

3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?

There are no governmental pre-notification or pre-approval requirements except in regard to products containing a narcotic, psychotropic, or other controlled substance. However, exported products are subject to the following requirements, under the Medicines Act and the Import/Export Guidelines:

- (i) medicines that have been withdrawn from the market on health precautions may not be exported;
- (ii) INFARMED should issue export certificates on request, summing up the medicinal product's characteristics on the terms in which it was approved;
- (iii) at the customs office, the exporting entity should exhibit:
 - (a) either the relevant wholesaling license or a registry issued by INFARMED attesting that the exporting entity has a duly licensed Technical Director at its service or that INFARMED specially authorized the entity for this exporting activity; and either
 - (b) for products marketed in Portugal, the relevant marketing authorization or a declaration from the exporter that the marketing authorization is valid containing a complete identification of the product in question. For products manufactured but not marketed in Portugal, a copy of the manufacturer license; or
 - (c) if the product does not have any of the documents in (b), an official document issued by the relevant authority in the source country attesting the relevant marketing authorization or manufacturer license.¹

4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?

There are no specific provisions dealing with trans-shipped products. The framework discussed above should be observed.

¹ The Directorate-General for Customs also requires evidence of the acceptance of the relevant medicinal product in the country of destination.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

INFARMED conducts all relevant inspections prior and/or subsequent to the issuance of any license or authorization. The Directorate-General for Customs should also conduct inspections and report to INFARMED. No evidence suggests that INFARMED's inspection or enforcement activities are less rigorous when products are intended only for export.

South Africa

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1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Medicines and Related Substances Control Act, No. 101 of 1965 (as amended) (“the Act”), together with the regulations published in terms of the Act (“the Regulations”) provide the legislative basis for control of medicinal products through a system of licenses and permits. Licenses and permits are issued by the Medicines Control Council (“the Council”) to those persons involved in the manufacture, sale, or supply of medicinal products, including wholesale and distribution activities. The Council also conducts inspections to ensure that license holders comply with the terms of their licenses and permits.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to section 19 of the Act, no person may sell medicines unless compliant with the Act and its requirements. Under section 14 of the Act, medicines may be sold only if they are duly registered by the Council in accordance with the provisions of the Act. The Council determines which medicines need to be registered.

- (b) **must manufacturers of such products hold a manufacturer’s authorization?**

Section 22C(6) of the Act provides that no manufacturer, wholesaler, or distributor may manufacture, import, export, act as wholesaler of, or distribute any medicine except under a license issued by the Council. Section 22C(1)(b) provides that the Council may impose such conditions in the license regarding the application of acceptable quality assurance principles, and good manufacturing and distribution practices, as may be determined.

Section 22H of the Act provides that no wholesaler may purchase medicines from any source other than the original manufacturer or primary importer of the finished products. An inspector from the Department of Health may inspect the premises of license holders for compliance.

Notwithstanding these requirements, the Health Minister has been given authority to prescribe the conditions for import of “gray market” goods—products that are deemed to be identical in composition to, meet the same quality standards as, and intended to have

the same proprietary name as a medicine already registered in the Republic—even though the importer is not the holder of the already-issued registration certificate. Regulation 7 governs the import of these medicines. Import requires documentary proof that the medicine is registered in the exporting country by a regulatory authority registered by the Council. It also requires an undertaking that the importer will ensure the continued safety, efficacy, and quality of the medicine. Medicines imported in this way may only be sold to the State or to a person who is licensed by the Council under section 22C(6) of the Act.

(c) must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?

Persons licensed to manufacture, act as a wholesaler, or distribute medicines must, as part of the license application, provide to the Council acceptable documentary proof of their ability to comply with good manufacturing or distribution practices, as determined by the Council.

(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?

Yes, under section 22C(6) of the Act, as described in sections 2(b) and 2(c), above.

3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?

No specific pre-notification or pre-approval requirements must be fulfilled prior to the export of medicinal products, unless the product contains a narcotic, psychotropic or other controlled substance.

The Council will issue export certificates on request, but these certificates are not legally required.

