SECOND EDITION 2015

DISTRIBUTION AND MARKETING OF DRUGS

A GLOBAL GUIDE FROM PRACTICAL LAW

This second edition of *Distribution and Marketing of Drugs* provides a high level practical overview of a number of key legal issues involved in the distribution and marketing of drugs in 28 jurisdictions around the world. Some of the key issues covered include the pre-conditions for distribution; licensing; wholesale distribution; marketing to consumers; marketing to professionals and engagement with patient organisations.

Written by leading lawyers in their countries, contributors are ideally placed to provide clear, concise and practical commentary on the inner workings of their respective legal systems.

General Editors:
Eric Stupp and Markus Schott, *BÄR & KARRER AG*
Alison Dennis, *FIELDFISHER*

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PREFACE

Eric Stupp, Markus Schott, BÄR & KARRER AG and Alison Dennis, FIELDFISHER

Given the recent developments in the field, two years after the successful launch of the first edition seemed to be a good time to follow up with a second edition of the handbook. We are delighted that so many of the authors of the first edition have been able to work over their contributions within a short timeframe. We are equally happy to have new, distinguished colleagues among the contributors who have agreed to participate in this book's second edition, adding some new jurisdictions such as Australia, Brazil, Canada, Indonesia, Russia, and South Korea. We also thank Emily Kyriacou and her fine editorial team at Thomson Reuters for all their efforts in bringing the project to fruition. Any errors or omissions are, however, ours alone and we welcome comments and ideas for the improvement of future editions from our readers.

Eric Stupp, Markus Schott and Alison Dennis

FOREWORD

Dr Oliver P Kronenberg, Group General Counsel, GALENICA

Demand for effective medicines is rising. As the population ages and increases, new medical needs emerge and the disease burden of the developing world increasingly resembles that of the developed world. The main emerging countries (that is, Brazil, China, India, Indonesia, Mexico, Russia and Turkey) are also becoming increasingly prosperous, with projections suggesting that these countries could account for as much as one-fifth of global pharmaceutical sales by 2020.

At the same time, commercialisation of pharmaceutical products has become more complex as the competitive and regulatory environment has evolved. Today, regulatory regimes not only aim to protect public health and to ensure that there is robust data to support the safety and efficacy of pharmaceutical products, but also to limit expenditure on pharmaceutical products by countries (for example, market access, pricing and reimbursement and distribution channels, among others). One recent development is the implementation of transparency regulations in the US, Europe and some other countries. These regulations require manufacturers of medicines, medical devices and medical supplies to collect and track all financial relationships with healthcare professionals and healthcare organisations, and to report this information to either the local regulators or to publish it on their own website.

This book focuses on the legal environment surrounding the distribution and marketing of medicines. As explained above, the legal framework has been tightened and the standards for compliance have been raised by the regulators. This has led to an increasing need for legal support (whether in-house or external). Jurisdictions differ significantly around the world and, as a consequence, this book has become an important reference guide for the industry.

As in the first edition, the topics addressed in this book cover all relevant aspects of the sale, distribution and marketing of drugs for human use. These range from substantive issues such as the existence of compassionate use programs; admissibility of direct mailing; provision of free samples and discounts and the ability to communicate directly with consumers, to more procedural aspects such as identifying the competent authorities and legal remedies available to parties. As professional and other industry organisations have set up their own codes of conduct in many countries, individual chapters also refer to such codes and describe their implementation.

In conclusion, this book provides everything in-house or external counsel need to understand the distribution and marketing of medicines in the jurisdictions covered. This will assist readers in evaluating legal risks and in providing sound legal and compliance advice to the organisations which they support.

Dr Oliver P Kronenberg, Group General Counsel, Galenica

ITALY

Laura Opilio and Maria Letizia Patania,
CMS ITALY (CMS ADONNINO ASCOLI & CAVASOLA SCAMONI)

DISTRIBUTION

PRE-CONDITIONS FOR DISTRIBUTION

1. WHAT ARE THE LEGAL PRE-CONDITIONS FOR A DRUG TO BE DISTRIBUTED WITHIN THE JURISDICTION?

Authorisation

Drugs can be distributed in Italy if they are either:

- Licensed by the Italian Medicine Agency (*Agenzia Italiana del Farmaco*) (which involves a national procedure) as provided in Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) (implemented in Italy by Article 8 of the Legislative Decree No. 219/2006).
- Licensed according to:
  - Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation) (which is a mutual recognition procedure); or
  - Regulation 1394/2007 on advanced therapy medicinal products and amending the Code for Human Medicines Directive and the EMA Regulation (which is a decentralised procedure).

