Sagaem for life is an independent, cost-effective consultancy company based in Frosinone, 80 km south of Rome, providing a number of services in the pharmaceutical field and related sectors.
sagaem for life was founded in 2004 by **Dr. Stefano Ceccarelli**, an experienced professional with wide knowledge of the pharma sector. Drug regulatory affairs, pharmacovigilance and business development are the core competencies of the company.

Since its foundation, sagaem turnover has constantly grown by approx. 20% year, thanks to the quality of the services offered and the deep commitment of its staff.

sagaem for life offers its enthusiastic partnership to discover business opportunites in one of the largest pharmaceutical markets in the world.

Take advantage of a wide range of services from skilled professionals with sound scientific background who understand local regulatory needs and have broad knowledge of companies, people and practices in the fast moving Italian scenario.

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sagaem
for life

THE BRIDGE TO ITALY
FOR PHARMACEUTICAL
COMPANIES WORLDWIDE

SERVICES *OFFERED*

- ***sagaem*** handles registration procedures for human medicinal products, esp. the national phase of applications submitted through MRP or DCP where Italy is a CMS, from translation into Italian of product information texts up to the grant of Marketing Authorizations (MAs)
- **Local assistance for all license maintenance activities can be outsourced to sagaem, e.g. submission of variations to the MAs and their follow-up, including publication in the Official Journal (Gazzetta Ufficiale)**
- sagaem offers advice and support on fees payable to the Italian authorities
- ***sagaem*** **is able to search for potential Italian domestic partners for license or distribution agreements possibly involving the transfer of the MA**
- Assistance in negotiations with the marketing partner up to the signature of license and supply agreements is offered by sagaem
- **For those companies wishing to set up a direct presence in Italy, sagaem can provide comprehensive advice and operational support until the start-up local branch is fully operational**
- ***sagaem*** acts as the local partner of big pharma regulatory providers, ensuring a continuous liaison with AIFA and a timely update on Italian rules and procedures
- **Pricing and reimbursement (P&R) negotiation with AIFA is a key step to be managed before the issuance of the MA takes place: the whole procedure, from the draft of the P&R dossier to direct attendance at the negotiation meetings, can safely be outsourced to sagaem**
- **For CE-marked medical devices, sagaem is able to fulfill pre-launch national obligations, particularly the product registration in the Italian Ministry of Health database in accordance with the Ministerial Decree 20 February 2007 as subsequently amended**
- Trained members of ***sagaem*** team can act as Local Safety Officers for Italy in the name of international pharma companies, monitoring ADRs and ensuring that PV systems are locally in place in compliance with current requirements
- **Domestic companies with a limited product portfolio may need to outsource their regulatory function: sagaem can fulfill the full range of regulatory duties, from the draft of administrative documents needed for the submission of applications up to the notification of the final official decision by the competent authority**
- For small domestic companies wishing to enlarge their portfolio sagaem can search for available product opportunities from foreign developers (e.g., CTD dossiers of generic products to be registered in Italy)
- **Companies interested in the acquisition of an existing marketing authorization can outsource to sagaem the due diligence of the technical/regulatory product documentation**
- ***sagaem*** can ensure full compliance with a wide range of regulatory obligations concerning medicinal products, e.g. “bollini” stickers ordering and traceability, annual submission of medical reps listing (January) and statement of promotional expenses (April), enforcement of bilingualism rules
- ***sagaem,*** **as a third party service provider, is able to support customers in fulfilling their pharmacovigilance obligations and in getting their organizations registered with EudraVigilance. Furthermore, having successfully completed the EudraVigilance knowledge evaluations, properly trained sagaem's staff can perform on behalf of the customer the electronic transmission of:**

  - Individual Case Safety Reports (ICSRs) and ICSR acknowledgements in the context of clinical trials and post-authorization of medicinal products;
  - Extended EudraVigilance Product Report Messages (XEVPRMs) for the submission of the information on medicines in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004.

- **For food supplements, sagaem provides the necessary advice and support (e.g., product notification to the Ministry of Health, assessment of compliance of labeling texts, composition and claims with national rules)**
- To survive in a challenging and competitive scenario, start-ups (typically: local subsidiaries of small/medium pharma companies headquartered in other EU countries) may need to reduce their own infrastructure to the minimum possible extent, thus outsourcing most of their functions. Besides regulatory support, sagaem can offer tender management services therefore helping to successfully market hospital generic products even without promotional support
- ***sagaem*** **can take care of the compliance of promotional material and congress sponsorship in accordance with national rules**