Original Article

Revitalizing portfolio decision-making at Merck Serono S.A. – Geneva

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ABSTRACT Comprehensive, metric-based portfolio management yields well-known benefits such as increased transparency and the potential for greater objectivity in decision-making. However, the research and development (R&D)-driven characteristics of the pharma and biotech space call for further refinement of general techniques now in use. Because of the years-long timeline for the R&D of products and treatments, and because of similar horizons for testing and for securing regulatory approval, the growth, stability, and even survival of companies in this space are especially sensitive to the quality of portfolio management. In this article, we (1) briefly describe the history of portfolio management and the uneven results of its application in the R&D-centric pharma and biotech space; (2) identify eight factors which can limit the impact and quality of portfolio management in the space; (3) document a four-step process for portfolio management that directly addresses these factors; and (4) document the results of the implementation of this process in the post-merger period at Merck Serono S.A.– Geneva.
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PART I: BACKGROUND AND PRACTICE

R&D-driven firms find significant shortcomings in standard portfolio management

Comprehensive portfolio management is a relatively recent development; its rapid and widespread acceptance is testament to its power.

Modern portfolio management has its roots in the Capital Asset Pricing Model.[1] In essence this model describes how a risky asset compares to a risk-free investment such as a government T-Bill that gives a stable return, and how that extra risk translates into increased demands for profit and value creation (through an increased 'hurdle rate'). This idea turned out to become very powerful as it set the premises for decades of portfolio management, where 'more risk = more required return' has become one of the fundamental pillars. Additional tools such as mean-variance optimization, pioneered by Harry M. Markowitz helped determine the best allocation of investments between different assets as a function of risk-return trade-offs. However, it proved inadequate outside of the financial sector for capturing all relevant dimensions around risk and return, and especially for accommodating the nature of research and development (R&D) activities.

Driven by the prospective, long-horizon nature of their R&D-driven business, the pharmaceutical and oil and gas industries led the way to more suitable methods by applying the principles of decision analysis to portfolio management on a project level (for example, assessing risk, return and strategic fit through decision-tree analysis and risk-adjusted net present value (NPV)). In the 1980s, this fortuitously coincided with the rise of popular management tools such as re-engineering, strategic planning, and shareholder-value-based management. Improvement in the approach was further fuelled by the IT revolution that made business data widely accessible throughout an enterprise. By the end of the 1990s, sophisticated modelling tools were available on desktop PCs and analytical portfolio management had become standard practice.[2]

Yet for increased operational and financial transparency to improve the evaluation of business opportunities, the data behind it would need to be impeccable – and data in those days were often poor. Initial enthusiasm for new tools and techniques gave way to scepticism. Openness to new opportunities outside of established markets was especially diminished when 'garbage-in, garbage-out' portfolio analysis frequently pointed to them. Some executives began sarcastically referring to NPV as 'no predictive value'. But instead of accounting for or correcting poor data, some managers used the weakness of a few efforts as an excuse to completely dismiss analytical portfolio management. This provided what some of them wanted in the first place: a reason to continue to base decisions largely on intuition, experience and a self-professed ability to see 'the big picture'. (See also Figure 1 for a description of the different stages that portfolio management went through in its 'life cycle'.)

Additional problems arose in the pharmaceutical industry as an R&D productivity crisis came into full bloom in the late 1990s. It continues today, and forecasts indicate that the end is not in sight. Over the next three years, the decline in productivity will have collided with an unprecedented wave of patent expirations, resulting in historic strategic challenges for pharmaceutical companies. Combined with onerous regulatory demands, along with the ongoing challenges of efficiently operating a business that relies on prospective research, this confluence of difficulties is forecast to drive a loss of up to 15 per cent of global market sales to generics in 2012 alone. The overall impact threatens the very survival of companies in this space.

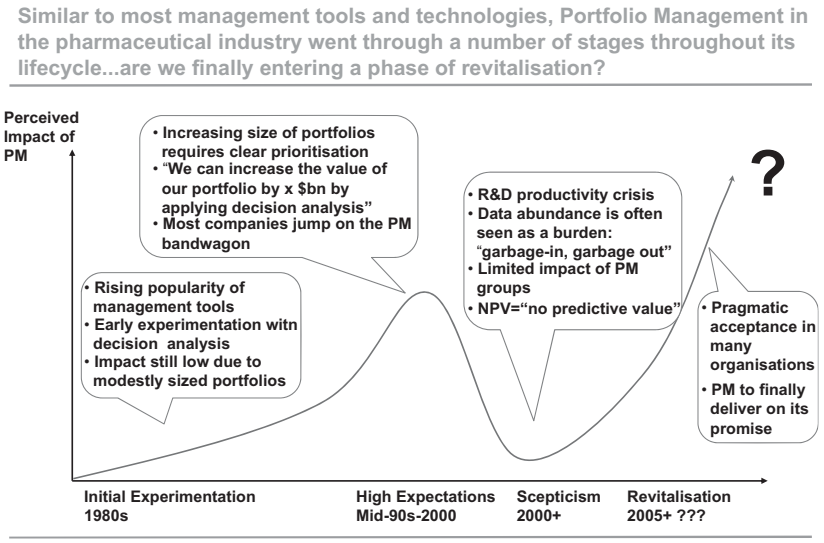

Figure 1: The life cycle of portfolio management.