4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?

The provisions of the Act do not apply to trans-shipped products. Trans-shipment of products *via* South Africa by road or rail is not subject to any licensing or oversight. Regulation 13 requires that medicines in the process of trans-shipment (e.g., by air or sea) be stored in a bonded warehouse that is registered with the Council. The Council can impose requirements regarding storage conditions. The Council has no jurisdiction over the products themselves.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

The Council regularly inspects bonded warehouses at airports and ports to oversee compliance in respect of trans-shipments. For regular exports of medicines, as well as permits and licensing compliance, the Council has to rely to a large extent on the vigilance of the Port or Airport Authorities and the Customs and Excise Officers.

Spain

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

Law 25/1990 on Medicines, as amended, provides the legislative basis for control of medicinal products through a system of authorizations. In particular, it prohibits the elaboration, manufacture, importation, exportation, distribution, and marketing of medicinal products without the required authorizations.

The requirements of Law 25/1990 are implemented by (1) Royal Decree 767/1993 on the evaluation and authorization and registry of medicinal products for human use, as amended; (2) Royal Decree 1564/1992 on the authorization of manufacturers and importers of medicinal products; and (3) Royal Decree 2259/1994 on warehouses and the wholesale distribution of medicinal products. Circular 8/2002 provides guidance on the export of pharmaceutical products from Spain.

The Spanish Medicines Agency regulates medicinal products for human use and grants the appropriate authorizations on behalf of the Ministry of Health. The Autonomous Communities of Spain are also responsible for the monitoring and enforcement of Spanish medicinal law. In particular, they are responsible for authorizing and monitoring warehouses and distribution of medicinal products.

2. **If the laws in your jurisdiction apply to products intended only for export:**
 - (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

Article 9 of Law 25/1990 and Article 4 of Royal Decree 767/1993 prohibit the placing on the market of any medicinal product that has not been granted a marketing authorization by Spain or the EU.

Law 25/1990 and Royal Decree 767/1993 do not define the concept of “placing on the market.” Article 81 of Law 25/1990, which regulates the importation of medicinal products, suggests that imported medicinal products require a marketing authorization if they are intended for distribution in Spain.

It is generally understood that the concept of placing on the market does not include the export of products to foreign countries. Therefore, medicinal products solely intended for export to foreign countries need not have a marketing authorization.

- (b) **must manufacturers of such products hold a manufacturer’s authorization?**

Article 70 of Law 25/1990 and Royal Decree 1564/1992 require any person engaged in the manufacture of medicinal products to obtain a manufacturer’s authorization. There is

no exemption for products intended solely for export. Circular 8/2002 regulates the procedure for obtaining an authorization to manufacture products that are intended for export.

Royal Decree 1564/1992 explicitly states that the requirements applicable to the manufacture of medicinal products also apply to laboratories that import medicinal products from non-EU countries. In particular, laboratories importing medicinal products must show that the products have been manufactured in accordance with good manufacturing practices equivalent to those applicable in the EU.

(c) must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?

Royal Decree 1564/1992 requires that manufacturers of medicinal products comply with European GMP, whether products are intended for export or not.

(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?

Law 25/1990 and Royal Decree 2259/1994 require persons (other than manufacturers) engaged in the warehousing, distribution, or export of pharmaceutical products to obtain an authorization from the Autonomous Community where they are located. Royal Decree 2259/1994 also imposes certain quality requirements for these activities, including good distribution practices.

3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?

Exports of pharmaceutical products that are subject to a marketing authorization in Spain must be notified to the Spanish Medicines Agency. Each export operation, product, and country of export requires a separate notification.¹ If a product is not the subject of a marketing authorization in Spain, the export must be authorized by the Spanish Medicines Agency. An authorization is necessary per product and country, but not per export operation. Law 25/1990 imposes these requirements, and the requirements are implemented by Circular 8/2002.

In addition, the Spanish Medicines Agency may provide, upon request of the exporter, a certificate stating that the manufacturer of the exported medicinal product holds an authorization for the manufacture of such product in Spain.

