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OTC MARKET EXPANSION CHECKLIST

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The OTC Market Expansion Business Case

The over the counter (OTC) medicines market presents a good opportunity for business expansion and competitive edge in the EU. As the market for self-medication continues to evolve, and changes in regulations mean there are more medicines available without a prescription, now is the time to look at expanding your OTC products into new markets. The potential for growth is very good; having delivered year on year growth since 2012, the value of OTC sales hit £2.74 billion at year ending February 2015 in Great Britain alone, and this pattern is being repeated across Europe. However, a company looking to expand in this area will face challenges and identifying the best opportunities is not always easy.

All Aboard

As with any challenge, you can't go it alone! There are many different areas and contributing factors that need to be reviewed to ensure success and it is extremely important you get the right groups involved. A key aspect of your expansion project will be understanding where and when outsourcing elements of the project will increase efficiency and reduce risk.

Tick	Support	Key Questions
☐	**Commercial support**	Is there a need or demand for your medicinal product in the new countries of interest? Is the marketplace saturated? Are your product costs, pack types and branding appropriate?
☐	**Manufacturing site support**	Does your current manufacturing site have the capacity and equipment to increase production volumes and support further development activities? Are there sufficient regulatory compliance personnel to support you in a timely manner? Are there any key activities that could impact your launch plans e.g. site audits?
☐	**Quality support**	Are the quality systems and resource in place to deal with higher volumes of production and release? Can the systems and processes cope with multiple market release and pack types?
☐	**Technical/R&D support**	Does the technical team have capacity to support in a timely manner? Do you need to look for external expertise to support further development activities e.g. analytical method development? Can the appropriate studies be conducted within your required timeframes?

Gaining regulatory approval in new markets

When these questions are addressed, and all answers lead to successful expansion of your OTC product, it is imperative that good regulatory support is put in place. Regulatory is the crucial link between your company, your products and regulatory authorities. Your regulatory team is therefore key to registration success which is vital to realise the expansion plans.

A good regulatory team will get your OTC product registered. An excellent regulatory team will also do this, however, in addition they will advise you of the most effective way to enable business growth in-line with regulatory requirements and will think past the registration; facilitating the future development and success of your product. Do not compromise on the quality of your regulatory support. OTC product expansion brings its own unique challenges and experience in this area cannot be underestimated.

Tick	Regulatory Process	Key Questions
☐	**Regulatory support**	Does your in-house regulatory team have OTC expansion expertise and capacity? Does your chosen external regulatory provider provide key added value services such as eCTD publishing and specialist translation? Can your regulatory team provide market specific intelligence and local partners for submission support? Do you have support to investigate any regulatory barriers for your product in the market and find solutions? Are the importance of your OTC product claims understood?
☐	**Conduct Gap Analysis of Dossier**	Is the dossier in standard CTD format? Are there sections missing from the current dossier? What changes are needed to meet current regulations?
☐	**Discuss key findings with site and R&D**	Does site need to be educated on the current regulatory requirements? Have the required development activities already been conducted but are not yet included in the dossier? Is there value in regulatory doing a physical search of site document archives also? When will the development activities be completed?
☐	**Regulatory strategy**	Which is the most effective way to meet the regulatory requirements in order to enable business growth? What are the estimated timelines for licence approval? Are there any market specific requirements outside of the core dossier? When should communications with authorities be made?

☐	**Dossier authoring and review**	Is the dossier structured to allow ease of lifecycle maintenance? Does the dossier address current guidance? Are expert signatures and supporting documents in place as required?
☐	**Remediation activities**	Are remediation activities to your current licence(s) required? Do these need to take place before you apply for new licences or in parallel? Does your regulatory team have remediation experience?
☐	**Submission to the Regulatory Authority**	Is the dossier in valid eCTD format? What is the correct submission channel for each market? Are any market specific submission activities supported appropriately?
☐	**Assessment procedure**	Is information available to address any agency questions in a timely manner? Should you talk to the assessor or Regulatory Authority directly to clarify any issues? Are there market specific aspects of the assessment procedure that need support?
☐	**Approval**	Success! Regulatory approval has been granted by the Regulatory Authority and you can now reap the rewards of product expansion.

Ongoing maintenance support

Remember, successful registration of your OTC product is just the beginning. You will need hard-working regulatory support to provide on-going protection for your investment, advising on all aspects of the scientific disciplines required for the maintenance and maximisation of your marketing authorisation, including renewals and variations.