All the procedural requirements listed in Article 28 of the Code for Human Medicines Directive (implemented in Italy by Articles 41 to 49 of the Legislative Decree No. 219/2006) apply.

Exceptions

Parallel imported drugs must be licensed by the Italian Medicine Agency according to Ministerial Decree dated 29 August 1997 (*see Question 3*).

2. DO ANY TYPES OF NAMED PATIENT AND/OR COMPASSIONATE USE PROGRAMMES OPERATE? IF SO, WHAT ARE THE REQUIREMENTS FOR PRE-LAUNCH ACCESS?

Licensing

A non-authorised drug can be requested from the manufacturing company for use outside a clinical trial when there is no valid therapeutic alternative for the treatment of:

- Serious illnesses.
- Rare illnesses.
- Illnesses which put the patient's life in danger.

The request can be made only if the trial drug has been or will be included in phase III clinical trials or, in the case of terminally ill patients, the drug has been induced in phase II clinical trials.

Such a drug can only be requested from the manufacturer by:

- The doctor, for a specific patient who is not subject to clinical trials.
- More doctors operating in different centres or multi-centre collaborative groups.
- Doctors or collaborative groups whose patients participated in a clinical trial and demonstrated a profile of efficacy and tolerability such as to make it necessary for the ones who participated in the trial to use it as soon as possible.

Following the request, the producer can provide the drug on the basis of a protocol in which the following are present and documented:

- The clinical motivation for the request.
- The relevant data regarding efficacy and tolerability.
- The comparability rate of the patients included in the trial and the ones for which the request was formulated.
- The modalities of information of the patient, that is, the practical way in which the patient has been informed about the drug, the state of the trial and possible side effects, to be established through a paper of informed consent.
- The method of data collection.

The protocol must be:

- Submitted for urgent approval from an ethical committee by a doctor, accompanied by a note in which the doctor takes responsibility for the treatment.
- Notified to the Ministry of Health.

Approval from the ethical committee must be presented for the drug to enter through customs.

3. WHAT IS THE PROCEDURAL STRUCTURE REGARDING LICENSING A DRUG FOR DISTRIBUTION?

Structure

Italy applies the national, mutual recognition and centralised procedures (*see Question 4*). The application is made to the Italian Medicine Agency (*see below, Regulatory authority*). A decision must be taken by the competent authority within the term of 210 days, from the reception of a valid application. The technical and scientific assessment is completed by the Technical Scientific Commission, with the co-operation of experts belonging to the National Institute of Health. Other experts with well-known experience who belong to the Italian academic and health community are also consulted.

Regulatory authority

The Italian Medicine Agency is the national body responsible for licensing new drugs or varying already granted licences.

4. IS THERE A SIMPLIFIED LICENCE PROCEEDING, OR RELAXED LICENSING CONDITIONS, FOR DRUGS WHICH HAVE ALREADY BEEN LICENSED FOR DISTRIBUTION IN ANOTHER JURISDICTION?

Both the mutual recognition and centralised procedures apply in the EU. The procedures set out under Article 28 of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) (implemented in Italy by Articles 41 to 49 of Legislative Decree No.219/2006) apply, depending on whether Italy acts as a reference member state or not. The mutual recognition procedure is where a company that has a drug authorised in one EU member state can apply for this authorisation to be recognised in Italy. The centralised procedure is where an application is made to the European Medicines Agency for a single authorisation which applies in all EU member states.

The above procedures apply also to parallel imports/exports. When there is parallel export of drugs licensed according to the mutual recognition procedure, the Italian Medicine Agency provides the requesting regulatory authorities from other member states with information regarding some of the identification elements of the drugs licensed in Italy.

