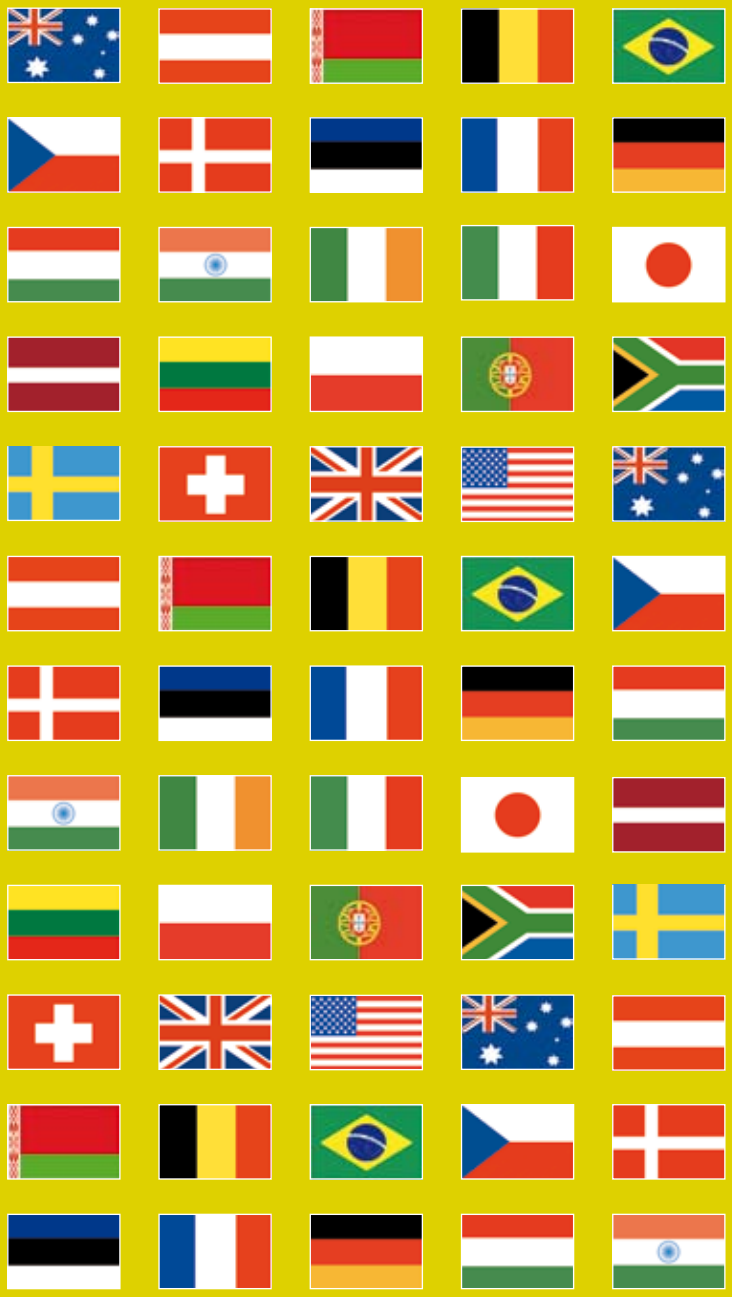
GETTING THE DEAL THROUGH

# Life Sciences

## in 24 jurisdictions worldwide

**Contributing editors: Alexander Ehlers and Cord Willhöft**

**2010**




**Published by**
***GETTING THE DEAL THROUGH***
**in association with:**

Advokaadibüroo bnt Attorneys-at-law
Anderson Mōri & Tomotsune
Arnold & Porter (UK) LLP
Beslay + Le Calvé
Biolato Longo Ridola & Mori
bnt Attorneys APB
bnt Klauberg Krauklis, Attorneys at Law
bnt legal & tax Minsk
Bowman Gilfillan
Brudkowski and Partners
Bruun & Hjejle
Dewallens & partners
DLA Piper LLP
Ehlers, Ehlers & Partner
Griffith Hack Lawyers
Lopes Dias & Associados
Matheson Ormsby Prentice
Mattos Muriel Kestener Advogados
Preslmayr Rechtsanwälte OG
Rajinder Narain & Co
Schönherr
Setterwalls Advokatbyrå AB
Szecskay Attorneys at Law
Wenger & Vieli AG

