10 ways to avoid delays in the launch of your product

A practical guide by John Russell

The launch of a new brand is a very special and infrequent event. This is something of a paradox, as one of the most important projects you will probably ever manage is the one you rarely have previous experience of and seldom get to repeat!

If you look at the CVs of marketers you will find that most, at best, have been lucky enough to have presided over one launch as a product manager. Small wonder then that the pre-launch and peri-launch periods are among the most stressful and challenging any product manager will face in their professional life. The reasons for this launch period angst are perfectly valid, as you only launch a brand once and the results of your efforts will have far reaching effects both for your company and your future career. Much time is spent ensuring nothing is forgotten and no details have been overlooked. This is, of course, a vital discipline – everyone wants to be remembered as the marketer who got it right.

This guide is designed to assist the marketer responsible for project planning the launch of their new brand and aims to cover both traditional issues and newer ground.
1. ESTABLISH YOUR PLANNING PROCESS

One advantage of the lengthy regulatory processes involved in brand launch is that you know it is coming for quite some time in advance, which helps you to plan this crucial event properly. If you start with the best estimate launch date and work backwards from it you are already working toward having all the elements in place where the time comes and are least likely to be flustered by unforeseen issues dropping into your lap at short notice. It is worth bearing in mind that regulatory processes can sometimes work more rapidly than expected, say if another product drops out of the process yours might proceed more quickly. Such good news would be very short lived if you were not geared up to take advantage of this. Gantt charts are recommended as a useful tool to help you track progress against objectives and they can easily be updated too. They should be stored on a shared access drive so that version control is not an issue and should probably be in a simple software package, such as Microsoft Excel so that no special additional software is required to view them.

2. GATHER THE TEAM THAT WILL HELP YOU LAUNCH YOUR PRODUCT

A really successful launch has a multidisciplinary team at its heart. Most launches have a team comprising of people from the following business areas:

• Marketing – you and your colleagues are here to manage the product and all components of the launch. Be the brand champion. If you do not believe in the brand and its launch plan, who will?

• Global Marketing – will be critical to keep updated of changes to core materials, as well as any issues you encounter. They can be an invaluable source of advice and help when difficulties arise and often know who to approach to overcome internal issues

• Market research – will work with you to develop
  • market insight to help steer campaign development
  • evidence on which to base your customer targeting and segmentation

• Sales – will work with you to develop
  • buy-in to the brand plan
  • sales targets and incentive schemes

• Medical – will work with you to ensure
  • your product claims are substantiated by the data you have
  • your materials are balanced and your campaign and activities fulfil all regulatory requirements

• Regulatory affairs – will monitor the regulatory process to ensure
  • information provided by the regulatory authorities to global regulatory affairs reaches the team quickly
  • changes to SmPC are communicated to you for onward transmission
  • campaign pre-vesting requirements of the MHRA and their timelines are understood by the team

• Training – will work with you and corporate training to
  • develop materials designed to ensure your sales representatives know about the therapeutic area and your brand plus its competitors
  • develop distance learning and training meetings to support the learning process

• Supply and Logistics – will
  • balance your demand requirements for finished packs with their supply capability and timelines
  • evaluate what can be shipped to your warehouse and when
  • select what can be shipped from your warehouse into wholesale trade and when

• Managed Entry – their responsibility is to
  • develop a more receptive marketplace
  • develop KOL advocacy for your brand, both to ensure a positive press launch and launch meetings and to enable issues and crisis management to be dealt with effectively should they arise

• Health Technology Assessment – will work with you to
  • map the HTA timelines and requirements for your brand
  • advise on early or late HTA submission, based on the clinical development plan for the brand and its likely impact on the range of licensed indications

Be the brand champion. If you do not believe in the brand and its launch plan, who will?

Marketing must work closely with multidisciplinary teams, provide timescales and warn of requirement changes

3. HOLD REGULAR LAUNCH TEAM MULTIDISCIPLINARY MEETINGS

The internal team shown above is a large and skilled one. Pre-launch, it is the responsibility of marketing to work very closely with this team and keep them informed of any changes to timescales and requirements. Regular meetings are suggested, as are well written minutes with clear actions and timelines. As this is a separate task in itself, it may be worth asking your PA to manage the meetings process and this may be viewed as an excellent developmental opportunity. In this role they should also attend the meeting, take minutes and be responsible for circulating them. It will be important to assess the agenda for each meeting to ensure you have a required list of attendees, as well as an optional one, or to have a section of the meeting to update everyone on actions and progress to date using the Gantt chart, followed by a session with specific agenda items that a core group attends.

