

## COMPANY PRESENTATION

*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, business development and tender management 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 manager.

In 2009, *sagaem for life* was awarded the Prize for International Enterprise from the Chamber of Commerce of Frosinone for its distinguished commitment towards sound business relationships with foreign companies.

*sagaem* has legally been recognised by the Italian Health Authorities (SIS Code No. 2690), thus enabling it to act as legal representative in Italy for foreign companies.

Typically, customers of *sagaem* are:

- small/medium European pharmaceutical companies without a direct presence in Italy
- EU-wide regulatory providers located abroad
- small domestic companies having no internal regulatory affairs or business development staff
- Italian subsidiaries of marketing pharma companies based in other European countries wishing to outsource most of their functions.

The logo for sagaem for life, featuring the word 'sagaem' in a large, bold, green, rounded font, with 'for life' in a smaller, lowercase, green font underneath it.The logo for sagaem for life, featuring the word 'sagaem' in a large, bold, green, rounded font, with 'for life' in a smaller, lowercase, green font underneath it.A large, green, curved graphic element on the right side of the page, resembling a bridge or a stylized 'C' shape. It has a textured, leaf-like pattern.

sagaem for life s.a.s.

Via Dante Alighieri, 3  
03100 Frosinone, Italy

Phone: +39 328 4158835  
Fax: +39 0775 835222  
e-mail: [info@sagaem.it](mailto:info@sagaem.it)

Contact: Dr. Stefano Ceccarelli

[www.sagaem.it](http://www.sagaem.it)

## 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
- *sagaem* offers its assistance to European Contract Research Organizations for the compilation of Clinical Trial Applications and their upload on the OsSC portal in accordance with Ministerial Decree 21<sup>st</sup> December 2007



- 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
- 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