The pharma-space challenge: Portfolio management must reflect R&D realities

The demands of business seem at odds with the demands of R&D-oriented pharma. Companies in this space seek breakthroughs – new products and treatments – that can arise only out of scientific research that is inherently prospective: That is, the price of developing a single treatment that works is to develop many that do not.

In its simplest form, the method of pharma R&D is anathema to managers: It is the pursuit of many (often costly) things that ultimately will not work in order to find one thing that *will* work. Multi-faceted investigation leads researchers to those vital few outcomes that address unmet needs – and thus creates new opportunities, new markets, new industries and even new business spaces. The fits and starts of investigative science are the foundation of the pharmaceutical industry. The problem therefore is not to re-invent R&D but to revise portfolio management methods to accommodate its realities. (And if the scientific method might somehow, someday be improved by a lesson from portfolio management, we will produce a paper on that, too.) The need exists at every level: corporate, therapy and project. The number of compounds coming out of Discovery and moving into Early Development has increased, as have potential development strategies, especially in high-interest areas such as oncology and inflammation.

Enhanced portfolio management becomes a Merck Serono priority

In 2006, Merck KGaA of Germany acquired Serono SA of Switzerland in a strategy to grow from a local, mid-sized pharmaceuticals and chemicals company into a leading global biopharmaceuticals player. Senior management declared the acquisition's goal to be the building of a 'Best Pharma' organization instead of another 'Big Pharma'. Executives of the newly formed company embarked on a major effort to revitalize portfolio-related decision-making and raise its priority throughout the organization. Leadership wanted to increase the quality of projects and processes, and manage the technical and commercial risks in the portfolio more effectively. In particular, Merck Serono

defined two objectives for the post-merger portfolio management review:

1. create a better balance between risk and potential return by basing decisions on clearly identified strengths and weaknesses of the current development portfolio; and
2. create a best-in-class approach to portfolio management covering the entire R&D portfolio.

To support portfolio management, leadership established a formal, board-level function for its oversight, with full line responsibility for all project leaders in Product Development. In particular, the group would act as a buffer and arbiter for reducing conflicts between R&D and Marketing over project strategies. A Portfolio Management Group was also installed within the Research function.

With explicit boardroom support and clear directives identified, the authors of this article, along with other key leaders in Merck Serono, set out to improve portfolio management within the company. We began with a survey of current practices.

PART II: LIMITATIONS OF CURRENT PRACTICES

Companies often get stuck in a vicious cycle that locks in a lack of productivity, which poor portfolio management reinforces. When short-term productivity goals produce sub-optimal project resource allocation, companies experience a decrease in project quality and an increase in attrition. To reverse that attrition, the productivity-driven approach jams more drug development projects into the pipeline – but it doesn't help, because it only spreads resources ever thinner. In the end the few projects that do generate products that make it to market tend to be modest in their innovativeness and of little interest to the buying public. The situation is further aggravated by what we call the 'organizational merry-go-around': Frequent re-organizations and shifts in strategic direction make it impossible for any change to 'grow roots' and have a significant impact. (See also Figure 2 for a description of the two homemade causes of the R&D Productivity crisis.)

To quantify the nature of these general conditions, we reviewed current practices to

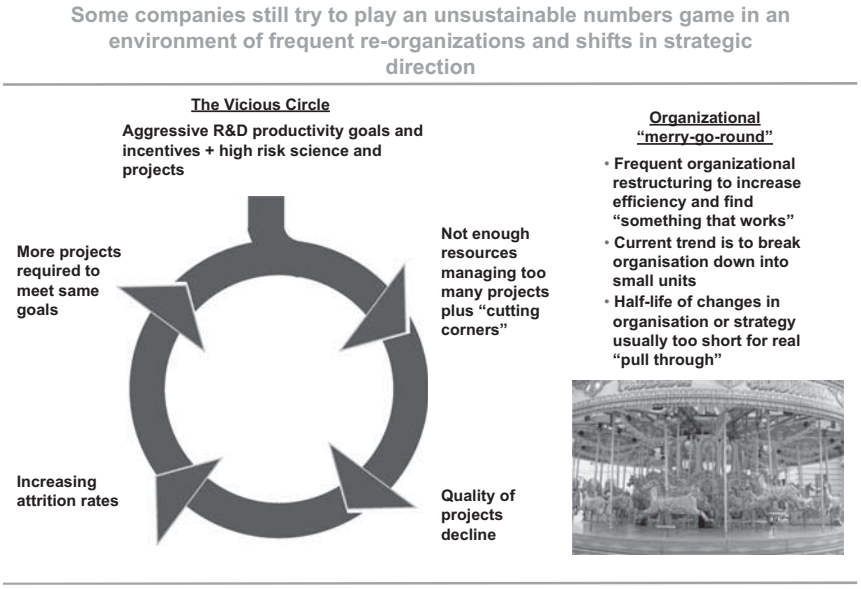

Figure 2: Two homemade causes of the R&D productivity crisis.

portfolio management in our industry and in legacy organizations, and identified four overall limitations:

- portfolio management had become a bureaucratic process that was not really embedded in the organization;
- senior managers were sceptical of the portfolio management process and tended to rely on their own experience and judgment rather than on analyses prepared by people with (in their view) less experience and an inferior track record;
- project teams saw the process as an added burden placed on top of their already heavy workloads, and one with little visible benefit to them; and
- the perceived high ratio of effort to benefit undermined the standing of the portfolio group, causing it to pull back and limit its role to keeper of data and templates. The group felt little inclination to challenge powerful line managers, and therefore had little impact on decision-making.

