An Innovation Scorecard for the Pharmaceutical Industry

Dimitris Dogramatzis, PhD
Regional Vice President – Northern Europe, Serono Pharmaceuticals Ltd, London, UK

Introduction

The new product development process is an arduous, time- and resource-intensive procedure, requiring up to 12 years and an average of US$ 500 million to complete. These facts, together with the patent exclusivity period lasting up to 20 years from the patent award date, make the new pharmaceutical product development an extremely expensive and risky procedure. Nevertheless, most pharmaceutical companies have, until very recently, treated R&D as a black box. It was, thus, thought that pouring more people, budgets, and assets into R&D would hopefully end up in producing more innovations. That situation can no longer hold true, as the intense competitive forces, increased government regulation, and scarcity of resources mandate a more proactive, accountable, and transparent project prioritization, resource allocation, and results’ evaluation process of the critical R&D sector.

This article discusses the gradually emerging trends in R&D evaluation. Interestingly, improving the industry’s R&D cycle times and reducing their costs are not the only benefits, or even the most important ones, to be gained from the universal development and practical application of better R&D evaluation methods. Indeed, the most important benefit from such a fundamental change in the industry’s way of thinking would be the wider, faster, and cheaper innovation of new medicines that would eventually improve the quality of patient lives. In 2000, USA’s-only pharmaceutical companies spent US $ 26 billion in R&D, and have introduced almost 70 major new medicines during the past 20 years (Source: PhRMA). Imagine the patient lives saved, the hospitalization hours avoided, the employment hours protected, as well as the priceless time with family and friends of all those patients whose life would be affected by an across-the-board increase in pharmaceutical industry’s R&D efficacy and efficiency. We would all agree with such a worthy cause.

Recently, an increasing number of government, independent, or industry organizations around the globe have been attempting to establish those procedures and mechanisms required for an effective R&D evaluation. In fact, in 1992 the Industrial Research Institute established a Subcommittee on the Measurement of Effectiveness in R&D, which has since conducted a series of pioneering studies on the prevailing trends in R&D evaluation among a large number of technologically driven industries. In 1993 the U.S. Government passed the Results and Performance Act, which provides for the establishment of strategic planning and performance measurement in the Federal Government. And in 1997, the Organization for Economic Co-operation and Development held a workshop on the evaluation of basic research, where several of its member States presented their national evaluation initiatives. In addition, several organizations have focused their evaluation efforts on the pharmaceutical industry, such as the Centre for Medicines Research International, the U.S. Congress Office of Technology Assessment, as well as several industry associations, including the Pharmaceutical Research and Manufacturers of America and the European Federation of Pharmaceutical Industries and Associations. Those organizations are using three main evaluation practices.

- **Qualitative:** This approach uses subjective scales, such as peer reviews and user surveys, focus groups or in-depth interviews. The evaluators range from external and internal experts to physicians, pharmacists, and consumers eager to give their input in new product development.

- **Semi-quantitative:** Here the emphasis is placed on case studies - either forward tracing of research funding or backward tracing of successful medicines, in trying to establish best practices in the development
Drug Discovery and Bionformatics

- **Quantitative**: These methods employ the use of benefit-cost analysis tools, as well as various benchmarks. In fact, the industry may use both a strategic and a performance benchmarking, or conduct either an internal or a wider, external R&D benchmarking, versus other therapeutic class competitors, the pharmaceutical industry as a whole, parallel industries (chemical, cosmetics, etc.) or even best in the world comparators (automotive, computers, etc.). The most commonly used R&D benchmarks can be categorized within five distinct steps of the R&D process, shown in Figure 1. Thus, every R&D organization employs a variety of inputs and processes to produce a series of valuable outputs, outcomes, and impacts.

Figure 1. The R&D process in the pharmaceutical industry.

An in-depth evaluation of a company’s R&D function should always be bifocal (see Figure 2). The first part focuses on the external R&D environment, which is important in reaching decisions on globalization, decentralization, or foreign investment. The second part focuses on the internal R&D environment, and is important in evaluating the R&D inputs, processes, outputs, and long-term impacts of industry R&D departments.

Figure 2. Factors influencing the external and internal R&D environment of the pharmaceutical industry.