¹ Specific rules apply to exports to the Protectorate of Andorra.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

Royal Decree 2259/1994 applies to all persons engaged in warehousing, distribution, or export. It does not exempt persons that import medicinal products solely for re-export. Furthermore, the export notification and authorization requirements in Law 25/1990 include no exemption for medicinal products that have been previously imported. In addition, Circular 8/2002 explicitly regulates the exportation of medicinal products that are not subject to a marketing authorization and that have been manufactured in a different EU Member State.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

Circular 8/2002 discusses in detail the manufacture and subsequent export of medicinal products and the export of medicinal products that have been manufactured in other EU Member States. The adoption of this Circular suggests that the Spanish Medicines Agency is aware of the issues involved and wishes to ensure compliance with the law.

Sweden

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- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The legislative basis for the control and surveillance of medicinal products and the trade of medicinal product is the Pharmaceutical Act (1992:859) and the Trades of Pharmaceuticals Act (1996:1152). In addition, the Swedish Medical Products Agency ("the MPA") has issued provisions and guidelines on authorizations and surveillance of medicinal products. The provisions issued by the MPA regulating the requirements for manufacturing of and trade with medicinal products are the Medical Products Agency's Provisions on Authorization for the Manufacturing of Medicinal Products (LVFS 1995:3) ("Provisions on Manufacturing Authorizations") and the Medical Products Agency's Provisions on Authorization for the Wholesale trade of Medicinal Products (LVFS 1997:3) ("Provisions on Wholesale Trade Authorizations").

According to the Pharmaceutical Act and the Trades of Pharmaceutical Act, it is unlawful to import, manufacture, acquire, possess, market, distribute, or export medicinal products to and from Sweden without authorization from the MPA. The MPA conducts surveillance. It controls medicinal products through, for example, quality controls and inspections for compliance.

- 2. If the laws in your jurisdiction apply to products intended only for export:**
 - (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to Section 5 of the Pharmaceutical Act, a medicinal product may only be marketed under an MPA or European marketing authorization. In Sweden, the term "marketed" is generally understood to include both sales and marketing.

A marketing authorization is therefore required before a product can be supplied or marketed in Sweden. However, a marketing authorization is not required prior to the mere act of import or export of a medicinal product into or from Sweden. Therefore, there is no marketing authorization requirement for products intended solely for export.

- (b) must manufacturers of such products hold a manufacturer's authorization?**

According to Section 16 of the Pharmaceutical Act, professional manufacturing of medicinal products may only be conducted under a manufacturer's authorization issued

by the MPA. Section 15 of the Pharmaceutical Act defines the term “manufacture” to include “preparation, packaging and re-packaging of medicinal products.” This obligation applies to the manufacture of any medicinal product, even if it is intended for export.

According to the MPA’s Provisions on Manufacturing Authorizations, an application to manufacture medicinal products must include detailed information about, *inter alia*, pharmaceutical form(s), sites, premises, and special equipment to be used in the manufacturing and quality controls, and information about a responsible qualified person. The MPA usually inspects the site prior to granting a manufacturing authorization, in order to ensure that the application is accurate and in compliance with requirements of the legislation.

(c) must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?

According to Section 3 of the MPA’s Provisions on Manufacturing Authorizations, a manufacturer’s license will only be issued if the applicant complies with European GMP.

For products imported from outside the EEA under a manufacturer’s (import) authorization, the authorization holder must, according to Section 6 of the Provisions on Manufacturing Authorizations, ensure that products have been manufactured in accordance with European GMP. The MPA may issue an exemption from these tests and controls if the EU has entered into a Mutual Recognition Agreement with the originating state.

(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?

According to Section 3 of the Trades of Pharmaceuticals Act, wholesale trade may only be conducted under a wholesale trade authorization granted by the MPA. The term “wholesale trade” is defined to include “all activities that encompasses acquisition, possession, export and distribution of medicinal products.” Therefore, a wholesale trade authorization is required to distribute or export medicinal products to or from Sweden, whether the products are exported to countries within or outside the EEA.

