

Commercial strategies for implementation of branding and OTC switching policies

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Abstract Historically pharmaceutical companies have handled the loss in revenue from patent expiry by developing and concentrating their focus on new drugs. With the number of new chemical entities (NCEs) being launched each year, on the decrease, companies need to update their strategies to embrace the OTC opportunity, rather than shy away from it. This paper outlines some commercial strategies to maximise RoI (Return on Investment) throughout the product life cycle, with a specific focus around the time of patent expiry.

INTRODUCTION

The importance of early planning

The initial focus for new chemical entities (NCEs) being launched in the pharmaceutical market is on the revenue that can be obtained during the years of patent protection and prescription-only sales. Patent expiry is inevitable and entirely predictable. However, this is not a recommendation to ignore the next NCE, which is a major source of future revenue, but a recommendation not to abandon the existing drug, which can be worked synergistically with new drugs to obtain good continued RoI. The key is to plan early. Ideally, planning should begin when the drug is first launched to enable a synergistic approach throughout the product life cycle, including all its licensing phases, from prescription only

(POM) through to pharmacy and over the counter (OTC) sales.

The financial management of an OTC drug is necessarily very different from a prescription-only medicine. Volume of sales is still an important factor, but now profit becomes more important. Ideally, this should be recognised internally within the organisation, by keeping the financials separate in order to be able to measure effectively and make sound decisions based on clear financial benefits.

Consider in the years (not the year) before patent expiry how to plan to manage the branding over the switch. Is a new brand appropriate for the OTC product? If not, does the existing brand need to be revitalised? Will a name be required? Will the same brand be used for both the prescription only form and the OTC form of the product? This can be

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done in some countries and may be beneficial for promotion as the OTC product may be advertised to the public thus also supporting, indirectly, the prescription-only product.

It is essential to begin the marketing plan early. For OTC medicines, a unique selling proposition (USP) is essential and, with regard to strap lines and claims, not only do these need to be factually correct, but they also need to appeal to the consumer as having some significant benefit over other, comparable products. Linked into strap lines and claims is the summary of product characteristics and the marketing authorisation (MA). Will it be necessary to carry out new clinical trials to support the MA? If so, at what cost and with what effect on your RoI? If additional clinical trials are to be carried out, is there any possibility that these might also lead to new patentable discoveries or pose a risk if the study fails its primary endpoints or produces unexpected data?

Consider what competitors to the OTC product might already be in the market, despite the years of patent protection on the molecule itself. An alternative solution for the same condition using a different molecule can be a very real threat and, if already established in the generic market, may present commercial barriers to the launch of a new OTC product. Once again, the USP is key.

Having stressed the need for long-term planning, it is also worth noting the benefit of the period of exclusivity following patent expiry. The usual 90-day exclusivity period might seem negligible, but consider the real timescales involved in bringing a new generic product to market.

- The UK operates in line with EU Legislation for granting a period of exclusivity, which links reclassification with the *licence* not with the molecule. Thus competitors are free to vary their

licence and submit a Type 2 application, which the MCA will take 90 days to assess.

- Without duplicating all the work themselves the application by a competitor to the MCA can only be made *after* the approval of a change in status from POM to P. Typically, it might take around 10 days to post such a variation and for it to be assigned within the MCA.
- Only after the change in licence has been approved will the MCA's product information unit review and assess artwork changes to packaging etc. Assuming that this is internally agreed within the company and is ready to submit on the day the new licence is agreed, it is likely to take a minimum of 30 days and, quite commonly, 90 days for the artwork to be approved.

Realistically, then, it might easily be 6 months from the initial application before a generic competitor is even approved for launch in the market.

Allow further time for print production of packaging and marketing materials needed for product launch, not to mention the time for internal company negotiations, approvals and decision making, and it is not improbable that the process might take 10 months or more. This, assuming the availability of a spare licence already being available — if a new licence is required, then another 710 months can easily be added to the timescale, since the MCA now require one licence per supply status, ie it is no longer possible to have one licence supplying both POM and OTC.

On paper, a 90-day exclusivity period might seem short, but the reality of meeting the regulatory requirements for a new OTC product actually provides for a much longer period of exclusivity.

BRANDING

Consider whether the brand will be a new brand, the existing brand, a revitalised brand or an acquired brand. Decide

whether the brand will be global, pan-EU or exist in only one EU Member State. Make no assumptions, for example about the language that can be used in different countries. Review branding strategy internationally. Consider safety above all, for example, if the plan is to launch under an umbrella brand for a particular therapeutic area, check with the technical team that the claims really are realistic.

Make a proposal and discuss it with the authorities concerned. In doing so, make sure that there are alternative options and suggestions. Giving the authorities only a single proposal with no room for manoeuvre only risks a flat rejection.

Finally, consider that the market position of a brand can be constantly updated and improved with new, improved claims and benefits. Depending on the competition, you might consider broadening the indications or extending age ranges in order to raise the ante year by year for your competitors. Keep moving to the high ground where the margins are, otherwise there will be increasing competition and shrinking margins.

