



Pharmaceutical branding: trade mark and regulatory considerations

There are many considerations when adopting a new pharmaceutical brand. These cover a range of creative and legal issues.

Adopting a strong brand for a pharmaceutical product cultivates an attractive image and embeds recognition of quality amongst consumers; this ultimately drives customer loyalty and commercial success. It is therefore important to protect that brand via registered trade mark rights (which are potentially perpetual) since that brand value is what will drive sales in the face of competition, particularly once the product is off-patent.

The branding process will involve multiple stakeholders, both internal and external to the business. Internal functions will include at least marketing, legal, and management. External parties may include a branding agency and will certainly include trade mark offices and regulators.

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The creative side includes:

- linguistics,
- concept,
- connotations, and
- aesthetics.

The legal side focuses on:

- clearance and registration of the trade mark, and
- obtaining regulatory approval for the name as part of the marketing authorisation process.

With so many key considerations, it follows that branding a new pharmaceutical product is a complex and lengthy process. It is important to start that process early during the product life cycle. This is due to the duration of the regulatory and trade mark clearance/registration processes and also to the need for alternative names. The need for alternative names arises from the high attrition rate of names during the branding process. There are two main legal factors behind this attrition:

- Crowding of the trade mark registers. For example, the EU trade mark register contains over 55,000 registered trade marks containing the word “pharmaceutical” in class 5 (NB that is the register for pan-EU trade marks only; it does not include the 26 national registers in the EU or International Registrations designating the EU). Accordingly the potential for trade mark opposition and infringement is significant. This necessitates thorough trade mark searching which will frequently uncover earlier rights that pose a risk to the use and registration of a name.
- The need for regulatory approval for pharmaceutical names as part of the marketing authorisation process. Marketing authorisations in the EU can be obtained in several ways, such as at pan-EU level from the European Medicines Agency (EMA), or at a national level from national regulatory offices like the UK’s Medicines and Healthcare Products Regulatory Agency. The regulator will assess the proposed name and decide whether it is acceptable.



Historically, approximately 50% of all names submitted to the EMA are rejected.

There are clear distinctions between the trade mark and regulatory processes. They are independent processes, typically administered by separate entities in each jurisdiction under different laws and timelines. Importantly, the outcomes of the processes have different effects:

- Trade mark registration provides exclusive rights in the name. In broad terms, those rights can prevent use of the same or similar name where there is a likelihood of confusion as to the trade origin of the products. However, obtaining a trade mark for a pharmaceutical does not entitle you to sell that pharmaceutical.
- Regulatory approval does entitle you to sell the pharmaceutical under the approved name. However, it does not create any enforceable rights in the name. The key consideration in the regulatory assessment of a name is whether there is any health and safety risk arising from confusion with an existing pharmaceutical name. "Confusion" in the regulatory context has a different meaning to "confusion" in the trade mark context. The latter relates to confusion as to trade origin whereas the former relates to confusion in the sense of medical confusion. That might include a drug being administered for an incorrect therapeutic indication or being mistaken for a generic name (a.k.a. International Nonproprietary Names or INNs).

A pharmaceutical name will therefore need regulatory approval and ideally trade mark registration in the target territories prior to launch. This combination ensures freedom to use the name and enforceable rights in the name.

To ensure the necessary regulatory approvals, trade mark registrations, and back-up names are in place for launch, a typical pharmaceutical brand development strategy is for many names (often several hundred) to be generated, normally by a branding agency, during phase I or early phase II of clinical trials. Those names will then be whittled down via preliminary creative and legal checks to produce 15 to 20 names. The remaining names may then undergo market research to generate a shortlist of perhaps six to eight names. That shortlist will then be subject to full legal checks, including trade mark clearance, checks of INNs, and pre-existing pharmaceutical names.

That process may knock out several shortlisted marks so there are only two or three remaining. The remaining names should then be applied for as trade marks and, at the appropriate time, submitted to the relevant regulatory authorities.

Key considerations for pharmaceutical branding:

- Start the branding process early in the product life cycle.
- Identify stakeholders early to ensure input from all relevant parties throughout.
- Keep in mind the distinction between trade mark and regulatory processes and outcomes.
- Create multiple candidate names to allow for trade mark and/or regulatory issues.

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Need advice?

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