Medical Scientific Information and Medical Compliance

IQVIA, renowned global leader in "*Human Data Science*", provides advanced services and works to support regulatory authorities, health technology assessment institutions, research organizations, national, regional and local providers, as well as companies in the life science, pharmaceutical, biotech and medical devices sectors.

IQVIA welcomes the opportunity to provide you a complete service on the activities related to **Scientific Service Support**. Our highly specialized team is ready, in fact, to offer a **personalized support** to meet the specific needs of your Company.

In particular, the **Scientific Service and Medical Compliance** ensures compliance with Art. 126 of Law 219/2006, regional, local and deontological regulations and compliance in the field of consultancy, advisory boards, sponsorships, donations, market research, investigator meetings, hospital meetings, public affairs. It also offers the management of accreditations of Sales Representatives, the assumption of responsibility of Scientific Service, the provision of training regarding Medical Scientific Information and support for regulatory requirements in promotional activities (congresses and promotional materials). Finally, it guarantees support for passing internal and external audits (e.g. Farmindustria) and the preparation of Standard Operating Procedures (SOP).

This service is suitable for subsidiary/MAH/Local Representative/Concessionaire in Italy and it is divided into different activities.

The Scientific Responsible Person (RSS): assumption of responsibility of Scientific Service on your behalf pursuant to Art. 126 of Italian DL 219/06

Under Article 126 of Law 219/2006, the MAH — or the Company commercializing the product in Italy, where the former is domiciled abroad — must have a **Scientific Service** in charge of the information about the medicinal products placed on the Italian Market. The director of this service shall have a degree in Medicine, Pharmacy, Chemistry or Pharmaceutical Technology. The Scientific Service shall be independent of the Company's marketing division.

IQVIA provides experienced specialists who can fulfill the role of Scientific Responsible Person, supporting in the following activities:

- **Medical Scientific SOPs preparation and review to guarantee a quality system, in compliance with national legislation and the code of ethics.**
- **Assure that actions required by AIFA/ Regions or Local Authorities are taken on for the Company, in relation to Scientific Service provision.**
- **Ensure that expected trainings, defined by law, are attended by Sales Representatives, with particular focus on the regulatory and compliance aspect.**
- **The revision of promotional materials, congresses and general advice on Italian requirements relating to the promotion of medicines.**

Recurring meetings are organized to have a constant follow up of the activities.

Database of regional regulations: an analysis of the legislative landscape is essential to fully comply with the regulations of the Italian Regions

Medical Scientific Information is constantly changing and is structured differently based on the different Regions and their provisions. For this reason it is necessary:

1. **Creating, monitoring and updating a Database relating to Regional Regulations on Scientific Information shared with the customer.**
2. **Notifying clients of any relevant updates and evaluating any actions to be taken.**
3. **A personalized consultancy on the specific needs of the Company on the different aspects of Regional Regulations (limits to visits of SR, presence of area manager, etc.).**