Four specific process-related shortcomings also emerged:

- science- and development-related risks of R&D projects tended to be under-assessed;
- valuation of early-state assets (such as projects in research, preclinical or Phase I development) lacked appropriate tools for analysis. Techniques developed for late-stage assets were misapplied to earlier stages of R&D; these efforts were resisted by R&D professionals, who asserted that they shackled creativity and innovation;
- while real (if hidden) value comes from structured dialogue between key stakeholders, such communication was rarely implemented. Templates and fill-in-the-blank exercises were often – and ineffectively -substituted; and
- managers often sustained projects past the point of productivity and possibility on the belief that 'additional studies' might validate an ongoing effort; however, the data necessary for a decision often existed and was missing or obscured because of abbreviated or over-simplified presentation and inadequate metrics (such as the expected net present value (eNPV)).

PART III: THE NEW PROCESS – FOUR CLEAR STEPS

With clear needs identified, we sensed an opportunity to create competitive advantage by directly addressing these shortcomings. The new process we designed consisted of four differentiated and task-oriented steps applying to both early- (Research, Preclinical Development and Phase I) and late-stage projects (Phase II and beyond) (see Figure 3 for a more description of the four steps).

Step 1: Project claims and strategies

For early-stage projects, we saw a need for teams to take into greater consideration the uncertainty and the bandwidth of opportunity in their projects. Therefore, we replaced static Target Product Profile (TPP) with *dynamic* Option Space Mapping process.

In current practice, TPPs often lead to the formulation of non-quantitative (and thus non-measurable) goals such as 'We want to be significantly better than the current or expected future "gold standard" at time of launch in terms of efficacy with a similar safety profile'. Sales forecasts and NPV models are built on this basis, often without proper risk assessment and scenario analysis to account for the significant uncertainty hiding in the TPP statement. We significantly improved on this by using Option Space Maps, which capture the uncertainty by defining several strategic alternatives and respective R&D requirements, such as 'Follow the leading competitor in development and meet threshold performance criteria for differentiation' or *Focus on high unmet need in an underserved niche indication for fast approval, and then expand into larger markets*. This simple requirement for quantitative goal-making embeds strategic thinking at the project team

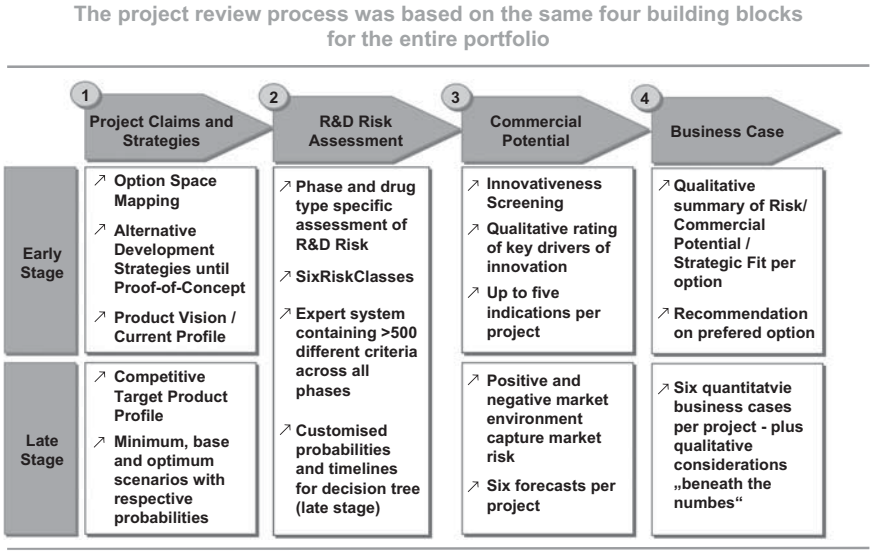

Figure 3: Overview of four building blocks for early-stage and late-stage projects. Step 1: Project claims and strategies.

level, where it is so necessary but often so lacking.

For late-stage projects, we emphasized discussing and challenging the clinical strategy with respect to the most likely outcomes (baseline profile), downside risks (minimum profile) and upside potential (optimum profile). These were captured in the Competitive Product Profile (CPP). Sometimes the probabilities assigned to the three CPP outcomes came as a surprise to the team; it did not always assign the highest likelihood to the officially approved baseline CPP profile. Similarly, significant risks sometimes were seen that increased the likelihood of a *minimum* outcome.

A key difference between this approach and previous approaches to portfolio management was that the reviewers of the Portfolio Group were often elevated to facilitators and catalysts in a project strategy discussion. In a number of cases, this led to a shift or complete change in project strategy. (See also Text Box 1 for a more detailed Description of the Option Space and CPP processes.)

