



Introduction to Pharmaceutical Trade Marks

A pharmaceutical trade mark is the same as any other trade mark in terms of the process for securing protection and the law governing the rights conferred on trade mark owners, but there are certain considerations which are unique to pharmaceutical trade marks ¹.

What's different about a pharmaceutical trade mark?

Names used for pharmaceutical products require regulatory approval in order to ensure that public health is protected. Pharmaceutical trade marks can only be used commercially once the drug in question has been granted a marketing authorisation. Part of that process is obtaining approval for the commercial name of the drug. The test for whether a name can be approved by the relevant agency (EMA in the EU, the FDA in the US and the MHRA in the UK) centres on similarity with existing brand names and International Non-Proprietary Names (INNs) with a focus on the potential for medication errors.

In addition to the regulatory hurdle, a candidate pharmaceutical name must also avoid conflict with earlier trade marks registered by third parties for pharmaceutical products.

Where similar trade marks are used for the same or similar medical indication, there is a trade mark conflict. Where similar trade marks are used for different medical indications, there is a public health conflict.

These two considerations are entirely independent of one another.

The need to consider both public health and classical trade mark infringement means the generation of names for pharmaceutical products is a complex process which requires considerable resource.

How are names for pharmaceutical products chosen?

This is a complex process. It is not unusual for up to 500 candidate brand names to be created by an external naming agency in order to produce 1 trade mark registration and 2 back up marks.

Screening / Searches

Initial online legal screening checks will be conducted to knock out the candidate brands which face clear obstacles in the EU and USA.

Those candidate brands which survive this process will then be put into full legal searches in these and other jurisdictions in which the product is planned for early commercialisation, which may include by way of example Switzerland, Japan, Canada, Argentina, Australia, Brazil, Mexico, China and Turkey.

The candidate brands are also subjected to safety testing ², in order to determine whether they fall within the guidelines

prescribed by the EMA and other relevant regulatory bodies. This safety testing comprises an analysis of how the marks look when written out by hand, by way of a doctor's prescription, whether they look or sound like any similar pharmaceutical brands, if they suggest any inappropriate or exaggerated claims or contain an inappropriate INN (International Non-Proprietary Name) stem and whether they are otherwise unsuitable on the basis of a linguistic, cultural and marketing evaluation.

Why is more than one candidate name required / advisable?

The rejection rate of candidate names by the European Medicines Agency (EMA) is typically around 50%. Rates of rejection by the FDA in the US are also high. It is therefore advisable to have one or two back up names.

What is the process for registering a pharmaceutical trade mark?

- *File*

Applications for the candidate names are placed on file with the relevant trade mark offices.

- *Examination*

Each office carries out an examination of the mark to ensure that it meets the standard for registration. This usually involves (i) an analysis of whether the mark is distinctive and in many countries/jurisdictions (ii) a check to ensure that the mark does not conflict with an earlier third party trade mark. The latter is usually not an issue if pre-filing searches have been carried out.

- *Publication*

Trade Mark Offices advertise their intention to register a trade mark and provide third parties with an opportunity to oppose the registration of that mark during a set period (usually 1 - 3 months).

- *Registration*

If no oppositions are encountered (or are successfully dealt with) then the Trade Mark Office will register the mark.

How long does a trade mark registration last?

Registrations usually last for a period of 10 years and can be renewed every ten years.

How long does it take to register a trade mark globally?

Different Trade Mark Offices examine and register trade marks in differing periods of time. In some countries, registration can be achieved in a matter of a few months whilst in others the process can take two years or more.

When should I start the process of choosing and registering a pharmaceutical brand name?

We advise clients to allow three to four years from the start of the name creation process through to registration of a mark globally. For pharmaceutical clients this would mean starting the process at the **start of phase II clinical trials** so that trade mark registrations are in place when marketing authorisations are applied for.

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Footnotes

1. This guide focusses on registering brand names as trade marks. It does not deal with obtaining approval as part of the marketing authorisation process.
2. Carried out by third party regulatory advisors.

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