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1.0 INTRODUCTION

The EphMRA Learning & Development Committee (formerly Primary Research Methods and Training) includes amongst its activities the development of research methods and training for EphMRA members. This particular guide has been designed to cover the Product Life Cycle. It is not meant to be a fully comprehensive manual, but a general guide.

This document (formerly called Strategic Guide to Identifying and Researching the Influencers on Pharmaceutical Prescription Products) was originally researched and compiled in 1996 by two members of the Committee, plus representatives from two agencies.

Included in this document is a chart which is designed to be a practical guide to illustrate the main groups of influencers on prescribing a pharmaceutical product. It also highlights the types of market research projects that could be conducted during the life cycle of a prescription pharmaceutical product. We do not suggest that every influencer and market research approach needs to be contacted/conducted for every situation.

The wall chart only shows influencers and market research up to one-year post launch; however, it should be assumed that similar post launch issues apply throughout the full product life cycle, although to a greater or lesser extent. Soon after launch, close monitoring is called for. Later in the product’s life cycle the research programme will depend on, for example, whether the product is to be relaunched, repositioned etc.

This document provides more information and attempts to clarify some of the issues involved. Within the document a summary table shows what type of market research could be conducted using the different groups of influencers as a sample at each stage in the product’s life cycle.
2.0 SUMMARY CHARTS

2.1 IDENTIFYING THE INFLUENCERS ON PRESCRIBING A PHARMACEUTICAL PRODUCT

RESEARCH THROUGH THE PRODUCT LIFE CYCLE

TIME FRAME

Pre-Development Phases | II | IIIa | Submission of file | IIIb | Launch | +6 months | Post Launch | IV | +1 year | In Line

- Regulatory/Authorities
- Payors/Purchasers e.g. MCO’s, Formularies
- Opinion Leaders
- Specialists
- Primary Care Physicians
- Pharmacists - Hospital
- Pharmacists - Retail
- Patients
- Nurses
- Carers/Partners

N.B. Arrows indicate stage at which influencer is important. The thickness of the arrow indicates relative importance.
2.2 RESEARCHING THE INFLUENCERS ON PRESCRIBING A PHARMACEUTICAL PRODUCT

Research required

Research required depending on therapy area

Pre-Development Phases

II

IIa Submission of file

IIb

Launch

+6 mnths Post Launch

IV

+1 yr In Line

Market understanding and patient flow

Trademark (brand name) research

Customer needs, behaviour and attitudes

Packaging & Handling

Product profile/concept

Primary

Secondary

Product positioning/branding

Pricing research

Market access

Communication messages

Detail aid/ad testing

Salesforce objectives

Brand performance

Life cycle management

Market forecasting

Competitive analysis

Ongoing

Strategic

Tactical

Ongoing
## 2.3 SUMMARY OF SAMPLE GROUPS USED IN A PHARMACEUTICAL MARKET RESEARCH PROGRAMME

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**STRATEGIC**

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**TACTICAL**
3.0 DESCRIPTION OF THE INFLUENCERS

Introduction

The descriptions highlighted below illustrate the main types of influencers on prescribing a pharmaceutical product.

Each group of influencers and the relative weight of their influences will vary according to several factors. For example, the issues will vary depending on whether it is a global, international or national product and whether it is a strategic or tactical issue. It also depends on the type of registration (centralised, MRP, country). The product itself will also have an impact on the influencers, for example, if it is a breakthrough product for AIDS or cancer, or an established type of product such as an NSAID. For the purposes of this document the emphasis will be on strategic market research.

Role/Involvement of Influencers

Regulatory Authorities (including pricing approval)
- Includes early discussions with authorities regarding approval requirements (e.g. FDA, EMEA, national authorities).
- Post launch may be involved in approval of line extensions or new indications.
- Post launch involvement in negotiations regarding adverse reactions (such as the UK contraceptive pill scare).
- Discussions regarding potential blacklisting.
- Discussions regarding the grade of innovation (e.g. in Italy and France)
- A further consideration of the influence of Health Economists.

Payers/Purchasers
- This includes the influence of formulary committees, management organisations (such as MCO’s in the USA) and pharmacy benefit managers (PBM) who are involved in the negotiation and buying of drugs.
- Also the influence of independent medical advisors, e.g. national committees for developing guidelines (DRGs, NICE) medical associations (physician societies) to advise on prescribing.
Opinion Leaders

- Are defined by their level of influence. They may be divided by Key Opinion Leaders (KOL, top level, global or national, more focused on publications and conferences) or secondary Opinion Leaders (e.g. head of hospital department, medical consultants, more focused on treatment decisions).
- May have greater influence or continuing influence, depending on the type of product (i.e. whether it is a new type of compound) or type of marketing approach (top down).
- May need to consider the influence of international bodies, for example the WHO, or local bodies, e.g. Diabetic, Heart Associations.
- Clinical trialists could also be included as a sub-group and these may be important initially for endorsement.

Specialists

- Specialists may vary by country.
- These can be office, hospital based (e.g. U.K.) or both (e.g. Spain).
- The extent of pre and post-launch involvement will be dependent on the product type, for example, if the product is hospital initiated there will be heavy pre-launch involvement and continuing involvement, if the product is primary care orientated their influence will be limited especially in the post-launch phase.
- Involvement of specialists will also depend on their influence on prescription decisions for other physicians (formularies, treatment protocols).

Primary Care Physician

- The extent of pre and post-launch involvement will again be dependent on product type. If the product is primary care orientated their influences will be much greater in both the pre and post-launch phase.

Hospital Pharmacist

- These are key influencers in getting the product onto the hospital formulary.
- Strong influence remains only if the product’s position on the formulary is likely to be reviewable. Hospital pharmacists are often represented on Drugs and Therapeutic Committees within hospitals.
Retail Pharmacist
- Increasingly influential in generic substitution although the level of influence depends on the country.
- May be more important for tactical launches, if the product needs co-payment or is closer to the OTC market.

Patients
- Influence of the patient is dependent on the product itself (disease or lifestyle drug), local regulations on DTC (Direct to consumer's advertisement) and the degree of patient organisation (e.g. HIV patient associations).
- Greater influence in areas where self-medication or OTC equivalent, and where consumer/lay press is influential, e.g. migraine, pain, soft tissue injuries and GI disturbances.
- Patient influence is increasing due to more informed patients and increasing financial burden for patients.

Nurses
- Influence is varied ranging from heavy influence in high dependency or chronic illnesses such as asthma, oncology/palliative care or kidney dialysis, to minimal involvement in conditions such as soft tissue injuries and hypertension.
- Influence is also varied depending on the different status of nurses in care in different countries (e.g. higher in the U.K., France, the U.S, lower in Germany).

Carers/Partners
- Carers can be a whole range of persons from partners, relatives or professional carers.
- The influence is varied on condition with heavy influence in high dependency of patient (e.g. mental health areas Alzheimer, Parkinson).
- Partners can influence where quality of life is an issue, such as diabetes, sexual dysfunction or obesity.
4.0 OUTLINE OF MARKET RESEARCH METHODOLOGIES

The precise nature of the research projects will depend upon the product itself, the therapeutic class it will be operating in, the marketing objectives and the resources allocated.

