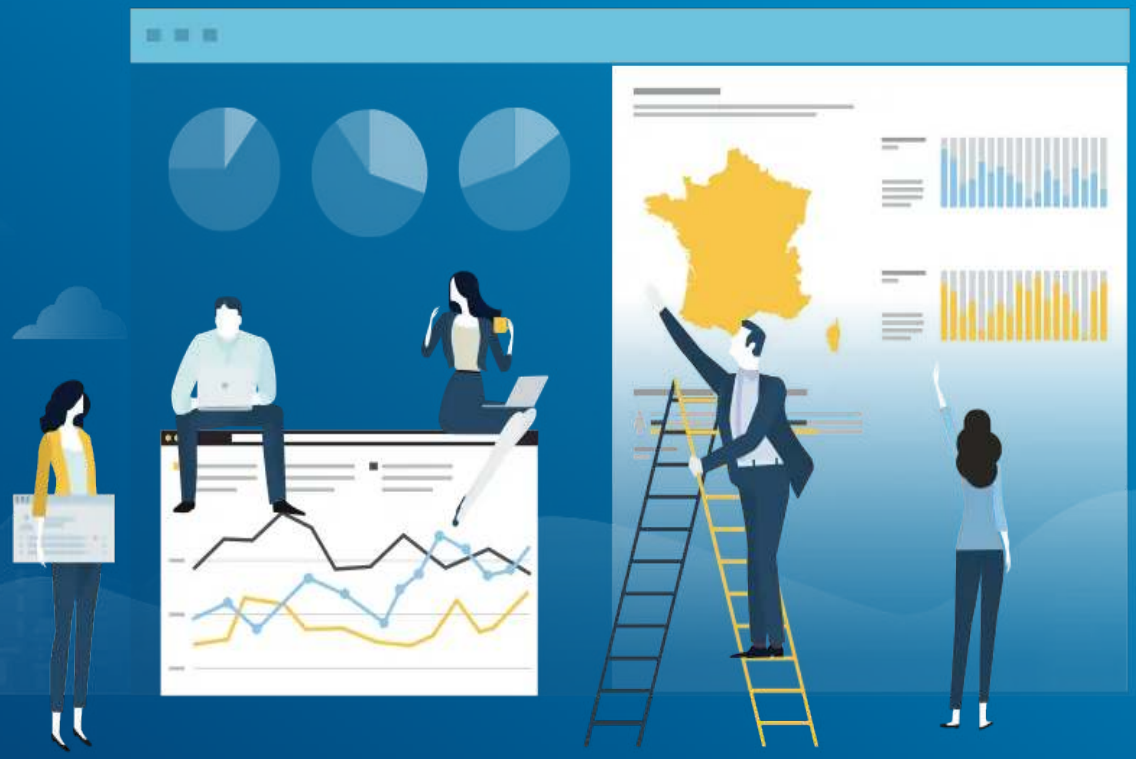
CASE STUDY

EARLY ACCESS PROGRAMS (ATU)

Temporary Authorisation for Use (ATU) in France



A French pharmaceutical affiliate entrusted BlueReg to support them for the whole process of submission (advice, writing activities and support for meeting with the Competent Authorities) of a cohort Temporary Authorisation for Use (cATU) request to the ANSM for a new chemical entity.

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Challenges

The project involved several activities (strategical advice, cATU dossier preparation, ANSM meeting) with tight submission timelines.

These activities were key for the client as they determine the early access to the French market for the patients.

During this project, a strong relationship was built with the client, putting their full trust in BlueReg expertise in regulatory affairs (especially on ATU specificities) and market access activities.

BlueReg support

BlueReg has a significant experience and a proven track record in ATU process. BlueReg put together a dedicated team of pharmacists with appropriate expertise, and project management skills to meet the ANSM requirements and to best satisfy the client's expectations.

PharmaBlue gave its support to BlueReg team thanks to its Exploitant Status and its multiple experiences in managing ATU for all practical aspects.

The client was seeking support from BlueReg for the preparation of the meeting with ANSM and the cATU application:

Strategical advice/guidance:

- on the positioning of the product, strengths and weaknesses of the project / product
- on provisional timelines
- on all expected steps and interactions with ANSM
- on the format of the dossier for a compliant submission

Writing activities:

- Preparation of full cATU dossier including the letter of intent, the application form, justification part and the Protocol for Therapeutic Use and information collection (PUT)
- Collection and implementation of the Client's comments in the above-mentioned dossier

Meeting with the ANSM:

- Preparation of the slide kit
- Organisation of the rehearsal before the meeting with Authorities

Project management:

- One main BlueReg contact point identified for the client
- Insurance that the project team was fully supported, and all timelines were met
- Close work with the company for the whole project
- Sharing of information with the company and the whole BR team to coordinate the consistency of the dossier

Achievements

- Full cATU dossier, ready for submission
- Meeting ANSM: slide kit - rehearsal
- Coordination of several meetings with the client and the ANSM
- Ad hoc advice
- Management of tight timelines according to client's expectations and Authorities' requirements
- Full client satisfaction, with great appreciation of the team's expertise and strong relationship for Regulatory Affairs, Market Access activities.

How BlueReg can support you ?

Early Access Programs (and ATU)

For some rare, life threatening conditions or those of major public interest, the early access to investigational drugs prior to regulatory approval is vital.

BlueReg can help navigate the complex environment of Early Access Programs (EAP) in the EU, we will work cross-functionally with your functional teams to ensure the correct timing of the EAP and strategically plan to avoid any possible hurdles. We have considerable experience in the arena of EAPs and can design and implement the programs on your behalf in the EU.

You can rely on the experience and expertise of our consultants for providing advice and efficient implementation of ATU projects (nominative and cohort):

- Provision of advice or responses to questions including strategy and/or positioning of ATU projects
- Preparation or review of ATU applications including the protocol for therapeutic use (PUT)
- Submission of ATU dossiers to the French National Agency for the Safety of Medicines and Health Products (ANSM) and follow up until ATU is granted

Via our in-house organization, PharmaBlue, we manage ATU programs in the following ways:

- Pre-launch activities for the management of ATU programs: setting up a dedicated ATU team (cell ATU), assigning toll-free phone / fax numbers and creation of a database for the management of the ATU
- Day-to-day management of ATU programs: Patient inclusion and follow up, validation of the pharmacist orders, processing and capturing all necessary data
- Generation and submission of ATU periodic reports
- Tailored approach to completely manage the end to end process or to complement existing supply chain

For more information please contact us

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