Italy

OVERVIEW
Pharmaceutical Market Value ($bn)
Total market: 18.9 (hospital and retail)

The total pharmaceutical market is forecast to grow at a CAGR of 2.7% (+0.5%) between 2010-2015.

The growing value of total export in 2009 (+2.3%, with CAGR of +7.5% since 1999) contributes 43% of the total ‘science-based’ exports from Italy. (Source: IMS Market Prognosis 2011-2015)

National spending on healthcare:
€140bn in 2009

Proportion of GDP: 9.2%
(Source: Istat)

INTRODUCTION
Italy emerged from economic recession in 2010 with gross domestic product (GDP) growing 1 per cent on rising exports. Economic growth will, however, be slow and modest until 2015. Domestic demand will be constrained by fiscal tightening, unemployment, low wage growth and low consumer confidence. Exports will suffer because of similar conditions abroad. Although business investment recovered a little in 2010, from a 12 per cent contraction in 2009, firms will be deterred by tight credit conditions and continuing surplus capacity. Italy has run current account deficits for at least 10 years and is likely to continue to do so in the medium term. Low productivity and high import penetration are symptoms of a loss of competitiveness which EU monetary union has done little to mollify. Services, income and transfer accounts will all remain in deficit until 2015.

HEALTHCARE OVERVIEW
Healthcare funding is no longer increasing year on year, despite the fact that Italy has one of the most elderly populations in the world. The authorities are attempting to impose tight controls on access to, and costs of, drugs that are only effective in some regions and in some therapeutic areas. There is also a chronic gap in long-term strategic vision from political decision makers. Meanwhile, a conventional model combining reps/share-of-voice and a plethora of medical education and congress invitations represents the pharmaceutical companies’ approach to the market.

This model is no longer sustainable from both an economic and ‘ethical’ point of view and, in the short term, will be difficult to change. Italy has an inflexible labour system and 49 per cent of physicians are set to reach retirement age between 2012 and 2017. This situation will change gradually from a majority of men to a progressive prevalence of women. Plus, both the healthcare authorities’ and pharmaceutical approaches leave the patient (including families and caregivers), virtually absent from healthcare decision-making processes. Stakeholders should put the interests of patients at the centre of decision-making. This could be achieved by providing more access to innovative drugs,
better management of adherence and side effects, more effective prevention to reduce the costs of acute events, improvement in patient education through empowering patients themselves and efforts to improve doctor-patient dialogue and relationships. Equally important is firmly to establish the pharmaceutical companies as the most informed about their products, and therefore able, and even obliged, to share openly this knowledge with doctors, payers and patients.

The aim should be a truly innovative alliance of stakeholders, recognising the value individuals place on health. If nothing is done, there will be less money for care, access to the ‘best care’ will be only for the privileged few, pharmaceutical companies will have less money to spend on R&D, and will be less willing to invest their money in the region.

The Author
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HEALTHCARE SYSTEM
The Italian national health service (Servizio Sanitario Nazionale, or SSN) is founded on the principle of universal healthcare access for all citizens. Currently, central government is responsible for healthcare policy, defining ‘essential levels of care’ (Livelli Essenziali di Assistenza, or LEAs) and safeguarding the availability of adequate funding for healthcare, while the 19 regions and two autonomous provinces are in charge of planning and organising healthcare provision in accordance with minimum standards and budgetary limits. The 145 local health authorities (Aziende Sanitarie Locali, or ASLs) across the country organise primary care provision by contracting services from a network of general practitioners (GPs), public hospitals and clinics, and from accredited private providers. As a result of local autonomy in setting co-payment rules, treatment access and prescription guidelines, there is a degree of variability in healthcare provision across the territory. Private sector involvement in healthcare provision is widespread, but the market for private health insurance remains relatively limited, due to the comprehensive coverage provided by the SSN. The majority of beneficiaries are covered by policies that supplement, rather than replace, SSN coverage.

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REGULATORY ENVIRONMENT
Marketing authorisation (MA) of medicinal products is controlled by the Italian Medicines Agency (Agenzia Italiana del Farmaco, or AIFA) to which a marketing application is filed by the applicant according to European law. It involves a national procedure and a European one comprising a Decentralised Procedure (DCP) and a Mutual Recognition Procedure (MRP).