Within these guidelines it is assumed that a variety of sources of secondary data should be referred to both initially and continually throughout the market research programme. Competitive intelligence analysis should be conducted in parallel to the primary market research programme as it underpins and informs market research and the evolving brand strategy. It is included as a new chapter in this version to provide more detail on this critical activity.

Likewise for market forecasting which is now included since it is intrinsically linked to the primary market research programme to ensure the results feed into disease and brand forecasting. Life cycle management will evolve with the product and the market research approaches outlined will feed into this process.

The majority of the primary market research programme will be conducted with the sample of the largest potential volume prescribers of the product. This will vary whether it is a hospital or a primary care product.

Patient research is likely to form a major part of a research programme where the patient has a large influence on their treatment, such as diabetes, or where self-medication is important, such as migraine.

Regulatory authorities have been excluded from this section, as it is almost impossible to conduct primary research with this group of influencers.

Device research (e.g. for asthma drugs), was not fully covered in the previous editions, but is within the scope of this document. The development and improvement of the method of delivery is becoming increasingly important in some areas, e.g. handling research for diabetic pens, safety features of pre-filled syringes or new drug delivery systems e.g. in pain management.

Additionally in this edition chapters on branding have been expanded and a new chapter on brand launch performance tracking included. This is in recognition of the important role market research plays in tracking and diagnosing launch performance to ensure any barriers are overcome and opportunities maximised.

The digital changes that have impacted the pharmaceutical sector have resulted in opportunities for market research to gather information and insights in this area as well as impacting on the communication and sales channel approaches as outlined in those new sections.

In recognition to the changes in the pricing and reimbursement environment a section on market access has been added to outline the key considerations for market research in this area.
At each stage of the product lifecycle the brand faces different challenges and there are different business objectives, questions and information requirements. To help address these needs market research is often required.

For each area or research across the product lifecycle typical business objectives, questions and market research approaches are included. These may not be relevant to all companies/products and indeed are not intended as an exhaustive list rather as a prompt to aid thinking around what are the right business questions to ask and what are the considerations when selecting the most appropriate market research methodologies. There will be common ground but no two brand journeys will be identical, so the market research plans will be similar but different too!

None of the activities described in each section are undertaken in isolation of each other. Therefore there may be some minor overlap of activities in the explanations. Furthermore, it must be remembered that other departments will be seeking similar information e.g. Health Economics and Outcomes Research will be reviewing epidemiology data, Pricing and Market Access will be compiling competitor prices and other external factors and therefore information sharing is essential.

4.1 MARKET UNDERSTANDING (MARKET SIZE AND POTENTIAL, MARKET SEGMENTATION AND PATIENT FLOW)

Throughout the product lifecycle, up-to-date market understanding is the critical foundation for the disease area, brand and finally the franchise strategies. In the early clinical development phases it is likely to involve broad disease market understanding activities which then evolve in depth and focus as the brand moves through the later stages of development. In these later stages the activities become more focused on providing up-to-date understanding of key market issues and the competitive landscape that could impact the type and size of the opportunity of the brand.

Overall Objectives

Examples of market understanding objectives are:
- Early development phases: To identify disease area targets and evaluate the commercial opportunity of each target.
- Pre-launch: To optimise brand performance through identifying key market issues, customer needs and competitor activities.
Questions/Issues

The business questions/issues that are typically addressed are:

- **Disease area**
  - How is the disease defined, classified and diagnosed?
  - What are the main symptoms?

- **Market size, structure and dynamics:**
  - What is the incidence/prevalence and morbidity/mortality of the area, diagnoses, and treatment rates?
  - What is the size of the market in terms of patient volume, monetary value?
  - What are the dynamics of the market?
  - What is the treatment profile (drug/non drugs and mono/multiple therapies)?
  - Are there any market trends?
  - Are there any barriers to entry?

- **Market needs**
  - What are the met/unmet medical needs?
  - What is the level of satisfaction/dissatisfaction with current treatments?

- **Market segmentation**
  - What are the disease and patient segments and how will they be identified in clinical practice?
  - What are the patient types and characteristics?
  - What is the size of the segments?

- **Competitors in development**
  - How similar are the competing drug profiles?
  - Who is the current and future competition?
  - How does a new compound fit in the marketplace?
  - Who are the leading companies in this area?
Approach

The starting point of research will be to initiate a review of the readily available secondary data sources. These are likely to include publications, online databases, market data and forecasts as well as the Internet (general searches of medical sites and company websites). A challenge when using secondary sources is how best to validate different sources and to make them compatible – combining data from a wide breadth of sources can help.

The secondary data sources can be used in the development of exploratory stage strategies and especially when prompt assessments of unmet medical needs and compounds need to be made. This type of study will then need to be reviewed and updated on an on-going basis and the type of secondary databases potentially extended to include disease specific sources and publications plus patient databases.

Some therapeutic areas, products or indeed the research objectives necessitate primary research, e.g. qualitative techniques with opinion leaders and the main volume prescribers or even quantitatively with the main volume prescribers to substantiate and develop secondary findings. Typically at the early stages conducting some small scale (5-6 in-depth qualitative interviews) derived from “expert judgement” e.g. international key opinion leaders should be sufficient to explore attitudes, perceptions and market dynamics. Primary research may also help create links to integrate “in compatible” secondary sources.

Internal expert knowledge within the company is also a great place to start and to assist in linking and interpreting the different information sources.

4.2 CUSTOMER NEEDS, BEHAVIOUR AND ATTITUDES

Overall Objective

To obtain an in-depth understanding of the market dynamics, confirm customer needs and confirm clinical and market segmentation.

Questions/Issues

The key areas and example questions that can be addressed in this research are summarised next.
• **Disease understanding and management**
  - How is the disease perceived by healthcare professionals/patients?
  - What terminology do both potential prescribers and patients use?
  - What is the impact on daily life for patients? And on the healthcare professionals - workload, feelings about management?
  - What are the triggers that drive patients to consult?
  - What is the decision making process for potential prescribers from presentation to treatment initiation?
  - Are there any barriers to consultation, diagnosis or treatment on the part of either health care professionals or patients?
  - What is the patient journey in terms of initial consultation, referral, treatment initiation and on-going management?
  - What are the reasons for and extent of brand switching?

• **Unmet Needs and Ideal Treatment Profile**
  - What are the unmet needs in this disease area?
  - What are the key characteristics of the ideal ‘treatment’ or approach (i.e. in terms of efficacy/tolerability/mode of action/dosing flexibility/etc)?
  - To what extent do existing treatment options meet current and future market needs?

• **What are the reactions to the product profile?**
  - What is the general reaction and views on the attractiveness and credibility of the product profile?
  - What are seen as the relative strengths and weaknesses (vs. existing and future competitors, and vs. unmet market needs)
  - What is the interest in use?
  - Are there any barriers to use/reservations/restrictions?
  - Do health care professionals confirm appropriateness of proposed clinical positioning in identifying patients most likely to benefit?

• **Segmentation**
  **Market (patient needs)**
  - What are the profiles of the different patient types currently presenting in terms of their characteristics (pathology, demographics, symptoms, severity, co-morbidities and treatment history)?
  - Can we define the resulting patient segments in terms of treatment needs, (relative) size and management?
  - What are the appropriate verbal descriptors/labels for the segments?