Step 2: R&D risk assessment

In contrast to classical portfolio management, in which reviewing risk is usually limited to discussing whether a project should have a higher or lower probability of success compared to industry benchmarks, we focused on reviewing and interpreting *all* R&D-related risks. We used a comprehensive and detailed expert system provided by Catenion adapted to Merck Serono's process and needs. (See also Figure 4 for a description of the six different risk classes in the system.) The system included seven years of data and analyses across all disciplines involved in R&D. This approach provided teams with the means for quantitative examination and analysis of their perspectives and conclusions. In some cases the results of the expert system triggered a discussion that led to changes in project strategies. This in-depth review of risk also proved instrumental in engaging senior management, providing it for the first time with a transparent and objective basis for comparing risks across projects. (See also Text Box 2 for a description of the risk assessment process.)

Box 1: From Target Product Profiles to Option Space Maps

In many companies, portfolio management places significant emphasis on Target Product Profiles (TPPs) in the early stages of R&D. However, the unwanted consequence of using a TPP too early and too strictly can be that valuable options are discarded when the goal should be to select the optimal development strategy. There is one exception: when dealing with clearly defined Lifecycle Management projects or incremental convenience-driven applications in well established markets.

To overcome this issue, we use the 'Option Space Mapping' process for early-stage projects. An 'Option Space Map' lists alternative project strategies, each comprising a different indication, patient population, development path and positioning objective in the target market. These options derive from the outcome of an intense discussion within the project team structured along four dimensions – 'Scientific Confidence', 'Market Situation', 'Competitive Clinical Data' and 'Position of Project in Merck Serono's Pipeline'. This process has been designed to stimulate an organizational dialogue that encourages creativity and out-of-the-box thinking, in striking contrast to the more formal TPP sessions that often feel like filling out templates.

The process for late-stage projects is more formalized as more critical data are available and there are usually better laid-out project strategies. For this purpose a Competitive Product Profile (CPP) is generated based on the existing strategy. In such a CPP, the project is compared along a number of dimensions (efficacy, safety, convenience) versus existing and expected future gold standard treatments. A strong focus is placed on unearthing the main risks associated with the profile, both R&D- and market-related.

In workshops to define the product profiles, the assumptions behind the clinical strategy are discussed in light of the competitive situation. Focus is put on an in-depth understanding and documenting of crucial 'make or break points', such as the variability of the clinical endpoints, the basis for the statistical powering of the study, and their respective upsides and downsides. To capture uncertainty, three profile outcomes are created, each one with a distinct probability (minimum, base and optimum profile).

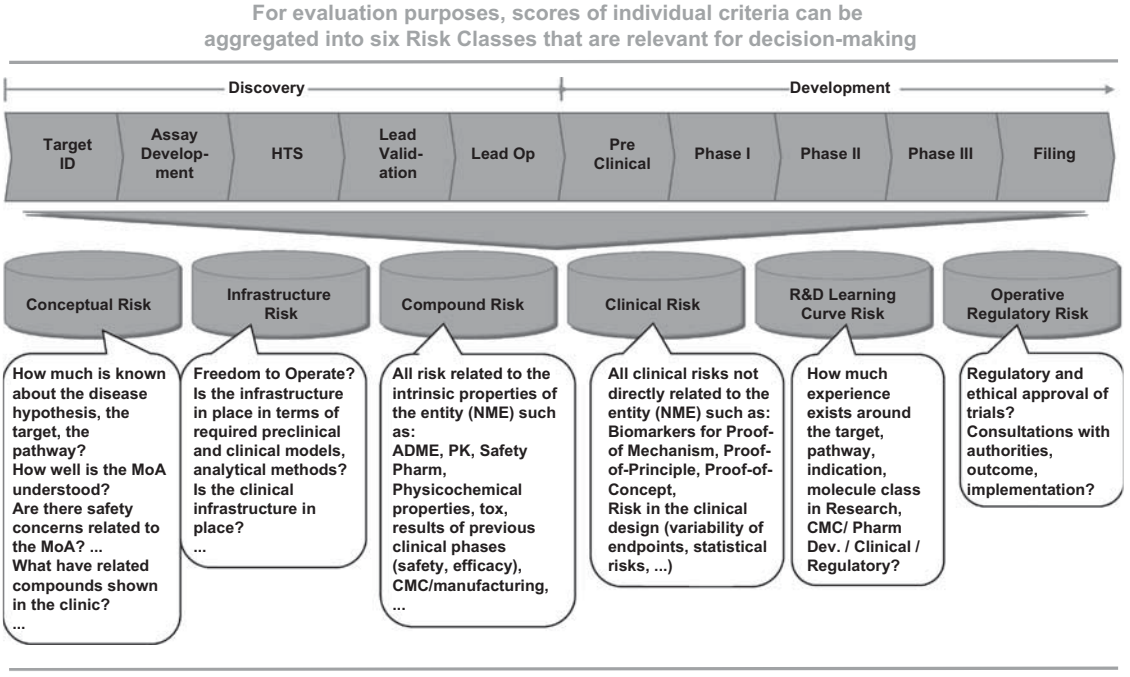

Figure 4: The R&D risk assessment evaluates six different risk classes.