The national procedure allows the MA holder to market the product only in Italy, though the assessment and registration process complies with EU procedures, since the national legislation integrates EU Directives. The MA application for a national procedure must be filed at AIFA by the applicant in Common Technical Document (CTD) format. Filing in the English language is acceptable, except for the Summary of Product Characteristics (SmPC), leaflet and labelling. The applicant is allocated a SIS Code after specific documents have been filed, which is necessary to interact with the health authorities and must be used in all correspondence throughout the process.

The Community MA procedures for new medicinal products are divided into:
• MRP, allowing the extension of a MA granted by a Member State to one or more other countries of the European Union (EU)
• DCP, allowing the MA to be granted at local level with a simultaneous application in two or more countries of the EU. The procedure can be used for a medicinal product not yet authorised in Europe
• Centralised Procedure allowing a single authorisation valid through all EU countries and managed directly by the European Medicines Agency (EMA).

For both, the AIFA can be involved as Reference Member State or Concerned Member State. AIFA’s MA assessment is performed to ensure adequate standards of quality, safety and efficacy of medicinal products through chemical, pharmaceutical, biological, pharma-toxicological and clinical evaluation. The Technical Scientific Commission (CTS) works with experts from the National Institute of Health (ISS) and other respected health experts to monitor and validate the assessment process. For European procedures, assessments are carried out with the other countries involved.

“In 2007 applicants were given access to a computerised system of transparency, the ‘Front End System’, enabling them to monitor the status of the authorisation process online”

AIFA issues the MA following positive assessment, once the price and reimbursement classification of the product is set. The price request and the filing of the SmPC, leaflet and labelling are the final steps of the process. The relevant office of the national Agency provides the review of the SmPC, leaflet and the labelling that are part of the official authorisation document (Decree of Registration). In 2007 applicants were given access to a computerised system of transparency, the ‘Front End System’, enabling them to monitor the status of the authorisation process online (national MA, MRP, DCP) and to submit and monitor Pricing and Reimbursement requests. The database is mostly in Italian and is managed via a password given to the applicant.

After registration, post-marketing surveillance starts, under the strict control of the National Agency. The aim of pharmacovigilance is to ensure a positive risk/benefit ratio for all authorised drugs through the continuous monitoring of all safety information and adverse reactions (ADRs). A National Network of Pharmacovigilance (RNF) collects spontaneous ADRs. It includes the Regional Authorities and the Autonomous Provinces of Trento and Bolzano, the Regional Centres of Pharmacovigilance, more than 200 Local Health Authorities, about 100 hospitals, several research institutes, more than 800 pharmaceutical companies and AIFA. The national network also operates in connection with the European network, EudrAVigilance.

The national authorities also promote programmes to improve the knowledge of the medicinal safety information and use. Specific monitoring programmes also operate for newly marketed drugs, medicines for which important MA changes have been approved, vaccines and orphan drugs.

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GOVERNMENT AND HEALTHCARE POLICY

Reforms like the amendment of Title V of the Italian Constitution have resolved a number of prior inconsistencies in providing universal access to care. However, although doctors should be able to prescribe the most appropriate treatments, regional guidance can sometimes prevent this. In fact, a doctor wanting to prescribe a drug that is not in the region’s handbook has either to start the lengthy implementation procedure, if the drug has not yet been rated by the region, or not prescribe it if the region has already turned it down. Even today, the average time taken to include drugs in the National Pharmaceutical Formulary, which requires marketing authorisation (MA) under the centralised procedure, is long (exceeding 220 days) and it can take over a year for drugs to be added to the Regional Guides after release by the European Medicines Agency.

Policy varies between the regions and new drugs may not be allowed, depending on budget, or received later. They take different decisions about the types of drugs used and take different lengths of time to introduce them, meaning that new drugs can be available in one region but not in another, resulting in inconsistencies in access to care. The new Statement of Conference of State provides for the automatic implementation of innovative drugs in all hospitals, thereby overcoming the problem of uniformity of access to innovative therapeutics.