In the case of parallel import of drugs already licensed in Italy, the procedure set out in Ministerial Decree dated 29 August 1997 applies. The importer must apply for authorisation by submitting an application to the Italian Medicine Agency providing:

- Details of the importer and the relevant member state.
- The name of the drugs to be imported.
- Qualitative and quantitative composition.
- Therapeutic specifications, contra-indications and side-effects.
- Dosage, medication, and so on.
- Summary of the product specifications and handout of the packaging both translated into Italian.

The Italian Medicine Agency must provide its authorisation (or refusal) within 45 days from the date the application was submitted.

There are no simplified licence proceedings or relaxed licensing conditions for drugs already authorised outside the EU. Therefore, the standard procedure of authorisation must be followed before such product can be distributed.

5. IS VIRTUAL DRUG DISTRIBUTION POSSIBLE FROM YOUR JURISDICTION?

Virtual distribution is only allowed for non-prescription drugs. Pharmacies and stores that wish to sell non-prescription drugs are authorised by the competent region or autonomous province (or other competent authorities) to remotely distribute the drugs.

It is a condition for virtual distribution that the following information be communicated to the relevant authority:

- Name, VAT number and full address of the logistics site.
- Date of the beginning of the remote sale activity to the public.

- Website address used for selling and all the necessary information to identify the website.

The website must contain:

- The address of the competent authority.
- A hyperlink to the competent authority's website.
- A common logo, clearly visible on each page of the website of the pharmacy or store.

6. WHAT IS THE PROCEDURE TO APPEAL (LEGAL REMEDY) A LICENSING DECISION?

If the licence application is refused, the Italian Medicine Agency must notify the applicant of this decision. The applicant is then entitled to submit an opposition to the agency. This opposition must be decided within 90 days.

Appeals against agency decisions are made to the Regional Administrative Courts within 60 days of the receipt of the decision.

7. WHAT ARE THE COSTS OF OBTAINING LICENSING?

The costs of obtaining a licence in Italy range between EUR21,600 or EUR36,000 for a new marketing authorisation not supported by a full dossier, to EUR55,680 for a new marketing authorisation supported by a full dossier.

DISTRIBUTION TO CONSUMERS

8. WHAT ARE THE DIFFERENT CATEGORIES OF DRUGS FOR DISTRIBUTION?

The different categories of drugs for distribution can be summarised as follows:

- Prescription drugs.
- Renewable delivery prescription drugs.
- Special prescription drugs.
- Restricted prescription drugs.
- Drugs distributable to consumers only under healthcare rules.
- Drugs usable only within healthcare rules.
- Drugs usable only by specialists.
- Non-prescription drugs.
- Over-the-counter drugs.
- All other drugs that do not require a medical prescription.

9. WHO IS AUTHORISED TO DISTRIBUTE PRESCRIPTION DRUGS AND OVER-THE-COUNTER DRUGS TO CONSUMERS?

Prescription drugs

Pharmacists are entitled to distribute prescription drugs to consumers. To be a pharmacist, an individual must have gained the relevant qualifications and be enrolled on a public register. Individuals can obtain a licence to operate on a physical premises after competitive state examinations and through, for example, acquisition or inheritance.

Over-the-counter drugs

Over-the-counter drugs can be distributed to consumers within pharmacies or supermarkets and other commercial shops. In the latter two cases, a pharmacist must always be present during store hours.

10. WHAT DRUGS CAN AN ATTENDING PHYSICIAN DISTRIBUTE AND UNDER WHAT CIRCUMSTANCES?

Attending physicians are not allowed to distribute drugs.

11. WHO IS AUTHORISED TO PRESCRIBE PRESCRIPTION DRUGS TO CONSUMERS?

Doctors are entitled to prescribe drugs to consumers. Dentists who graduated before 1985 are also allowed to prescribe since they are doctors who are specialised in dentistry. Dentists who graduated after 1985 are only entitled to prescribe drugs connected with their profession.

12. IS DIRECT MAILING/DISTANCE SELLING OF DRUGS PERMITTED IN YOUR JURISDICTION?

Conditions

Distance selling is not allowed for prescription drugs. Pharmacies and stores that wish to sell non-prescription drugs are authorised by the competent region or autonomous province (or other competent authorities) to remotely distribute the drugs (*see Question 5*).