• **Customer (characteristics based)**
  - Are there any attitudes or behaviours that distinguish physicians that might form the basis of customer segmentation and profiling?
**Approach**

Both qualitative and quantitative approaches can be used to answer the questions, although it tends, primarily, to be the former as it is still in the early explorative stages of the product lifecycle. Obviously the approach taken will vary according to the complexity of the disease area and the number of prescribers.

Often this type of research is the basis for a series of market research activities. To gain a qualitative understanding of customer needs, behaviour and attitudes then consider conducting:

- **Individual depth interviews with:**
  - prescribers/influencers
  - other healthcare professionals
  - patients
  - patient support groups
  - spouses/carers.
- **Group discussions.**
- **Include creative techniques to provide rounded (rational & emotional) perspective of disease and its impact.**

Quantitative MR approaches are required when there is a need to quantify unmet needs or to provide accurate measurement of potential presenting patient population.

**Approaches to consider are:**
- individual interviews
- prospective patient diary
- retrospective record study
- recall of recent patients.

**Options to consider including are:**
- product placement to complement diary
- Conjoint (full profile or CBC) for relative importance of attributes & levels that impact on product choice
- Brand mapping of relative competitor strengths & weaknesses plus differential advantages.
One solution would be to conduct various stages of the research in one project.
1. Individual depth interviews with prescribers and patients.
2. Placement of a one-page diary with prescribers (5-10 to complete).
3. Group discussions with patients and prescribers.
4. Conjoint measurement techniques.

This type of approach will enable a complete overview of the market with a qualitative understanding of customer needs, behaviour and attitudes and some quantitative measures included so that, for example, options for primary positioning of a product can be determined.

The sample size will depend on the therapy area under consideration. However, it is worth bearing in mind that the sample sizes of different prescribers/doctors do not have to be the same and can vary between countries. Secondary analysis will highlight who the prescribers are. At this stage it is important to ensure that all those involved in the treatment of a patient are included (sample sizes will reflect the importance of each) in order to have a complete understanding of the market. Samples of patients/nurses/carers should be considered depending on product orientation.

4.3 TARGET PRODUCT PROFILE/CONCEPT TESTING

During the product lifecycle we are typically dealing with a number of unknowns in terms of product features and performance levels – simply because the product is still in development. There are a number of key business investment decisions (both commercial and clinical) that need to be made throughout the product life cycle and target product profile testing research plays a critical role in supporting these.

Overall Objectives

- **Early development phases:** Identify and develop target product profile options which will help shape clinical plan and business case.
- **Prior to Phase III:** Identify the right patients and the right target profile claims that will direct the design of Phase III to secure commercial value.
- **Pre-launch:** Test product concept to evaluate how Phase III results have impacted the commercial opportunity to inform Go-No-Go decision for launch.
Questions/Issues

Product profile testing helps to inform these commercial and clinical business decisions across three broad areas:

- **Assessment of commercial potential:**
  - What drives product choice?
  - What could be the key drivers for prescription?
  - What is the level of improvement required to generate interest and prescription of the product?
  - How much value will this product generate (financial and reputational)?
  - What is the value of different options/scenarios (e.g. worst, base and best case scenarios)?
  - Where will this value come from (source of business/competitor impact)?

- **Identification of clinical performance requirements:**
  - Who is the target patient population with greatest unmet need and potential to demonstrate clinical benefit?
  - What are the levels of performance achieved with current standard of care and the requirements for improvement for any new product in this setting?
  - What clinical trial comparator?
  - What are the reactions to and acceptability of different side effects?

- **Identification of the optimum product profile/concept:**
  - What is the best way of describing a product and its attributes to each type of customer being considered?
  - What terminology should be used and avoided?
  - What order should product attributes be presented to achieve maximum impact?
  - What are the trade-offs of specific profile features? How do they inter-link? Which take priority over the others?
  - Which concept is the most understandable, credible and appealing?

In early stages of the product development the product profile/description is quite “medical” and consists usually of expected “hard clinical data” (target product profile). Through primary market research and the outcome of clinical trials the relevant therapeutic benefits will be identified and the associated performance levels more defined and finally the profile turns into a product concept including marketing considerations.
**Approach**

Overall it can be helpful to split product profile/concept research into two broad stages:

- Target product profile development
- Target product profile/concept testing

First the benefits of clinical product features in the sense of relevance in daily practice (unmet needs) must be evaluated qualitatively. The elements of the profile to be tested will be based on a combination of the clinical product profile and previous research (e.g. customer needs, behaviours and attitudes). This stage should be conducted on a wide variety of respondents to ensure that the ultimate product description is as appealing as possible to the broadest range of respondents. It is likely to be conducted qualitatively by individual depth interviews or group discussions to identify the benefits of clinical product features. Initially conducted with opinion leaders, but more likely to be main volume prescribers and possibly patients. The use of creative research techniques using a number of product statements would provide a forum for creativity and enable respondents to create their own product concept and ensure a rounded (rational and emotional) perspective on the target product profile.

Throughout the product lifecycle the product profile changes from a largely uncertain profile with lots of attributes and levels to a more certain profile and finally a fixed profile prior to launch. As outlined above the specific nature of the business issues to be addressed will also change along the lifecycle but will certainly include questions to ascertain the likely uptake of the product and to determine the trade-offs of specific profile features both of which necessitate a quantitative approach.

Robust quantitative assessments are often required to support company investment decisions of a product in development. These will of course vary by company but are often necessary at the three key stages in the product lifecycle shown in the table below. There are a variety of quantitative approaches that can be utilised to address the different business and research objectives and that work with the different types of product profiles and stage of development. The following table provides a simplified overview of these:
<table>
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<tr>
<th>Product lifecycle stage</th>
<th>Overall Objectives</th>
<th>Type of Product Profile</th>
<th>Quantitative Approach</th>
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</table>
| Early development phases | Identify and develop target product profile options which will help shape clinical plan and business case. | Uncertain product profile (lots of attributes and levels). | Conjoint  
- ACA (adaptive conjoint analysis)  
- CBC (choice based conjoint) |
| Prior to Phase III | Identify the right patients and the right target profile claims that will direct the design of Phase III to secure commercial value. | More certain product profile (fewer attributes and levels). | Conjoint  
- FPC (full profile conjoint) |
| Pre-launch | Test product concept to evaluate how Phase III results have impacted the commercial opportunity to inform Go-No-Go decision for launch. | Fixed product profile/concept. | Fixed profile market research |

The choice of quantitative approach is determined by a number of factors:
- Nature of the market research objectives
- Number of attributes and levels to be tested
- Number and nature of patient type analysis required
- Requirement for respondent segmentation
- Availability of sample
- Budget

Using patient records during the course of the quantitative research will assist in:
- eliciting the real drivers of prescribing that are key to making treatment decisions
- ascertaining the opportunity for the product in specific patient types

Questions would be asked around which treatment the patient would receive, and more importantly what were the reasons for the treatment choice. Towards the end of the interview physicians would additionally be asked the likelihood that the patient would receive the product and why, for different profiles generated from the conjoint exercise.
4.4 TRADEMARK (BRAND NAME) RESEARCH

Gaining approval for trademarks can be difficult due to legal and regulatory constraints. Trademarks cannot communicate unsubstantiated claims nor be confusingly similar (sound and look alike) to other trademarks.