Authorized wholesale traders are subject to the obligations contained in Section 4 of the MPA’s Provisions on Wholesale Trade Authorizations, including requirements for product quality and safety. These require that traders follow good distribution practices (“GDP”).

3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?

Unless the product contains a narcotic, psychotropic or other controlled substance, there are no Swedish government pre-notification or pre-approval requirements prior to the export of medicinal products. The MPA may issue export certificates on request to assist

exporters in satisfying import requirements in other countries. However, these are not legally required.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

According to the Trades of Pharmaceuticals Act, an authorization from the MPA is required to engage in wholesale trade, including all activities that encompass acquisition, possession, export, and distribution of medicinal products. The requirements in the MPA's Provisions on Wholesale Trade Authorizations apply equally to trans-shipped products. Thus, trans-shipped products are subject to requirements relating to control of product quality and safety and to compliance with GDP. Trans-shipped products also are subject to the MPA's surveillance.

According to Section 17 of the Pharmaceutical Act, medicinal products may only be imported from a country outside the EEA by someone who holds a manufacturer's authorization or a wholesale trade authorization. The MPA may approve a specific authorization for such import. The importer must have a suitably qualified person to oversee compliance with the requirements for the medicinal products' quality and safety. Importers must obtain an import authorization if they do not own any products and act solely as transporters or importer agents for products imported from outside the EEA.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that a Swedish manufacturer's or wholesale trade authorization is required, the MPA will conduct quality controls and inspections prior to granting the authorization and on a regular basis thereafter, to ensure compliance with the conditions of its authorization, with the law, and with European GMP and GDP as appropriate. Nothing implies that inspections and enforcement activities are less rigorous when products are intended only for export.

Switzerland

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The manufacturing, importation, placing on the market, and exportation of medicinal products is primarily regulated by the Federal Law on Medicinal Products and Medical Devices (*Heilmittelgesetz*, or “HMG”) and its implementing decrees, such as the Regulation on Licenses in the Medical Field (*Arzneimittel-Bewilligungsverordnung*, or “AMBV”).

Swissmedic is the authority competent to grant authorizations and licenses for the marketing, distribution, importation, and exportation of medicinal products. Swissmedic is also in charge of conducting inspections to ensure that marketing authorization holders, manufacturers, importers, and exporters comply with their obligations.

2. **If the laws in your jurisdiction apply to products intended only for export:**
 - (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to article 9 of the HMG, no medicinal product can be placed on the market without a marketing authorization. The term placing on the market is defined as “the distribution and the supply of therapeutic products.”¹ A marketing authorization is therefore required before a product can be marketed in Switzerland.

Article 20 of the HMG states that finished medicinal products may be imported only if they either are authorized or are not required to hold a marketing authorization. Pursuant to Article 9, galenic preparations, investigational products, and customized products are not subject to a marketing authorization. Medicinal products that are imported by individuals in small amounts for their personal use or by medical professionals also are exempted. Any other imported finished product must be covered by a valid Swiss marketing authorization.² According to section 18(4) of the HMG, storage in custom warehouses is considered to be importation.

No marketing authorization is required to export medicines, but certain restrictions apply (see section 3 below).

¹ The term “therapeutic product” encompasses medicinal products and medical devices.

² This is confirmed by the Fact Sheet on Importation of Medicinal Products published by Swissmedic in January 2003, which states that “because the owner of the import license must also be the marketing authorization holder of the finished product, he is responsible for placing the product on the market and therefore, must ensure that each batch is released prior to the placing on the Swiss market.”

(b) must manufacturers of such products hold a manufacturer's authorization?

Article 5 (1) of the HMG requires that any person who produces a medicinal product must hold a manufacturer's license.³ This obligation applies for any manufacture or assembly of any medicinal product, irrespective of whether it is intended for export. Such a license is granted if (i) the professional and operational conditions imposed by the law are fulfilled and (ii) an appropriate quality system is established.

(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?

Article 7 of the HMG requires that manufacturers of medicinal products comply with "recognized principles of good manufacturing practice." Annex I of the AMBV sets out the applicable GMP provisions.