Cross-border sales

In relation to parallel imports/exports, see *Question 4.*

13. WHAT REGULATORY AUTHORITY IS RESPONSIBLE FOR SUPERVISING DISTRIBUTION ACTIVITIES?

Local health authorities (*Aziende Sanitarie Locali*) are responsible for supervising the distribution and prescription of drugs to consumers.

The supervision is carried out through sample checks in the pharmacies and through the publication (after the verification of the provided data), on the national pharmacovigilance database, of the possible reporting made by professionals on the malfunctioning of a drug. The report must also be communicated to the relevant company.

14. WHAT IS THE PROCEDURE TO APPEAL (LEGAL REMEDY) A DISTRIBUTION DECISION?

Appeals against decisions made by the local health authorities must be made before the Regional Administrative Courts (*Tribunale Amministrativo Regionale*) within 60 days from the date when the decision was notified to the interested party or the latter became aware of it.

15. WHAT ARE THE LEGAL CONSEQUENCES OF NON-COMPLIANCE WITH CONSUMER DISTRIBUTION LAWS?

In cases of non-compliance, the local health authorities report to the Ministry of Health and to the Italian Medicine Agency. Penalties of up to EUR3,000 can be imposed and the pharmacy/commercial shop can be closed for a period of up to 30 days.

WHOLESALE DISTRIBUTION

16. WHAT IS THE LEGAL REGIME REGARDING WHOLESALE DISTRIBUTION OF DRUGS?

The wholesale distribution of drugs is provided for by Articles 79 and 80 of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) (implemented in Italy by Articles 101 to 104 of Legislative Decree No. 219/2006). The wholesale distributor must keep a record of all drugs that are distributed.

The wholesale distributor must employ a "qualified person" as set out in Article 79(b) of the Code for Human Medicines Directive, who must be a graduate in pharmaceuticals, chemistry, industrial chemistry or pharmaceutical and chemical technologies. This person must have a clean criminal record and should not be linked to the unlawful trade of pharmaceutical products. If a wholesale distributor owns more than one wholesale outlet, he or she is not required to employ more than one qualified person provided that the appointed qualified person is able to fulfil his or her tasks within reasonable working hours.

The competent authorities responsible for authorising wholesale distribution are the regions or the autonomous provinces where the wholesale activity will be carried out. In the case of wholesale distribution in more than one region, authorisation for each region is required. The authorisation must be granted within 90 days of receipt of the application, although time to grant varies depending on the region. Each region is entitled to ask for certain documents and certificates with the application, however the following certificates are required as standard:

- Fitness for use of the buildings issued by the territorially competent municipality.
- Enrolment on the Companies' Register.
- Prevention of fire.
- Wiring system compliance (and others such as atmospherics and grounding safety certificates).

The internal procedures covering points 2 to 6 of the Guidelines of 19 March 2015 on Good Distribution Practice of active substances for medicinal products for human use must also be submitted. It is important to bear in mind that authorisation requirements will differ from region to region.

17. WHAT REGULATORY AUTHORITY IS RESPONSIBLE FOR SUPERVISING WHOLESALE DISTRIBUTION ACTIVITIES?

Regulatory authority

In addition to the territorially competent region, both the Ministry of Health and the Italian Medicine Agency are entitled to undertake inspections of the wholesale distributors' premises.

Supervision

In cases of non-compliance, penalties of up to EUR18,000 can be imposed on wholesale distributors.

Rights of appeal

Appeals against decisions made by the authorities can be made before the Regional Administrative Courts within 60 days from the date when the decision was notified to the interested party or the date the latter became aware of it.

18. WHAT ARE THE LEGAL CONSEQUENCES OF NON-COMPLIANCE WITH WHOLESALE DISTRIBUTION LAWS?

In cases of non-compliance, penalties of up to EUR18,000 can be imposed on wholesale distributors (*see Question 16*).

MARKETING

PROMOTION

19. WHAT IS THE GENERAL LEGAL REGIME FOR THE MARKETING OF DRUGS?

Legal regime

Drugs can be marketed if they have been duly licensed either pursuant to the national procedure or to the mutual recognition and decentralised procedures.