Step 3: From innovation to value – Capturing commercial potential

There are numerous anecdotes in the pharmaceutical industry showing the near impossibility of forecasting the commercial potential of highly innovative early-stage projects; even for late-stage projects the uncertainty is often significant. (As a recent

Box 2: Assessing R&D risk

Assessing and interpreting R&D risk is one of the fundamental activities of a pharmaceutical R&D organization. There are many unknowns and risks in a typical pharmaceutical R&D project and any one of them can turn out to be a showstopper. Interpreting them correctly is something that can make or break a career (or even a company) and it takes lots of expert knowledge and experience. This is one of the most critical capabilities in which a large organization should have a clear advantage over less experienced smaller biotechs.

In light of costly late-stage failures that sometimes come as a surprise to management and force companies into the next spiral of restructuring or M&A, managers must make risks more transparent, understandable and comparable across projects. Most attempts to systematically and objectively assess risks have not gone beyond generating simple checklists, scoring schemes and decision trees using average industry benchmark data that may fluctuate by year and source. None has gained broad acceptance.

The risk assessment scheme used here differentiates phases of R&D and drug types; for example, small molecules versus monoclonal antibodies versus vaccines. This system has been built over several years by Catenion with various pharmaceutical clients. The otherwise undocumented knowledge of hundreds of experts from all disciplines involved in the R&D process has been uploaded into an expert system, ordered, ranked and appraised.

This blueprint scheme has been specifically adapted by internal experts to be consistent with the Merck Serono R&D process. Owing to the large number of criteria, many of them carry only little weight if there is no severe issue associated with it. But even criteria of little overall weight can turn out to be showstoppers. To model these potential showstoppers (for example, the toxicity of a poor physicochemical property of a compound) and make them visible in the overall score, we came up with an adaptive system that adjusts weights according to the severity of the identified issue.

The results of our risk assessment contained few surprises for team members with long tenures. However, newer members and those not intimately involved in the projects were quite surprised by the magnitude and nature of risk in some of the projects. This approach to R&D risk assessment brings openness and transparency to a field that tends to be shielded by experts whose attitude is often 'don't talk about these risks or issues, because non-experts will misinterpret them anyway and endanger the project's status'.

Culturally, it is always a challenge to inculcate such openness in an organization. But the fact that all this happened as part of Merck Serono's post-merger review made it much easier, as processes, practices and behaviours were evolving throughout the organization. In that environment, previously held beliefs could be challenged safely.

Box 3: Assessing commercial potential

For early-stage projects (Late Research to Phase I) we decided to use a qualitative approach for assessing commercial potential. The 'Innovativeness Screening' reviews the different drivers of innovation. While the logic of the 1990s was very much 'we can turn any drug into a blockbuster' through massive sales force and marketing investments, this has changed dramatically as reimbursement and co-payments are now increasingly linked to the degree to which a particular drug is innovative. The 'Innovativeness Screening' approach used is based on four factors: Novelty, Relative Usefulness, Theoretical Market Potential and Exploitability. These factors are scored and can be displayed in two simple matrices looking at the strength of the product *per se* (Novelty versus Usefulness) and how that strength translates into attractive sales potential for Merck Serono (Theoretical Market Potential versus Exploitability).

For projects from Phase II onwards, it is possible to build a full-blown market forecast and valuation model. The determination of market shares is based on a rating scheme in which the product profile features, price, order of entry and marketing strength are rated against competitors. This approach ensures maximum transparency, as all ratings are subject to intense challenging and debate in the teams. It also forces the teams to fully understand the competitive environment and the strengths and weaknesses of their project. Significant emphasis is put on capturing the major uncertainties in the product profile and the market environment through the creation of six scenarios per project and then estimating their respective probabilities. The creation of these scenarios sometimes leads to a large spread in the resulting sales forecast and valuation model. However, this only added to the approach's credibility with R&D and marketing professionals, who have been trained by experience to be sceptical of allegedly precise sales models.

example, the inhaled insulin Exubera, predicted to be a blockbuster, was pulled off the market by Pfizer in late 2007 after a dismal first year.)

Our approach to assessing commercial potential differentiated between early-stage and late-stage projects and relied on creating scenarios and alternatives. (See also Text Box 3

for a more detailed description of the approach.) To account for the significant uncertainty in forecasts and NPV models, we abandoned point estimates and single best guess value for unknowable data, and instead defined potential uncertainties as clearly as possible, with estimates of their probability.

In some cases, the range of forecasted peak sales or value was broad. While this might have been a disappointing result, teams and management ultimately came to appreciate this range of statistically justifiable (and therefore realistic) possibilities. Managers preferred impartial, quantitative analysis to single point estimates built on intense political debate, personal interest and inherent but unrecognized bias. By creating six scenarios, we focused on possibilities as the product of quantifiable reason instead of the 'best guess' of an analyst or manager. (See also Figure 5 for an example of the six scenario approach.) However, we encountered resistance to this multi-factor approach, with some managers preferring the 'gut check' simplicity of single point estimates, and others focusing only on positive scenarios and ignoring negative ones.