(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?

Wholesalers need a license under Swiss law.

In addition, Article 18 of the HMG requires that any person exporting finished products obtain an export license. An exportation license will be granted if the applicant (i) fulfills the necessary professional and operational conditions, and (ii) establishes an appropriate quality system. The Fact Sheet on the Exportation of Finished Products published by Swissmedic in January 2003 states that exporters must follow good distribution practices.

3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?

No Swiss government pre-notification or pre-approval requirements must be fulfilled prior to the export of medicinal products, unless they contain a narcotic, psychotropic or other controlled substance. Section 21 of the HMG, however, prohibits the export of medicinal products if (i) they are prohibited in the country of destination or (ii) if circumstances suggest that the medicinal products are intended for illegal purposes.

Swissmedic will issue export certificates on request to assist exporters in satisfying import requirements in other countries.

³ Article 4(1)(c) of the HMG defines the term "manufacture" to include "all stages of manufacture of therapeutic products, from the acquisition of the starting materials through the processing to the packaging, storage and delivery of the final products as well as the quality controls and batch release."

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

No license is required for products merely trans-shipped *via* Switzerland, but according to section 37 of the AMBV, any transport of medicinal products endangering human health, is prohibited.

If the medicines are stored in a customs warehouse, they are considered to have been imported into the country, and subject to the legal requirements for importing medicines.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that a Swiss manufacturer's or wholesale dealer's license is required, Swissmedic will conduct inspections prior to the grant of the license and on a regular basis thereafter. These inspections are intended to ensure that license holders comply with the conditions of the license, with Swiss law, and with Swiss GMP or GDP as appropriate. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

UK

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Medicines for Human Use (Marketing Authorizations, Etc.) Regulations 1994 (SI 1994/3144) (“the Regulations”) and the Medicines Act 1968 (“the Act”) provide the legislative basis for control of medicinal products through a system of licenses and authorizations. Amongst other things, it is unlawful for medicinal products to be imported, marketed, manufactured, distributed, sold, supplied in, or exported from, the UK except in accordance with the appropriate approvals, unless an exemption applies.

The Medicines and Healthcare Products Regulatory Agency (“MHRA”) regulates medicinal products for human use on behalf of the UK Licensing Authority. It issues licenses to those engaged in the manufacture, sale, or supply of medicinal products and conducts inspections to ensure that license holders comply with the terms of their licenses.

2. **If the laws in your jurisdiction apply to products intended only for export:**
 - (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to regulation 3 of the Regulations, no medicinal product can be placed on the market or distributed through wholesale dealing unless the Licensing Authority or the European Commission has granted the product a marketing authorization. The term “wholesale dealing” encompasses the sale of a medicinal product in the course of a business, to a person who buys it for sale or supply, or for administration to a human being. The term “place on the market” is not defined under UK law, but it is generally understood to involve transfer of the product to a third party.

A marketing authorization is therefore required before a product can be supplied or marketed in the UK. Marketing authorizations are not required prior to the mere act of import or export of a medicinal product into or from the UK. Thus, there is no marketing authorization requirement for products intended solely for export.

- (b) **must manufacturers of such products hold a manufacturer’s authorization?**

Section 8(2) of the Medicines Act requires a manufacturer's license to manufacture or assemble a medicinal product in the course of business.¹ This obligation applies to whether or not the product is intended for export.

Applicants for manufacturing licenses must provide the MHRA with a Site Master File ("SMF") containing detailed information about the production and/or control of the pharmaceutical manufacturing operations.² The Licensing Authority will only issue a manufacturer's license when it is satisfied that the information contained in the application is accurate and in compliance with requirements of the legislation. This usually follows a site inspection.

Under European Community law, importation of a medicinal product from outside the EC or EEA is considered to be a manufacturing operation. This is reflected in Section 8(3) of the Medicines Act, which requires that the importer of a medicinal product from such "third countries" must hold a wholesale dealer's import license, which is equivalent to a manufacturer's license.

(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?