### The catalytic role of government

Several countries around the world have provided significant support of state and private R&D over the recent years, and such interaction has added value to their national innovation levels. In fact, the healthcare industry
holds a primary position among the industrial sectors supported by government funding worldwide. The assessment of the external R&D environment should focus on the role of government in the form of financing, establishing interaction, and transferring the technology from into the industry. Commonly used financial benchmarks are the science education expenditure, the higher education expenditure on R&D, and the gross domestic expenditure on R&D.

The industry-to-government interaction can materialize through different types of collaboration or networking. Examples include the industrial liaison offices at academic campuses or the establishment of innovation clusters, such as Silicon Valley in the US. The number and size of cooperative agreements, the commercialization incentives, and the number and activity of technology transfer intermediaries - information database vendors, technology brokers, R&D parks, consulting firms, venture capital firms - are some of the parameters that companies have used to evaluate the transfer of technology between industry and government. The existing science and technology (S&T) infrastructure is a major determinant of industrial R&D decentralization, foreign investment, and globalization. The national income, imports and exports, and foreign direct investment are some of the measures that can evaluate the socioeconomic infrastructure. The measurement of the interaction between government and industry, the diffusion of knowledge, and the mobility of human resources can indirectly evaluate the national innovation system. By measuring the exchange of resources, personnel mobility, technology trade, or publication flows across national borders industry insiders have also evaluated the internationalization of a given national S&T environment.

The power of intellectual property

The term of a patent for an invention is presently 20 years from the date on which the application for the patent was filed in the United States. However, as much as 12 years are needed for the completion of a product’s R&D phase. Therefore, a pharmaceutical innovator is left with only a limited period in which to get a return on the significant R&D investment allocated to its discovery. Consider also the fact that, a patent for a pharmaceutical invention may have different legal statuses, being valid in certain geographical regions only, or a large number of remotely located countries, depending on the existence of a patent protection framework. National membership in global economic/trade organizations (European Union, World Trade Organization, etc.) is a positive step in establishing such frameworks.

Some national authorities may strictly enforce the market exclusivity provided by a patent, while others may not have the resources, or the means, or even the political will to bring it into effect. In such situations, the marketplace doors are wide-open to “me-too” manufacturers, and the return-on-investment of the original manufacturer becomes a distant goal. Leading industry players now proactively conduct thorough analyses of national intellectual property frameworks, before investing in those territories.

Are you a good R&D general?

An organization's ability to set a visionary, clear, achievable, and effective R&D strategy is of paramount importance in maintaining a long-term innovative record, and ensuring the long-term viability of the organization under the intensely competitive environment of the pharmaceutical industry. Is a company’s innovation strategy possible to evaluate though? – critics may be fast to ask. Indeed, as industry insiders and observers have been looking at its companies’ strategic intent, intellectual capital management, portfolio management, and the existing interfaces.

Leading companies are exploring various approaches to evaluate their R&D strategic intent, i.e. which therapeutic area to invest into. Let’s take the example of a fictitious pharmaceutical company, namely Hypothetical Pharma. For reasons of limited resources, the company’s top management has been currently trying to decide whether to invest in either of two promising new compounds, molecule-X potentially indicated for asthma, or molecule-Y potentially indicated in obesity. The major considerations in defining their strategic intent included the market size, market potential, the therapeutic area expertise, the identification of an unmet therapeutic need, as well as the internal R&D capabilities. In this case, the volume of asthma prescriptions written last year far exceeded those of obesity (asthma had a larger market size). On the other hand, the number of obesity sufferers as well as the use of “lifestyle products”, such as the anti-obesity medications, has been forecasted to rise tremendously in the next decade, indicating a greater market potential for the obesity market. Hypothetical Pharma’s management unanimously agreed that the company’s therapeutic area expertise was far superior in obesity, having introduced a series of less successful products in the eighties. Furthermore, consumer market research analyses from the top 6 national markets clearly indicate a substantial therapeutic need for a new and effective anti-obesity medication. Finally, Hypothetical Pharma’s internal R&D capabilities offered less promise for a top-of-the-line anti-asthmatic spray formulation, as opposed to their significant experience in developing oral formulations. Their decision was ultimately to support further research and development of molecule-Y in the obesity market.
Some companies are re-evaluating their decision making process, while others are focusing on the decision method itself. Within Hypothetical Pharma, the traditional top-down model of their CEO solely deciding on their future direction has recently been replaced by a more efficient bottom-up approach, where marketers identifying unmet therapeutic needs convey their findings to their R&D colleagues, who then set about discovering new molecules to treat those needs. Lately Hypothetical Pharma has been listening to both its internal customers (marketing, research and development, regulatory, legal, and public relations), as well as its external customers (physicians, pharmacists, nurses, patients and their families, and the media) in search of their new R&D targets, via a series of internal and external focus groups. In fact, the chief scientist of Hypothetical Pharma recently gave a lecture to an industry symposium, where several companies were presenting their own market-driven only approach to innovation, i.e. solely focusing their efforts where both patients and their prescribers felt a significant therapeutic need.