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PHARMACEUTICAL INDUSTRY OVERVIEW

The pharmaceutical market is a major industry in Italy, consisting of more than 300 enterprises providing 68,000 jobs directly and even more indirectly. Total market value (retail and hospital) amounts to €18.9bn (2010), growing at 3 per cent, with a retail Rx market flat (€10.1bn) and hospital component contributing to growth (up 5 per cent).

Italy is ranked among the top countries in Europe, through its manufacturing capacity:
- Third by number of employees (after Germany and France)
- Third by value of production (after Germany and France)
- Fourth by investment (after Germany, France and UK)
- Second by number of enterprises (after Germany) and first in SME.

The growing value of total exports in 2009 (+2.3 per cent, with CAGR of +7.5 per cent since 1999) accounts for 43 per cent of the total ‘science-based’ exports from Italy. Despite these positive statistics, competitive strength and growth potential are under pressure from several quarters, both local and global. In particular, employment has been falling as a result of salesforce reorganisation (-2.9 per cent); R&D investments have been decreasing compared to the past (+1.3 per cent in 2009 versus +2.0 per cent in 2008 and +6 per cent for the period 2002-2007) amounting to a total value of €2.3m in 2009. Pricing has been stretched by the severe budget constraints faced by the public healthcare system. With pressure on the public healthcare budget continuing to mount, cost containment will dominate healthcare policy at both national and regional level for the next few years. In addition, measures to sustain and reward innovation, preclinical and clinical development work are facing delays and multiple constraints.

According to Farmindustria (Indicatori Farmaceutici), in 2009 total pharmaceutical exports (medicines, basic ingredients, other products) increased by 2.3 per cent to €12.2bn (€9.3bn for medicines, -0.5 per cent).

REGIONAL VARIATION IN HEALTH SYSTEM ORGANISATION

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<th>Presence of Provincial Formulary (Regional/Aree Vaste)</th>
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Source: Il sistema dei prontuari in Italia 2 - Mauro De Rosa, Andrea Messori, Giovanna Scroccaro
Total imports, €16.1bn, grew by 10 per cent (+12.3 per cent for medicines, valued at €10bn).

The main countries dealt with are in Europe (76.3 per cent of exports and 85.2 per cent of imports). The main trading partner outside Europe is America (9.9 per cent of exports and 10.4 per cent of imports), while Asia accounts for 10.8 per cent of exports and 4.1 per cent of imports.

**GENERICS**

According to the Italian association of generic producers (Assogenerici) in 2010 this segment amounted to 58 per cent (volumes, sell-in) of the whole Italian pharma market, of which 46 per cent were branded products off-patent and 12 per cent generic medicines. The market is highly concentrated, with 87 per cent represented by only six corporations and 13 companies having the remaining 13 per cent.

With many patent expiries in therapeutic areas, the main one of which is oncology, it is likely that there will be a large number of launches of new generic products that, because of their lower cost, will bring considerable savings to public expenditure that could sustain investment in new drug R&D. Compared with the European average of generic market share (50 per cent) and because of the higher costs of these medicines than in other EU countries (five- to 10-fold more), AIFA has recently decided on a 40 per cent reduction in the price of generic medicines that could result in €800m in savings for the government. Assogenerici’s president, Giorgio Foresti, said: “By cutting the prices of generic drugs by up to 40 per cent, as decided by AIFA, the market share now covered by generics will fall further, down from 10 to seven per cent, because many companies, after this manoeuvre, will withdraw from the Italian market, with very heavy consequences. This decision benefits pharmaceutical companies that produce ‘branded’ products, and will penalise generics, so that they will have no resources for communication purposes, or to grow and develop new projects. This will destroy not only the generic industry, but also the entire pharma industry. And with fewer companies in the generic market, there will be fewer products, and therefore less supply and competition.”