The marketing authorisation holders must establish a scientific service within their company which will be responsible for co-ordinating information about the drugs. This information must in turn be managed by a Qualified Person under Article 79(b) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) who is a graduate of medicine, pharmaceuticals or chemistry.

Through the scientific service, the licence holder must comply with all of the following obligations:

- Ensuring that the promotion of drugs is compliant with the regulations.
- Verifying that pharmaceutical sales representatives employed by the company have been adequately trained and act in compliance with the regulations.
- Providing assistance to the authorities and complying with their rules.

All members of the marketing team must comply with these obligations.

When advertising to consumers and healthcare professionals, there are special restrictions on some promotional activities.

Limits on marketing activities

Promotional information must always be truthful as to the exact nature of the drug and must:

- Aim to encourage the rational use of the drug, presenting it in an objective way and without exaggerating its properties.
- Not be misleading.

When advertising to consumers and healthcare professionals there are special restrictions on some promotional activities.

Regarding the limitations regarding advertisement to consumers, it is forbidden to:

- Advertise prescription drugs to consumers.
- Make the intervention of a doctor appear as superfluous.
- Induce the consumer to think that the drug has superior effects than it actually does.
- Aim the advertisement to children.
- Advertise the product through a widely known person.
- Compare the drug to a cosmetic, a food product or another consumer product.
- Induce to a wrong auto-diagnosis.
- Connect the security or efficacy of the drug to its "natural" nature.
- Make abusive, shocking or misleading reference to certificates of healing and to visual representations of the human body's alterations due to an illness, and the action of the drug on the body or one of its parts.
- Indicate that the drug has received an authorisation for distribution.

For the advertisement before professionals, it can only be made to these professionals entitled to prescribe it and by the companies which are authorised for the distribution of the drug or their Italian representative if the company is foreign. The advertisement must always include the description of the drug and its class of reference.

If the use of scientific reports, papers or materials is made during the advertisement, such material must be presented integrally and not just in reference to some parts of it.

20. ARE THERE OTHER CODES OF CONDUCT FOR THE MARKETING OF DRUGS (FOR EXAMPLE, BY PROFESSIONAL OR INDUSTRIAL ORGANISATIONS)?

In addition to the legal regime, and separate from the codes of conduct implemented by each company, there are also guidelines concerning the promotion of drugs set out in the Farmindustria Ethics Code (Code). Farmindustria is the Italian pharmaceutical companies' trade association. The Code represents the commitment of the industry not only to abide by specific laws in force but also to operate on the basis of transparent standards of conduct that regulate the various circumstances in which corporate activities take place. The Code is a voluntary agreement entered into by pharmaceutical companies belonging to Farmindustria, and is designed to regulate relations not only between companies but also between companies and the health industry.

All members of Farmindustria must accept and comply with the provisions of the Code. The Code is considered to be a reference guideline for companies that are not necessarily members of Farmindustria.

MARKETING TO CONSUMERS

21. WHAT IS THE LEGAL REGIME FOR MARKETING TO CONSUMERS?

Legal regime

A specific application for each advertisement (even if this advertisement is released through several different media) must be submitted to the Ministry of Health for authorisation to market drugs to consumers.

If the Ministry of Health does not provide this authorisation within 45 days from the date of the application, it is deemed to have been granted. The authorisation lasts for 24 months.

Authorisation is not required when:

- The promotional message is included in newspapers or periodical press and reproduces in full the information provided in the patient information leaflet.
- It consists of a picture of the package put on price tags.

Italian regulations require that promotion to consumers:

- Is clear that the message is a promotion and about a drug.
- Includes the following minimum information:
  - the name of the drug as well as the name of the active ingredient (if the drug contains only one active ingredient);
  - the information necessary for correct use of the drug;
  - an express and legible invitation to read carefully the instructions on the package leaflet or on the outer packaging. For promotional messages included in newspapers or periodical press, this invitation must be in font size nine.

Products

Promotion of drugs to consumers is only permitted if the drugs are non-prescription or do not need the intervention of a doctor for diagnostic purposes.

