Distribution and marketing of drugs in the EU: overview

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distribution
Pre-conditions for distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Drugs cannot be marketed or sold in the EU unless they are the subject of an EU or national marketing authorisation. Drugs that benefit on an exceptional basis of an exemption from the requirement of a marketing authorisation can be sold or supplied, but cannot be promoted.

Authorisation
The term "medicinal product" is used in the EU rather than "drug", and is defined as:
- Any substance or combination of substances presented for treating or preventing disease in human beings.
- Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

In the EU, there are essentially four different procedures for obtaining a marketing authorisation, although these can be linked. These are the:
- Centralised procedure.
- Decentralised procedure.
- Mutual recognition procedure.
- National procedure of each individual member state.

The centralised procedure is available for a limited range of products listed in the Annex to Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation).

The centralised procedure is compulsory for the following drugs:
- Drugs for the treatment of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS), cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases.
- Drugs derived from biotechnology processes, such as genetic engineering.
- Advanced therapy drugs, such as gene therapy, somatic cell therapy or tissue-engineered drugs.
- Officially designated "orphan drugs" (that is, drugs used for rare human diseases).

The centralised procedure is optional for the following drugs (which will otherwise be authorised nationally):
- Drugs containing a new active substance that was not authorised in the EU on 20 April 2004.
- Drugs that are a significant therapeutic, scientific or technical innovation.
- Drugs whose authorisation would be in the interest of patients.

Applications through the centralised procedure are submitted to the European Medicine Agency (EMA). The EMA's scientific committees take up to 210 active days (plus "clock stops") to give an opinion on whether the drug should be marketed or not. This opinion is transmitted to the European Commission, which is then responsible for granting the marketing authorisation.

Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) is the legal basis for both the mutual recognition and decentralised procedures. These are intended to allow applicants to obtain national authorisations in multiple member states of the EU more rapidly and/or with a lower administrative burden than would be the case if each application were examined completely separately in each and every member state. They are different from a centralised authorisation in that each member state issues its own authorisation, which means that pharmacovigilance reporting and variations to authorisations must be made separately in each member state.

The mutual recognition procedure allows applicants, once they have obtained an authorisation in one member state, to request that other member states, on an individual basis, "recognise" an earlier granted authorisation from a member state, subject to meeting local requirements for labelling and patient information leaflets.

The decentralised procedure is available if there is no authorisation in any country of the EU, and allows for one application to be made with a list of countries in which authorisation is sought, and for one reference member state to make a decision for and on behalf of all member states in which the application is made. In both the mutual recognition and the decentralised procedures, divergences of opinion about whether a product should or should not to be authorised are arbitrated by the Committee for Medicinal Products for Human Use (CHMP).

Application procedure. The procedure and content requirements for applications, including for national applications in the EU, are set out in EudraLex volume 2 "Pharmaceutical legislation on notice to applicants and regulatory guidelines for medicinal products for human use". This volume is broken down into a series of chapters, which together contain the procedural and regulatory requirements for the different types of marketing authorisation application.

The process is intended to be, in its essential elements, the same in all EU member states. There is also a 210-day limit on the time taken to authorise a drug in the EU (Article 17(1), Code for Human Medicines Directive), although this time limit is extended if more
information is requested. For a drug for which an application is made via the centralised procedure and which is of "major interest" from the point of view of public interest and therapeutic innovation, an accelerated assessment can be requested, reducing the time limit to 150 days instead of 210 days (Article 14(9), EMA Regulation).

Article 21 of the Code for Human Medicines Directive requires that member states make the details of the application and the decision publicly available. Details of marketing authorisations granted through the centralised procedure are published in the Official Journal.

Marketing authorisations are normally initially valid for a period of five years, and must then be renewed and subject to a further risk/benefit analysis. At that point they can, if renewed, be subject to a further five-year renewal, or will otherwise continue indefinitely. If there are concerns about the product, a one-year authorisation can be granted, subject to meeting specified conditions for a renewal thereafter.

