Life Sciences

Contributing editor
Alexander Ehlers

2019

GETTING THE DEAL THROUGH

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Preface

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Tenth edition

Getting the Deal Through is delighted to publish the tenth edition of *Life Sciences*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Serbia.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Alexander Ehlers of Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB, the contributing editor, for his continued assistance with this volume.

GETTING THE DEAL THROUGH

London
November 2018

Italy

Laura Opilio and Maria Letizia Patania
CMS Adonnino Ascoli & Cavasola Scamoni

Organisation and financing of healthcare

1 How is healthcare in your jurisdiction organised?

The Italian healthcare system (SSN) is a comprehensive system of structures and services aimed at granting all citizens equal access to healthcare treatment, and represents a direct expression of article 32 of the Constitution, under which 'the Italian Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent'.

The main rules and principles of the SSN are laid down by Law No. 833/1978, which also established the SSN.

Regarding the specific services offered by the SSN, a Presidential Decree dated 29 November 2001 provides a list of the essential levels of assistance (LEAs) that must be granted to all citizens for free or, at most, subject to the payment of a prescription charge. The LEAs represent minimum performances equally granted throughout all of the Italian territory; regions can also guarantee additional – but no fewer – services if they so autonomously decide so.

The SSN consists of different territorial levels (central, regional and local), mostly operating on a decentralised basis.

At the central level, the Ministry of Health serves policy and coordination purposes, mainly by drawing up the national health plan (PSN), laying down the LEAs and issuing guidelines on technical issues of national importance.

At the regional level, the regions hold legislative and administrative powers that include implementing the PSN, adopting a regional healthcare plan, setting forth rules regarding the organisation of local health authorities (ASLs), and accrediting and arranging agreements with public and private health entities.

At the local level, the ASLs, which deliver the health services related to the LEAs, are divided into territorial areas managed by a general director appointed by the competent region.

2 How is the healthcare system financed in the outpatient and inpatient sectors?

There are no differences between the outpatient and inpatient sectors in Italy.

The SSN is mostly financed through the tax system, with citizens being directly charged only in a few specific cases and for low amounts; as seen above, pursuant to article 32 of the Constitution, the state guarantees free medical treatment to all citizens. Therefore, no compulsory health insurance is required in Italy.

In particular, the SSN is financed as follows:

- taxation collected by the regions, specifically regional business tax and an additional personal income tax;
- prescription charges to patients, which also serve to discourage people from requesting unnecessary health services. Prescription charges are provided for the following: specialist services; first aid services; thermal treatments; and charges for the purchase of drugs, if a region so decides, citizens may be relieved from paying for prescription charges depending on their income, age, social condition, whether they are suffering from specific diseases or disabilities, or in other particular situations (eg, pregnancy, cancer prevention, HIV testing);
- incomes of public hospitals deriving from private intramural activities performed by employed physicians; and
- the state budget, which finances SSN's needs where these are not already covered by other funding sources. Resources derive from VAT, excises on fuel and the National Health Fund

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

The advertising of medicinal products in Italy, both to the general public and to healthcare professionals (HCPs), is regulated by Legislative Decree No. 219/2006 (also referred to as the Code of Drugs) implementing Directive No. 2001/83/EC and Directive No. 2003/94/EC.

Articles 113 to 128 of Decree No. 219/2006 specifically address the rules and procedures related to the advertising of medicinal products.

Furthermore, guidelines issued on 20 December 2017 by the Ministry of Health concerning the advertising of medical products through new media, as well as guidelines and directives issued by the Italian Medicine Agency (AIFA), must also be considered.

Finally, it should be noted that all advertising is subject to the general rules set forth by Legislative Decree No. 145/2007 on misleading and comparative advertising.

4 What are the main rules and principles applying to advertising aimed at healthcare professionals?

Marketing activities can be directed only to HCPs authorised to prescribe or supply the relevant drug.

No prior authorisation is required. Nevertheless, undertakings shall submit the marketing material to AIFA in advance. If within 10 days following the submission AIFA does not prohibit the use thereof, the material can be freely delivered to HCPs.