Holders of a manufacturing license must comply with the requirements set out in Schedule 2 of the Medicines (Standard Provisions for Licenses and Certificates) Regulations 1971. These Regulations require the license holder to conduct all manufacture and assembly operations in such a way as to ensure conformity with the standards of strength, quality, and purity applicable under the marketing authorizations and in accordance with European GMP.

Where product is imported from a third country under a wholesale dealers (import) license, the license holder must ensure that the manufacture and assembly operations outside the EEA have been carried out by a duly authorized manufacturer or assembler; that the products have been manufactured and assembled in accordance with European GMP; and that each production batch has undergone a full qualitative analysis and a quantitative analysis of at least all the active ingredients. Unless the EU has entered into a Mutual Recognition Agreement with the originating state, the importer must perform all other tests or checks necessary to ensure that the quality of the product satisfies the requirements of any relevant marketing authorization and that it has been manufactured in accordance with GMP. All associated testing and quality control operations must be in accordance with European GMP.

¹ Section 132 of the Medicines Act 1968 defines the term "manufacture" to include "any process carried out in the course of making the product" and "assemble" as "enclosing the product (with or without other medicinal products of the same description) in a container which is labeled before the product is sold or supplied, or, where the product is already enclosed in the container in which it is to be sold or supplied, labeling the container before the product is sold or supplied in it." "Manufacture" includes testing and may include "assembly."

² Medicines (Applications for Manufacturer's and Wholesale Dealer's Licenses) Regulations 1971 (SI 1971/974, as amended).

(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?

Section 8(3A) of the Medicines Act requires a wholesale dealer's license in order to distribute medicinal products by way of "wholesale dealing" in the course of a business. Distribution by way of wholesale dealing includes any act of selling or supply, or procuring, holding, or exporting a product for sale or supply. However, an importer who does not own products and acts solely as a transporter or import agent for products imported from third countries (i.e. outside the EC or EEA) need not hold a wholesale dealer's license.³ Similarly, a wholesale dealer's license is not necessary to export medicinal products from the UK direct to countries outside the EEA. A wholesale dealer's license is necessary, however, to export products to other EEA member states.⁴

Authorized wholesale dealers must fulfill the obligations contained in Schedule 3 to the Medicines (Standard Provisions for Licenses and Certificates) Regulations 1971 (SI 1971 No 972), as amended. These include obligations to provide and maintain suitable staff, premises, equipment, and facilities and to comply with good distribution practices ("GDP"). The current GDP requirements are set out in European Commission guidelines, and are intended to ensure that product quality is unaffected during storage and transportation.⁵

3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?

No UK government pre-notification or pre-approval requirements must be fulfilled prior to the export of medicinal products, unless the product contains a narcotic, psychotropic, or other controlled substance. The MHRA will issue export certificates on request to assist exporters in satisfying import requirements in other countries, e.g. to confirm whether the product or manufacturer to which the certificate applies has met UK legal requirements.⁶ However, the UK does not require such certificates.

4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?

The trans-shipment of products *via* the UK is currently not subject to any MHRA licensing or oversight, unless the products are subjected to a manufacturing operations. Section 14 of the Medicines Act provides that the wholesale dealer and import licensing requirements imposed by section 8 of that Act do not apply to the exportation or the sale

³ Medicines (Exemption from Licenses) (Wholesale Dealing) Order 1990 (SI 1990 No 566).

⁴ Section 48 1(b) of the Act.

⁵ See <http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2001/may/GDPGuidelines1.pdf>.

⁶ Section 50 of the Act.

or offer for sale for the purposes of exportation, of any imported medicinal product if it is, or is to be, exported:

- (i) in the form in which it was imported; and
- (ii) without being assembled in a way different from the way in which it was assembled on being imported.

If the products are subject to manufacturing operations, a manufacturing license is required.

5. If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?

To the extent that a UK manufacturer's or wholesale dealer's license is required, the MHRA Medicines Inspectorate will conduct inspections prior to granting the license and on a regular basis thereafter. These inspections are intended to ensure that license holders comply with the conditions of their license, with UK law, and with GMP or GDP as appropriate. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.