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TAKE POLE POSITION

Introduce new therapeutic area strategies to ensure first place on the winners' podium

Many large pharmaceutical companies have started to move away from their long-established R&D areas, leaving behind the experience and knowledge they had built over decades to enter new therapeutic fields. They have made this choice with good reason.

Despite ever-increasing expenses in global R&D over the last decade, output in terms of new medical entities (NME) has been stagnating and even decreasing. In addition to the challenges faced in the quest for real innovation, R&D costs have kept rising due to the growing number of regulatory requirements. Taking all terminated projects into account (both successes and failures), the overall cost for taking just one NME to market stands at over $1bn today.

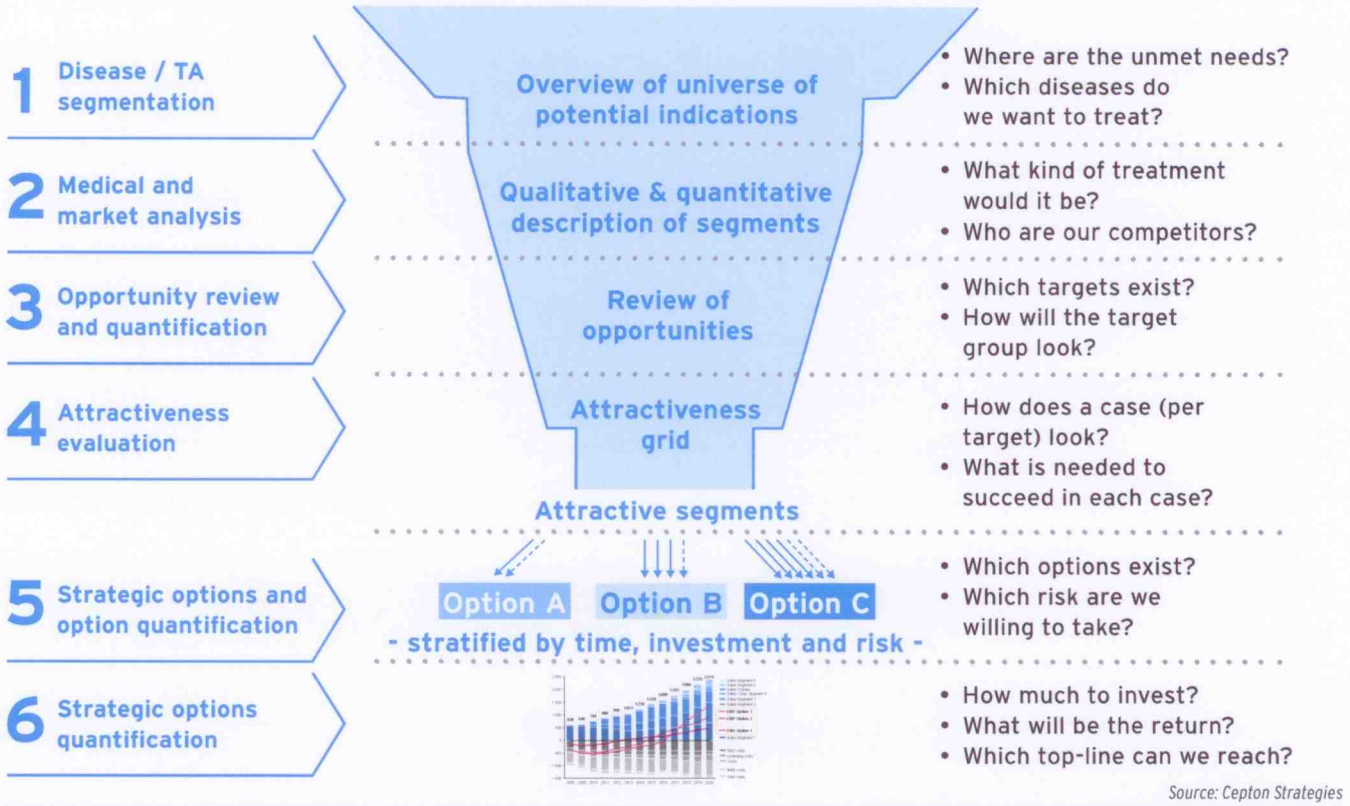
"Defining therapeutic area strategies today has little to do with 'company heritage' ... firms increasingly need to take into account future commercialisation potential, market access and pricing hurdles, as well as the competitive situation"

As a consequence, companies have been forced to shift their therapeutic area focus, building new strategies that are not solely based on existing areas of expertise and assets. Defining therapeutic area strategies today has little to do with 'company heritage'. Instead, firms increasingly need to take into account future commercialisation potential, market access and pricing hurdles as well as the competitive situation.

For an innovative pharmaceutical company, the therapeutic area (TA) strategy represents the core of its corporate strategy, defining which indications it will focus on and outlining how these will be addressed along the value chain. It is a strategy chosen from a number of different possibilities, laying out a plan of action for all functions across the organisation on how to achieve defined long-term goals in a consistent and aligned way.