Adverts must always include a summary of the product's characteristics, specify the classification for the purposes of distribution, and indicate the selling price as well as the conditions under which it can be reimbursed by the SSN. As an exception to the above, advertising can merely include the drug's denomination and the name of the related active ingredient or ingredients, together with the name of the licence holder and of the co-promoter (if any) when, for instance, due to reasons of space more detailed information cannot be included.

Furthermore, all marketing statements must be accurate, up to date, supported by verifiable evidence, complete enough to allow the addressee to be properly informed on the characteristics of the product and its therapeutic effects, and present the product in an objective, non-exaggerated manner. The information must be consistent with the documentation issued to obtain the marketing authorisation and the relevant revisions thereof.

Insofar as the above-mentioned principles and further relevant specific provisions are complied with, the following kinds of marketing activities are allowed:

- delivery of verbal information;
- delivery of promotional material;
- delivery of free samples;
- invitations to scientific congresses and conventions;
- refresher courses;
- visits to company laboratories;
- investigators' meetings; and
- scholarships and scientific consultancy.

5 What are the main rules and principles applying to advertising aimed at the general public?

Advertising to the general public is subject to stricter requirements than those aimed at HCPs.

First, marketing towards customers is allowed only insofar as the drugs are not subject to prescription or do not need the intervention of a doctor for diagnostic purposes (ie, over-the-counter drugs). Furthermore, it is forbidden to promote drugs that are available on medical prescription only; contain psychotropic or narcotic substances; or are, even partially, reimbursed by the SSN.

As a general rule, advertising aimed at the general public, when allowed, is subject to prior authorisation by the Ministry of Health, with the only exceptions being promotional messages included in newspapers or the periodical press that thoroughly reproduce the information contained in the patient information leaflet; or advertising consisting of a picture of the package with price tags added on. Specific authorisation must be sought for every single advert, even if the same content is released through different media (internet, on paper, etc). The Ministry of Health has 45 days to grant the authorisation: if 45 days elapse without any resolution, the authorisation is deemed as granted and will last for 24 months.

Detailed provisions are provided for regarding both the minimum content of advertisements and forbidden messages.

Minimum requirements

Advertisements of drugs aimed at the general public must always:

- have a plain commercial purpose;
- make it clear that the product is a drug; and
- include at least the drug's name and, if the product is not composed of multiple active principles, the relevant common denomination; information essential for the correct use of the drug; and a clearly written warning to carefully read the patient information leaflet or the external packaging, or both.

Forbidden content

Advertisements of drugs aimed at the general public cannot:

- contain any element that may persuade users to believe that:
  - consulting a physician or undergoing surgery is unnecessary, in particular by offering a diagnosis or suggesting a mail-order treatment;
  - the product entails no side effects, or that it is superior or equal to any other treatment or to another drug;
  - the drug can improve their regular state of health;
  - failure to use the drug, except for vaccinations, may entail detrimental effects on their regular state of health; or
  - the drug's safety or efficacy derive from it being a 'natural' substance;
- be exclusively or mostly addressed to children;
- include advice from scientists, HCPs or famous people;
- assimilate the drug to a foodstuff, cosmetic product or any other consumer product;
- induce a wrong self-diagnosis;
- make improper, striking and misleading reference to their healing capacities; or
- make use of visual representations of alterations to the human body brought about by a disease, or visual representations of the effects of the drug on the human body, or part of it, in an improper, striking and misleading manner.

Furthermore, promotional messages whose commercial purpose is concealed by a plethora of other information are forbidden.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

Infringements concerning advertising rules are mostly related to promotional messages aimed at customers. Specifically, manufacturers often fail to comply with the rules on forbidden content, for example, by including misleading messages that may induce customers to believe that a drug has no side effects or that it is not necessary to seek a physician's advice. Another common infringement is not including a sufficiently clear warning to read the patient information leaflet or the external packaging, or both.

With specific reference to advertising aimed towards HCPs when manufacturers advertise products on their websites, a common infringement is a failure to publish a warning stating that information in such advertising is aimed towards HCPs only.