Questions/Issues

From a commercial perspective the key issues are:

- assess most appropriate name from a range of possible alternatives (uniqueness, pleasance, fit to indication)
- avoiding negative connotations
- measuring recall, pronunciation, spelling and writing
- acceptance across various languages

Approach

Trademarks are normally created by an independent agency whose task it is to identify names in various countries, which are not already being utilised. However, trade names to be tested can be generated by suggestions from company employees or the target audience and these are usually screened to reject any which are similar to existing trademarks. Ultimately all names to be tested must be checked legally prior to research! Quantitative research amongst potential prescribers is required to determine overall preference and to highlight country differences. The number of names to be tested is usually an issue; there can be differing views on the upper limit of names tested per respondent. Linguistic differences need to be borne in mind, as letters or combinations of letters are pronounced differently in different countries.

In face-to-face interviews, the proposed names are usually presented to the respondents on individual cards in rotated order (to avoid recency effects) without saying (to avoid interview bias in pronunciation). Respondents may be asked to write the name, and underline parts of the name where the emphasis is stressed to check spelling and pronunciation. In a second step recall can be measured at a set time after the interview, for example by follow-up telephone call.

Telephone or online interviews can also be used and the choice depends on the condition and type of drug.

The “street” interview approach with patients may also be appropriate for acute conditions such as migraine. Interviews should be tape recorded to evaluate pronunciation – especially if telephone interviews are used.
Although much thought is placed on the highly important aspects of product, including the medication’s features, benefits and branding; packaging, on the other hand, can sometimes take a back seat in the development process. Sometimes this area suffers from poor funding.

Recent, new packaging regulations and guidelines in both the USA and Europe, increasing demands for tackling counterfeiting around the world, advancements in packaging technology and investments into new drug delivery systems and an increasingly larger elderly population in both the USA and Europe is transforming marketers’ views on packaging and highlighting its importance in the marketing mix pot.

Not only do pharmaceutical manufacturers have to ensure that packaging and labelling meet the varying legal regulations in each different market, but they must also have to pay particular attention to the aging populations’ handling capabilities with both packages and devices, the different cultural barriers to particular designs, colours and/ or shapes and to eradicate any possibilities in counterfeiting within each country, therefore providing packaging solutions that are legally standing, user-friendly and tamper proof. The type of packing may also influence the rate of parallel trade, re imports and fakes (as it is the case for high priced drugs e.g. ARVs, antibiotics).
Questions/Issues

Typical questions and issues would be:

- Who is concerned with packaging (e.g. patients, nurses, physicians, pharmacists, wholesalers)?
- What packaging strategy should a company take?
  - Have only one pack type?
  - Have a limited number of styles to meet various needs?
  - Therapy packing? (combination of different drugs in one package e.g. PPI and antibiotic for H-Pylori eradication)
- What treatment patterns do patients follow? Is it a condition, which requires constant medication, e.g. diabetes, asthma, hayfever, migraine?
- Where do patients keep their treatment? How many packs of one medication do they have at a time?
- What is their opinion on current packaging options and how well accepted are they?
- What are their options regarding any prototypes?
- What is their ideal? Size, weight, colour, texture etc.
- Is packing in line with marketing objectives (e.g. innovative or reliable medication)
- What handling problems occur that may lead to safety problems (e.g. with pre filled syringes), improper intake, switch to competitor drugs, wastage.

There are two main types of packaging to be researched:

Primary Packaging

Refers to all packaging directly in contact with the active ingredient/medication: (e.g. tablet blisters, dispensers, and pre filled syringes, patch pouches, infusion bags, tubes).

Aspects of research include:

- selecting the most appropriate material and establishing the ideal form and size, number of handling steps required, error and time reduction, security, memory functions, singling out daily dosages thus optimising ease of access, administration, storage and disposal,
- focusing on design aspects, mainly concerned with aesthetics, ergonomics, colour appeal and coding, attractive box sizes, design, weight, hepatic appraisal, etc. in order to improve functionality, compliance, branding and attract attention and interest.
Secondary Packaging

a) Passive packages for wrapping and bundling = outer packaging (tablet boxes, syringe blisters)

See above Primary Packaging

b) Active packages (e.g. insulin pens, inhaler devices)

See above plus: readings of units/dosages, arming/filling, application, carry on/transport, multiple use aspects.

If the product is a primary care one then there are several basic criteria which the packaging must fulfil:

- Distinctive and differentiated
- User-friendly and reassuring
- Practical and functional
- Suitably ethical
- Fits into the patient’s management of their disease
- Special conditions may apply to nurses, care givers, pharmacists

When it comes to professional use of medical delivery devices, e.g. in clinical settings or especially demanding intensive care environments, time is a further important aspect to be taken into consideration for packaging or device research. The possibility to spare a few minutes or even seconds can be decisive for the chance of a patient to survive.

For this reason, so-called **Time & Motion** studies can be conducted, exploring the time needs of current therapeutic or interventional procedures and testing which effect in terms of timing improvements of procedures or the associated devices will have.

**Approach**

As the two aspects of **Packaging** research studies are, at least partly, interwoven and dependent on each other, respective surveys most often comprise of both a handling exercise and an evaluation of various design options.

For this reason, face-to-face interviews are the method of choice, whereby it is recommendable to conduct at least a sub sample of these interviews in central facilities, where they can be directly observed by the researcher and taped for detailed analysis.

Handling tests need intensive training and highly homogenous testing conditions (e.g. to avoid distracting or varying factors lightening, space etc.) Allow time for learning and repetitive handling exercises. Be aware of special shipping and legal restrictions.
Prototypes are an important part of the research as they provide a basis from which further ideas can be generated. However, if none are available then existing packaging can be used. A collection of different packagings from various countries can help with this process. It is important to bear in mind that respondents find “creativity” difficult once they have seen a number of examples. Therefore it is best to provide as much stimulus material as possible – getting respondents to design and draw their own packaging is one approach.

When testing first prototypes of packaging, a limited number of respondents per target subgroup (ideally prescribers, users and pharmacists) are sufficient.

Once a short list of alternatives has been reached, a quantitative approach may be appropriate to identify customer preference. It has to be assured, however, that the respondents can get a direct look (and feel) of the relevant packaging aspects, i.e. see a real packaging or a realistic illustration in case of design questions or even be able to touch the prototype in case of handling issues.

Research in this area, however, should be conducted in the earliest phases of the package development process where even major changes in basic product properties such as material, size, and coating can be performed without huge investments in new machinery or production processes.

As Time & Motion studies will focus on individual performance, Individual depth interviews (IDIs) are the appropriate methodology, as they not only allow a detailed analysis and prescription of the current procedures but also to measure possible time savings based upon the modified procedures or devices. These IDIs should be conducted in central facilities, allowing a standardised conducting of the interview and the time measurement.

Taking both into account the need for highly qualified respondents (e.g. nurses in ICU units), but also the need for a sound and reliable data base, sufficient sample points need to be used.
4.6 PRODUCT POSITIONING

Overall Objective

Product positioning is the act of creating and communicating what a product can offer, to whom and why it should be adopted so that it will occupy a distinct and sustainable competitive position in the mind of the target customer. The overall objective is to ensure that new brands that are built and launched are truly differentiated in a positive way from the alternative choices customers have.

