WHITE PAPER

WEBINAR - LAUNCH ACTIVITIES

Q & A'S FROM THE WEBINAR: «HOW TO ACCELERATE YOUR MEDICINAL PRODUCT LAUNCH IN EUROPE ?»

BlueReg
PHARMA CONSULTING

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Introduction

In this White Paper, we will be sharing all the Q & A's from our previous Webinar on 'How to accelerate your medicinal product launch in Europe'. We have divided the Q & A's into 4 main topics.

I Topic: Project Management

Question 1:

We are currently setting up our launch governance, our CEO is keen for the supply chain to take the lead. Do you have any thoughts on this?

Nadia Boehringer:

'So, the supply chain like any other department can take the lead for the launch in fact. The goal is to on-board the appropriate stakeholders and as explained that should involve regulatory, marketing, quality and so on. We really need to be sure that all the local requirements are fulfilled on time to be compliant to the planning.

As an example, let's say that the supply chain takes the lead and your company may like to print the packaging components at risk (I mean before EC decision). When I mention packaging components I speak about the outer and immediate packaging and the patient information leaflet. The inner component can be printed first, as soon as the process linguistic review is completed for the concerned country. But for the outer packaging, it will be linked to the blue box availability, is there a need to validate the blue box at local level, how long it takes to obtain the national code if any, etc that will play a part in determining when the packaging can be finalised.

Regarding the patient leaflet, the formal approval date, information that you get when the EC decision will be issued, will also have to be printed in the patient leaflet (at least month and year). Thus, just with this example, which mainly concerns the manufacture part, without an input from the local team, it will be difficult for the supply chain to do everything by themselves. And I did not address other activities to handle simultaneously. So, any department can lead the launch sequence, but it is essential this is in very close collaboration to the other departments whatever can happen.'

Question 2:

In term of launch sequences, if a company would like to launch in all the EU countries at the same time, how you will manage that? How should you prioritise one market in comparison to another?

Nadia Boehringer:

'It comes back to my earlier slides about planning and anticipation. Once the initial launch plan is defined, it is important to carefully consider the resources you have to dedicate to the launch at the global and country level. Moreover, based on experience, and even if marketing expects to accelerate the launch in some key countries, the country requirements tend to dictate the launch sequences and timings at the end.

So once you have compiled all requirements linked to the specificities of your product, you can start to assess if your priority countries will match with what you can really do. Your final plan will be a mixture between your company expectations and the real life.

Finally, let's say you conduct several launches in parallel, that will be a very intense period for your team, so do not underestimate the time & effort required. You may need to accelerate even further your recruitment or extend the support provided by your partners.'

Question 3:

We are mainly based in the US with only one affiliate located in Europe. Our product is at the beginning of the registration through the centralised procedure and we are planning to launch in the G5. Is it already too late to initiate the launch plans?

Nadia Boehringer:

'No, not at all, but of course the time is disappearing quickly so you should not lose more time. As a start, I would initiate the global launch team internally so as to structure the definite priorities for your launch and agree on the R&R of each team members. That should be the very first step.'

Question 4:

We have a very enthusiastic US marketing department who are keen to start promoting our product as soon as possible. How do you manage the challenge of US based marketing teams and navigating the complexities of the European market?

Nadia Boehringer:

'They are indeed different situations to address, before CHMP opinion, between CHMP opinion and EC decision, and after EC decision. In addition, depending of the type of events, which countries are concerned and the kind of materials you plan to use different responses can occur. For example, a symposium where a discussion around clinical results is possible in one country, maybe forbidden in another one until the EU decision is issued. So, I cannot respond with what is possible or not possible, it's really dependant on the different local regulations. BlueReg are supporting this challenge on a daily basis and can provide you more support if required.'

Question 5:

Nadia, in your presentation, you mentioned planning is key and this should be undertaken in advance. In your experience, when should this planning be initiated in the process?

Nadia Boehringer:

'The best would be to start planification when you initiate the strategy for the registration in Europe. All the steps are linked together is important when you are considering file submission to plan for approval of your product and how you will market and launch across Europe.'