7 Under what circumstances is the provision of information regarding off-label use to healthcare professionals allowed?

This is not allowed under any circumstances. It is a fundamental principle that all advertising concerning a medicinal product – directed both to HCPs and to the general public – must comply with the product's instructions of use (IFUs). By definition, off-label use is the use of medicinal products for an unapproved indication not stated in the IFUs. As a consequence, since advertising can only refer to approved uses indicated in the IFUs, provision of information regarding off-label use is forbidden.

On a side note, under the following very specific circumstances, physicians are nevertheless allowed to use drugs off-label:

- medicines can be used off-label and are reimbursed by the SSN if no valid therapeutic alternative exists; supporting data deriving from Phase II clinical trials are present; or the drugs are inserted in a specific list drawn up by the AIFA (as per article 1.4 of Law Decree No. 536/1996, converted into Law No. 648/1996). In exceptional cases, medicines used off-label may be reimbursed by the SSN, even if a valid therapeutic alternative does exist, provided that AIFA deems that specific use is known and compliant with the researchers conducted on national and international levels (as per article 1.4-bis of Law Decree No. 536/1996, converted into Law No. 648/1996); or
- physicians, on their own responsibility, can use a medicine off-label – including a drug not present in the AIFA list referred to in the bullet point above – if the physician deems that the patient cannot be successfully treated with a different product, even if said product has been authorised with respect to the relevant disease; after having been duly informed, patients give their consent to such use; the off-label use is consistent with scientific papers credited by the international community; and supporting data deriving from Phase II clinical trials are present. In this case, the SSN shall not reimburse the drug (as per article 3, paragraph 2 of Law Decree No. 23/1998, converted in Law No. 94/1998).

However, under no circumstances shall the SSN reimburse the use of off-label drugs if such use acquires a regular and widespread character.

8 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sector?

The relevant legislation is Legislative Decree No. 219/2006.

Further guidance is provided for by the Code of Professional Conduct issued by Farmindustria, the Italian pharmaceutical companies trade association. While not legally binding – it is a voluntary document that pharmaceutical companies belonging to Farmindustria agree upon adhering to – the Code is also considered as a general guideline for companies that are not members of Farmindustria. As mentioned in question 2, there is no difference between the outpatient and inpatient sectors.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

The main principle governing relationships between pharmaceutical companies and HCPs is that the former shall behave in a fair and transparent manner such as not to illicitly induce the latter to prescribe their products. Therefore, the relevant rules and regulations limit the possibility for pharmaceutical companies to grant benefits to HCPs.

With reference to gifts, it is forbidden to grant, offer or promise any goods or advantages, either monetary or in kind, unless they are of negligible value and refer to an HCP's activity.

As to congresses, very strict rules are set forth by the Farmindustria Code:

- they shall be inspired by ethical, scientific and cost-effective criteria;

- hospitality offered on occasion of such events shall be limited to travel, accommodation and payment of registration fees;
- pharmaceutical companies may only offer economy-class air travel to Italian HCPs invited to congresses in Italy or abroad;
- the category of hotel accommodation shall not exceed four stars;
- under no circumstances can scientific venues also serve touristic purposes. Therefore, it is forbidden to provide accommodation in the following: resorts, ships or castles that lie outside the city where a conference is being held; or farms, golf clubs, thermal baths or other venues whose main activity is dedicated to health or spa services;
- meals and drinks can be offered only up to a threshold of €60 for each professional per meal for all events in Italy; and
- the number of invitations to HCPs (save to speakers or moderators) cannot exceed two a year.

Congresses and scientific venues must be authorised by the AIFA beforehand. Applications must be delivered to the AIFA 60 days before the proposed commencement of the congress and must encompass the following information:
- the company's particulars;
- place and date of the congress;
- addressed professionals;
- the subject and programme of the conference, as well as its relation to the marketed drug; and
- professional and scientific information.

With specific reference to collaboration, pharmaceutical companies can avail themselves of physicians as scientific consultants and as moderators at conferences, provided that the following requirements are complied with:
- the parties shall stipulate a contract clearly identifying the relevant services;
- the physician shall 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 contract refers;
- the company shall keep the documentation on the services offered by consultants for at least three years;
- fees paid by pharmaceutical companies shall meet cost-performance criteria and reflect the market value of such services; and
- the decision on such initiatives shall be reserved to the executive senior management.