GETTING THE DEAL THROUGH

**Life Sciences 2010**

**Contributing editors**
Alexander Ehlers and Cord Willhöft
Ehlers, Ehlers & Partner

**Business development manager**
Joseph Samuel

**Marketing managers**
Alan Lee
Dan Brennan
George Ingledew
Edward Perugia
Robyn Hetherington
Dan White
Tamzin Mahmoud
Ellie Notley

**Subscriptions manager**
Nadine Radcliffe
Subscriptions@
GettingTheDealThrough.com

**Assistant editor**
Adam Myers

**Editorial assistant**
Nick Drummond-Roe

**Senior production editor**
Jonathan Cowie

**Chief subeditor**
Jonathan Allen

**Production editor**
Joanne Morley

**Senior subeditor**
Kathryn Smuland

**Subeditors**
Laura Zúñiga
Ariana Frampton
Charlotte Stretch

**Editor-in-chief**
Callum Campbell

**Publisher**
Richard Davey

**Life Sciences 2010**
Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

ISSN 2042-4329



Printed and distributed by
Encompass Print Solutions.
Tel: 0870 897 3239

Law
Business
Research

## CONTENTS

# Italy

**Linda Longo and Andrea Moretti**
Biolato Longo Ridola & Mori

## Organisation and financing of health care

**1** How is health care in your jurisdiction organised?

The Italian health-care system (Servizio Sanitario Nazionale or SSN) was established in 1978; today, after a process of decentralisation (from state to region) it is mostly under the control of regional governments and is administered by approximately 200 local health authorities (*azienda sanitaria locale* or ASLs) and about 100 independent public hospitals (*aziende ospedaliere* or AOs). The central government sets the major targets for the SSNs through a national health plan and fixes the essential levels of care that has to be provided to the national population by the regions, which have responsibilty for the organisation and management of the supply of health-care services as well as financial liability. The SSN is facing significant financial problems and the health-care system is a matter of continuous debate in Italy, and it will probably undergo substantial reform in the next five years.

**2** How is the health-care system financed in the outpatient and inpatient sectors?

In 1998 the SSN was separated from the social security system in Italy (the INPS) and funded directly via the IRAP tax (regional tax on productive activity), which is paid by employers on behalf of employees and by the self-employed who pay for themselves through their taxes.

All inpatient treatment (treatment requiring hospitalisation) is free under the Italian health-care system if supplied by ASL hospitals and health centres.

Outpatient treatment supplied by the SSN includes family doctor services, class A medicinal products (which are supplied free of charge (see question 21) upon prescription by a physician belonging to the SSN or with a limited contribution (ticket)), visits to medical specialists, and diagnostic tests.

## Compliance – pharmaceutical manufacturers

**3** Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

Advertisement of medicinal products is governed by sections 113 to 128 of Legislative Decree No. 219 of 24 April 2006 (the Decree), which has implemented in Italy Directive 2001/83/EC (and subsequent modifications) on the Community code regarding medicinal products for human use and Directive 2003/94/EC.

Other relevant provisions on the advertising of medicinal products are set out in Legislative Decree No. 206/2005 (unified consumers' code) as amended by Legislative Decree No. 145/2007 on unfair and comparative advertising, implementing Directive No. 2006/114/EC (unified code on misleading and comparative advertising).

The code of professional conduct issued by Farmindustria (the Italian association of pharmaceutical industries) contains several provisions dealing with the advertising and promotion of medicinal products. The rules of the code have no legal force and are binding only on the members of the association.