Step 4: The business case

While several clear-cut decisions were taken on the project level, the ultimate aim was to create a better portfolio risk/return profile. For this purpose, projects were placed in risk/return matrices based on commercial potential or value versus risk. For early-stage project comparisons, we created 'heat maps' that allowed a quick overview of the entire portfolio and its strengths and weaknesses. For the late-stage portfolio, we created 'Value-at-Risk' plots for each therapy area and the entire company based on probability density functions. These plots allowed senior management to fully appreciate both value potential and risk across the entire portfolio. (See Text Box 4 and Figure 6 for a more detailed explanation of the 'Value-at-Risk' approach.) For instance, pronounced differences between therapy areas led the team to an analogy of managing a pharmaceutical R&D portfolio as managing financial assets in a classic investment portfolio: the risk profiles of some areas looked like high risk/high reward 'options', some looked like low-risk 'bonds', others like 'blue chip stocks'.

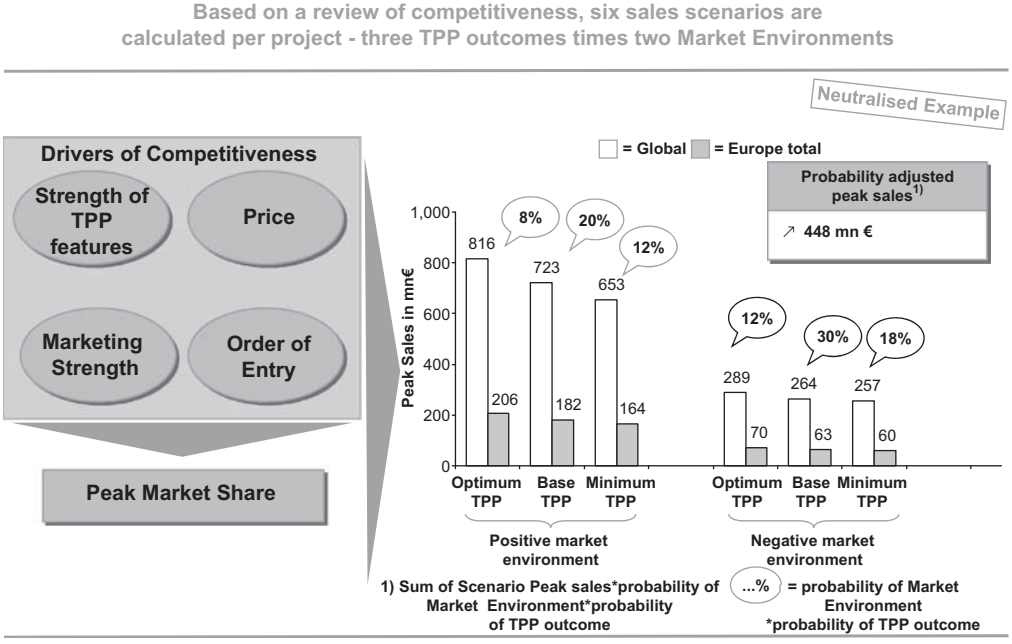

Figure 5: Six scenarios capture market and TPP uncertainty.

Box 4: A portfolio simulation

To assess risk at the portfolio level, we developed a stochastic simulation model that generates distribution curves for each therapy area and the entire late-stage portfolio. This Monte Carlo simulation can best be explained through the analogy of a card game. Each project is represented by a deck containing 100 cards, each card reflecting a 1 per cent likelihood of a given scenario. (For each project, at least six distinct market scenarios are represented, plus their respective failure scenarios.) For example, if a scenario has a likelihood of 15 per cent, the deck would contain 15 cards representing that scenario.

All projects are then lined up with their respective deck of cards and one card is randomly selected per project. The scenario values of the drawn cards are summed up to calculate the portfolio NPV. This is repeated 100 000 times, as the cards are always returned to their original decks (that is, sampling with replacement). The frequency of scenarios gives the probability distribution and is a clear indicator of the true risk/return profile of the portfolio. The mean of all scenarios in this simulation is identical to the classical Expected NPV.

An important outcome of this analysis is to illustrate the impact and importance of risk diversification. The larger the portfolio, the less likely is it to fall victim to extremely negative (and positive) scenarios. Apart from project quality, this is the best insurance against the catastrophic scenarios in which several projects fail simultaneously. On that basis we have developed a number of metrics for the portfolio on a therapy area and corporate level. These represent the 'Mean Value' of the portfolio, the 10th and 90th percentiles as well as the 'Catastrophic Risk Probability', which would give the likelihood of the portfolio value being below an acceptable threshold (for example, sales or value objective in the long-term plan of the company). (Incidentally, this type of simulation also provides a powerful argument for a networked and diversified R&D model – owning two 'halves' of a project through in-licensing leads to a more favourable risk profile than fully owning one internal project, even if the Expected NPVs are defined as equal).

The aim of this portfolio simulation was help create a curve with a more favourable risk-return profile from Merck Serono's perspective. It is important to note that there is no such thing as an ideal profile. Each company must define how much risk it will accept within its portfolio – that is, how many portfolio outcomes with only marginal or even negative value are acceptable. Should some upside (of the more favourable scenarios) be traded against a lower risk of catastrophic multiple failures or scenarios that end in very negative market environments? Ultimately, the question every company must answer for itself is, 'What is the value and risk combination in my portfolio that best meets the strategic goals of the company?' But to answer that question, the organization first has to learn how to ask it.