10 What are the most common infringements committed by manufacturers with regard to collaboration with healthcare professionals?

The most common infringements concerning collaboration with HCPs derive from non-compliance with the rules on congresses set forth in question 9. Undertakings sometimes try to improperly impress physicians by setting up scientific venues not chosen according to cost-effective criteria or by offering them unlawful benefits, or both.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

This matter is governed by Chapter 4 of the Farmindustria Code of Conduct; as previously stated, the Code is not legally binding, but is a voluntary document that pharmaceutical companies belonging to Farmindustria agree upon adhering to, and is additionally considered as a general guideline for companies that are not actual members of Farmindustria.

As a general rule, pharmaceutical companies can grant either direct or indirect economic support to patient organisations. However, this is subject to very strict requirements:
- a preliminary agreement regulating the amount of financing and the related grounds shall be executed. For this purpose, pharmaceutical companies shall develop a standard internal procedure for the approval of such agreements;
- the use of the logo or other material belonging to the patient association (or both) by the pharmaceutical company shall be authorised in advance by the patient association;
- any form of sponsorship by pharmaceutical companies in relation to patient associations shall be transparent and have no promotional objectives;
- the pharmaceutical company cannot make a request to be the sole financer of a patient organisation; and
- pharmaceutical companies shall disclose, for at least the first quarter of each year, a list of the patient organisations it has financed during the previous year (including the monetary value of the financial support granted to each individual organisation) on their websites.

Furthermore, the execution of contracts concerning the services to be provided by patient organisations to companies is allowed. For example, patient organisations can be appointed as experts for services such as acting as speakers during conferences. Nevertheless, it is necessary that the contract be executed in writing and in advance, specify the nature of the services and state the basis for payment of those services. With reference to this final point, compensation for the services shall be reasonable and must not exceed the relevant fair market value. For the purposes of transparency, pharmaceutical companies shall disclose, on an annual basis, the list of patient organisations they have engaged to provide the mentioned services.

Considering that the above-mentioned rules are not statutory, but on the contrary are provided under the Farmindustria Code, the competent enforcing bodies are Farmindustria's own supervisory committee, single-judge tribunal and jury. Related powers and procedures are set forth in the last section of the Farmindustria Code.

12 Are manufacturers' infringements of competition law pursued by national authorities?

Yes. The competent authority is the Italian Antitrust Authority (AGCM), which enforces articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) on anticompetitive agreements and abuse of a dominant position. Appeals can be filed with the Regional Administrative Court against AGCM decisions, while the Council of State acts as judge of final instance.

In cases of anticompetitive behaviours affecting more than one member state, the competent authority is the European Commission.

13 Is follow-on private antitrust litigation against manufacturers possible?

Yes, as was stated by the Italian Supreme Court in judgment No. 2207/2005.

Follow-on actions must be lodged with the ordinary courts and generally aim to seek compensation for damages. Bearing in mind that punitive damages cannot be awarded in Italy, private parties can request, for example, the difference between the price actually paid and the one they would have presumably paid had the restrictive agreement or abuse of dominant position not been carried out.

Pursuant to article 140-bis of Law Decree No. 206/2005 (Italian Consumers' Code), class actions are possible in the case of antitrust private enforcement.

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

The EFPIA Disclosure Code has been implemented by the Farmindustria Deontological Code – Chapter 5, governing the transparency of transfers of value among pharmaceutical companies, healthcare professionals and healthcare organisations. Although the Farmindustria Code is compulsory for those pharma companies that are members of Farmindustria only, as a matter of fact, almost all the companies operating in Italy are enrolled with Farmindustria. Chapter 5 is fully compliant with the EFPIA Disclosure Code, therefore each pharmaceutical company must, on an annual basis, document and disclose on the company website all transfers of value carried out directly or indirectly to healthcare professionals and organisations. The disclosure of this data shall come about on an individual basis and any eventual disclosure in aggregate form shall represent an exceptional circumstance.