**OTC MARKET**

The President of ANIFA (Italian association of companies producing OTC products), Sergio Daniotti, said: “The 2010 OTC market was stable, characterised by decreasing sales (3.8 per cent) and stable turnovers (+0.4 per cent). Data underline how the liberalisation process, due to Law 248/06 – the so-called Bersani Law, that’s to say the possibility to sell all industrially manufactured non-prescription medicines in non-pharmacy outlets (mass distribution outlets and parapharmacies) but with a pharmacist present – did not generate the predicted market growth. Indeed, it offered gains for consumers due to widespread distribution and greater price competition. Since January 2008, the public price of all non-prescription medicines has been determined by the person making the final sale. Nevertheless, pharmacies remain the favoured dealers (92 per cent sales market share) thanks to their strong and established presence nationwide and the stable market, as shown by a CAGR 2006/2010 of zero. OTCs are brought only when necessary and the market is strongly affected by the seasonality of minor illnesses. Regarding consumers’ attitudes towards self-medication, people are increasingly interested in their health and wellness. Correct information and education on self-medication are important to ensure informed and responsible medicine choices. This was the aim of the media campaign carried out by ANIFA in collaboration with the Ministry of Health, following which one in three Italians now correctly identifies OTC medicines and their value thanks to the promotion of the red ‘bollino’. This special label, designed and realised by SH Group Italy, now has to be printed on the outer packaging of all non-prescription medicines under Law 405/2001 to identify OTCs.”

**COUNTERFEITING**

The counterfeiting of medicines has spread through sales channels everywhere, particularly through online channels. In fact, the size of the problem can only be guessed at: according to research from a leading national research institute (Censis) the phenomenon relates to 0.1 per cent of products. The drugs involved are primarily expensive ones and so-called ‘lifestyle’ drugs, for impotence or sports. Analysis of seized products has shown that counterfeits often lack active ingredients, have different dosages from those stated, use toxic substances or have degraded active ingredients or excipients.

“One of the main initiatives undertaken to counter this problem is ‘Impact Italy’, a taskforce representing AIFA, Ministry of Health, National Institute of Health, Police-Nas, Customs Agency, Ministry of Economic Development and the Ministry of Interior. The alliance is further strengthened by collaboration with private players such as Farmindustria, Assogenerici, Federfarma and the Italian association of parallel importers.”

**SUPPLY CHAIN AND DISTRIBUTION**

The distribution of drugs and medical devices is influenced by the mountainous terrain of Italy and the legal need for product traceability, from production site to disposal. About four billion packages of medicinal products are handled per year in Italy. The sector is characterised by numerous delivery points due to the fragmentation of distribution and widespread numbers of chemists and ASL (territorial end-point of public health system) that have started centralising logistics recently. Transport is almost all by road and there is a high demand for orders, requiring deliveries as often as twice a week for many wholesale stores, along with frequent distribution services to pharmacists.

A central computerised system with a database for tracking drugs was created in 2008 by the Ministry of Health and AIFA, designed to follow the movements of all medicinal products marketed in Italy. It covers the full distribution chain and has about halved the number of packages of drugs being stolen or lost compared to 2006 levels.
There are now logistics service providers that offer pharma companies integrated services in addition to storage, warehousing and distribution, including demand management, commercial operations (customer service, billing, debt collection), support marketing (direct marketing, as well as contract sales organisation), secondary packaging and traceability. 

Looking ahead, the industry will closely follow the market transformation, which will be part retail, characterised by mature products, OTC products and those related to wellness and part other niche products with high added-value, for secondary care. According to Pierluigi Petrone, owner and CEO at Petrone Group and vice president of Assorom (Italian Association of pharma product distributors) and Gianpiero De Mestria, CEO at Pharmidea and member of the National Council at Assorom: “The downturn in the market and its profitability because of the entry of generic drugs and the subsequent reduction in market value highlights the instability of pharmaceutical distribution. The drugs, because of the optimisation of spending by the public health system, are registered in to be reimbursed and distributed to the patient directly from the hospital pharmacy or from DPC (distribution into account), to the detriment of the supply chain and its mid-term margins.”

“Direct-to-pharmacy allows supply of the drug from the manufacturer to the pharmacy without going through the intermediate distributor, providing a subsequent recovery in margins”

Despite its widespread logistical coverage, Italy is witnessing a merger of partners within the supply chain. Further, ongoing discussions on the principles of reimbursement could mean reimbursement is provided partly as a fixed amount and partly (minimum value) as a percentage.