A marketing authorisation for products that are not placed on the relevant market in the first three years of the authorisation will automatically cease to be valid.

Other regulatory regimes (herbal medicinal products, food products and cosmetics). There are other regulatory regimes that can apply to products that in other countries could be considered as drugs. There are separate regulatory regimes for "foods for special medical purposes" (including specific categories of food), dietary supplements and "herbal medicinal products". Case-by-case guidance might be needed from national competent authorities to help determine which regime applies for "borderline" products. Which category a product falls into can depend on its mode of action, its ingredients and/or the claims made about the product in labelling and/or its promotion.

"Foods for special medical purposes" are defined as any of the following (Regulation (EU) 2016/128 on specific compositional and information requirements for food for special medical purposes):

- Nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended.
- Nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended.
- Nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.

"Herbal medicines" are defined as "any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations" (Directive 2004/24/EC on traditional herbal medicinal products).

For example, any medicine that contains algae, fungi or a plant part as an active ingredient may be regulated as a herbal medicinal product.

Marketing authorisations are required within the EU for all medicinal products and herbal medicinal products. The only exception to this is the simplified registration procedure that exists for traditional herbal medicinal products if the applicant can demonstrate that the constituent(s) of the product have a well-established medical use and safety level.

Food supplements are defined as foodstuffs "the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect (...) to be taken in measured small unit quantities". "Nutrients" means vitamins or minerals (Directive 2002/46/EC on food supplements).

Food supplements and foods for special medical purposes, in contrast to medicinal products, do not require an authorisation, but only registration with the national agencies responsible for their regulation in the countries in which the products are sold.

Cosmetics are defined in Regulation (EC) 1223/2009 on cosmetic products as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them or keeping them in good condition or correcting body odours".

Generic products. Generic products are products that have the same qualitative and quantitative composition and active substances, and the same pharmaceutical form, as a "reference medicinal product". A reference medicinal product is a product that has already been authorised as a national or centrally authorised product and on whose clinical efficacy and safety data filed by the originator the applicant for the generic intends to rely. Applicants for a marketing authorisation for a generic product have the advantage of not being required to provide the results of pre-clinical tests and clinical trials. However, there is a period of time during which generics cannot take advantage of the data already in the regulators' files. This is known as the period of data or market exclusivity.

Originator applications for marketing authorisations made after 30 October 2005, whether under the centralised, mutual recognition or decentralised procedures, benefit from:

- Eight years of data exclusivity, during which no applications can be made citing the clinical data supplied with the originator application.
- A further two years of market exclusivity, during which the generic product cannot be placed on the market, giving ten years of exclusivity on the market.
- An additional year (extending the protection to 11 years) if (Article 10(1), Code for Human Medicines Directive):  
  - a new indication is added that is of significant clinical benefit in comparison with existing therapies; or  
  - there is a change of classification supported by additional and significant preclinical tests or clinical trials within the first eight years.

Separately, orphan products benefit from ten years of total regulatory exclusivity (although this can be reduced if market conditions change), which can be extended to 12 years if the requirement for data on the product's use in the paediatric population is fully met.

If an application is made for a new indication of a well-established substance, a period of one-year data exclusivity is granted on condition that significant pre-clinical or clinical studies were carried out in relation to the new indication.

Exceptions
See Question 2.
2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

National authorisations under EU law

To increase the availability of drugs, in particular on smaller markets in the EU, Article 126a of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) allows, in the absence of a marketing authorisation or of a pending application for a medicinal product that has already been authorised in another member state, a member state to authorise the placing on the market of that medicinal product for justified public health reasons. In such cases, the competent authority of the member state must inform the marketing authorisation holder in the member states in which the medicinal product concerned is authorised of the proposal to authorise the placing on the market under this Article. The competent authority of the member state applying Article 126a must notify the European Commission of drugs authorised, or which cease to be authorised, under this provision. Each member state has enacted its own specific mechanisms to implement this provision.

