CASE STUDY

PharmaLex successfully changes legal status of product from POM to P

PharmaLex leveraged their regulatory expertise on the switching requirements and process, and their working relationship with the regulatory authorities to successfully change a product from prescription only medicine (POM) to pharmacy medicine status.

Situation

An EU-headquartered company, a client of PharmaLex, acquired a POM from a large, multinational pharmaceutical company. The multinational had twice tried and failed to change the legal status of the product in the UK from POM to P. The MHRA rejected their applications because they considered the indication was not suitable for self-diagnosis, self-diagnosis and treatment would mask more serious underlying conditions and because of the risk of serious adverse events.

> ***PharmaLex have been an invaluable partner in this project with their regulatory knowledge and insight. They have proved effective, proactive and attentive to detail in all matters concerning this application to register this drug as an over-the-counter medicine and the successful outcome is down to them.***

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Challenge

The challenge was to identify a regulatory strategy and path for a proposed switch that would overcome the MHRA's previous objections. This objective was made more difficult because, if successful, this would be the first time a product with this active ingredient would be classified as an OTC medicine in the UK.

Solution

Using our significant knowledge and experience of legal status switches, PharmaLex quickly developed a potential path to approval. By swiftly grasping the complexities of the therapeutic area and the previously identified areas of concern for safe OTC use, PharmaLex produced robust, evidence-driven arguments and a compelling benefit risk assessment to support the proposed switch.

- Arranged and held a positive scientific advice meeting with the MHRA to pave the way for a successful switch
- Identified new data and authored a strong, supportive clinical overview and safety assessment
- Initiated interactions with patient and pharmacy groups, and potential patients in order to generate suitable a SmPC, PIL, risk management plan and pharmacy materials
- Proposed proportionate risk minimisation measures that were acceptable to both the client and MHRA.

Benefits

PharmaLex's engagement delivered:

- Access to a new OTC market worth a potential £486M per annum
- Preservation of the POM and its existing sales
- A switch dossier that could be used in other EU and ROW markets.

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