**4** What are the main rules and principles applying to advertising aimed at health-care professionals?

Advertising to health-care professionals is regulated in sections 119 to 123 of the Decree. Any advertising messages or documents that companies wish to provide to medical practitioners, other than the mere reproduction of the summary of products characteristics (SmPC), must be previously submitted to the Italian Medicines Agency and Regulatory Authority (the AIFA) and cannot be utilised until 10 days have elapsed since the date of submission. At any time, the Italian regulatory authorities can prohibit or suspend their diffusion.

In cases of infringement of the rules regarding advertising to health-care professionals, an administrative pecuniary sanction of an amount ranging from €2,600 to €15,600, in accordance with section 148(15) of the Decree, is imposed on offenders.

Furthermore, when the product in respect of which the unlawful advertising has been committed is on the list of reimbursable products, the AIFA may also impose suspension from reimbursement for a period of between 10 days to two years depending on the seriousness of the irregularity (section 148(19) of the Decree).

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

Advertising to the general public is regulated in sections 115 to 118 of Decree No. 219 and is allowed only in respect of over-the-counter medicinal products (OTC). Any advertisement aimed at the general public (other than a mere reproduction of the product and the full text of the indications, contraindications, special notices for its use, interactions, etc) must be approved by the Italian Ministry of Health after having heard a special experts' commission, the duties and composition of which has been recently regulated by Presidential Decree No. 86/2007. Advertising messages are considered approved if an express denial it is not issued by the Italian Ministry of Health within 45 days of the date of the application (tacit approval). The opinion of the special experts' commission is not necessary when the advertising is to be published in the press or broadcast by radio and has been approved by an authorised industry entity duly recognised by the Ministry of Health. Television advertising of medicines is always subject to the experts' commission's opinion.

In case of infringement of the rules provided in respect to advertising to the general public, an administrative pecuniary sanction of an amount ranging from €2,600 to €15,600, in accordance with section 148(15) of the Decree, is imposed on offenders.

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

The most common infringement committed by manufacturers is to advertise a product that is not a medicinal product, which claims properties equivalent or similar to those of a medicinal product. This kind of infringement is normally sanctioned by the Italian antitrust authority, which is also in charge of unfair and misleading advertising.

In respect of advertising medicinal products to health-care professionals, common infringements are the distribution of 'scientific' material that has not been previously deposited with the regulatory agency and is marked 'for internal use only', the distribution of samples in excess of the authorised number or the supply of gifts or benefits of a value in excess of that set forth in the regulations.

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

Section 114(1) of the Decree provides that advertising of medicinal products may relate only to products for which the marketing authorisation has been issued either in accordance with the national procedure or under the centralised EMEA procedure. Such prohibition, which reflects the provisions of the Community code, is extended to off-label use of an authorised medicinal product; however, it cannot be interpreted in such a restrictive manner as to conflict with the principles set forth in the Italian Constitution regarding the development of culture and of scientific and technical research, as well as the freedom to express, verbally or in writing, one's own opinion, and the liberty of the press. Therefore, at scientific meetings it is possible for independent speakers belonging to the scientific community to provide information regarding new active principles or new off-label indications, or discuss recent developments of clinical trials regarding unlicensed products, or new indications. In such a case, however, reference to the product is generally made to the active ingredient only. Furthermore, upon specific written request of health-care professionals, it is possible for pharmaceutical companies to provide information or copies of reports of scientific studies of a product not yet authorised in Italy but authorised abroad.

Information regarding clinical trials carried out in respect of an unlicensed medicinal product can be published in the scientific press or when the information has an interest for the general public (for instance, when it concerns a significant development in an area or disease of general interest) the information can be published also in the lay press provided that the commercial name or trademark of the product is not mentioned. Furthermore, the Decree provides that at 'international' congresses, the distribution, in the original language, of information material complying with the marketing authorisation issued in the foreign country is permitted, provided that physicians of such foreign countries are attending the meeting.

**8** Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals?

The collaboration between the pharmaceutical industry and health-care professionals is not specifically regulated in the Decree.