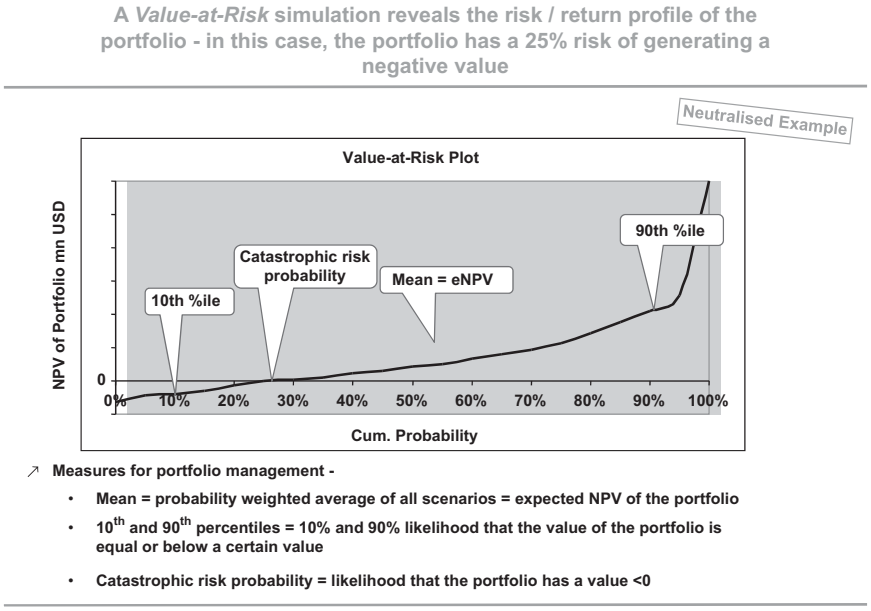

Figure 6: A value-at-risk portfolio simulation.

PART IV: THE RESULTS OF IMPLEMENTATION

Revitalized portfolio decision-making

On the basis of our improved system, executive managers redirected resources toward improving the risk/return profile of the company's portfolio. This was done by taking an integrated view based on quantitative assessment of risk, the quality of the science involved and the value of clinical data. In contrast to the standard approach to portfolio management, a more vigorous and quantitative system made the Merck Serono executive team willing to spend several days over the course of seven months discussing projects and the portfolio in detail, to study the technical risks and the range of potential project and portfolio values. The systematic approach made complex decision-making more manageable, reducing the temptation to consider only aggregated results and leave detail to 'specialists'.

Leaders prioritized projects using a system of four 'buckets': High Priority, Continue, Clarify and Exit. The prioritization was based on a holistic view of all elements of the assessment: risk, return and strategic fit, and the portfolio group drafted a recommendation for consideration by the executive team.

Structured dialogue with project teams and key stakeholders

A key factor for the success of the new organization was the securing of an adequate time commitment for effective portfolio analysis. Project teams and other key stakeholders were heavily involved from the start. On average, we had four intense half-day workshop sessions with each project team. In these sessions, the teams not only reviewed the baseline strategy but also used the process to create new or revised strategies, which were then recommended to Senior Management. With their unbiased perspectives, consultants from Catenion acted as process catalysts. Taken together, these players formed the Portfolio Group.

At the beginning of the process, a typical response was, 'Just send us the templates and we will fill them out. There is no need to meet and spend a lot of time on this'. Yet in a survey at the end of the first-year process, and after literally hundreds of meetings, a clear majority of the teams described the intense process and interaction as 'helpful' or 'very helpful'.

Ongoing improvements

In 2008, two years after the merger, we introduced an important modification. The cross-functional groups responsible for Therapy Area Strategies, a major area of concern for our company, came up with their own recommendations for prioritization and resource allocation within their areas. The executive team ensured that corporate goals and objectives were reflected in the portfolio, and then they set the overall therapy area budgets based on the value and risk profile of each area.

The nature of the improved portfolio

In the first year post-merger, the organization's focus was on reducing and mitigating risk by pruning the portfolio, as well as generating a realistic view of the growth potential and value of what remained. Across the joint portfolio, executive management

- *stopped* 19 Development projects, from phase 0 to III;
- *repositioned* or *changed the strategy* of 19 other Development projects; and
- *stopped* 37 projects in Research.

The fact that the executive team took control of the portfolio and made difficult decisions was seen as a positive signal by the organization. Naturally, not all decisions were applauded by everyone, but the fact-based approach to prioritization and resulting clarity was highly appreciated.

In the second year, the focus turned toward balancing the portfolio and allocating resources according to potential. It became evident that in some areas such as oncology, there was significantly more potential than

what could be sufficiently funded.[3] A strict prioritization was performed and executed to avoid underfunding of high-priority projects for the sake of trying to do everything (and essentially feeding the vicious circle of doing many projects weakly instead of doing promising projects well).