Question 6:

I would be interested in hearing of any common pitfalls you commonly see with regards to the launch planning?

Nadia Boehringer:

'I come back to my previous responses... We commonly see companies starting too late in their planning, and even continue to adjust their plan at EC decision. Some start-ups may also consider that they can handle all the local activities at the global level, just by themselves, using existing employees. But there is a real underestimation of the local complexities including language barrier, knowledge of local rules, evolution of local legislation etc..;

Finally, launch is a collaborative planning approach with different stakeholders and we regularly observe a launch plan based on a standalone marketing strategy, which can cause issues further down the line when materials, for example, are not allowed to be used at a national level'.

II Topic: Launch

Question 7:

My supply chain have no experience of serialisation, when do you recommend we initiate the planning for this?

Anne-Valérie Faucher:

'Serialisation impact different departments and sites. At the minimum the manufacturing site, the supply chain team, the regulatory affairs team and the IT team. The planning must be initiated as early as possible with the supply chain and manufacturing site, and in parallel to that, the Marketing Authorisation Holder must be registered at the European and at local level (in country of interest). The registration at European level takes around 2 months and at local level between 2 to 6 months and when the registration is completed the manufacturing site can start some pilot tests to be ready on time.'

Question 8:

in terms of local databases, do you recommend inclusion in all databases at a local level?

Anne-Valérie Faucher:

'When the databases are optional, it's a company decision to register the product in these databases. Decisions are generally aligned to the commercial strategy. On one hand you have to pay for these optional databases and the information must be kept up to date but on the other hand it can give to your product visibility for Health care professionals. The use of databases should be evaluated on national level where these are not mandatory in order to assess the importance of registered in these.'

Question 9:

For serialisation, in Italy you mention the bollino. Can you expand on this, is it a code?

Anne-Valérie Faucher:

'The Italian bollino is an optical sticker carrying the product name, the strength, the pharmaceutical form, and the concerned local code. The sticker is then stuck to the packaging. To obtain the bollino, some local steps must be completed in the Italian dedicated platform in local language. In practice, the manufacturing site which is authorised to undertake the secondary packaging operations is able to add the sticker on the carton. It is very important to make aware your manufacturing site on this specific sticker, nonetheless, sometimes this activity is performed in Italy at a dedicated registered site for adding the bollino.'

Question 10:

For educational materials, do you have any tips for this part of the process as we are about to start local translation of our materials?

Anne-Valérie Faucher:

'Like for the product information translations, the quality of the translation of the educational materials must be very high quality. All the local requirements must be fulfilled (such as the blue hand in the German document). The regulatory affairs team must work on these documents in close collaboration with the medical and pharmacovigilance teams. A global implementation plan can be drafted to be used as a basis for the local implementation plan. All the good manufacturing practices for pharmacovigilance must be followed. The use of educational material is followed closely by the EMA and the national agencies. During a Pharmacovigilance inspection the implementation & follow-up of educational materials can be subject to investigation by inspectors.'

Question 11:

MHRA vetting, you mentioned it is not always required? Can we anticipate it would be required in advance for our product?

Anne-Valérie Faucher:

'Brexit has no impact on advertising materials, all the rules are common for Great Britain and Northern Ireland. In the United Kingdom, advertising materials for certain products may be required to be submitted for assessment by the MHRA prior to issue, this is called the vetting process. There are two, no sorry tree main cases where vetting may be required:

- Newly authorised products subject to additional monitoring and for all new active substances

- Products which are reclassified (OTC switch procedure in other words from "prescription only medicine or POM status" to "pharmacy or P status" medicine)

- When previous advertising for a product did not follow the regulations

The MHRA will inform the Applicant when vetting will be applicable for their product. For example, during a registration procedure, the Applicant will receive an email from the advertising department from the MHRA about the need of vetting for their product.

The period of vetting will normally be 1 to 3 months and would normally not extend for longer than 6 months. This time period may be reduced or extended depending for example on the quality of the advertising submitted.

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Question 12:

You mentioned that for Great Britain, the registration process is different. What about the launch? Does that trigger additional challenges too?