The following kinds of drugs must not be promoted to consumers at all:

- Drugs which are available on medical prescription only.
- Drugs which contain psychotropic or narcotic substances.
- Drugs which are totally or partially reimbursed by the National Health System.

22. WHAT KINDS OF MARKETING ACTIVITIES ARE PERMITTED IN RELATION TO CONSUMERS AND THE PRODUCTS WHICH MAY BE ADVERTISED TO THEM?

See *Question 19, Limits on marketing activities.*

23. IS IT PERMITTED TO PROVIDE CONSUMERS WITH FREE SAMPLES? ARE THERE PARTICULAR RESTRICTIONS ON SPECIAL OFFERS (FOR EXAMPLE, "BUY-ONE-GET-ONE-FREE")?

It is not permitted to give consumers free samples or to give them promotional offers on drugs.

24. ARE THERE PARTICULAR RULES OF PRACTICE ON THE USE OF THE INTERNET/ SOCIAL MEDIA REGARDING DRUGS AND THEIR ADVERTISING?

No specific legal provisions are provided on the use of the internet in respect of advertising drugs. The general principles concerning marketing to consumers apply, including the authorisation procedure for advertising. The only specific provision is provided for in the Farmindustria Ethics Code. This requires that websites opened by an Italian company or a company operating in Italy which is addressed either to consumers or to healthcare professionals must clearly identify the:

- Company on whose behalf the advertising is placed.
- Source of all information provided on the site.
- Designated recipients of such information and the objectives of the site.

In all cases, access to sections providing promotional information on the company's products must be exclusively reserved to healthcare professionals for products which are not permitted to be advertised to consumers or for which authorisation to advertise has not yet been granted.

25. WHAT REGULATORY AUTHORITY IS RESPONSIBLE FOR SUPERVISING MARKETING ACTIVITIES TO CONSUMERS?

Regulatory authority

The Ministry of Health is the authority responsible for supervising marketing activities to consumers.

Supervision

In cases of non-compliance, the Ministry of Health is entitled to order the immediate termination of promotional activities as well as circulation of a press release containing a retraction. As a general rule, fines from EUR2,600 to EUR15,600 can be imposed. Higher amounts are imposed in cases of infringement of the prohibition against showing a drug in a non-advertising context to indirectly promote its use. Fines ranging from EUR10,000 to EUR60,000 can be imposed, for example, if the drug is shown in movies or television shows.

Rights of appeal

Appeals against decisions made by the authorities can be made before the Regional Administrative Courts within 60 days from the date the decision was notified to the interested party or the date the latter became aware of it.

26. WHAT ARE THE LEGAL CONSEQUENCES OF NON-COMPLIANCE WITH CONSUMER MARKETING LAWS?

See *Question 25, Supervision.*

MARKETING TO PROFESSIONALS

27. WHAT KINDS OF MARKETING ACTIVITIES ARE PERMITTED IN RELATION TO PROFESSIONALS?

Marketing activities can only be directed to healthcare professionals who are authorised to prescribe or supply the relevant drugs. Marketing material must first be submitted to the Italian Medicine Agency and ten days later can be delivered to healthcare professionals. No actual authorisation is required, there is only a duty to submit it to the Italian Medicine Agency. If the Italian Medicine Agency prohibits it, it cannot be used.

In general terms the following kinds of marketing activities (some of which will be better examined in the following questions) are permitted with regard to healthcare professionals, provided that the relevant material meets the above-mentioned requirements:

- Verbal information.
- Delivery of promotional material.
- Free samples.
- Scientific congresses and conventions.
- Refresher courses.
- Visits to companies' laboratories.
- Investigators' meetings.
- Scholarships and scientific consultancy.

28. ARE THERE ANY RESTRICTIONS ON MARKETING TO PROFESSIONALS?

Marketing activities

Exaggerated statements, universal and exaggerated claims and comparisons without any objective basis are not permitted. Use of e-mail, automated calling systems and other electronic communication aimed at divulging promotional material regularly approved by the Italian Medicine Agency is prohibited, unless the company holds a prior written and informed consent from the healthcare professionals to whom the material is addressed.

