The Pharma
Legal Handbook

Market Access & Health Technology Assessment

Italy

PHARMA BOARDROOM

Italy

The Market Access & Health Technology Assessments answers essential questions about this environment for pharmaceuticals in Italy.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Wenger Plattner, a leading corporate law firm in Italy.

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He earned a PhD in Italian and EU constitutional law from the University of Teramo in 2010 and is admitted to the bar before the Italian Supreme Court and the Council of State.

Roberto advises primarily on pharmaceutical and healthcare matters. These include product licensing and marketing, clinical trials, pricing and reimbursement, promotions, interactions with healthcare professionals, distribution of products, and public procurement issues.

Additionally, he assists in anti-bribery matters and related investigations, and helps set up internal compliance models preventing corruption-related crimes, money laundering and corporate crimes.

As well as training and tutoring in the master's degree program on clinical trials of pharmaceutical products at La Sapienza University of Rome, Roberto regularly publishes articles and scientific contributions. He also frequently hosts and participates in seminars and presentations on pharmaceutical and administrative law matters.

MARIO CIGNO

Mario is a counsel in the Public Law and Healthcare practice of Baker McKenzie and is based in the Milan office. He regularly advises on administrative and healthcare law, with specific regard to public law and regulatory issues. He works on public contracts and permits, as well as proceedings before Italian regulatory authorities, especially in relation to product recalls, public tender procedures, distribution, promotion activities and the conduct of clinical investigations.

He has been nominated by Legal500 EMEA for 3 consecutive years (since 2020 to 2022) (i) as Raising Star in the Healthcare and LifeScience industry, and (ii) as Testimonial for his work in Public and Administrative law, while in 2022, he has also been short-listed as (iii) Best Lawyer of the Year for his work in the sustainability field (and extensively contributed to the award to BM Italy as Best Law Firm of the Year for sustainability).

He is a regular speaker in our events for clients (e.g. annual conferences for pharma and medtech industries, as well as on public procurement issues) as well as in symposia and training organized by clients and/or private organizations.

RICCARDO OVIDI

Riccardo Ovidi has been a lawyer at Baker McKenzie since September 2014. He is a Senior Associate and focuses his practice on pharmaceutical and healthcare law issues, advising on regulatory and compliance matters concerning the manufacturing, marketing, distribution and import of medicinal products and medical devices. Riccardo was awarded his law degree from LUISS Guido Carli of Rome in 2005, subsequently earning a Master of Laws in international business and trade law from Fordham University School of New York in 2011. He is admitted to the Italian Bar and the New York State Bar.

Riccardo regularly advises pharmaceutical and medical device companies on complex matters related to the advertising and promotion of medicines and medical devices, interactions with HCPs and HCOs and the payback system. His expertise includes the drafting and negotiation of warehousing, distribution and logistics agreements, professional services agreements, clinical trial and sponsorship agreements.

Riccardo has also an extensive experience in corporate compliance matters assisting companies operating in the healthcare sector with the setting up and updating of compliance models aimed at preventing corruption-related crimes and corporate crimes, and with the construction of internal policies and procedures and codes of conduct.

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2. Please provide any infographics including
   a. The actors involved in the market access process (market authorization, pricing decisions, reimbursement decisions)
   b. The information and data required
   c. The process and flow

1. Please make a general introduction to the public health sector in your country and its organization

The Italian National Healthcare System ("NHS") provides citizens with a uniform level of healthcare services throughout the country. It encompasses hospital care, assistance by affiliated doctors, and reimbursement of those medicinal products that are considered essential for health protection.

The NHS is based on the following fundamental principles:

- Public responsibility on health protection;
- Universality and equal access to health services;
- Public funding through general taxation;
- Portability of rights throughout the country and reciprocity of assistance among Italian Regions.

The NHS is administered by public bodies at different institutional levels, each of which contributes to the achievement of the objectives of protecting the health of citizens, including:

- The Ministry of Health ("MoH"), which is the national central body;
- The Italian Medicine Agency ("AIFA")
- The National Institute of Health; and
- Local Health Authorities (Aziende Sanitarie Locali - ASL) and Public Hospitals (Aziende Ospedaliere).

Proceeds from national and regional taxes fund the NHS.

2. Please provide any infographics including

a. The actors involved in the market access process (market authorization, pricing decisions, reimbursement decisions)

b. The information and data required

c. The process and flow

The main actor involved in the market access process for medicinal products is the AIFA, a public entity under the supervision of the MoH, which is responsible for drug approvals as well as for reimbursement and pricing decisions.

APPROVAL PROCESS

Under Italian law, there are two main routes for authorizing medicines: a centralized route, governed by Regulation (EC) No. 726/2004 (i.e., the centralized authorization procedure), and a national route, regulated by Legislative Decree No. 219/2006 ("Pharma Code"), which in turn provides for three different authorization procedures, namely the national procedure, the mutual recognition procedure and the decentralized procedure.

