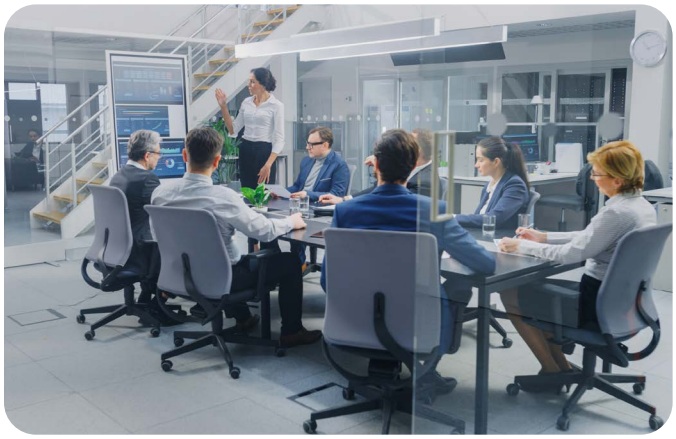
# Start-Up

*Companies that decide to enter into the Italian market with medicinal products find themselves facing various challenges in meeting the requirements of current legislation and health authorities.*


IQVIA is a partner capable of answering these questions, offering a wide range of services in the Life Sciences sector.

Through a dedicated team of experts in the regulatory and pharmacovigilance sector, with a deep knowledge of European and local regulations, IQVIA is able to support companies during the early stages of life of a medicinal product (set-up and pre-marketing) and throughout the product life cycle (launch and post-marketing activities).



## Company set-up and pre-marketing activities

- **SIS code Request**: identification code assigned by AIFA to any Company that markets medicines in Italy. The assignment of a SIS code is a mandatory requirement also necessary to begin the registration procedure in the various databases required by law
- **Registration on the AIFA Front End platform**: the Front End is the platform through which companies interact with AIFA. Each Company is required to register on the platform in order to submit all the documentation requested by the authority
- Support in the **management of the quality, compliance and medical-scientific information system**
- Set-up of the **Pharmacovigilance System**, quality management as required by GVP (PSMF, SOPs, Agreements, etc.)
- **Evaluation of the necessary figures based on the Company structure**:
  - **Identification of the Legal/Local Representative**: every Company that is based abroad and obtains an authorization to market a medicinal product in Italy is required to identify a legal/local representative and notify it to the authority
  - **Assumption of responsibility as Simple Prosecutor**, reference contact for the direct

management of relations with the authority on behalf of the MA holder and as **Special Prosecutor**, reference contact for the authority with signing power

  - » **Assumption of responsibility as Head of the Scientific Service (RSS)**, it is mandatory in accordance with the legislation (art. 126 of Legislative Decree 219/2006) that each Marketing Holder must identify a head of the scientific service responsible for the scientific information on medicines
  - » Appointment of **Conference and Congress Representative** for the management of conferences and congresses it is necessary to have a figure appointed within the AIFA platform
  - » Assuming responsibilities as **QPPV/Deputy QPPV**
  - » Assumption of responsibility as **Local Contact Point for pharmacovigilance** which represents the reference contact for AIFA and is registered in the national Pharmacovigilance database "RNF"

- **Evaluation of conference events (ECM and non-ECM), institutional activities, market research and disease awareness activities** from the point of view of adherence to compliance requirements

## Product launch

- **Management of the translation of Product Information** (Summary of Product Characteristics, Information Leaflet and Labels) which must be prepared as required by current legislation and in accordance with the QRD template
- **Management of bilingualism requirements**, the owner must provide the translation into German of the package leaflets of medicines marketed in the provinces of Trento and Bolzano, as required by law
- Sending the **communication of first marketing**, each MA holder must communicate to AIFA the date of first marketing and the relative price before starting marketing on Italian territory
- **Management of "bollini"**, adhesive stickers that are applied to each package put on the market to guarantee traceability: management of purchase requests via specific platform and shipping of stickers as well as support in the management of the sticker/data matrix transitional period in accordance with the provisions of legislation
- **Management of the traceability system**, the marketing authorization holder must comply with the requirements established by the Ministry of Health and AIFA to guarantee the traceability of each package placed on the market
- **Management of medical-scientific information activities**: **review of promotional and non-promotional materials** and management of **requests for authorization of conferences and congresses** in order to comply with all the requirements required by AIFA and current legislation

## Post marketing

- **Marketing authorization maintenance activities** (submission of variations, notifications, renewals and direct management of the relationship with the authority during the evaluation of practices and follow-up phase)
- **Management of safety and non-safety updates of product information**, providing support in translations into the local language, ensuring compliance with the templates required by law and managing relations with the authority during the review phase
- Management of the **bilingualism platform**, with each update of the package leaflet the German package leaflet must be updated through a specific platform
- Management of communications requested for **Farmastampati**, in the event of specific updates to the package leaflet and labels as envisaged by the AIFA determination relating to the criteria for the application of the provisions relating to the disposal of stocks, the Marketing Authorization Holder has the obligation to send the updated package leaflet and the labels to Farmadati database in accordance with the established methods and timing
- Support in the evaluation of **medical compliance of symposia, ECM/non-ECM conferences, press releases, institutional activities, market research, advisory boards, hospital meetings, scientific consultancy**
- Management of **notifications to AIFA and the Regions relating to the activities of Scientific Informers** and accreditation/disaccreditation activities of Pharmaceutical Representative
- Maintenance of the **Pharmacovigilance System**, quality management as required by GVP (PSMF, SOPs, Agreements, trainings, audits, etc.)
- **Management of pharmacovigilance cases** (receipt, processing, submission, reconciliation, aggregate reports, signal detection, literature screening) from any source
- Management of activities relating to the **Risk Management Plan** (RMP management, Educational material, DHPC)

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