Section 123 of the Decree contains restrictions on the supply of gifts or benefits in kind to physicians during promotional activities except for gifts of negligible value linked to the professional activities of health-care professionals. Violations of this rule are sanctioned by imprisonment of up to one year and a fine of between €400 and €1,000. If payment is made to induce a professional to prescribe a medicinal product, criminal sanctions are more severe and may also affect the pharmaceutical company pursuant to Decree No. 231/2001 on administrative liability of companies (pecuniary sanctions and interdictive measures such as suspension of the activity or revocation of licences), where the crime being prosecuted will be corruption. The same provision is applicable to physicians, who cannot solicit or accept compensation or gifts for prescribing medicinal products.

Furthermore, the Unified Act on public servants' work relationships prohibits public servants and government officers (such as physicians belonging to the national health-care system) from carrying out any other form of compensated collaboration with private or public entities without the prior written consent of the government or public office to which they belong.

**9** What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

In addition to the above, a general rule on collaboration between health-care professionals and the pharmaceutical industry has been introduced in section 4(1) of the Farmindustria code of professional conduct. According to such rule, pharmaceutical companies may collaborate with health-care professionals for consultancy services (such as speakers at congresses, participation in observational studies, training and educational services) providing, however, that the following criteria are fully complied with:

- the agreement with the health professional is in written form;
- the health professional must undertake to disclose his or her relationship with the pharmaceutical company whenever he or she speaks or writes in public on a subject that is part of the consultancy agreement;
- any compensation paid to the health professional for such consultancy must be reasonable and appropriate, taking into account the 'market value' of the services rendered; and
- the company must retain the documentation on the consultancy agreement for a period of at least three years and the decision on such initiatives are to be taken at the higher executive management level of the company.

**10** What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

The most common infringement committed by manufacturers is the payment of compensation to health-care professionals for consultancy services without prior approval of the public structure (hospital or university) by which they are employed.

Any consulting or service arrangements providing a payment to doctors who are employed full-time by public entities, hospitals or universities must be previously notified to and receive clearance from the relevant employer. Exceptions to this obligation are for payments made for the following activities: collaborations with newspapers, magazines, encyclopaedias and similar publications; royalty or lump-sum payments for use of intellectual property; participation (as speaker or chairman) in congresses and seminars; or compensation for the mere refund of documented expenses.

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

Italian law does not contain any provisions regulating the issue of the support by the industry of patient organisations.

The Farmindustria code of professional conduct specifically addresses the issue of relations between pharmaceutical companies and patient associations and establishes that any form of economic support, whether direct or indirect, by the pharmaceutical company towards a patient organisation must satisfy the following criteria: a specific and preliminary agreement aimed at regulating the amount of financing and the reasons for its disbursement must be reached. For this reason, each pharmaceutical company must develop a standard internal procedure for the approval of this category of agreement.

Public utilisation by a pharmaceutical company of the logo or material owned by a patient organisation must be authorised in advance

by that organisation. Any form of sponsorship by pharmaceutical companies with regard to the patient organisations must be transparent and without promotional objectives. No company can request to be the sole financier of a patient organisation.

In all cases in which travel or other forms of hospitality are provided, the restrictions set out in the code on conferences and congresses apply. Pharmaceutical companies must include on their own websites a list of the patient organisations that they support.

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

Infringements of competition law by manufacturers of medicinal products such as anti-competitive agreements or conduct are pursued by the Italian Antitrust Authority (Autorità Garante per la Concorrenza ed il Mercato), which has the power to implement antitrust law, including in the pharmaceuticals sector. In addition, if the anti-competitive conduct also constitutes an infringement of the law regarding the authorisations of medicinal products or advertising or pricing, the competitor affected by such conduct can also address the complaint to the AIFA whose decision can be appealed by the competitor before the regional administrative court to obtain the annulment of such decisions.

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

When the conduct of the competitor is such as to constitute unfair competition it is possible for the affected competitor to file a claim before the ordinary courts to obtain discontinuance of the conduct and to claim for damages.