Notifications to Regions/AIFA

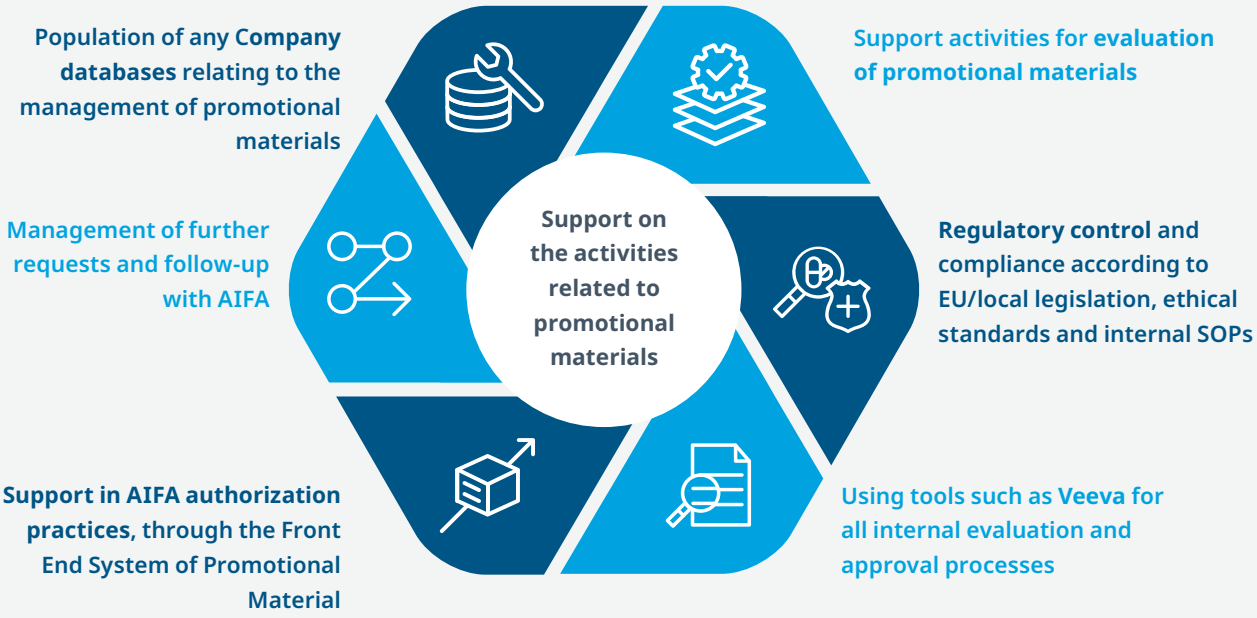
IQVIA supports the Company in all activities relating to the Scientific Service, managing the entire process of data transmission of Sales Representatives to the relevant Authorities. In particular, the service includes:

- The **identification of roles** who require an accreditation to Regions/Local Health Authorities/ Hospitals (in accordance with Regional Regulations or indications from the Local Health Authorities);
- The **accreditation** and the **disaccreditation** of Sales Representatives (SRs);
- The predisposition of **identification cards** for Sales Representatives (SRs);
- Support for the **annual/biannual Communications to the Regions** referred to SRs' visits (in accordance with regulations issued by each Region);
- Support for the **annual notification to AIFA** of SRs' visits, face to face (F2F) or remotely. In fact, every year in January, each Pharmaceutical Company must communicate, on regional basis, to AIFA the number of healthcare professional visits made by their Sales Representatives in the previous year, specifying the mean number of visits made.

Support on the activities related to promotional materials

Another fundamental auxiliary activity consists in the development and/or review of promotional materials and disease awareness materials and related submission to AIFA Front-End where applicable, so that they are in compliance with Italian legislation, constituted primarily by Law 219/2006, which represents the Italian regulatory reference for everything concerning medicines for human use. Since the field of advertising of such medicines is a complex area and subject to various regulations and codes of ethics, IQVIA offers a pool of experts capable of preventing regulatory violations, reducing legal risks, and preserving the integrity of promotional activities, allowing pharmaceutical Companies to responsibly promote their medicines and in line with current regulations, ensuring the accuracy of the information conveyed.

Therefore, IQVIA undertakes to follow you throughout the entire process, from the review and evaluation of promotional material to the submission in AIFA system and subsequent follow-up. Specifically, the following services are offered:



In conclusion, IQVIA prepares ad hoc **working instructions and/or Standard Operating Procedures (SOP)** to plan a specific flow of information between the different roles present in the Company, in order to ensure a rapid response to each request and to achieve the highest level of compliance with the regulations for passing internal and external audits (e.g. Farmindustria).

CONTACT US

Federica Santagostino

Regulatory & PhV Engagement Manager IQVIA

federica.santagostino@iqvia.com

IQVIA Solutions Italy S.r.l.

Via Fabio Filzi, 29

20124 – Milano – Italy

iqvia.com