The publicly available register of drugs authorised to be placed on the market under Article 126a is available on the European Commission’s website:

Compassionate use

While compassionate use programmes are within the remit of the member states, the Committee for Medicinal Products for Human Use (CHMP) can, at the request of a member state, provide recommendations to all EU member states on how to administer, distribute and use certain medicines for compassionate use. The CHMP can also provide recommendations when it becomes aware that compassionate use programmes with a given medicine are being set up in a number of member states. The recommendations are optional only and do not create any legal obligation in EU member states.

EU level exceptions

Conditional marketing authorisations. The European Medicines Agency (EMA) is able to issue conditional marketing authorisations on an exceptional basis under Regulation (EC) 507/2006 on the conditional marketing authorisation for medicinal products for drugs that would otherwise, if the clinical data were complete and acceptable, be subject to the centralised authorisation process. These drugs must meet unmet medical needs and satisfy one of the following conditions:

- Aim at the treatment, the prevention or the medical diagnosis of seriously debilitating diseases or life-threatening diseases.
- Be for use in emergency situations, in response to public health threats.
- Be designated as orphan drugs in accordance with Article 3 of Regulation (EC) 141/2000 on orphan medicinal products.
- The CHMP Guideline EMEA/509951/2006, Rev 1. of 25 February 2016 applies to these authorisations.

Marketing authorisations in "exceptional circumstances". In circumstances where comprehensive data cannot be provided under normal conditions of use, an authorisation can be granted in "exceptional circumstances" (Article 14(8), Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency). There are three reasons why such data may not be available (Part I, section 6, Annex I, Code for Human Medicines Directive):

- The condition is too rare.
- The present state of scientific knowledge does not allow it to be collected.
- It would be unethical to collect the data.

Authorisations granted in exceptional circumstances are distinct from conditional authorisations, for which the data will be provided but cannot be provided in the immediate future.

Licensing

3. What is the procedural structure regarding licensing a drug for distribution?

See Question 1.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

The holder of a wholesale dealer’s licence has the right to parallel export the product from one EU member state where there is a marketing authorisation in place for the product to another EU member state where there is a marketing authorisation in place for a similar product. Where the original manufacturer of the product owns intellectual property rights, including trade mark rights, in the product, they are not permitted to exercise their rights to oppose the importation of a product that has been lawfully placed on the market in another member state by, or with the consent of, the proprietor of that right. Because of cultural and, in particular, language differences, products that are parallel traded are frequently repackaged. Such activities have been the subject of a substantial number of court decisions, including many from the European Court of Justice (ECJ). The conclusion of these cases is essentially that the trade mark proprietor cannot use its right to prevent repackaging of a product imported in parallel when:

- The use of the trade mark right by the owner, having regard to the marketing system that it has adopted, will contribute to the artificial partitioning of the markets between member states.
- The repackaging cannot adversely affect the original condition of the product.
- The name of the repackaging company is stated on the new packaging.
- The presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and its owner.
- The proprietor of the trade mark receives prior notice before the repackaged product is put on sale.

The European Commission has outlined its view of the law on parallel imports and repackaging in its Communication on Parallel Imports of Proprietary Drugs for Which Marketing Authorisations Have Already Been Granted (COM(2003) 839). More recently, the ECJ has confirmed that it is lawful for the original trade mark holder to object to the continued marketing of a parallel imported, repackaged pharmaceutical product on which its trade mark has been re-affixed if the trade mark holder has marketed the product in the same volume and packet size as the repackaged product, essentially because this proves that the repackaging is not necessary to prevent an artificial partitioning of the market (Ferring Lægemidler A/S and Orifarm A/S (C-297/10)).