LEADING THE FIELD

Most companies are still not good at achieving real competitive leadership, despite the obvious advantages in doing so. This may be because, in the past, too much emphasis has been placed on IP protection, but IP protection is a scarce resource in the OTC environment, so the main advantage is the brightness of ideas and the speed of implementation.

Best practice in this area is seen in companies that have small teams of experts to run the project on a day-to-day basis, teams that include experienced personnel from both the technical *and* marketing sides of the business. Close work by these two functions is essential. The marketers will ensure that product claims and the USP are appealing to the OTC customer, while technical experts can advise on what

will be required to support such claims and, if they are not supportable then they can suggest alternative claims.

A small, expert team should be able clearly and quickly to define the RoI, time to market, any development costs (eg trials to support claims) and the cost of goods. When building the team, challenge and question the need for each person in the team and each piece of work being carried out to make sure that everything contributes to the bottom line profitability. The key words are: small and relevant. The team should be only large enough to drive the project through its timeline, and sufficiently relevant that no unnecessary resources are being wasted on the project or, worse, slowing it down.

Wherever possible, run work in parallel to shorten the time to market. Ensure sufficient resources (time and money) to keep the project running smoothly and as quickly as possible against a true and accurate timeline, with real and measurable milestones. Speed to market is crucial — RoI is zero until the product is actually in the market and being sold. Every day that the product is off the shelf loses sales that can never be recovered, no matter how long the product lifetime. Each day the product remains in development or internal negotiation is a day that brings the competition one day closer.

Lastly, but perhaps most importantly, the team needs to be empowered, but with the direct endorsement from the Board. The Board must have full buy-in to the OTC strategy and support its objectives in order to avoid a kind of schizophrenic relationship between OTC and prescription-only sides of the business, which can lead to objectives and decisions being made that are inconsistent with the best focus of an OTC strategy.

The company's OTC activity must be seen as a clear strategic decision from senior management. It should be kept financially separate from the prescription-

only side of the business, but nonetheless technically integrated to ensure that opportunities for synergy are used to best advantage, providing benefit to both sides of the business. OTC work should not be seen as a threat or risk to the company's prescription only work, and nor should it be allowed to compromise that activity. In portfolio terms, an OTC product might be viewed as a 'cash cow' that can be used to generate revenue, which can be invested in the 'stars' and 'question marks' in the development pipeline. In addition, the OTC activity can enhance the position of prescription medicines in a number of ways; for example, the ability to advertise an OTC medicine can indirectly support a prescription only medicine with the same brand.

FRANCHISES

Consider new franchise opportunities and the opportunities to build on existing ones. One advantage of this option is that advertising regulations are starting to show signs of becoming relaxed (although in some countries, such as the UK, they are still extremely restrictive).

There are a number of factors to consider when making franchise decisions: the prospect of innovation, interest in a particular therapeutic area, sociological need; but ultimately the factor that overrides all others is the need for a good RoI. Seek advice from the MCA about which areas they are keen to support and get their guidance on your proposed priorities. For new franchises, refer to MLX 279: (<http://www.mca.gov.uk/inforesources/publications/mlxpub.htm>) for guidance on areas where opportunities exist, but do bear in mind that, while your product may offer an improved solution with significant benefits, if you cannot communicate those benefits to consumers either through advertising or some other means, your investment is unlikely to produce the necessary returns.

Existing franchises to consider include:

- better, safer analgesics and migraine treatments
- treatments for the upper GI tract such as proton pump inhibitors and prescription dose histamine 2 receptor antagonists (H2RAs)
- flu treatments such as anti-virals
- allergy treatments.

GOVERNMENT SUPPORT

The UK's National Health Service has pledged clear support for over the counter medicines and there is open government support in many countries, especially in the EU, for generic solutions. Generic and OTC medicines are recognised by both consumers and governments as offering a wider choice and for governments the added benefit of shifting the cost of treatment from the health service to the individual is clear.

The MCA has re-launched its reclassification regulations, shortening the assessment period and eliminating the restrictive fixed application windows. In addition they are openly receptive to pre-submission meetings with companies to try to help speed up the assessment process.

CONCLUSIONS

The definition and management of the project critical timeline is crucial. It is very easy to miss deadlines and delay the project unnecessarily. Be aware of all stages, coordinate activity carefully and remember that the critical date is the date of the first sales invoice.

Integration of technical and marketing expertise is crucial. The strap line or product claims need to be both technically accurate *and* form a USP that appeals to the consumer.

Switches can and have been successfully sponsored by third parties before patent expiry without infringing IP on both sides of the Atlantic.

The market is more complex and rapidly changing than it has ever been. There are more major innovative POM to P switches than ever before and if you do not choose to do them, your competitors

will. By not driving this inevitable process and taking control, originators are effectively handing over long-term opportunities and control of this part of the market to the competition.