## Compliance – medical device manufacturers

**14** Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Advertising of medical devices in Italy is regulated by Legislative Decree No. 46/1997. The rules are less rigorous because they regulate only advertising to the general public. Article 21 of Legislative Decree No. 46/1997 provides that no advertising to the general public can be made for custom-made medical devices, medical devices that can be sold only upon medical prescription or those that can be used only with the assistance of a doctor or another health professional, while other devices can be advertised to the general public only with the prior authorisation of the Ministry of Health. Infringement of the provisions of article 21 is no longer punished with criminal sanctions, but with an administrative fine of between €2,600 and €16,000.

There are no codes of practice on advertising issued by the Italian Medical Device Business Associations.

In the absence of specific regulations, the general rules regarding fair advertising apply. In particular, all information supplied to doctors or health professionals must be in compliance with the approved label and the information leaflet.

No regulations specifically provide restrictions on payments or hospitality offered to doctors in connection with the promotion of medical devices. However, medical devices are mostly purchased by public entities or enterprises (ASLs, hospitals) belonging to the SSN. Therefore, the general rules regarding corruption and bribery, as well as fraud and other malpractices in public procurement, will apply to the officers or purchasers of the purchasing public entity. These rules will be applicable where a public employee has received money or any other benefits in connection with performing or omitting to perform his or her official duties, or when anybody disturbs or manipulates the regular bidding process for public procurement supplies.

## Pharmaceuticals regulation

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

The Decree is the legislation concerning the granting of marketing authorisations of medicinal products as well as the other authorisations required for the manufacturing, importation and distribution of medicinal products. The rules contained in the Decree are very similar to those set forth in Directive 2001/83/EC.

**16** Which authorities may grant marketing authorisation in your jurisdiction?

The competent authority for granting the marketing authorisation for medicinal product is the AIFA, which should officially adopt a decision no later than 210 days after the filing of the relevant application provided such application is complete, with all the required documentation.

**17** What are the relevant procedures?

The relevant procedure for obtaining the marketing authorisation of a medicinal products is set forth in the Decree, the applicable rules that mirror those of the Directive. In order to obtain a marketing authorisation, applicants must submit a full dossier to the AIFA that details, among other things:

- the common or scientific name;
- the commercial name;
- the qualitative and quantitative particulars of the product;
- the proposed therapeutic indications;
- contraindications and adverse reactions; and
- the results of pharmaceutical and pre-clinical tests and clinical trials.

The national procedure can be used if the product is not already registered in any member state and if the application is restricted to one member state. The official time limit for granting a licence is 210 days from receipt of the full dossier, but in reality the average is more than one year. The marketing authorisation is then issued by the AIFA.

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

Marketing authorisations are valid for an initial period of five years, after which they may be renewed for an undefined period provided that they satisfy a reevaluation of the risk–benefit balance. The AIFA may decide after the expiry of the first five-year period to renew the authorisation for another five years for justified reasons linked to pharmacovigilance. Periodic safety update reports must be submitted every three years.

Pursuant to section 38(5) of the Decree (the 'sunset clause') a marketing authorisation will no longer be valid if a product has not actually been placed on the market in the first three years following grant of its authorisation, or is not on the market for a period of three consecutive years. Once a marketing authorisation has been granted, if the product is not actually marketed within the following 60 days, the holder is under the obligation to inform the AIFA of the delay in the placement on the market and thereafter of the date of the commencement of marketing.

**19** Which medicines may be marketed without authorisation?

No medicines can be placed in the market without the prior authorisation of the national regulatory authority or an EU centralised authorisation.

An exception to such general rule is the possibility of importing, distributing and selling medicinal products for a special need that are

regularly authorised abroad, but not authorised in Italy. Such cases are governed by the Decree of the Ministry of Health of 11 February 1997 (the Ministry of Health Decree).