Producers are setting up direct-to-pharmacy and direct-to-patient initiatives. Direct-to-pharmacy allows supply of the drug from the manufacturer to the pharmacy without going through the intermediate distributor, providing a subsequent recovery in margins for the manufacturer and possibly for the pharmacist. This often occurs for off-patent products, often via sales and promotion directly to the pharmacist. The direct-to-patient service provides access straight to the patient with home delivery services.

MARKET ACCESS

In Italy, as in many developed countries, the demand for health services and the expenditure from the State continue to grow, sustained by the ageing population and rising life expectancy. This is set against ever more scarce economic resources. It is becoming increasingly important for decision makers to be shown how a new drug is better than others when it has a higher cost. At the same time, key decisions about including new drugs in the therapeutic formulary are becoming less a national matter and more part of the regional or even local remit. Regions, intermediate levels of government (Aree Vaste), local health authorities, departments and districts have greater involvement in the management of healthcare, with responsibility for healthcare costs and greater autonomy over government decisions on pharmaceuticals. Therefore, knowledge of the health system and the relations between it and corporations is increasingly important for all suppliers to the NHS. Every company seems to have its own model to deal with this changing environment and often there is confusion over what the term market access actually means. In some companies the market access person reports to the Directorate of Public Affairs or Marketing Communications, while in other cases, Communications are led by Market Access. Often, the field force comes from medical representatives, used to communicating with physicians on medical science topics, who find themselves having to deal with stakeholders and opinion leaders who often have no scientific background and may be more interested in pharmaeconomic or socioeconomic issues related to new products. It is essential that the field force is able to communicate the value of the product to the decision makers, efficiently and effectively. The success or the failure of the market access of a product or new indication depends on some critical factors:

- Knowledge of the players on the decision path, their objectives, decision logic and the relations existing between them
- Knowledge of the legislation on the State-Region relations
- Ability to interpret, guide and anticipate the actions of public bodies
- The proper use of tools for managing relations with the public sector
- Ability to integrate different business functions, including Medical, Marketing & Sales, Regulatory, Health Economics, to achieve common goals.

To implement a winning time-to-market strategy it is therefore necessary to:

- Set market access strategies before the launch of new products
- Move from a global view to a strategy focused and designed around regional health systems
- Identify new forms of dialogue and instruments to support the value of the product to the public policy makers in terms of effectiveness of the drug/medical device and cost savings for the NHS.

It is therefore important to know the right information to provide to each type of decision maker, in the most usable form for them and with the most appropriate timing in the life of a product.

In other words, both a market access strategy (Figure 1) and a series of communication activities (Figure 2) are needed alongside the product before, during and after launch.

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Above two sections by Carlo M Buonamico, project director, Sudler Market Access, S&H Group Italy.

PRICING & REIMBURSEMENT

The pricing and reimbursement (P&R) of medicines by the NHS is regulated at the central level by AIFA. For non-reimbursed medicines the prices are established, with some limitation by pharmaceutical companies, and monitored by Regulatory Authorities. In order to contain pharmaceutical expenditure levels, the authorities have introduced some measures like the reference price system (RPS) for off-patent medicines and a pay-back mechanism as an alternative to price cuts. If the applicant seeks reimbursement, a specific dossier must be filed through the Front End System. The dossier must be in Italian and meet the general criteria listed below. The proposed price for the product is subject to negotiation with the Pricing and Reimbursement Committee.
assigned to Class A, H or C. The general conditions of the reimbursement system, once established on a national level are then implemented on a regional level by governmental bodies. Class A includes essential products and those intended for chronic diseases and is fully reimbursed by the NHS. Class H is a sub-class of A and includes products that are only fully reimbursed in the hospital. Class C includes other products which do not fit Class A and are not reimbursed. The price and the reimbursement class must be published in the official journal, Gazzetta Ufficiale.

(Comitato Prezzi e Rimborsa, or CPR) and the CTS (Comissione Tecnico-Scientifica).