Also in the second year, the focus turned to broadening the skill base throughout the organization in decision analysis and portfolio management. To achieve this, we designed a series of case studies for early- and late-stage projects. We then trained groups over a few days by working on a case study and on the modules of the project evaluation. This proved to be an essential element in overcoming internal resistance and enabling the project teams to use basic elements of decision analysis themselves to better navigate the vast option space of clinical development and market strategies.

Crucial success factors and next steps

Although the new process has now been in use for two years, this is really just the first step in revitalizing and improving portfolio decision-making at Merck Serono. The culture of fully transparent, engaged and consistent decision-making will certainly evolve, very much in the spirit of other continuous improvement processes. The overall effort is substantial, but the returns on better decisions at all levels add substantial value of its own. All this comes at a time when the industry is spending billions on developing and marketing new drugs through partnering and the acquisition of high risk early-stage technologies. Compared to these efforts, an effective portfolio management process is a relatively cost-efficient way of improving the quality and risk/return profile of R&D output.

In retrospect, a number of factors proved essential for successful implementation: We engaged the organization very broadly; at the same time, we called for strong top-down leadership to make things happen and to not get stuck in fruitless debates about process and tools. A strong and neutral Portfolio Group was installed, complemented by external facilitators empowered to challenge project teams and key stakeholders on a peer level. Clear governance principles were also developed; while the Executive Management Board was given ultimate accountability for developing the portfolio, the cross-functional Therapy Area leadership teams were given the mandate to prioritize within their areas and to align portfolio and strategy. In addition, only one high-level committee in R&D focused on reviewing and approving technical and clinical plans as well as milestone decisions. The appropriate tools and process served as a strong foundation, but in our view, any portfolio management effort can only be successful if the above-mentioned organizational factors come into play.

The process has also created a new role for the Portfolio Group. While previously the focus was on crunching numbers and preparing reports for senior management, now it functions as a partner for the project teams and the Therapy Area strategy groups. By moderating key workshops and digging deep into project and therapy area strategies, the Portfolio Group has essentially turned into a knowledge broker facilitating idea sharing, implementing best practices across fields, making connections at the working level, and providing input and guidance on process and content. (See also Figure 7 for a summary of the crucial success factors.)

Although portfolio management at Merck Serono was off to a quick and successful start, continued success will require perseverance, ongoing support from senior management, and reinforcement within the infrastructure. The attraction of habit – basing decisions primarily on hierarchy and experience – is strong, and this barrier to effective portfolio management should not be taken lightly. However, success is a strong incentive, so based on results so far, we are greatly optimistic.

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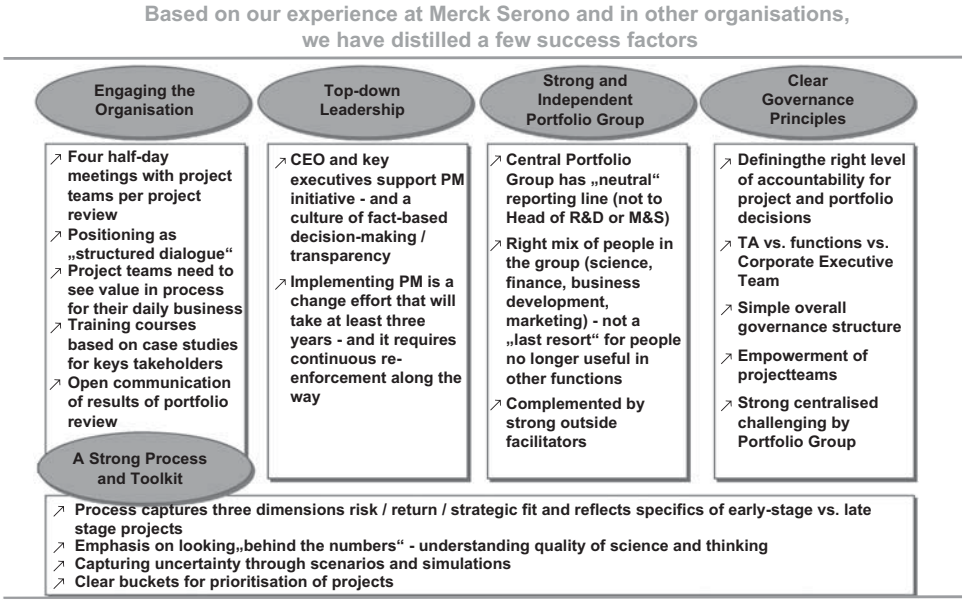

Figure 7: Crucial success factors.

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1. Sharpe, W.F. (1964) Capital asset prices: A theory of market equilibrium under conditions of risk. *Journal of Finance* 19(3): 425–442.
2. In 1994, then-CFO of Merck & Co Judy Lewent discussed the benefits of decision analysis and real options principles at Merck & Co. with the *Harvard Business Review* ('Scientific Management at Merck: An Interview with CFO Judy Lewent'; January-February 1994). In 1998, Tom Keelin and Paul Sharpe wrote a seminal *HBR* paper on the use of decision analysis at SmithKline Beecham ('How SmithKline Beecham Makes Better Resource-Allocation Decisions', March 1998).
3. For example, one of the pillars of the Merck Serono oncology strategy has been to drive novel-novel combinations. Numerous potentially synergistic internal combinations are possible.