Section 2(1) of the Ministry of Health Decree regulates the procedure for the importation of such products and in particular states that the physician must submit to the competent Office of Maritime, Air and Border Health of the Ministry of Health (USMAF) an application containing the following data:

- the medicinal product name and its pharmaceutical formula;
- the foreign company manufacturer or supplier;
- the name of the marketing authorisation holder;
- a declaration stating that the subject product is duly authorised in the country of origin;
- the quantity of the product needed, specifying that it corresponds with a therapeutic treatment not exceeding 90 days;
- the special need that justifies the recourse to the unauthorised drug, in absence of a valid therapeutic alternative; and
- the undertaking of the physician to utilise the medicinal products under his or her own responsibility.

Where an equivalent authorised product in the Italian market is present the competent authority should deny the authorisation or should instruct the local health offices to refuse the authorisation to import the products.

**20** What, according to the legislation and case law, constitute medicinal products?

Section 1, paragraph 1 of the Ministry of Health Decree provides the following definition of medicinal product or medicinal that is the same contained in Directive 2004/27/EC1 on medicinal products, amending Directive 2001/83, providing the revision of the definition of medicinal product, reading as follows:

*Medicinal product:*

*(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*

*(b) 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.*

Such provision is to be read in accordance with section 2(2) of the Ministry of Health Decree (similar to the relevant Directive provision) according to which: 'In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Decree (Directive) shall apply.'

The most interesting legal cases regarding the definition of medicinal products concern the 'borderline' products where it is not clearly possible, taking into account all their characteristics, including their therapeutic, preventive or diagnostic properties, to determine under which legislation a product should be regulated. The courts confirmed the principle set forth in section 2(2) of the Directive: if a doubt exists, for the sake of consumer protection, medicinal law should prevail.

## Pricing and reimbursement of medicinal products

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

Law and regulation on the market price of medicinal products in Italy has undergone various changes in the past few years due to the high impact of the health-care system on the national economy. As already explained, the Italian health-care system is characterised by the presence of the state and the main part of health-care services being free of charge for the population.

The present regulation dealing with the market price of a medicinal product is represented by Law No. 537 of 24 December 1993 (as amended by Law No. 311 of 30 December 2004), which classifies the medicines into 'classes' of products based on the different level of reimbursement. Therefore, class A includes all the essential products and those intended for chronic diseases. The products included in this class are fully reimbursed by the SSN. Class C includes all the products not listed in class A and they are not reimbursed by the SSN. Class H includes products that can be provided only to hospital inpatients and they are fully reimbursed by the SSN. OTC products are included in class Cbis and not reimbursed by the SSN.

Moreover, according to section 48 point 33 of Law No. 326 of 24 November 2003, the price of the products reimbursed by the SSN (classes A and H) are to be agreed between the pharmaceutical companies and the AIFA following the guidelines issued by CIPE (an ministerial economics committee) on 1 February 2001. The application for opening the market price procedure can be filed through the AIFA website. The criteria taken into account by the AIFA when negotiating the price include: the relation between costs, risks and benefits, the cost of an efficient alternative therapy, the general cost to the SSN, the possible market share of the new product, and the situation in other EU member states. The procedure ends with the execution of an agreement with the pharmaceutical company that includes the price and the reimbursability regime.

The price of medicinal products included in class C and OTC products are fixed by the holder of the marketing authorisation (class C products) and by the retailers or pharmacist (OTC products); moreover, the price of class C products can be increased only once a year and must be notified to the AIFA.

Law Decree No. 87 of 27 May 2005 has introduced certain provisions in order to increase the sales of generic or equivalent medicines to the general public with reference with non-reimbursable products; therefore, the pharmacist to whom a prescription of a class C product is shown must inform the patient about the existence (if such exists) of an equivalent product at a lesser price. In case of infringements of the rules governing equivalent products, the pharmacist is subject to administrative sanctions; in case of repeated infringements, the sanction may include the temporary suspension of the licence to run the pharmacy.

A 'transparency list' of equivalent medicines is to be compiled by the AIFA and every pharmacy must keep a copy of the list at the disposal of its clients.