To obtain a marketing authorization through the national, the mutual recognition or the decentralized procedure, the interested company must submit an application to the AIFA in compliance with Art. 8 of the Pharma Code, which identifies the information and documents that are essential for regulatory assessment purposes. These include particulars on the applicant (e.g., the corporate name and permanent address) as well as on the drug for which the marketing authorization is sought[1]. A simplified

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procedure for the authorization of generic drugs[2] as well as schemes for expedited approval and programs to encourage the development of new drugs are available.

Marketing authorizations granted by the AIFA are valid for an initial period of 5 years and can be renewed. To this end, the marketing authorization holder ("MAH") must submit a renewal application to the AIFA before the expiration of the validity of the authorization enclosing an updated version of the drug dossier covering the quality, safety and efficacy profiles. After renewal, the authorization is valid indefinitely, unless otherwise specified by the AIFA, which may decide to proceed with an additional five-year renewal.

PRICING AND REIMBURSEMENT

Pursuant to Law No. 326/2003, the AIFA is the body in charge of negotiating the cost of medicines reimbursed by the NHS and, more generally, monitoring prices of medicinal products. As to pricing, medicines not reimbursed by the NHS are governed by Law Decree No. 87/2005, pursuant to which the MAH can freely determine the price of the relevant product although the AIFA must still ensure that: (i) price increases occur at least every two years (odd years); and (ii) increases do not exceed the inflation level.

With respect to medicines reimbursed by the NHS, Law No. 326/2003 provides that the relevant price is established through a bargaining procedure between the AIFA and the concerned MAH in accordance with the modalities and criteria provided for by the Decree of the MoH dated August 2, 2019. The criteria for the evaluation of a medicine for reimbursement purposes are mainly the following: "added therapeutic value" that the medicinal product must ensure with respect to the main treatments to which it is compared; economic evaluation; availability, consumption and possible reimbursement of the concerned medicinal product in other countries; annual market shares that the MAH expects to acquire in the following 36 months; MAH's production capacity and ability to manage unexpected events; assessment of the economic impact on the

1Documents and information relating to the drug include: the name of the medicinal product; the qualitative and quantitative particulars of all its constituents; the description of the manufacturing method; the therapeutic indications, contra-indications and adverse reactions; the posology, pharmaceutical form, method and route of administration and expected shelf life; the results of pharmaceutical and pre-clinical tests and of clinical trials; a detailed description of the pharmacovigilance system, the summary of the product characteristics, a mock-up of the outer packaging and of the immediate packaging of the medicinal product; etc.

2 Pursuant to the Pharma Code, a generic medicinal product is a medicinal product which has the same qualitative and quantitative composition in active principles and the same pharmaceutical form of the reference medicinal product, and whose bioequivalence with the latter has been demonstrated by appropriate bioavailability tests. In other words, generic drugs are those medicinal products that, on the basis of predetermined, objective and measurable scientific and methodological criteria, can be regarded as equivalent, in terms of quality, safety and efficacy, to reference originator drugs developed and authorized following clinical studies which confirmed the relevant prerogatives.

NHS; the patent status of the relevant medicinal product; etc.

The added therapeutic value of the medicine and the adequacy of the reimbursement price are assessed by the AIFA with the support of the Drug Scientific and Economic Committee.

In successful negotiations, the parties enter into an agreement setting the relevant price and the conditions for the reimbursement. The price agreed by the AIFA and the MAH is the maximum selling price to the NHS. In particular, the selling price is established on the basis of the ex-factory price negotiated between the AIFA and the MAH to which the percentages due to wholesalers and pharmacists are added. The agreement may also provide for an expenditure ceiling applicable to the concerned medicinal product.

The price determined through the agreement is valid for an initial period of 24 months. Upon expiration of this term, the agreement is automatically renewed for a further 24 months unless the parties agree to amend it within 60 days of the expiry date.

Conversely, if the outcome of the negotiation is negative, the medicinal product is put in Class C with no NHS reimbursement. Simplified procedures for establishing the reimbursement price of generic and biosimilar drugs are available.

Medicines reimbursed by the NHS are listed in the National Pharmaceutical List (Prontuario Farmaceutico Nazionale - "List"), which is published in the Italian Official Journal and is updated every 6 months.

02 HEALTHCARE ACTORS AND PAYERS

1. Which are the administrations, bodies and institutions in charge of public health in your country and what are their respective responsibilities?

2. Which are the administrations, bodies and institutions in charge of drug approvals in your country and what are their respective responsibilities?

3. Which are the administrations, bodies and institutions that qualify as “payers” in your country and what are their respective responsibilities?

4. Which are the administrations, bodies and institutions in charge of pricing decisions in your country and what are their respective responsibilities?

5. Which are the administrations, bodies and institutions in charge of reimbursement decisions in your countries and what are their respective responsibilities?

6. Which are the administrations, bodies and institutions in charge of Health Technology Assessment in your countries and what are their respective responsibilities?

7. Which are the administrations, bodies and institutions in charge of public procurement and tendering in your country and what are their respective responsibilities?

8. What are the other actors of significance with regards to market access in your country and what are their respective responsibilities?