The general criteria used during the negotiations are:
- Cost-effectiveness for pharmaceuticals where no effective therapy exists
- Risk-benefit ratio compared to alternative pharmaceuticals for that indication
- Therapy costs per day in comparison to products of the same efficacy
- Evaluation of the economic impact on the national health system;
- Estimated market share of the new pharmaceutical
- Prices and consumption data in European countries.

According to the reimbursement classification a medicine can be

Make target decision makers/influencers/users (eg hospital pharmacists, stakeholders, institutions) aware of new treatment options that meet unmet needs, to promote its inclusion in the therapy handbook and maintain an optimal position with respect to its competitors even post-launch

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DISEASE BURDEN
The Italian population is living longer, which means mortality due to infectious disease has been overtaken by chronic-degenerative diseases. The main causes of mortality are cardiovascular diseases, cancer and respiratory tract diseases. Cardiovascular diseases are among the most significant and represent a leading cause of morbidity, disability and mortality, having a huge socio-economic impact. In 2010, diabetes prevalence stood at 5.2 per cent in women and 4.5 per cent in men, rising with age. Although mortality due to diabetes has shown fluctuations in recent years, it remains a leading cause of death.

In recent decades, cancer epidemiology has changed due to the introduction of effective therapies and improved early diagnosis. In women, the most frequently observed are breast, colorectal, endometrial and thyroid cancer. In men, prostate, bladder and colorectal cancer are most common. There have been increases in melanomas in women and men and an increase in lung cancer in women.

Diseases affecting the respiratory tract, such as asthma, COPD, allergic rhinitis, sleep apnoea syndrome and pulmonary hypertension, are widespread in the population, having a significant socio-economic impact. After arthritis, hypertension and osteoporosis, COPD is most prevalent in the elderly. Rheumatic and osteoarticular diseases like arthritis and osteoporosis are common chronic conditions and expected to increase as the population ages. Dementia, particularly Alzheimer’s disease, is increasing in incidence, especially among women. The most frequently observed infectious diseases are non-typhoidal salmonellosis, tuberculosis and infectious diarrhoea. Diseases on the increase are those lacking effective vaccination strategy. Though preventive and therapeutic measures have reduced mortality, poor lifestyle choices, such as unbalanced diets, lack of physical activity, increased alcohol and drugs consumption, are still challenges.

PATIENT PERSPECTIVE
Italians are generally satisfied with the public health service, within which pharmacies and general practitioners are the primary points of care, according to a survey carried out by Censis in 2010. A total of 64.4 per cent of Italians felt that their local health services were efficient and well organised, compared to 35.6 per cent who did not. The most positive views were held in the north-west and north-east (73.9 per cent and 83 per cent, respectively), but these decreased sharply in the south (54.3 per cent) and central regions (51.5 per cent).

Despite the general satisfaction, the supply system is uneven, to the detriment of the southern regions, particularly regarding hospitals and primary care (negative views exceeding 26 per cent against a national average of 19 per cent), homecare (34 per cent compared to 28 per cent nationally) and rehabilitation facilities (34 per cent as opposed to 27 per cent).

SOCIAL PERCEPTION/BELIEFS
The healthcare system is seen as able to respond to the expectations and care needs of citizens. The cover provided by pharmacies and general practitioners is adequate in most cases, as well as perceived quality, which has taken a positive transformation of pharmacies in health and social safeguards, which provide more and more front-line services such as withdrawals and pressure measurement, the participation of the pharmacy, home care service integrated dispensing and delivery of pharmaceuticals and medical devices needed at home, and the ability to book directly into hospital outpatient visits and pharmacy.

ROLE OF PHARMACISTS
Pharmacy services are perceived as good quality by 62 per cent of Italians, adequate by 35 per cent and mediocre or poor by 2 per cent. The general practitioner (GP) remains a key and trusted point of contact (92 per cent judged them adequate or good, with only 8 per cent judging them inadequate). Also viewed positively were public laboratories (84 per cent), clinics and public clinics (84 per cent), hospitals and primary care (81 per cent), rehabilitation of public facilities (73 per cent) and home care (72 per cent).

However, in a minority of cases, people cited problems with their GP. A total of 13.6 per cent of the sample said that they had had to resort to a private doctor because of the inadequacy of the service provided by the GP, plus 10.5 per cent of Italians stated that the GP had not diagnosed a disease that emerged later from more detailed checks.