Questions/Issues

Market research is required to define the core elements of product positioning that will effectively communicate the product offering. It can be used to generate, develop and assess the appeal of alternative positioning platforms to identify the optimal product positioning. There are different questions that need to be considered at each of these three stages.

Generation of alternative positioning platforms by identifying:

- What are the elements (content/structure/terminology) that will make up alternative product positionings?
- How does a new compound fit in the marketplace?
- What are the differential product advantages and how do they meet the needs of key customers (e.g. patients/physicians)?
- How similar is the perception of the competing drug profiles? (i.e. What are the key differential strengths/benefits vs. competition?)
- Recommendations as to how to effectively communicate and support positioning are required.
- Level of potential substitution/cannibalisation?

Development of alternative positioning platforms through identifying the best way to communicate the following:

- Product usage (what/when/where/why)
- Terminology and descriptors
- Clinical claims
- Logical and emotional arguments to convince physicians to prescribe and patients to request/accept the product.
Assessment to identify the optimal product positioning in terms of:

- Interest, credibility, relevance
- Whether they fulfil the need
- Clearness
- Persuasiveness
- Benefits and limitations
- Differentiating characteristics
- Impact on product uptake (by patient type/disease stage/frequency and duration)
- Identification of any information gaps or barriers.

**Approach**

Both qualitative and quantitative research can be employed, the target group being those physicians anticipated as being the main volume prescribers. (Although research with other influencers such as payers/purchasers, opinion leaders and pharmacists may also be required).

**Qualitative research** – focus groups or individual depths – is essential to develop and refine alternative positioning options. The alternative positions need to be assessed for initial impact and then reviewed in greater detail to understand this impact. At this stage a number, or all but one, of the positions may be discarded. Consider using rolling fieldwork to allow (iterative) development of stimulus materials.

**Quantitative research** – may be required if small differences are noted, more than one alternative position has yet to be discarded or the proposed market is highly competitive. The alternative positions can be tested against one sample or the sample split into equally matched groups, with different positions being tested with the different groups. Furthermore, Simalto and Conjoint techniques can be employed and market maps generated to better understand the positioning and impact of your product against its likely competitors.
4.7 BRANDING RESEARCH

Overall Objective

The overarching goal is to achieve brand loyal customers with an attachment or support for the brand seen by their continuing usage/endorsement of it. Branding generates a set of unique and often intangible values associated with a product creating added value in the minds of customers.

Questions/Issues

There are a number of elements involved in the creation and development of branding and therefore research is required to explore and identify:

- **Disease image** - Need to explore the visual (and verbal) imagery associated with the disease in terms of the:
  - characteristics of the disease itself
  - impact of the condition on the patient
  - impact of managing the disease on the physician

- **Brand value and association** - Need to explore the core values associated with:
  - the disease area
  - existing treatment approaches
  - the product offering itself

- **Brand personality** - Need to explore and define what are:
  - the core elements of the product's Brand personality and character
  - the associated physical and emotional human traits

- **Brand image**
  - How is/should the brand perceived by its target audience?
  - What should the visual execution of the image be (colours, visual themes etc.)?

Other critical elements of branding are tracking the brand loyalty (degree of attachment by consumers in continuing usage/endorsement of the brand) and the brand equity these elements are covered under Brand Performance Tracking (4.15).

Approach

Both qualitative and quantitative research can be employed with main volume prescribers (and patients) as target group.

**Qualitative research** - to build the brand or explore a brand – focus groups or individual depths – maybe using creative techniques (e.g. brand party) to support the development of the brand and understand the brand associations. Consider using rolling fieldwork to allow (iterative) development of stimulus materials.

**Quantitative research** - often a quantitative evaluation with a sample of main volume
prescribers of branding preferences is employed. Either a monadic approach or testing of multiple (rotated) options depending on requirements. This could be carried out by telephone or online depending on time and budget. The decision for a panel approach or ad hoc samples should be discussed intensively as the selection of respondents depends on the research objectives and has a strong impact on generalisation of results.

4.8 MARKET ACCESS

The environment for the pricing and reimbursement of pharmaceuticals has become increasingly challenging. Regulation in these areas has tightened and across Europe a fourth hurdle – cost-effectiveness – has supplemented the accepted wisdom of safety, efficacy and manufacturing quality as a further requirement to secure market access. This shift has accelerated the emergence of a key group of influential stakeholders, namely payers.

Essentially, market access is about:

- considering the implications a product may have on the wider healthcare market
- understanding the impact the changing healthcare market will have on a product
- preparing a positive healthcare environment which supports product uptake
- communicating the ‘value’ of a product to the full range of customers who influence uptake

Overall objective:

Understand the needs of payers to develop an effective market access strategy to ensure the right information is communicated in the right way, for the right customer at the right time to drive product uptake.

Questions/Issues:

- Identify current and likely future changes to pricing and reimbursement policies.
- Identify who are the influential payer stakeholders (e.g. national and local decision-makers, policy makers and budget-holders) for disease area/market.
- How do the needs and assessment goals differ by the different payer types?
- What are the information needs for the different steps within the payer evaluation and adoption process?
• What level of evidence (clinical and economic) is required to meet needs?
• What are the therapy endpoints required for clinical development (i.e. pivotal phase III development programme)?
• Are there any market access hurdles and challenges that need to be overcome?
• What is the best way to communicate the core benefit and value of the product to payers?

Approach

Secondary research can assist in understanding the different market access environments and landscapes and identify different payer types. Primary qualitative individual depth interviews with payers and KOLs are then needed to explore perceptions of value drivers, unmet needs and payer evidence requirements for successful market access and reimbursement. Further quantitative research (including conjoint methodologies) with payer attribute value mapping and value proposition validation and optimisation is likely to be required. Although here the work may still have to be qualitative in nature, or use minimum quantitative sample sizes due to the relatively low number of available respondent types to interview.

Multi-sponsor syndicated studies can be useful tools in terms of the understanding and quantification of disease burden; market opportunities; the demonstration of product value and the generation and communication of value messages to support pricing and reimbursement.

4.9 PRICING RESEARCH

Overall Objective

To determine the optimum price, taking into account value delivered to policy makers/influencers, prescribers and patients that will optimise profitability and sustainability.

Questions/Issues

Pricing research is required to:

• Determine whether price sensitivity exists
• Determine price/volume relationships across customer types
• Investigate impact of price on:
  – Physician willingness to prescribe
  – Type of patient
  – Patient willingness to pay (where patient pay or co-pay applicable)
  – Payer willingness to reimburse/grant access
• Understand the impact on price/volume relationships of alternative:
  – Positioning options
  – Indications
  – Length or treatment/dosage regimens
• Determine the impact of price from future competitor products
• Understand impact of international variations on pricing strategy

**Approach**

Quantitative research is the most appropriate approach particularly with the anticipated main volume prescribers.

However, as noted above the role and influence of payers/purchasers is extremely important and they will also have to be included to establish the maximum price acceptable to achieve unrestricted access to prescribing physicians. Pharmacists may also have an important role to play in the research and also patients if the product is likely to be driven by patient requests for treatment, e.g. a migraine product or if the patient has to pay either in part or full. The final research design will depend, in part, on whether a clear idea of the price range has been established or not.

