applies to the following:

1. Hospital wards which only perform additive service
2. Hospital wards which only perform simple labelling and preparation of registered radiopharmaceuticals
3. Companies authorised by the Danish Medicines Agency to order medicine for life rafts, etc.
4. Companies that exclusively pass on orders for medicinal products to another company, pay for or collect payment for medicinal products, and which are therefore not subject to the rules on good manufacturing and distribution practice (GMP/GDP).

With reference to item 4 above, please note that a company must hold a section 39 authorisation if it handles, distributes or partakes in the conduct of tasks described in the GMP and GDP executive orders. For example, outsourcing of a medicine stock to another company does not exempt your company from obtaining a section 39 authorisation. If a company only engages in complaints about and withdrawals of medicines, a section 39 authorisation is also required.

Companies that are unsure about whether they fall under item 4 above are advised to contact the Danish Medicines Agency.

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