AIFA

Agenzia Italiana del Farmaco

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Professor Guido Rasi
- Director General -

Professor in Clinical Microbiology
Medical Doctor specialized in *Allergy & Clinical Immunology* and in *Internal Medicine*

Professor Sergio Pecorelli
- Chairman of the Board-

Chancellor of University of Brescia
Surgeon. Professor of *Obstetrics and Gynecology* at the University of Brescia

The Agency

The Italian Medicines Agency (AIFA) is the national authority responsible for regulation of medicinal products in Italy.
AIFA guarantees access to medicines and their safe and appropriate use as means to protect public health; ensures unity of the national pharmaceutical system in agreement with the regional authorities; ensures innovation, efficiency and simplification of the marketing authorization procedures, in order to grant rapid access to innovative drugs and to drugs used for rare diseases; provides drug expenditure governance in the framework of economic and financial viability and competitiveness of the pharmaceutical industry; encourages investment in research & development in Italy; strengthens the relationship with the Agencies of other member States, the European Medicines Agency (EMA) and other international bodies; interacts with the community of patients' associations, learned societies, academia, pharmaceutical companies and distributors; promotes pharmaceutical culture and knowledge.

Our Mission

Promote good health through medicines

Set fair pharmaceutical policies and assure their consistent application nationwide

Manage the value and cost of medicines

Promote pharmaceutical research and development

Demonstrate independence and leadership both at home and internationally

The Organization

The management of AIFA is structured as follows:
- The Director General, Guido Rasi;
- The Board, chaired by Sergio Pecorelli, with four Board Members;
- The Board of Auditors, with a President and two members.

The Agency is structured into five technical-scientific departments and one administrative area:
- Pre Authorization; Registration;
- Post-Marketing Surveillance;
- Pharmaceutical Strategy and Policy;
- Inspections and certification;
- Administrative Affairs.

The structure of AIFA further consists of the Staff of the Director General, the Office of the Chairman and a Press and Communication Office

AIFA is supported in its activities by two Technical Scientific Committees consisting of experts of well established experience:
- Technical Scientific Committee;
- Prices and Reimbursement Committee.

AIFA Topics at DIA

HMA

AIFA is an active member of HMA, the network of all Heads of the European National Competent Authorities whose organizations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area. The network is a unique model for cooperation and worksharing on statutory as well as voluntary regulatory activities and was established to contribute to the development of a strong European pharmaceutical system. Its meetings are attended also by the European Medicines Agency (EMA) and by the European Commission.
The Heads of Medicines Agencies is supported by the Heads of Medicines Agencies Management Group, of which Prof. Guido Rasi, the Director General of AIFA, is a member, and by working groups covering specific areas of responsibility.
The initial focus of HMA was on the smooth functioning of non Centralized regulatory applications. Over the years HMA has extended its coordination activities to encompass clinical trials authorization, worksharing of PSURs and Paediatric indications, interpretation of legal provisions and product testing. Common initiatives to strengthen the system have resulted in Europe-wide projects concerning IT infrastructure, communication policy, training programs, benchmarking and more.

June 20, 10:30 AM, Room W183c
European Heads of Medicines Agencies (HMA) Town Hall
Guido Rasi, MD, Director General

HTA

AIFA is the Italian public authority responsible for all matters regarding approval and appraisal of pharmaceuticals for human use, including: marketing authorization, pharmacovigilance, reimbursement decision and pricing negotiation procedure for reimbursable medicines.
The licensing procedure and the pricing and reimbursement decisions are strictly interlinked. In order to determine appropriate price and reimbursement conditions of innovative medicines, AIFA performs a benefit/risk assessment to evaluate the efficacy, safety and quality of the pharmaceutical product combined with a Health Technology Assessment process, based on cost/efficacy evaluation and relative effectiveness analysis. Furthermore, addressing the need to guarantee an early patient access to innovative but costly medicines, like new cancer drugs, Managed Entry Agreements - such as risk or cost sharing or payment by result - have been developed. These arrangements, supported by post marketing data collected through Monitoring Registries, allow the place in therapy re-evaluation at regular intervals, in a reiteration of HTA process based on cost/effectiveness criteria.
AIFA activities related to the process of HTA are: approval of new medicines, appraisal procedure to define pricing and reimbursement, managed entry agreements, periodic revision of the list of reimbursed pharmaceutical products, recommendations on rational and appropriate use of medicines.

June 22, 10:00 AM, W184d
Emerging Trends in the Economics of the Biopharmaceutical Industry
Paolo D. Siviero, Dr, Head of Economic Strategies and Pharmaceutical Policy Dept.

Counterfeit Drugs

The phenomenon of illegal and counterfeit medicines is showing a growth trend worldwide.
In comparison with other European Countries, Italy is less affected by the problem (estimated incidence under 0,1%) as a consequence of two main reasons:

- the intersectorial taskforce IMPACT Italia, counteracting illegal and counterfeit medicines;
- the medicines tracking system tracing every package in the whole legal distribution chain, from manufacturing to retail.

In Italy, in the last five years there were no cases of illegal medicines in the legal distribution network, so AIFA focuses its activities on rogue and fake e-pharmacies.
The main activities carried out by AIFA and IMPACT Italia are related to:

- IT intelligence projects to study the phenomenon;
- Ad hoc training for enforcement officers;
- Information campaigns and publications;
- Handling of reports of suspected cases, in cooperation with other administrations;
- Enforcement activities at national and international level.

June 22, 3:30 PM, Room W180
Risk Communication in an Age of Uncertainty: The Legal, Regulatory and Compliance Implications of Disclosing Safety Information
Domenico Di Giorgio, PhD, Director of Unit "Counterfeits"

Risk Sharing

Risk Sharing schemes as well as Monitoring Registries are tools implemented by AIFA to facilitate early access to innovative medicines, to collect real clinical usage data, to avoid unnecessary expenditure, to optimise the spending allocation and to maintain the overall system sustainability.
The Risk Sharing schemes are Managed Entry Agreements (Cost/ Risk-Sharing and Payment by Results) agreed by AIFA with manufacturers in order to grant the coverage by the National Health System, when uncertainty or scarcity of clinical evidence occurs during the authorization process of new medicines whose cost is very high.
In the Cost Sharing scheme the manufacturer applies a pre-agreed discount on price on initial therapy cycles for all patients eligible to the treatment, whereas in the Risk Sharing scheme the discount is applied on price of initial therapy cycles for non responder patients. In the Payment by Result scheme the initial cycles for non responder patients are fully reimbursed by the marketing authorization holder, whilst the NHS fully reimburses treatment for responders.
The purchasing of medicines under Managed Entry Agreements is conditional to the enrolment of patients in AIFA Monitoring Registries. The Registries are intended to verify the appropriateness of prescriptions, to get additional data on clinical effectiveness and the safety profile, and to evaluate the economic effects of Managed Entry Agreements.

June 22, 1:30 PM, Room W184d
Using Real-world Data for Making Real-world Decisions
Luca De Nigro, PMP Project Manager RFOM

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