There are four main approaches to pricing, the Gabor-Granger technique, van Westendorp, Brand Price Trade-off and Conjoint Analysis. These techniques are used to determine the price that products can command in the marketplace, understand the value of product features or attributes, and investigate the role of competitors on pricing thresholds.

Physician reaction to price can be measured through one (or a combination of) the following approaches. These are based on perceived value and/or on the concept of price being a monadic variable.

• Conjoint techniques (especially discrete choice models as they do not require independence of product attributes as needed for techniques based on regression analysis) are widely used to measure price elasticity and to calculate price-volume functions). Note that conjoint techniques can be applied to issues other than price, for example, predicting likely product uptake.
• Ordinal price benchmarking for determining upper price limits when price transparency is lacking
• PSM (Price Sensitivity Measurement, “van Westendorp Method”) when price ranges are not fixed before research
• Gabor-Granger Method when respondents are shown a product profile and asked whether they would be willing to buy it/prescribe it/recommend it at each of a randomised series of prices in order to measure price elasticity
• Price Class Tests to determine Price/Volume Function in highly competitive markets.
The successful acceptance and prescribing of the product relies not only on the profile and its positioning, but how the product benefits and claims are communicated to the customer. All means of communication must convey consistent key messages to the target audience.

Overall Objective
To identify the key messages and develop the optimal brand story flow that resonates with the target audience to motivate prescribing behaviour.

Questions/Issues
- Confirm the specific language used by target customers.
- Identify the optimal expression of words or phrases that facilitate clear communication of product benefits and claims.
- Identify any terminology that has negative associations, confusing meaning or act as a barrier to clear communication.
- Identify which claims/messages are the most motivating? In terms of:
  - believability / credibility
  - appealing
  - interesting
  - persuasive
  - easy to understand / clear
- How do the claims/messages fit together to tell the most synergistic and motivating brand story?
- Which aspects of the story best connect with the physicians emotionally and fill an unmet need in order to motivate prescribing behaviour?

Approach
The most appropriate approach is likely to be qualitative and individual depth interviews (IDIs) with influencers and target prescribers, as this will allow an unbiased view from each respondent.

Adopting an iterative approach, to ensure that future discussions are shaped on the key learning to date, can work very well. i.e. By using earlier research to decipher the claims of most interest/best positioning then focussing attention on the selected claims for the remaining research depth interviews.

The use of creative tools and explorative questioning techniques will ensure views are elicited on the proposed brand story and individual claims and messages. Increasingly more creative and interactive approaches are employed where respondents’ are actively involved in the creation and development stages. Here physicians are more fully engaged in the task and are
allowed to work in small teams to build the most persuasive story, using what they perceive to be the best messages, charts and data.

Once the product is launched, quantitative information will be required on the actual market performance. Additionally, to investigate whether the product is being used as it is intended, i.e. for the right symptoms and in the correct patient types. This also allows any deficiencies in the communication of the product to be addressed. This is covered under Brand Performance Tracking, 4.15.

4.11 COMMUNICATION CHANNEL RESEARCH

Having identified the communication messages by target customer to deliver now need to think about the most effective way to communicate them. The traditional ‘media’ world is changing rapidly, and whilst pharmaceutical medical media consumption habits are changing slower than consumers’, the trends in consumer media consumption also apply to the medical world.

Overall Objective

Determine the most appropriate channel mix (incl. sales channels, advertising, digital, education, conferences, KOL engagement, PR, etc.) to best communicate with target customers to maximise the return on investment.

Questions/Issues

Market research can be utilised to assist in identifying suitable channels which can vary by customer type, disease area and market.

- What is the channel landscape (by disease area/market)?
- What are all the possible touch-points between brand and target customer?
- What channels are best suited for each customer type?
- Identify potential weak links in interaction.
- Understand information flow.

Approach

Secondary and syndicated study data can be used to assist in building a market contact audit to understand the channel landscape in the disease area and in specific markets. Observational studies to observe how target customers use different communication channels to understand usage patterns and identify areas of needs and potential barriers are a useful approach although do have implications on budget and time. A more cost effective approach is to utilise online studies to gather information on different media touchpoints both in a work and social environment.
4.12  SALESFORCE OBJECTIVES RESEARCH

Although field force (sales representatives) remains the most impactful sales channel to drive share, in launch and early growth stages, the use of other approaches such as service teams and different channels have evolved to complement and at times partially replace the field force. Service teams (provide services / deliver materials for physicians/practices) have evolved to try and better meet customer needs and meet business targets since they tend to provide a lower cost base to continue promotion especially in later stages of the product lifecycle.

Overall Objective

Market research is required to assist in the generation and evaluation of sales force objectives as well as new service concepts for sales channels.

Questions/Issues

- Identify target customer groups and specifically individual customers.
- Determine and measure key messages, which must be communicated to target customers.
- Measure impact of call/effectiveness of detail on target customer including message recall (both positive and negative) and intention to prescribe. Identify reasons for not prescribing.
- Modify sales message according to impact on prescribing.
- Understand what the pain points and unmet needs are by customer type?
- Identify improvements on existing services (e.g., different positioning, packaging or delivery)
- How attractive to physician/practice are the delivery of different services (e.g., leaving behind materials, invitations, samples)?
- Are there any potential barriers to delivery of the service ideas?
- What is the preferred delivery mode (e.g., postal send-out, face to face interaction)?
- What is the preferred timing of delivery (e.g., with/without appointment, time of the day)?
Approach

Specific target customers are usually identified from secondary sources and databases may already be available within the company. Customers are prioritised in terms of influence on prescribing or prescribers and representatives target these specific individuals with the communication messages. In order to measure the impact of the sales call, customers who have been recently detailed on the product are interviewed either by telephone or by completing a diary and information is collected about the products detailed, the performance of the representative and levels of customer satisfaction. These surveys may be conducted ad hoc or as a syndicated study.

Qualitative research such as observational research “Day in the life” (where a physician’s daily tasks are observed in the practice) followed by individual depth interviews or focus groups with target customers. This approach would allow a full exploration of the role of each person in the practice and identify pain points/needs as well as exploring value adding services already provided and ideas for new services that could positively impact on patient care and prescribing. Again observation studies do have budgetary and time implications and more standard IDIs or focus groups can also be used.

If there is a need to evaluate and prioritise between different service concepts then a quantitative online survey may be required where physicians can choose between different service concepts which are differentiated by individual services, delivery modes and timing of delivery. Selection is repeated multiple times to flesh out preferences.

4.13 ADVERTISING TESTING

Questions/Issues

- Which themes or concepts meet the communication objectives for the product?
- Which execution of the theme is the most appropriate for the target audience, bearing in mind the product positioning?
- Impact of the advertisement, likelihood to remember product name and key messages.
- How do the various elements of the advertisement work together – visual, headline, strap line, copy, and logo?
- How does the advertising differentiate the product from the competition?
Approach

Both qualitative and quantitative research can be employed. Qualitative is used more when creative development is required, and quantitative where preference, particularly evaluating alternative advertisements, is required.