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<table>
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<tr>
<th>Question</th>
<th>Answer</th>
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<tr>
<td>5. Is virtual drug distribution possible from your jurisdiction?</td>
<td>This area is governed by the national law of the EU member states.</td>
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<td>6. What is the procedure to appeal (legal remedy) a licensing decision?</td>
<td>Applications for EU central authorisations are reviewed by a scientific committee of the European Medicines Agency (EMA), but the authorisation is granted by the European Commission. If the Commission refuses to grant authorisation, recourse must be made through the European courts.</td>
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<td>7. What are the costs of obtaining licensing?</td>
<td>For a centralised marketing authorisation application to the European Medicines Agency (EMA) for approval to market a medicine within the EU (single strength, one pharmaceutical form, one presentation), fees start at EUR286,900. Details on fees can be found here: <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp">www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp</a>.</td>
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<tr>
<td>Distribution to consumers</td>
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<td>8. What are the different categories of drugs for distribution?</td>
<td>There are three categories of drugs:</td>
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<td>• Prescription-only medicines (POM).</td>
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<td>• Pharmacy medicines (P).</td>
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<td>• General sales list (GSL) medicines.</td>
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<td>9. Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?</td>
<td>Authorisations for the provision of drugs to consumers are regulated at national level. There are significant differences in the way in which prescribing is handled in the different EU member states.</td>
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<td>10. What drugs can an attending physician distribute and under what circumstances?</td>
<td>This area is governed by the national law of the EU member states.</td>
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<td>11. Who is authorised to prescribe prescription drugs to consumers?</td>
<td>This area is governed by the national law of the EU member states.</td>
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<td>12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?</td>
<td>Article 85c of Directive 2001/83/EC on the Community code relating to medicinal products for human use contains provisions on online sales of medicinal products in the EU, including provisions on:</td>
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<td>• The requirements applicable to persons selling drugs to consumers online.</td>
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<td>• Controls by member states.</td>
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<td>• An EU-wide logo scheme.</td>
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<td>13. What regulatory authority is responsible for supervising distribution activities?</td>
<td>This area is governed by the national law of the EU member states.</td>
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<td>14. What is the procedure to appeal (legal remedy) a distribution decision?</td>
<td>This area is governed by the national law of the EU member states.</td>
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<td>15. What are the legal consequences of non-compliance with consumer distribution laws?</td>
<td>This area is governed by the national law of the EU member states.</td>
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<td>Wholesale distribution</td>
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<td>16. What is the legal regime regarding wholesale distribution of drugs?</td>
<td>Articles 77 to 85 of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) require that member states regulate, and in particular issue, authorisations to wholesalers of medicinal products after checking and inspecting the wholesaler's premises. Inspections can also be carried out at any time after authorisation. If a wholesale dealer's authorisation is withdrawn by a member state, the European Commission must be informed of this. The Code for Human Medicines Directive requires that no more than 90 days is taken for the examination of applications for authorisation. This period is suspended on any requests for additional information. Key conditions are:</td>
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<td>• Suitable premises.</td>
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<td>• Installations and equipment for the protection and distribution of the medicinal products.</td>
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<td>• Properly trained staff, including a designated qualified person.</td>
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<td>Wholesale dealers must only obtain medicinal products from other persons that are authorised to process and distribute those products (for example, a marketing authorisation holder or another wholesale dealer). They can only supply medicinal products to another wholesale dealer or persons that are authorised to supply the medicinal products to the public. Wholesale dealers must ensure that the medicinal products they receive are not falsified by checking their packaging.</td>
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Wholesale dealers must have emergency plans in place to effect recalls, whether instituted by the competent authority, manufacturer or marketing authorisation holder.

Wholesale dealers must keep records of all sales and purchases for at least five years. These records must be available at all times for inspection by the national competent authority that has granted the authorisation and must include at least the following information:

- Date.
- Name of the medicinal product.
- Quantity received or supplied.
- Name and address of the supplier or consignee.

Information must be provided by the wholesale dealer to its onward purchasers, which provides a certain level of traceability through information including the supplier, and the name, pharmaceutical form and quantity of the medicinal product supplied.

The EU also publishes its own guidelines on good distribution practice, with which wholesale dealers must comply.