Therefore, on the one hand, TA strategies must comprise long-term projections for corporate functions like R&D, with time horizons of 15-20 years owing to the time needed

Figure 1. Strategy definition from scratch via the 'strategy funnel'



Source: Cepton Strategies

for a research project to make it to the market. On the other hand, such strategies also need to cover mid- to short-term plans for the Marketing and Sales departments regarding activities such as pending product launches or the positioning of a product.

Pharmaceutical companies must embark on such strategy exercises at regular intervals in order to question and revisit existing decisions. The objectives of these are to:

- Define the directions of the company with regard to exploiting future market opportunities at max
- Realign regularly to the changing market and environmental conditions as well as to changes in its own portfolio assets
- Obtain a sound and current understanding of the revenues to be expected and the investment required to implement the strategy.

The building or rebuilding of a strategy from scratch, i.e. challenging all prior strategic plans, is not usually performed more than once every 3-5 years, owing to the long-term nature of the pharmaceutical product life cycle. In contrast, an existing strategy has to be updated around once a year, which examines all assumptions and the corresponding strategic conclusions based on a review of what has changed since the last exercise.

Strategy funnel

A systematic and comprehensive evaluation of market and product opportunities is necessary to build a new TA strategy. An overview of the necessary steps of the definition process is shown in Figure 1.

Step 1: First, a systematic segmentation of the therapeutic area is required. The objective of this is to obtain an in-depth understanding of the overall landscape of existing indications within the respective therapeutic areas and their corresponding unmet medical needs. Adjacent co-morbidities and complications are often included at this point.

After plotting the landscape, an initial high level filter is applied based on a rough evaluation of criteria such as principle development feasibility, unmet need, target group or overall fit to company expertise. Usually more than two-thirds of the initial long list of indications can be ruled out here.

Step 2: For each remaining indication a detailed analysis of medical, scientific and market potential must be performed using all available in-house knowledge, pipeline databases, scientific literature and external experts/key opinion leaders from different fields. In this way, a comprehensive overview can be prepared for each indication, including:

- Epidemiology, including regional dynamics
- Current standard of care and possible future therapeutic schemes
- Definition of what would be required to address the unmet medical need
- Current and future market size
- Current and future competitive environment
- Relevant customer target group and

Figure 2. Attractiveness evaluation process

Source: Cepton Strategies

required commercialisation structures
- Availability of therapeutic approaches (modes of action) in research and concrete projects in development stages including high-level assessment of their prospects and their potential availability in case of in-licensing targets
- Existing in-house assets and expertise
- Anticipated hurdles for development, registration and market access.

Step 3: Based on information from the previous step, the individual attractive opportunities need to be analysed and described in greater detail to enable quantification. Such evaluation comprises defining achievable price level, size of eligible patient population, feasibility of bringing the product to the market and availability in case of in-licensing targets. In addition, a high-level assessment of the required investment for in-licensing (deal terms), development and commercialisation as well as the expected peak sales and anticipated time until loss-of-exclusivity is performed for each opportunity.

Step 4: Finally, all the results have to be consolidated using a systematic attractiveness evaluation across all indications under review. This comparison is facilitated by attractiveness matrices covering a previously defined and agreed range of criteria, ranging from market potential, entry barriers and commercialisation aspects to the R&D opportunity, in-house assets and expertise as well as associated R&D and commercialisation risks (see Figure 2).

Step 5: Based on the attractiveness evaluation, individual indications are bundled into packages as a foundation for strategic options. These options are described in terms of how to approach the 'packaged' indication focus, covering different strategic timeframes:
- Short-term, commercial front-end strategic components for on market/ late stage pipeline products
- Mid-term, life cycle management strategic components building on these products
- Long-term, R&D strategic components for early stage and research projects, and
- Business Development and M&A strategic components for complementing all three components above.

At this stage, the regional dimension is introduced into the strategy building process to cover regional opportunities and differences.

The strategic options generated have to be formulated such that they are feasible but also differ significantly in terms of criteria such as:
- Investment
- Topline
- Time to break-even
- Risk
- Share of in-licensing.

Usually between three and five options have to be developed to describe the spectrum of possibilities (option space) for how a company or business unit may move in future to leverage the most attractive opportunities.

Step 6: These strategic options are then quantified in terms of investment and return in order to evaluate their financial impact, feasibility and overall value. For the R&D part in particular, with a time horizon of 10 years or more and the implicit risk of clinical trials, this implies calculating with many unknown variables. Therefore, it is important to lay out all assumptions and develop decision trees for risk adjustment. To account for environment uncertainty, these options may be quantified in various market scenarios, like base, best and worst case. Generally different but aligned quantification standards have to be applied for existing late stage/on market products and potential but not yet existing

in-licensing targets, respectively. In addition, for late stage/on-market products a feedback loop with important countries is advisable.

Defining a TA strategy requires the involvement and full commitment of key management from various corporate functions and senior input from country level. Despite the manifold input required, the strategy process should be driven only by a small core team (3-5 people) and led content-wise by corporate strategic marketing. Usually Medical, Development, Research, Commercial and Business Development departments should be represented in this core team as well (Figure 3). In addition, ongoing close contact with board members is a key success factor.