Frequency

There is no provision concerning frequency of marketing activities.

Provision of hospitality

The Italian Medicine Agency must be informed at least 60 days before the start date of any event, meeting, conference (or similar) organised or funded by an Italian drugs company. This includes both in Italy and abroad and applies to any gathering designed to discuss matters related to the use of drugs that are an occasion for pharmaceutical companies to meet healthcare professionals. The following information must be provided to the Italian Medicine Agency:

- Details of the pharmaceutical company.
- Location and date of the event.

- The matters to be discussed during the event.
- The possible attendees.
- Speakers' qualifications.
- A detailed estimate of the costs.

Any positive opinion from the Italian Medicine Agency will be issued within 45 days.

Should the event be held abroad or involve costs higher than EUR25,822.85, specific authorisation must be granted by the Italian Medicine Agency for events in Italy or involving Italian healthcare professionals before the commencement date as well as the payment of a rate equal to EUR1,859.24.

During the events, no kind of display and/or distribution of samples for promotional purposes is permitted with the exception of leaflets and other information-bearing conference materials.

As far as hospitality is concerned, pharmaceutical companies may only offer economy-class air travel to Italian healthcare professionals invited to conference events in Italy or abroad. Any category of paid-for hotel accommodation must not exceed four stars. In addition, the same healthcare professionals cannot be invited by the same pharmaceutical company more than twice a year. This restriction does not apply to speakers or moderators.

No events may be directly or indirectly organised by a pharmaceutical company outside Italy if it is to be mainly attended by Italian healthcare professionals.

The duration and the venue of the event are also subject to specific conditions. Events must be held in places and venues chosen for logistical, scientific and organisational reasons, which excludes restaurants. If the conference is to be held in a location popular with tourists, the following restrictions apply:

- No conferences are to be held at seaside resorts during 1 June to 30 September.
- No conferences are to be held in mountain resorts during 1 December to 1 March, and 1 July to 31 August.

The hospitality offered to the participants cannot exceed a 12-hour period before and immediately after the event and the hospitality must be secondary to the technical and/or scientific content of the event. No hospitality of any kind can be offered to guests of the invited healthcare professionals.

29. WHAT INFORMATION IS IT LEGALLY REQUIRED TO INCLUDE IN ADVERTISING TO PROFESSIONALS?

Marketing statements must always be substantiated by documented and verifiable evidence. The minimum particulars that must be included in all advertising are:

- The information listed in the summary of the product characteristics.
- The supply category of the drug.
- The selling price and the conditions under which it can be reimbursed by the national health system.

The promotional material may also include the name of the drug and the name of the active ingredient, together with the name of the licence holder and of the co-promoter, if any.

30. ARE THERE RULES ON COMPARISONS WITH OTHER PRODUCTS THAT ARE PARTICULARLY APPLICABLE TO DRUGS?

Comparisons without an objective basis are not permitted (*see Question 28, Marketing activities*).

31. WHAT OTHER ITEMS, FUNDING OR SERVICES ARE PERMITTED TO BE PROVIDED TO PROFESSIONALS?

Discounts

No discounts from the sale price are permitted. Promotion to healthcare professionals must be carried out by pharmaceutical sales representatives who belong to the scientific service of the company. This service must be independent of the company's marketing service.

Free samples

Free samples of drugs can only be supplied to healthcare professionals qualified to prescribe them and then only exclusively by pharmaceutical sales representatives. Healthcare professionals are required to keep the samples according to the instructions on the packaging or in the patient information leaflet.

The following strict criteria must be followed:

- Any supply of samples must be in response to a written request, signed, stamped and dated by the healthcare professional.
- In the first 18 months after the first marketing of the drugs, only two samples for each drug can be supplied to one healthcare professional during each visit and in any case no more than eight samples per year.
- After this time period, only four samples of each drug can be supplied to each healthcare professional during each visit and in no case more than ten samples per year.
- Each sample must be equal to or less than the smallest package put on the market, provided that this is expressly stated on the sample's label.
- Each sample must always be supplied together with a summary of the products' characteristics.
- Each sample must be marked with "free sample – not for sale" or other similar wording.
- No samples of drugs containing psychotropic or narcotic substances can be supplied.