An additional transparency requirement applicable to Italian pharma companies is set forth by article 48, paragraph 17, Legislative Decree Law No. 326/2003 and the implementing ministerial decree

of the Ministry of Health dated 23 April 2004, according to which, by 30 April of each year, pharma companies are subject to the duty of disclosing to AIFA the cost supported in the preceding year for promotional activities (including samples, gadgets, advertising, promotional material, etc) in order to assess a 5 per cent contribution to be paid to the AIFA each year.

Italian companies are also subject to the enforcement of the Legislative Decree No. 231 of 8 June 2001, which has introduced an administrative liability of the companies in connection with criminal actions performed directly by their chief executive officers or employees in the interest of or to the advantage of the company.

Compliance – medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Despite being governed by a different set of rules (ie, Legislative Decree No. 46/1997, implementing Directive 93/42/EEC, in addition to further regulations and guidelines set out by the Ministry of Health on 28 March 2013), medical devices are regulated in a manner quite similar to drugs. Nevertheless, it mostly depends on the specific area and on the category of medical device (eg, whether high risk or low risk) under consideration.

With reference to advertising of medical devices towards HCPs, the rules are less rigorous since no prior communication to the AIFA is necessary. On the contrary, as concerns the general public, the limitations are very similar to those provided for medicinal products: it is forbidden to advertise medical devices that can be used upon medical prescription only or that require the assistance of professionals, or both; and advertisements, when allowed, must be duly authorised by the Ministry of Health, which assesses both the content of advertisements and the chosen marketing method. The evaluation process may take up to 45 days running from the date when an application is submitted. Should no formal resolution be issued within that time period, the authorisation is deemed granted. As an exception, mere accessories of medical devices are not subject to the above-mentioned rules insofar as they are chosen by the patient only on the basis of aesthetic factors and without considering any medical aspects (eg, frames for glasses).

Regarding cooperation, Assobiomedica (the Italian association of companies operating in the medical devices sector) has issued a Code of Ethics, renewed in February 2018, that provides for rules thereof. As per section 2.7, congresses and other similar events shall respect sobriety. As such, for example:

- it is forbidden to provide accommodation in five-star hotels;
- between 15 June and 30 September, events shall not be organised in seaside resorts, whereas between 15 December and 30 March and between 15 June and 15 September, mountain resorts are forbidden;
- flight tickets shall be economy class only; and
- meal costs shall be reasonable.

Furthermore, in the event that HCPs are entrusted with a paid task (eg, speaker duties), the medical device company shall receive proper authorisation thereof from the public body at which the HCP works.

Pharmaceuticals regulation

16 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

This matter is governed by the Code of Drugs, EC Regulation No. 726/2004, EC No. Regulation 1394/2007 and a Ministerial Decree dated 29 August 1997. The relevant law depends on the activity being considered.

17 Which authorities may grant marketing authorisation in your jurisdiction?

The competent Italian authority for granting marketing authorisations is the AIFA.

18 What are the relevant procedures?

Marketing authorisations can be granted pursuant to different procedures: national procedures, EU procedures (mutual recognition and decentralised procedures) and parallel import procedures.

Rules concerning national procedures are provided under article 8 of the Code of Drugs. The concerned undertaking must submit an application with the AIFA, providing it with all the required information and the results of any clinical trials. The AIFA, assisted by the Technical Scientific Commission (CTS) and by experts belonging to the National Institute of Health (ISS), reviews all the documentation and performs the necessary assessments. No later than 210 days from the date of receipt of the application, and if all the requirements are met, the AIFA shall grant the marketing authorisation (AIC) to the pharmaceutical company. Although the registration process complies with the same criteria provided for by the EU procedures, the AIC will only be valid in Italy.

In respect of EU procedures, the relevant rules are provided for under articles 41 to 49 of the Code of Drugs. Specifically, the mutual recognition procedure allows the extension of a marketing authorisation granted by a member state to one or more other countries of the European Union, whereas the decentralised procedure allows the granting of a single marketing authorisation that is simultaneously valid in all the countries belonging to the European Union for a medicinal product that has not yet been authorised in Europe.