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

As explained above, products that are included in classes A and H are fully reimbursed by the SSN. Classes H products are reimbursed only if they are used inside hospitals.

The reimbursement of a medicine by the SSN can be limited to specific diseases or patients through the placement of a 'note' by the AIFA. In order to obtain the reimbursement therefore, the prescription of a medicine subject to a note must include the therapeutic use for which the product it is prescribed. The AIFA notes are periodically revised and published in the Italian Official Gazzette and on the AIFA website. The application of a note is considered an administrative act by a public administration and therefore the holder of the marketing authorisation may challenge the decision in front of the administrative regional court.

Prescription of a product for compassionate purposes must be authorised by the Italian authorities (see question 19 above) and it is not reimbursable by the SSN unless it is authorised by the public hospital or similar public health structures. In this case, no pricing restrictions are applicable and therefore, the purchaser (hospital or physician) can negotiate the price with the supplier.

**Update and trends**

Litigation in medical practice has arisen as an important issue in Italy. A recent study carried out by ORME (the Observatory for the Medical Professional Liability) jointly with the University of Rome Tor Vergata, and the courts in Rome evidenced that in the period from 2001 to 2007 the number of litigations brought before the Italian criminal and civil courts increased significantly and, on average, 65 per cent of the claims were accepted in all or in part.

Many Italian regions are implementing risk-management plans in order to reduce the costs not only of litigation and insurance coverage, but also the cost of 'defensive medicine', which is estimated to be €2 billion to €3 billion per year; such costs derive from laboratory and diagnostic tests that are redundant or unnecessary but that may be useful to protect the position of the medical doctor, as well as protracting hospitalisations longer than necessary. The risk-management plans implemented on an experimental basis by some Italian regions (eg, Tuscany, Veneto and Sardinia) include actions for the prevention of mistakes, incident reporting and promotion of practices for the patient safety. Furthermore conciliation committees have been created in order to reach out-of-court settlements of disputes with patients in order to reduce the cost of the insurance.

Since the pressure of the malpractice litigations is increasing also because of the jurisprudence, which is largely favourable to the patients, several bills of law have been submitted to the parliament in order to regulate and restrict the criminal liability of medical doctors in more severe cases and concentrate the actions on the structure to which the professional belongs. Also, the action of providing the patient with adequate communications and obtaining the written consent form seems to be mandatory to reduce litigation. A patient's written informed consent remains an integral part of the communication between physicians and patients, and importantly offers professional protection along these lines.

The management of malpractice and reduction of the level of litigation is important also for the manufacturers of medicinal products because there is an increasing reluctance for physicians to prescribe medicines using an off-label dosage or for off-label indications and this can certainly have a negative impact on the sales of the ethical medicinal products. On the other hand, the increase of 'defensive medicine' certainly has a favourable impact on the sales of a vast number of medical devices for the diagnostic exams.

The cost of a medicinal products used off-label is reimbursed by the SSN providing, however, that the use is duly authorised by the competent authorities and the product is included in a special list by the AIFA (see question 7).

## Medicine quality and access to information

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

The national approach to counterfeiting and illegal distribution of medicines is based on a multi-action strategy that includes the implementation of a medicines traceability programme and cooperation with the authorities of other EU members.

The medicines traceability programme was introduced in Italy by Legislative Decree No. 540 of 30 December 1992 (implementing Directive 92/27EU) on labelling of medicines, which must include the reference product number and other information to trace the product. Labelling requirements are now regulated by the Ministry of Health Decree. The database containing the list of products on the market was established by Law No. 39 of 1 March 2002 and the subsequent Ministry of Health Decree of 15 July 2004. The database is kept by the Ministry of Health and the criteria for compilation are based on a stringent code system that is given to all those involved in the production and distribution chain of the medicines, which is followed during the entire life cycle.