Qualitative research – usually in two phases on main volume prescribers and patients if an OTC/self-medication product. Group discussions allowing creative exploration of the themes put forward by the advertising agency, along with explanation of the product and its positioning, to determine which theme is most appropriate to develop further. Individual depth interviews to refine execution and optimise various elements to ensure communication objectives are conveyed. The status of the stimulus material can vary from conceptual designs to almost the final execution, however, reaction and discussion can often be easier the more finished the materials are.

Quantitative research – usually conducted using some form of “mocked up” folder test where the respondent first of all browses through a folder including the test ads. They are then questioned regarding recall of ads and messages as well as level of interest and likely usage.

4.14 DETAIL AID TESTING

Questions/Issues

Similar objectives to advertising testing in terms of ensuring that the materials communicate the determined positioning of the product. Additionally, to ensure that the representatives can use the material to support the product messages, that the material is credible and has a logical flow, and what changes are necessary to enable representatives to use it more effectively.

Approach

Respondents are “detailed” by representatives or someone role-playing the part of a representative, using the new material, and then they are interviewed about their response in a subsequent interview. After a general discussion, the respondent is shown every page in detail and asked questions on their reaction towards it, how useful it is in communicating information about the product and how the representative used it. Representatives are also asked for feedback and modifications will then be made to enable representatives to use the material more effectively.

An alternative approach in order to avoid a ‘selling scenario’ (which may come across if respondents “detailed” face to face in one interview), is to use a detailing scenario via video. Here a ‘mock’ sales discussion will be recorded in the local language for each market and then played to the respondents in order for them to give their comments and thoughts. The benefit of this approach is that the respondents are a ‘third party,’ only observing the sales pitch and not actually participating which can encourage more open exchange of views and opinions. As discussed previously, the more final the materials that are tested, the better.
4.15 BRAND PERFORMANCE TRACKING

Having developed the key brand elements including positioning, communication and branding it is critical to be able to measure and track the impact and performance of these elements and make any necessary changes to the marketing strategy to optimise brand performance.

Comprehensive brand performance tracking relies on and builds on earlier market understanding work (market definition, drivers of choice, competitor sets etc.) which along with the marketing strategy helps to define the key performance indicators (KPIs). The KPIs are designed to measure launch performance and enable accurate measurement of how successful or not the brand is at achieving its strategic objectives.

Overall Objective

Determine how brand is performing against plan and identify what is required to optimise brand performance.

Questions/Issues

- **Key Performance Indicators (KPIs)**
  - Identify and develop the KPIs/targets of prescribing intent & brand engagement that will be used to track brand performance versus forecast.
  - Develop tools in order to monitor the progress of the launch against the set of key performance indicators/targets.

- **Attitude, Trial and Usage (ATU)/Brand Equity (BE)**
  - What is the level and source of awareness pre and post launch of brand and key competitors?
  - Monitor trial and usage in key patient segments
  - Monitor the adoption level among all relevant physician specialties.
  - Monitor key brand and promotional message recall
  - Identify rational and emotional perceptions and experience of brand
  - Measure key uptake metrics: penetration, profile of patients, source of business, switching, and future prescribing intent
  - Understand barriers to trial/adoption amongst rejecters
  - Measure and understand the effectiveness of the launch campaign
  - Impact on the competitive set to be monitored.
**Approach**

Typically there are three sources of information that will be used to measure how well a brand is doing against its KPIs:

- primary research to understand the physician attitude, trial and usage of the brand and its brand equity,
- secondary research - internal (e.g. sales, forecast, field force reporting) and
- secondary research - external (e.g. retail/hospital sales, promotional data)

The need to be able to quantifiably measure launch performance means that the primary research ATU and BE studies are usually quantitative questionnaires and usually administered via the internet. Qualitative elements can be employed in the design stage and later stages to explore or understand results from the tracker.

Study and questionnaire design will vary by research objectives/brand/disease area and proprietary methodologies of specific research agencies however it is likely to include a list of both rational and emotional brand attributes to allow consistent and accurate benchmarking against agreed KPIs as well as include a mixture of open ended and pre coded questions, scales and a trade-off technique.

A typical questionnaire flow might include the following:

- Physician profiling/workload
- Brand awareness/source of awareness/expectation
- Brand usage and experience
- Patient records
- Max Diff Scaling (What elements are important to prescribing decisions?)
- Brand image perceptions
- Campaign performance (e.g. message recall/relevance)

Typically brand launch performance tracking is conducted in waves:

- **1st wave**: Pre-launch benchmark which is usually a shorter version of post-launch questionnaire and aims to cover current market landscape, level and source of awareness of brand.
- **Subsequent waves**: Post launch comprehensive tracking of awareness and perception of brand, adoption and use by physicians and patient segment, evaluation of campaign performance towards building rational and emotional drivers of prescribing and growth of brand equity.
- **Qualitative post launch**: Following analyses of results from quantitative tracking waves in depth interviews with physicians from countries that are either performing well or where there are problems with brand uptake can be useful to explore the drivers and barriers to uptake.
Data from the primary research studies (ATU and BE) will often be combined with secondary data (i.e. in house and external sales data) to inform the KPIs and build a complete view of the performance of the brand.

**4.16 DIGITAL RESEARCH**

In a digital world in which conversations are initiated and driven by customers rather than just companies and brands merely pushing their messages it is important for companies to develop a digital marketing strategy.

**Overall Objective**

To understand customers’ needs their digital usage and digital trends to successfully leverage key digital channels to improve customer understanding, brand development, communication and the customer experience.

**Questions/Issues**

- Establish the overall volume of conversations for a specific disease area/brand.
- Identify topics and type of information about medication's indication, usage, and therapeutic effect.
- Identify sentiment and sentiment drivers for disease area/brands.
- Determine how conversations differ by different customers (inc. physicians, patients, friends/relatives of patients, carers, etc.) and by different countries/regions.
• Determine the type of websites or online communities where discussions are taking place.
• Determine impact of a specific event (e.g. release of key clinical trial data, competitor launch)

Approach

Digital research at its simplest can be described as the core digital data collected about a specific customer brand or market.

Digital listening is the approach where data is collected from a number of online and offline sources where potential customers are posting and sharing information. Sources including online media (news sites/online publications) customer generated media (social networking sites/blogs/forums) and offline media (print/TV/radio) are mined. The data is processed either by simple text mining, human analysis of postings or via natural language processing. Key outputs are typically customised reports or self-service analysis via dashboards that can be interrogated to track discussions, understand sentiment and identify influencers.

4.17 LIFE CYCLE MANAGEMENT (LCM)

The initiation of LCM planning can start at early stages of the product lifecycle to ensure strategies are in place to maximise the potential brand franchise. In many ways this process should mirror that of the stages in the product lifecycle. The LCM plan will need to evolve to ensure it reflects changes to the product profile, brand positioning and any likely changes in healthcare environment or competitive situation.

Overall Objective

Understand the impact of patent expiry and identify and develop the LCM options that will maximise and extend the brand franchise.

Questions/Issues

• What is the likely impact of patent expiry extent of expected generic erosion?
• Assess the potential value of alternative LCM strategies that could be developed to reinforce brand image, maintain brand loyalty and extend use:
  – potential new markets and customer segments
  – opportunities for line extension (new indications, line extensions)
  – promotional and communication initiatives
  – OTC-switch
  – two brand strategy
Is there an opportunity to develop disease area franchise through effective portfolio management and future opportunity analysis?