Pharmaceutical companies must train their pharmaceutical sales representative in accordance with the above criteria and keep records of requests made to them for free samples over an 18-month period.

Sponsorship of professionals

Pharmaceutical companies may work with healthcare professionals as consultants for services such as speakers and moderators at conferences, or may invite them to participate in observational studies or training and education services. Based on the Farmindustria Ethics Code, the following criteria must be fully complied with:

- A written agreement must be signed between the healthcare professional and the pharmaceutical company specifying the nature of the service. The need for the service must be clearly identified and stated.

- The agreement must also state that the healthcare professional undertakes to disclose his or her relationship with the pharmaceutical company whenever he or she writes or speaks in public on the subject matter to which the co-operative relationship refers. The same obligation also applies in the event that the pharmaceutical company employs practising healthcare professionals on a part-time basis.
- The company is required to keep the documentation on the services provided by healthcare professionals for at least three years.
- The fees paid by pharmaceutical companies for the services must meet cost-performance criteria and reflect their market value. The initiative must guarantee coherence and appropriateness in respect of the pursued objectives and it must be capable of being fully documented.

Other items, funding of services

No other indirect incentives are permitted.

32. WHAT REGULATORY AUTHORITY IS RESPONSIBLE FOR SUPERVISING MARKETING ACTIVITIES REGARDING PROFESSIONALS?

Regulatory authority

The Italian Medicine Agency is the authority responsible for supervising marketing activities to healthcare professionals.

Supervision

In cases of non-compliance, the Italian Medicine Agency is entitled to order the immediate termination of the promotional activities and require circulation of a press release containing a retraction to be uploaded to the corporate website. Fines from EUR2,600 to EUR15,600 can be imposed. Higher amounts are imposed if free samples are marketed without the indication "free sample – not for sale" (from EUR5,000 to EUR30,000) (*see Question 31, Free samples*).

Rights of appeal

Appeals against decisions made by the authorities can be made before the Regional Administrative Courts within 60 days from the date the decision was notified to the interested party or the date the interested party became aware of it.

33. WHAT ARE THE LEGAL CONSEQUENCES IN CASE OF NON-COMPLIANCE WITH PROFESSIONAL MARKETING LAWS?

See *Question 32, Supervision*.

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?

Any form of economic support (whether direct or indirect) by pharmaceutical companies to a patient organisation must comply with the following criteria (*Farmindustria Ethics Code*):

- A specific and preliminary agreement aimed at regulating the amount of and reasons for financing must be reached. For this reason, each pharmaceutical company must develop a standard internal procedure for approving this category of agreements.
- Any public utilisation by a pharmaceutical company of the logo or material owned by a patient organisation must be authorised in advance by the organisation. To acquire that authorisation, the objectives for, and the manner of use of the logo, must be clearly defined.
- Any form of sponsorship by pharmaceutical companies given to patient organisations must be transparent and without promotional objectives.
- No company can ask to be the sole financier of a patient organisation.
- In all cases in which journeys or other forms of hospitality are provided, the above provisions, as also set out in the Farmindustria Ethics Code, must apply.
- Companies must publish on their websites a list of all patient organisations that were financially supported by it in the previous year. This list must detail the monetary value of the support and must be publicly available for a period of three months coinciding with the first three months of each year.

Agreements between pharmaceutical companies and patient organisations under which the organisations provide any type of services to the companies are only allowed if the services are aimed at supporting healthcare activities or research. Patient organisations may be engaged as experts and advisors for services such as participation at advisory board meetings and speaker services. A written agreement must be executed in advance in order to specify the nature of these services and the basis of payment for them. A legitimate need for the services must be clearly identified and documented in advance of requesting them. Compensation for the services must be reasonable and not exceed the fair market value of the services provided. Companies are required to publish an annual list of the patient organisations which they have engaged to provide services.

REFORM

35. ARE THERE ANY PLANS TO REFORM THE LAW ON THE DISTRIBUTION AND PROMOTION OF DRUGS IN YOUR JURISDICTION?

There are no plans to reform the law on the distribution and promotion of drugs in Italy.

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