The Authors
Above four sections by Maurizio Mioli, CEO S&H Group Italy, and Francesca Castano, Scientific Supervisor S&H Group.

RULES ON PROMOTION
Advertising of medicinal products is governed by Legislative Decree n. 219/2006 and subsequent updating and Italy, as part of the EU, has implemented Directive 2001/83/EC (as amended).

In 1981, Italy was one of the first countries to include several limits on promotion of medicinal products. Promotion is subject to authorisation by the Health Authorities for ethnic and OTC products. Even if the silent consent procedure has been used, it must be remembered that the consent does not mean approval but only consent to distribute the material. The MA holder must have a Scientific Service responsible for assuring that promotion is performed according to the current rules regarding medicines on the market. The Scientific Service position must be independent from the Marketing department and cannot be held by the same person who is responsible for Pharmacovigilance. For foreign companies, compliance with the scientific service requirement must be ensured by the company that represents the MA holder in Italy or that imports and distributes the medicinal product.

The rules for promotion should be applied both at national and regional level. Sometimes the regional rules are more restrictive than the national ones.

In addition, self-regulation is coordinated by Farmindustria, the Association of the Pharmaceutical Industry, which has a code of practice on the advertising of prescription-only medicines. This code is not legally binding and applies to members of the association only.

The main obligations for the MA holder are:
• Submission of promotional materials to AIFA
• Limitations to use of promotional materials – mandated contents
• Authorisation of congress activities
• Accreditation of sales reps (AIFA/Regions)
• Notification of visit numbers to AIFA/Regions
• Obligations on the quantity and management of free samples
• Limitation for websites.

In conclusion, promotional materials can be used and promotions can be carried out provided that they comply with all the relevant rules at national and regional level.

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FUTURE DIRECTIONS

In Italian pharmaceutical organisations, two major themes can be identified. First: an increased, almost obsessive, focus on excellence in execution, ie. to be fast, able to adapt to, but not dramatically change, to meet local needs through outsourcing, with a close eye on savings, or preferably on maximising value for money. Second: a strong focus on innovation (dramatic if possible) in the approach to the marketplace, its protagonists and the marketing mix. They are even likely to accept some risks in adopting solutions that may still be in the ‘pilot’ phase.

For the ‘execution’ goal the current need is to improve on processes. There is a lot still to be done by both companies and agencies to maximise quality and minimise loss of revenue. It is vital to balance the value of having professionals with a deep knowledge of the Italian market, but without too much ‘entrepreneurship’ that could jeopardise the effective execution of global/regional strategies that consequently guarantee the attainment of financial objectives.

In the area of innovation the major, but not exclusive, focus is concerned with a partial replacement of human reps with something more efficient, ie. equal effectiveness with reduced costs per contact. In reality, this ambitious goal is unlikely to be achieved for many years.

The rep-based, one-to-one marketing model that has characterised the pharmaceutical business has been one of the key drivers of success for this industrial sector, not only in terms of growth but also in terms of financial margins. Given this, the digital expansion in Italy and among physicians themselves (which is expected to improve dramatically with the average age of doctors expected to decrease over the next five years) is creating an opportunity to develop a new communications model (both promotional and educational) by leveraging new technologies such as smartphones, the web and social networking. This means moving towards a ‘permission marketing’ environment, where knowledge of the client’s need is a necessity in order to achieve success.

However, it is not simply about the relationship with doctors. There is also potential in using digital channels to create a new, and necessary, relationship with patients and caregivers.

A final, and even more challenging, territory for innovation is the evolution of the current role and professionalism of reps. This means tailoring them to the emerging needs of the continuously changing healthcare system, moving from being a purely advertising or, in the best case, a CRM-terminal, to becoming a real territorial manager of the healthcare environment, able to understand the challenges, the opportunities and the risks for the company and its products, able to deal with physicians, but also with payers, pharmacists and even patients and, consequently, effectively to handle everything from access to promotion and medical education to patient empowerment.

They must align themselves with the decentralised model prevailing in the Italian healthcare system and in most of the major European countries.

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