**Approach**

Qualitative research (individual depth interviews, focus groups with prescribers and payers) should be conducted to understand the impact of patent expiry and explore reasons for potential brand loyalty.

Frequently a combination of secondary prescription data and quantitative primary research data incorporating conjoint techniques is required to calculate different scenarios. As there is a strong linkage to forecasting issues, market forecasting and competitive intelligence should be linked to the primary marketing research programme.

Target groups will be main volume prescribers and in the case of OTC switch also patients.

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**4.18 NEW OPPORTUNITY/LICENSING EVALUATIONS**

Companies often conduct commercial reviews of disease areas outside their core therapy areas to assist in developing LCM or discovery targets or to identify partnering opportunities. Additionally commercial evaluations may be required to be conducted on specific external in-licensing candidates.

**Overall Objective**

To evaluate new disease area market opportunities and/or potential in-licensing candidates in terms of their commercial attractiveness and strategic fit.

**Questions/Issues**

Opportunity and in-licensing evaluations are often directed at answering key business questions across three key areas:

- What are the external market environment dynamics and trends? In terms of:
  - Competitive landscape/ key players with launched and development products
  - Unmet needs and patient segmentation
  - Treatment algorithm
  - Market forecasts
- What is the clinical and market need for the product? In terms of:
  - Important product attributes (valued today and in future)
  - Fit in treatment algorithm (today and in future)
  - Competitive differentiation – what constitutes a step change in way disease is treated
  - Revenue forecasts for target product profile scenarios
• What will be required to be successful? In terms of:
  - Development time and costs
  - Technical feasibility
  - Commercial requirements
  - Regulatory and market access requirements
  - Risk-adjusted forecasts

Approach

Secondary research plays a central role in opportunity and in-licensing assessments with pipeline analysis, company research, treatment trends and algorithms being conducted to understand the external market environment and to identify gaps or questions to be addressed by primary research.

Qualitative research, most likely individual depth interviews with key opinion leaders (and payers if the focus is on the long term reimbursement perspective and criteria for a novel treatment) will then be conducted. Key opinion leaders are typically selected due to the fact they tend to balance practical experience with academic expertise and influence on the physician community.

Typically a quantitative online survey, again with key opinion leaders (payers), would follow the qualitative research to provide attribute trade-offs and quantitative modelling assumptions to build market and target product profile forecast scenarios.
Overall Objective

The forecasting needs and outputs change across the product lifecycle and can be summarised by stage:

- **Early development**: Top line disease area forecast that reflect the potential size and value of target disease area/opportunity area.

- **TPP options**: Range of product opportunity forecasts that reflect the different options and uncertainties in terms of the product profile and market.

- **At launch**: A detailed (monthly) launch forecast which brand launch performance will be measured against.

- **Post launch**: Likely to include short-term operational monthly volume forecasts and longer term forecasts to include the impact of LCM activities and Loss of Exclusivity erosion.
Questions/Issues

Type of information required:

- Size of the target patient population
- Size of the drug treated population
- Disease area population
- Price assumptions
- Competitive landscape – estimate order of entry
- Peak market share (based on TPP)
- Rate of uptake
- Local market access
- Local selling practices

Approach

Both primary and secondary market research are required to meet the information needs outlined above to be able to generate an accurate forecast. For example, secondary research provides epidemiology data (incidence and prevalence), competitor landscape and pricing input whilst results from primary research will deliver guidance on market share, local market access and selling practices etc.

There are often a number of forecast tools that can be utilised to assist with the challenge of modelling uptake curves or peak market share and trends. Learning from previous product launch analogues and loss of exclusivity models are also useful inputs to assist in determining likely uptakes and erosion curves respectively.

Each forecast has its own challenges and forecast assumptions are important to capture and track to ensure transparency in forecast generation and to facilitate easier comparisons and updates following key events.

4.20 COMPETITIVE INTELLIGENCE

Competitive intelligence can be defined as the systematic gathering of information about competitors – products, research and development, production methods, costs, designs, financial status and marketing strategies. With the wealth of competitive data readily available the challenge is one of focus and ensuring that the relevant intelligence is captured and acted on. Key intelligence topics (KITs) and key intelligence questions (KIQs) help to focus intelligence activities and form the basis of both discrete intelligence projects and ongoing efforts.
Overall Objective

Determine how competitor strategies and tactics impact product/brand development in order to mitigate risk or maximise opportunities for brand.

Questions/Issues

The questions and issues will be very specific and focused by disease area/brand but broadly would cover:

- What are the KITs and KIQs for disease area/brand?
- What does the competitor pipeline look like?
- What is the competitive set (i.e. define key competitors to focus on)?
- What is the development and commercial strategy for key competitor companies?
- What are the resource levels of key competitors?

Approach

There are multiple secondary data sources providing competitor intelligence including newswire services (e.g. company press releases, analyst briefings, conference sessions, and key publications) and databases (e.g. clinical trial designs and results, scientific publications, conference abstracts and patents).

Gathering competitive intelligence at scientific conferences (e.g. from symposia, poster sessions, or “soft intelligence” through direct interaction with competitors and their investigators) is also a useful approach.

Use of a war game (competitor role play) workshop, where teams role-play competitors reacting to specific situations, can be a useful approach to anticipating competitor actions in response to that situation. Typically the format for these workshops is for different competitor teams to formulate and present strategies in turn, before reflecting and responding with counter-strategies, and then for all to come back together and resume own company roles to discuss implications and actions arising for their company/brand.

Information gained from all sources and approaches play a role in competitive intelligence but is the interpretation of implications – the ‘so what?’ - that adds the real value.
5.0 PULLING THE RESULTS INTO A COHERENT MESSAGE

Taking into account the market environment, the product, customer needs and clinical/competitive data, all the information is continuously collected, integrated and analysed to form a body of information and insights from which the product strategy and plan of action can be developed. Continuous monitoring during the life cycle allows the company to maximise the product potential and consider new/additional indications.

HOW CAN RESULTS BE PULLED TOGETHER INTO A COHERENT MESSAGE?

*SWOT analysis of product + market
INFLUENCERS

N.B. Arrows indicate stage at which influencer is important. The thickness of the arrow indicates relative importance.

Regulatory/Authorities
Payors/Purchasers e.g. MCO’s, Formularies
Opinion Leaders
Specialists
Primary Care Physicians
Pharmacists - Hospital
Pharmacists - Retail
Patients
Nurses
Carers/Partners

MARKET RESEARCH

Pre-Development Phases
II
IIIa
IIIb
Submission of file
Launch
+6 mths
Post Launch
IV
+1 yr
In Line

TIME FRAME

Research required
Research required depending on therapy area

Strategic

Packaging & Handling
Product profile/concept assessment

Primary
Secondary

Market positioning/branding
Pricing research

Market understanding and patient flow
Trademark (brand name) research

Customer needs, behaviour and attitudes

Ongoing

Detail aid/ad testing
Sales force objectives
Brand performance

Life cycle management

Market forecasting
Competitive analysis

Learning & Development Committee 2012