An external adviser may facilitate the overall process by driving it forward and ensuring the different team members are coordinated and understand each other. He provides an objective external perspective, challenging assumptions and strategic options, ensuring the required quality in the different workstreams and serving as a sparring partner for the core team.

There are 10 key factors influencing whether the process is a success, based on experience gained over the last 15 years:

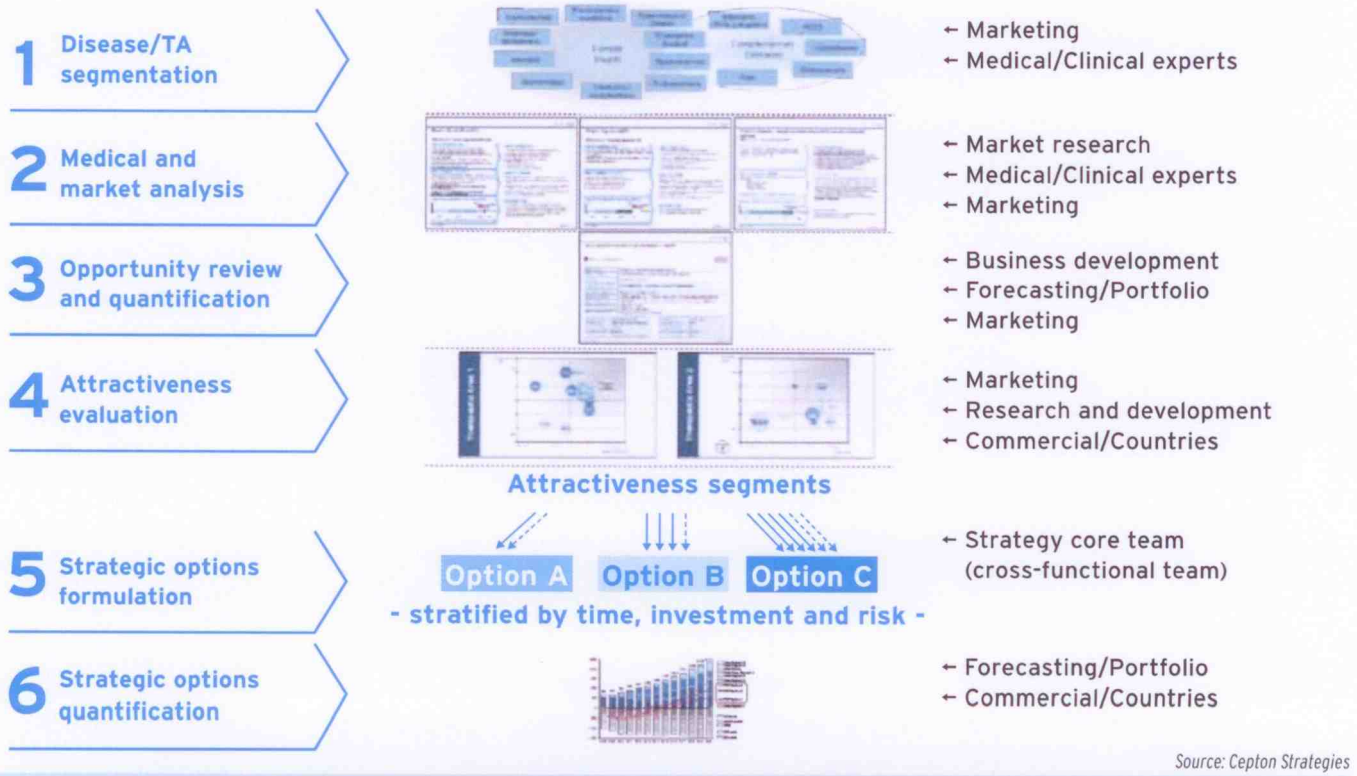
1. Light project team with a highly committed, strong and well accepted strategy core team.
2. Full support from the organisation which is involved throughout the strategy process.
3. Clear guidance on the scope of the exercise, strategic timeframe, format and strategic cornerstones from the outset.
4. Systematic approach to evaluate market and product opportunities.
5. Top-down strategy development, starting with the strategic story and focusing on the most decisive aspects, pro-actively managing the complexity.
6. Solid bottom-up foundation providing sound rationale for strategic conclusions.
7. Methodological stringency while dealing with strategic options and scenarios and clear and consistent quantification standards.
8. Open-minded approach such that no possible options are ruled out.
9. Include external perspective by involving external advisers in the strategy process who challenge objectively.
10. Continuous and open exchange with the board throughout the strategy process.

Pharmaceutical companies have to question their therapeutic area strategies more than ever before. This need is being driven by changing market environments, the ceasing of work on 'classic' indications in favour of the evolution of new attractive niches, the trend towards personalised medicine and the quest for innovation. The changeover has to be done with thorough planning to ensure success.

The Authors

Dr Urs C H Wiedemann is principal, **Ira Wenninger** is consultant and **Dr Michael C Müller** is managing partner at Cepton Strategies, all based in the Munich office in Germany.

Figure 3. Input and functions to involve



Source: Cepton Strategies