With reference to the parallel import of drugs already licensed in Italy, the relevant rules are set forth by a Ministerial Decree dated 29 August 1997. The importer shall submit an application for authorisation to the AIFA, which will then make a decision within 45 days. The application must include:

- details of the importer and the relevant member state;
- the name of the drug to be imported;
- the drug's quantitative and qualitative composition;
- the drug's therapeutic purposes, contraindications and side effects;
- use of the product in terms of dosage, medication, etc; and
- a summary of the product's specification and a hand-out of the packaging, both translated into Italian.

It is possible to file an opposition with the AIFA, to be decided within 90 days, should a licence application be refused. Subsequently, the concerned party can lodge an appeal with the regional administrative courts within 60 days of receipt thereof.

19 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Under article 38, paragraphs 5 to 8 of the Code of Drugs, any marketing authorisation lapses if the medicine is not actually marketed in Italy within three years following the grant of the authorisation. Furthermore, even if the drug is marketed for a period of time after the authorisation, any marketing authorisation lapses if the drug stops being marketed in Italy for a consecutive period exceeding three years.

In very exceptional circumstances and for public health reasons, the AIFA, by means of a justified measure, may prevent the above-mentioned lapse of the authorisation.

20 Which medicines may be marketed without authorisation?

No medicine lacking an authorisation can be marketed. Even in the case of homeopathic and equivalent generic products, marketing authorisations must be obtained, although in this case the authorisation is achieved through a simplified procedure.

As per article 7 of the Code of Drugs, the sole exception to the above are radiopharmaceuticals prepared at the time of use by people or by plants authorised to use such medicinal products, in an approved healthcare complex, and exclusively from authorised generators, kits or precursor radiopharmaceuticals in accordance with the manufacturer's instructions.

21 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Article 5(1) of Directive 2001/83/EC was implemented into Italian law by article 5, paragraph 1 of the Code of Drugs.

Therapeutic use of unlicensed drugs is allowed only if a physician that has a patient under his or her care specifically so requests and if the

following conditions are met: the required drug is deemed as absolutely necessary for the patient's treatment, and no equivalent licensed product is present on the Italian market. Applications must be addressed to the Ministry of Health, and must include:

- details of the healthcare centre;
- details of the custom office territorially competent for the importation;
- details of the foreign pharmaceutical company;
- details of the drug (name, active principle, dosage, etc);
- confirmation that the drug is duly authorised in the country of origin;
- confirmation that the drug cannot be replaced for the same therapeutic purpose by another drug licensed in Italy; and
- the volume required.

Furthermore, the physician must undertake that the drug will be used only with respect to a limited number of patients under his or her responsibility, and that the latter have given their informed consent to the therapy. Such therapy cannot last longer than 90 days for each patient. After the authorisation is granted, the drugs can be imported.

Moreover, unlicensed drugs can be used following the end of a clinical trial in order to continue to provide the trial drug – still unlicensed – to trial participants upon specific request of the physician and provided that trial drug has been – or will be – included in Phase III clinical trials or, in the case of terminally ill patients, Phase II clinical trials; and results of the required trials show efficacy and tolerability to the trial drugs. Such use is allowed both on participants in the clinical trials and on new patients. The above access falls within the scope of compassionate usage programmes governed by the Decree of the Ministry of Health, dated 8 May 2003.

Pricing and reimbursement of medicinal products

22 To what extent is the market price of a medicinal product governed by law or regulation?

This depends on the refundability class of the concerned drug.

Under Law No. 326/2003, if a drug cost is reimbursed by the SSN, the price is set through negotiation between the AIFA and the marketing authorisation holder.

On the contrary, the price of drugs whose cost is charged to customers can be freely determined by the pharmaceutical company. Nevertheless, price adjustments are limited and can take place only once every two years.

Italian law does not envisage any differences to the above that depend on whether the outpatient or inpatient sector is involved.

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare providers?

No; any negotiations over prices are carried out between the pharmaceutical companies and the AIFA alone.