Anne-Valérie Faucher:

’Due to Brexit, the situation is a little bit complex for the moment being in Great Britain. Some guidelines are not available at the MHRA level, such as the serialisation guideline. Thus, if you plan a launch in the coming months or years it is important to check the MHRA website to find any news and useful information linked to your launch. But keep in mind that MHRA is a very pragmatic agency, thus if you plan a launch for example in Q four two o twenty-one, you can discuss with MHRA to find a solution for your own product, maybe you will be allowed to import a Northern Ireland pack as example.’

Question 13:

You never mentioned Switzerland during the presentation, so what about a launch in Switzerland ?

Anne-Valérie Faucher:

‘In fact, even if Switzerland is geographically located in the Europe, Switzerland is not part of any European procedure, and to be able to commercially launch your product in Switzerland, you need to obtain a local Swiss marketing authorisation. The Swiss rules to obtain a marketing authorisation are similar to the European regulations, and if your product has obtained a marketing authorisation through a centralised procedure, your Swiss assessment might be prioritised meaning that the Swiss data file is generally submitted by companies after receiving European approval. Market launch requirements will need to be planned as discussed in the presentation in order to take into account the national Swiss launch requirements.’

III Topic: Shared Packs/Blue Box

Question 14:

If a company decided to use shared packs, must all the launch sequences for all the concerned countries align with the same launch date?

Anne-Valérie Faucher:

‘As I said, the option to use a shared pack is really a company decision. But in all the cases (shared pack or stand-alone pack), all country requirements must be followed. To give you a more concrete example, a shared pack can be used for the Baltics countries, and you can launch first in Estonia and potentially one or two months later, or even later in Latvia and / or Lithuania. There is no requirements to launch in the tree concerned countries in parallel.’

Question 15:

If an exemption has been obtained regarding the local languages, is this exemption also applicable to the blue box?

Anne-Valérie Faucher:

‘Very good question. Unfortunately, the answer is No. The exemption is only applicable to the outer packaging, the blue box must be printed in the local language, unfortunately, there is no exemption for the Blue box. If you want to rationalise further the packs, you can try to obtain the use of stickers for the blue box instead of direct printing, depending on your product / market size, the competent authority may authorise this process.’

IV Topic: Orphan drug/EAP/PIP

Question 16:

We have an orphan drug in development, is there anything special we need to consider for launch?

Nadia Boehringer:

'Well, in Europe, an orphan drug requires registration through the centralised procedure. As presented in the webinar, all the European and local requirements must be fulfilled to be able to launch your product in the concerned country. Most of the time , for such a launch, the applicant wants to set up a specific early access program for key markets. It's exactly the kind of product for which you need to think about several strategies, starting with EAP, then when EC decision is issued, start the transition phase up to the real commercial launch.

You may also need to consider specific distribution for orphan depending of the nature of your products. In any case, as I said, I recommend to start working on the launch sequence as soon as possible. Depending on the registration process (accelerated or classical pathway), this can have an impact on your strategy to market the drug.'

Question 17:

Can you outline how you would plan in a bit more detail the transition period? What should my team consider or should we maintain EAP whilst we launch in other countries?

Nadia Boehringer:

'In terms of process, if your company is considering an early access program this must be part of the launch sequence as I just said. Depending upon the country regulations, and the product, and where you are in the registration procedure, the EAP can be set-up in some markets. Here again the country requirements are not the same and are country dependant. An EAP can be set-up in one country, free of charge on a named patient basis local regulation, whereas in the second country, it can be considered as a cohort early access program which will be covered by health insurance. The transition to a commercial launch will be determined by the local law in terms of timing and requirements. In each country launch, using EAP first, should be carefully studied in terms of constraints and future impacts for your market.'

Question 18:

Is there anything special concerning paediatric requirements that we need to consider for our launch?

Nadia Boehringer:

'The paediatric requirements have no impact on the launch. The paediatric requirements are the requirements which must be met to obtain a marketing authorisation. Depending on your product, a paediatric indication can be approved, but this has no impact on your launch. The launch timings of your presentations is often a decision taken in conjunction with marketing and the patient need.'

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