Supply Shortage Management Plan

Achieving a successful outcome on behalf of a client

A French pharmaceutical firm (generic products) was directed by the French Health Authorities to prepare a Supply Shortage Management Plan (SSMP) for one of its medicinal products used in the context of a temporary recommendation for use*. This was a directive of the French legal system and presented a significant challenge for the client. The client entrusted BlueReg to manage the project and support a successful outcome. The SSMP request for this product was made directly to the Pharmacien Responsable by the French Health Authorities. **According to the Article L5121-12-1 of the Public Health Code : a pharmaceutical specialty may be subject to a prescription that does not comply with its marketing authorization in the absence of a specialty with the same active ingredient, the same dosage and the same pharmaceutical form with marketing authorization or a temporary authorization for use in the indication or conditions of use considered, provided that a temporary recommendation of use established by the French Health Authorities secures the use of this specialty in this indication or these conditions of use. When such a temporary recommendation for use has been established, the specialty may be subject to a prescription in the indication or the corresponding conditions of use as soon as the prescriber judges that it meets the needs of the patient. The fact that there is also a specialty which, for the same indication, has been the subject of a marketing authorization, since it would not less meet the needs of the patient, does not preclude such a prescription.*

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Challenges

This project consisted of support for developing an SSMP in the following context:

- A request coming directly from the French Health Authorities
- The temporary recommendation for use driven by French law
- Medicinal product shortage is a sensitive topic, is reinforced by French Public Health Law, and the request put a great deal of pressure on the client
- The indication for which the product is temporarily authorized is sensitive area and a public health issue (alcohol addiction)

BlueReg support

Our senior Consultant

- Acted as main contact point to the client

- Had previous experience of developing and managing SSMP

- During her previous professional experience interacted with the French Health Autorities in this and many other areas

Function

- Thanks to her experience and expertise, the consultant took over the development of the SSMP

- To do so, she needed to assess and request information:

    o She asked for the product manufacturing flow chart from the client

    o She carried out literature searches to develop a critical medical arguments in the context of the public health requirements:

        • Official reports concerning the alcohol addiction problem on French Health Authorities and French Public Health website

        • Opinion of the Transparency Committee

- With collected data and information, the consultant developed the SSMP according to a specific template:

    o General information (indication, registration status, marketing status, medical setting, market share, patient impact in case of stock-outs,...)

    o Weaknesses identified during the risk analysis (manufacturing and distribution flowchart, supply of critical components, critical manufacturing stages/ weaknesses/outsourcing, fragmentation of the manufacturing/supply chain, ...)

    o Measures already in place to avoid and manage stock-outs (surveillance and prevention, remediation action in case of supply shortage,...)

    o Mid-term measures assessment and presentation

    o Shortage Management Plan Review Frequency

Achievements

- The SSMP was developed and delivered to the client on time who was able to answer the French Health Authorities request (SSMP for a molecule which can reduce a Public Health burden (alcohol addiction))
- Client's acknowledgment of BlueReg skills and expertise
- Relationship of trust between the client and BlueReg