Member states can impose public service obligations on wholesale dealers, such as obligations to help maintain supplies of medicinal products. These must be applied to any wholesale dealer operating in the member state, including under authorisations issued by another member state.

Member states must ensure that wholesale dealers details are registered in the EU database (Article 77(4), Code for Human Medicines Directive).

17. What regulatory authority is responsible for supervising wholesale distribution activities?

This area is governed by the national law of the EU member states.

18. What are the legal consequences of non-compliance with wholesale distribution laws?

This area is governed by the national law of the EU member states.

MARKETING

Promotion

19. What is the general legal regime for the marketing of drugs?

Articles 86 to 100 of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) contain the general principles governing the advertising of drugs in the EU. Supervision and enforcement of the laws on advertising and promotion are devolved to member states. Member states must have in place procedures that allow them to order particular advertising to cease or, in the case of pre-vetting, to not be published, and to have an accelerated procedure for doing so. Member states are permitted, but not required, to publish the decision and/or a corrective notice. Member states can give self-regulatory bodies the authority to regulate pharmaceutical advertising.

General principles included in the Code for Human Medicines Directive are that:

- Drugs that are not authorised cannot be advertised to any person (including the medical profession).
- Prescription-only drugs and drugs containing ingredients that are psychotropic or narcotic must not be advertised to the public.
- All permitted advertising must conform to the summary of product characteristics.
- All permitted advertising must encourage rational use, and must not be misleading.
- Member states can choose to ban the advertising to the public of drugs that are reimbursed.
- Companies must establish their own scientific service. They must retain copies of advertisements published and must provide those to the authorities on request.

In addition to the directives and regulations that relate specifically to the pharmaceutical industry, the following four general directives and regulations apply:

- Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market, which regulates advertising to consumers.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

Companies operating in Europe refer to applicable codes of practice, in particular the:

- European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on the Promotion of Prescription-Only Drugs to, and Interactions with, Healthcare Professionals.
- EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

Marketing to consumers

21. What is the legal regime for marketing to consumers?

Legal regime

Articles 87 and 88 of Directive 2001/83/EC on the Community code relating to medicinal products for human use requires member states to prohibit advertising:

- Of drugs without a marketing authorisation.
- To consumers of drugs available on prescription only.
- To consumers of products containing psychotropic or narcotic substances.

Drugs intended to be used without intervention of a medical practitioner can be advertised to the public but must:

- Clearly indicate that the product being advertised is a medicinal product.
- Include the name of the product and its common name if the medicinal product contains only one active substance (member states have the option to derogate from this and to allow
reference to the name of the product and the international non-proprietary name (INN) only).

- Include information necessary for correct use of the product.
- Include an express legible invitation to read carefully the instructions on the leaflet or packaging.

Advertising to the public must not:

- Give the impression that a medical consultation or surgical operation is unnecessary.
- Suggest that the effects are guaranteed, without adverse reactions or better than or equivalent to those of another treatment or product.
- Suggest that health will be enhanced by taking the product.
- Suggest that health could be affected by not taking the product (except for vaccination campaigns).
- Be directed exclusively or principally at children.
- Refer to a recommendation by persons such as scientists, health professionals or celebrities which could encourage consumption.
- Suggest that the product is a food, cosmetic or other consumer product.
- Suggest that the safety or efficacy of the medicinal product is due to the fact that it is natural.
- Lead to erroneous self-diagnosis, due to a description of a case history.
- Refer in improper, alarming or misleading terms to claims of recovery.
- Use improper, alarming or misleading terms, or pictorial representations of changes in the human body caused by disease or injury or action of a product on the human body.

Apart from the rules above, the advertising of drugs is regulated nationally.

22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

See Question 21

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, "buy-one-get-one-free")?

This area is governed by the national law of the EU member states.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

This area is governed by the national law of the EU member states.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

This area is governed by the national law of the EU member states.