Italy has been part of the IMPACT WHO programme against counterfeiting and illegal distribution of medicines since 2005 when a national IMPACT task force was established within the AIFA. IMPACT Italy was formed by experts such as members of the AIFA, from the ISS (the National Superior Health Institute), the counterfeiting department of the Arma dei Carabinieri and the Ministry of Health. Over the years, IMPACT has been extended to also include experts from the private sector (Farmindustria), police authorities and other participants in the sector.

One of the main tasks of IMPACT Italy is to promote international cooperation between similar agencies spread across the world and to develop systems for use against counterfeiting and the illegal distribution of medicinal products. Within its activities, IMPACT Italy promoted various courses for the training of the border police personnel directly involved in the matter, created a database including all the registered trademarks of authorised medicinal products and introduced the guidelines issued by IMPACT WHO in Italy with the intention of unifying the international investigative methods used against counterfeiting and illegal distribution.

Moreover, an important part of IMPACT Italy's activity is to promote advertising campaigns aimed at the general public in order to inform them of the risks.

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

The list of all the medicinal products authorised within Italy is published in the Italian Official Gazette as well as on the AIFA's website. The list includes the code of the product, the active substance, the owner of the marketing authorisation, the AIFA note (if applicable),

BIOLATO LONGO RIDOLA & MORI
STUDIO LEGALE ASSOCIATO

**Linda Longo** **linda.longo@blrm.it**

Via del Babuino 51
00187 Rome
Italy

Tel: +39 06 3233001
Fax: +39 6 3234238
www.blrm.it

the final price and the reimbursement price. An indication as to whether or not an equivalent product is available is also included.

The definition of equivalent product is set forth in Law Decree No. 87 of 27 May 2005, converted into Law No. 149 of 26 July 2005. It states that medical products without patent coverage but that have the same requirements that lead to inclusion on the transparency list (the same composition in active principles, pharmaceutical form, method of administration, way of release, same number of posology unit and equal unitary dosage) are 'equivalent'. The transparency list is revised by the AIFA on a monthly basis and published on its website (see question 21).

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

The pharmacoviligance department within the AIFA is the authority in charge of the safety monitoring of medicines. The AIFA is part of EudraVigilance, a data processing network and management system for reporting suspected adverse reactions.

The present national pharmacovigilance system was revised in 2001 following a scandal that involved an anti-cholesterol product recalled in August 2001 when some suspected adverse reactions (also leading to the death of a number of patients) were discovered. As a result, a national pharmacovigilance network (Rete Nazionale di Farmacovigilanza or RNF) was created with the aim of collecting, analysing, managing and disclosing all data on adverse drug reactions. The national network – based in Rome – is linked to more then 350 local units. Any observed suspected adverse reaction is reported by the local unit to the national database and from here into the EudraVigilance database.

Since 2007, the RNF has published a bulletin, which is constantly updated and is also available online.

GETTING THE DEAL THROUGH®

## Annual volumes published on:

Air Transport
Anti-Corruption Regulation
Arbitration
Banking Regulation
Cartel Regulation
Climate Regulation
Construction
Copyright
Corporate Governance
Dispute Resolution
Dominance
e-Commerce
Electricity Regulation
Environment
Franchise
Gas Regulation
Insurance & Reinsurance
Intellectual Property & Antitrust
Labour & Employment
Life Sciences
Merger Control
Mergers & Acquisitions
Mining
Oil Regulation
Patents
Pharmaceutical Antitrust
Private Antitrust Litigation
Private Equity
Product Liability
Product Recall
Project Finance
Public Procurement
Real Estate
Restructuring & Insolvency
Securities Finance
Shipping
Tax on Inbound Investment
Telecoms and Media

**For more information or to purchase books, please visit:**
www.GettingTheDealThrough.com

ABA Section of International Law
*Your Gateway to International Practice*

Strategic research partners of the ABA International Section

THE QUEEN'S AWARDS FOR ENTERPRISE 2006

INTERNATIONAL BAR ASSOCIATION

The Official Research Partner of the International Bar Association

LIFE SCIENCES 2010 ISSN 2042-4329