24 In which circumstances will the national health insurance system reimburse the cost of medicines?

Medicines are divided into the following refundability classes:

- Class A, including medicines required for the treatment of serious, chronic and acute diseases and those necessary to guarantee the LEAs (see question 1), are reimbursed by the SSN, although prescription charges may be applied;
- Class H, which covers the same medicines as Class A, but under Class H they are only supplied in hospitals, and not in chemist's shops; and
- Class C medicines are used for the treatment of slight illnesses, and are thus not essential. These are fully chargeable to customers.

Italian law does not envisage any differences in the outpatient and inpatient sectors regarding the above.

Pursuant to Law 648/1996, provided that no therapeutic alternative exists and that the AIFA's CTS expresses a favourable opinion thereof, the SSN also reimburses innovative medicines marketed in a different country; medicines not yet authorised under clinical trials; and drugs used off-label that may be reimbursed, in exceptional cases, even if a valid therapeutic alternative does exist, provided that AIFA deems that specific use is known and compliant with the researchers conducted on a national and international levels. In any case, data pertaining to Phase II clinical trials must be present. Drugs reimbursed as above are then inserted in a specific list drawn up by the AIFA.

25 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The competent authority is the AIFA's price and reimbursement department.

The application for reimbursement and pricing negotiations must be started jointly. Specifically, negotiations operate in three steps: submission of the dossier, discussion and final contract. Negotiations usually last 90 days, but this term length is not mandatory. The contracted price is valid for 24 months and is subject to tacit renewal unless the parties decide to renegotiate the terms.

26 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

The relevant rules do not provide for such an obligation.

However, chemist's shops are allowed to give discounts on all medicines that are directly paid for by customers, provided that the latter are so informed in advance and there is no discrimination among customers. However, promotional sales (eg, three-for-two deals) are forbidden.

C/M/S/
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Medicine quality and access to information

27 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Under articles 147 and 148 of the Code of Drugs, unlawful distribution of medicines can entail both criminal and pecuniary sanctions.

Furthermore, IMPACT Italia, a task force involving the AIFA, the ISS, the Carabinieri NAS, the Ministry of Health, representatives from other administrations and private stakeholders, is dedicated to tackling counterfeiting and the illegal distribution of medicines.

28 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

On 13 November 2013, the AIFA launched a medicines database (available at https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci). The database contains information on all licensed drugs available in Italy and is freely accessible to the general public.

29 Outline major developments to the regime relating to safety monitoring of medicines.

Italian rules concerning pharmacovigilance are contained in the Code of Drugs, and the competent authority is the AIFA.

The European legislation on pharmacovigilance was recently amended by Regulation No. 1235/2010 and Directive No. 2010/84/EU, which are currently implemented in Italy through Ministerial Decree dated 30 April 2015.

The introduced changes aim at increasing the efficiency, speed and transparency of pharmacovigilance operations through rules that will:

- strengthen the systems for pharmacovigilance;
- streamline activities between member states;
- increase the participation of patients and HCPs;
- improve the communication systems of decisions taken and the reasons thereof; and
- increase transparency.

Vaccination

30 Outline your jurisdiction's vaccination regime for humans.

By virtue of Legislative Decree No. 73/2017 the number of the compulsory vaccinations has been now increased to include the following: anti-poliomyelitis; anti-diphtheria; anti-tetanus; anti-hepatitis B; pertussis; anti-Haemophilus influenzae type B; measles; rubella; mumps; and varicella.

Further vaccinations, although not compulsory, are strongly encouraged (eg, for measles, papilloma and parotitis). All of these vaccinations are supplied by the SSN.

Vaccinations are scheduled according to the age of the person concerned (mostly in children) and are administered by HCPs.

As for adult population, some vaccinations are compulsory for specific categories of people or workers:

- meningitis, typhus, measles, mumps and rubella for the military personnel at the moment of enrolment (Decree of the Ministry of Defence dated 19 February 1997); and
- tuberculosis, only for sanitary personnel, medicine students, trainee nurses and whoever, with a negative tuberculin test, operates in healthcare environments or high-risk drug-resistant environments.

Vaccination rates in Italy for DTP3, HepB3, Hib3, MCV, Pol3 and Rubella1 all exceed 90 per cent.

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