26. What are the legal consequences of non-compliance with consumer marketing laws?

This area is governed by the national law of the EU member states.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

Promotional materials

Advertising to health care professionals (including all supporting documentation included as part of the promotion) must:

- Be accurate.
- Be up to date.
- Be verifiable.
- Be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value.
- Contain essential information compatible with the summary of product characteristics.
- Indicate the supply classification of the medicinal product and the date when it was drawn up or last revised.

Quotations and tables or illustrations from medical journals must be faithfully reproduced and sources indicated. Member states have the option to require advertising to health care professionals to include the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies. Member states also have the option to permit reminder items to include only the name of the product or the international non-proprietary name (INN).

Activities of sales representatives

It is the responsibility of the company employing sales representatives to ensure that they are adequately trained and knowledgeable to provide complete and accurate information about the medicinal products they are selling. At each visit, they must provide a summary of product characteristics and, if permitted by national legislation, the product’s price and reimbursement status. If a health care practitioner shares their experience of the use of the product, this must be transmitted to the scientific service of the company.

No gifts of advantages must be provided to health care professionals, except for gifts that are inexpensive and relevant to the practice of medicine or pharmacy.

Provision of hospitality

Article 94 of Directive 2001/83/EC on the Community code relating to medicinal products for human uses requires that hospitality at sales promotion events is strictly limited to the main purpose of the events and not extended to persons other than health care professionals. Hospitality can be offered at events for purely professional and scientific purposes, strictly limited to the main scientific objective of the event. EU law does not deal with sponsorship of professionals at educational events, as this is regulated at a national level.

28. Are there any restrictions on marketing to professionals?

See Question 27.
29. What information is it legally required to include in advertising to professionals?

See Question 27.

30. Are there rules on comparisons with other products that are particularly applicable to drugs?

Directive 2006/114/EC concerning misleading and comparative advertising applies to all comparative advertising, but without specific reference to medicinal products. This area is governed in more detail specific to medicinal products by the national law of the EU member states.

31. What other items, funding or services are permitted to be provided to professionals?

Under Article 96 of Directive 2001/83/EC on the Community code relating to medicinal products for human use, free samples can only be provided exceptionally for medicinal products that do not contain psychotropic or narcotic substances, and only to persons qualified to prescribe such products if the following conditions are met:

- The number of samples for each medicinal product each year must be limited.
- Any supply of samples must be in response to a written request, signed and dated, from the prescribing individual.
- Persons supplying samples must maintain an adequate system of control and accountability.
- Each sample must be no larger than the smallest presentation on the market.
- Each sample must be marked: “free medical sample – not for sale” or any equivalent wording.

- Each sample must be accompanied by a copy of the summary of product characteristics.
- Samples must not contain psychotropic or narcotic substances.

32. What regulatory authority is responsible for supervising marketing activities regarding professionals?

Member states are responsible for monitoring marketing activities regarding professionals. Member states have more detailed legislation than is provided at EU level. Member states must confer on courts or administrative authorities the power to order the cessation or prohibition of advertising.

33. What are the legal consequences in case of non-compliance with professional marketing laws?

This area is governed by the national law of the EU member states.

ENGAGEMENT WITH PATIENT ORGANISATIONS

34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

This area is governed by the national law of the EU member states.

REFORM

35. Are there notable recent developments or regulatory projects in the field of distribution and marketing of drugs?

There are currently no major plans to reform the law on the distribution and promotion of drugs at EU level.

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Non-professional qualifications. LLB Hons, European Legal Studies, Bristol University; Masters in Law and Economics, University of Oxford

- Advising on options available under the orphan drugs regime and its applicability to competitor products.
- Detailed response on ABPI Coderefering to an advertising complaint letter from a competitor.
- Advising on nuances of the Pharmaceutical Price Regulation Scheme (PPRS) and statutory scheme.
- Designing compliance processes and procedures for worldwide applicability for an international company.

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Professional associations/memberships

- Chair of the Legal and Compliance Committee of ABHI.
- Member of OBN.
- Member of BIA.

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