The external team, comprising the agencies working on the brand also need to be brought together for regular update meetings. In some instances these should be with the internal multidisciplinary team, as this will provide everyone with a sense of the scale of the task and the resources available to tackle it.
4. ASSESS THE MARKETING TEAM WORKLOAD AND RESOURCE ACCORDINGLY

The pre-launch and peri-launch periods are times when brand teams are stretched to the limit in terms of their workload and the number of issues they need to juggle to ensure success. A number of potential solutions to this can be considered, including:

• secondment from the fieldforce of a representative or sales manager who can work on marketing assistant type roles, such as approval of campaign items, etc
• secondment from another marketing team, backfilling with a fieldforce secondee enabling a more skilled individual to be deployed into the team, thereby increasing the range of tasks that can be tackled by them
• contracting interim resource or specialist brand launch consultants with a track record of successfully launching products and dealing with specific issues that may delay or de-rail the launch if not handled correctly, such as MHRA campaign pre-vetting or price application

Each above solution has its merits and is best suited to different situations. The specialist brand launch consultant option is the most flexible and offers the widest range of potential work types that can be tackled. Although it is likely to be the most costly solution, this can easily be balanced against the additional value that experienced external resource can bring at a very busy and challenging time and can result in quicker return on investment if delay in brand launch is prevented. Other business areas can also benefit from this approach as they do not lose key people from their teams to supplement the brand launch team.

5. UNDERSTAND YOUR BRAND SMPC, CLAIMS AND PROPOSED CAMPAIGN

Gone are the days when the labelling, claims and campaign were UK-specific and assembled by the UK brand team. We are now in the era of the globally researched campaign, the claims within which are consistent with European-wide labelling. However, global campaigns will usually need some degree of claims modification in order to comply with UK specific regulations. Market research changes should be considered, so that the merits of alternative solutions may be compared. The earlier that the UK brand team has sight of the global materials, the earlier they will be in a position to review them against the brand SmPC and the claims that can be made from it. UK marketers and their agencies will then be able to work with global marketing to ensure that the brand campaign meets their requirements as well as those of the UK regulatory bodies.

6. THOROUGHLY UNDERSTAND THE REQUIREMENTS OF MHRA PRE-VETTING

The new version of MHRA pre-vetting of promotional campaigns for new products has been in existence since November 2005 and is now a requirement for all new chemical entities, as well as for some other types of launch.

All items that form part of the launch campaign must be submitted and cannot be used with customers until written approval has been received. Bear in mind that if the approval process demonstrates to the MHRA that the brand team is able to effectively produce compliant materials, then the requirement to submit all materials is suspended. If, on the other hand, the materials supplied to the MHRA do not meet the required standard consistently, then it is more likely that the MHRA will wish to continue to see materials for up to six months post-launch. Although the MHRA has demonstrated that it is very efficient when provided with materials that meet its required standards this still adds additional time to the approval process, so it is in the interests of the brand team to prove compliance as quickly as possible.

Deciding on the order in which items are submitted, how many items should be submitted at any one time and whether the look and feel of the campaign is consistent with SmPC labelling are among the numerous issues to be considered to ensure a good outcome. Specialist brand launch consultants with experience of successfully managing the MHRA pre-vetting process can be very useful at this time, especially as this process usually happens at the very peak of pre-launch activity, when the brand team are already stretched will a multitude of other tasks.
7. UNDERSTAND YOUR SUPPLY CHAIN
One of the brands I launched crossed the Atlantic twice in its manufacturing and packaging process prior to being shipped by refrigerated lorry from Europe to the UK. The logistics and the lead times were very challenging, so we were careful to forecast continually so as not to run out of stock. Thankfully, such supply chain issues are uncommon, but it does illustrate the importance of understanding the journey that the brand may need to take before it arrives in the UK. With supply chain, it is recommended that the issues on the table on page three are reviewed as part of the launch plan.

8. FIX AND APPLY FOR YOUR PRICE EARLY
Many companies now research and set pricing ranges at a corporate level. This means that when it comes to agreeing a UK price for the launch brand the alternatives on offer are often within a comparatively narrow band. The Department of Health is very efficient regarding the approval of a price (depending on the submission being acceptable) once you have an approved license and SmPC. However, if the plan is to launch immediately upon receipt of the license, then it may be necessary to start to apply early for the price. Where a product is entering a crowded class or market, more work may be needed to justify an unusually high price compared with other products in the class and this may also need to be supported by an approved SmPC. Again, consultancies that specialise in brand launch can be of great assistance if the price needs to be available as soon as the license is granted.

Once the price is fixed and approved it can be disseminated to the software houses that supply information to GP computer systems (if it is a primary care product). This must be achieved in a timely fashion, as the research suggests very few GPs hand write prescriptions even for exciting new products!

Tracking the development of advocacy of KOLs can be a challenge around launch, but it is also a launch key performance indicator. The development of the KOllage advocacy management system has been specifically designed to address this need. KOllage, or products like it, should be seriously considered as a critical component of the launch and post-launch plan for a brand, as they can track emerging advocacy or lack of it, which can be so critical to the success of a newly launched brand.

9. DO NOT LOSE CUSTOMER FOCUS – LEVERAGE MANAGED ENTRY AND HTA
Although many of the issues covered so far predominantly deal with avoiding a delay in making the product available to the marketplace, it is equally important to ensure the marketplace is ready to receive your new brand.

Ensuring that market access activities are entrenched well before launch and that health technology assessment information is being gathered and formed into a cohesive case is critical to near-term success in brand launch. Key opinion leaders (KOLs) must be profiled and developed so that launch plans can be seamlessly implemented. This is especially important around such activities as launch press conferences, where timescales and venues can change at the last minute. In these circumstances, a group of KOLs that have bought into the development and implementation of the launch process are more likely to be flexible with changing arrangements.

Marketers who always ask themselves “What am I missing?” are far more likely to miss nothing

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A practical guide by John Russell
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