As far as the decision making method is concerned, Hypothetical Pharma’s teams have been involved in strategic brainstorming, submitting written proposals, or relying on detailed business analysis proposals coming from both internal or external (consultants, authorities, medical associations) experts. Another method that has helped them reach an R&D investment decision was the use of product champion presentations, e.g. their brand, business unit or marketing managers presenting their expert rationale for pursuing a certain therapeutic area in the future. Quality function deployment is another product development process that Hypothetical Pharma has recently been experimenting with. This method was first developed by Japanese companies, and involves the drawing of a house of quality, i.e. a detailed product development blueprint incorporating the customer wants/needs, customer perceptions, cost attributes, design attributes, as well as elements of the relationship between the customer and the planned product design.

Pharmaceutical companies are using a variety of intellectual capital estimation benchmarks - citation references per patent (the number of times the patent has been cited in publications), publication references per patent (the number of publications cited by the patent application), technology cycle time, and market-to-book ratio (stock market to asset value). Undoubtedly, the R&D portfolio management is one of the most critical tasks of Hypothetical Pharma’s corporate strategy. The main elements of that activity are to create a balanced portfolio across therapeutic areas, research platforms, and development phases, and also to allocate R&D resources in the most efficient way.

A closer look at the tools Hypothetical Pharma uses to select their portfolios reveals that those can be grouped under five different approaches, namely human judgement, financial modelling, risk strategy analysis modelling, statistical forecasting, or proprietary modelling. In-house research scientists frequently use human judgement tools, including checklists, project profiles, and scoring systems. These systems are more experience-based, comparing new projects with historic data, and taking into account internally acceptable cut-off points, e.g. time, cost, etc. Their R&D project managers are trained in using a plethora of financial modelling benchmarks, such as the payback period, and the net present value (NPV). In particular, the NPV method attempts to estimate the net present value of a project’s future earnings, based on the expected commercial value of the project, the probability of its technical and commercial success, as well as its associated costs (development and commercialization).

In their risk strategy analysis modelling, Hypothetical Pharma attempts to rank all their product portfolio projects using a two-dimensional axis of financial rewards versus their anticipated risks. For estimating the potential rewards, they take into consideration a variety of parameters, including the tentative pricing, the average duration of patient treatment, and the time from launch to peak sales. Furthermore, they define risk as the magnitude of their potential financial losses times the probability for failure.

Finally, Hypothetical Pharma has occasionally depended on statistical forecasting, i.e. trying to estimate the potential usage of their product after launch, by defining the percentage of patients in each step of the patient journey, that is from the healthy person becoming ill, becoming aware of it, seeking medical advice, becoming diagnosed, being prescribed a medication, and eventually complying with that treatment. Several industry insiders have reported a variety of external customer input benchmarks. In fact, a lot can be done to assess whether companies are listening to their customers. Measures range from the degree, timing, frequency, and contact method of direct input from customers, to customer satisfaction, as well as the percentage of innovation budget devoted to customer-originated projects, and the percentage of technical features equalling or exceeding competition.

And how about the financial investment in innovation, one of the major inputs into the R&D process? Here things to look at are the amount of the investment budget, its origin, and also the method spent. Once again, pharmaceutical companies vary widely in their R&D capital expenditures, budgets invested in new chemical entity development versus improvements/modifications of existing medicines, and also their therapeutic line split (e.g. investments in their antibiotics line, versus the cardiovaculars, oncologicals, etc.).

An R&D laboratory arsenal
Pharmaceutical companies are spending ever-increasing budgets in gradually building a formidable laboratory arsenal, thus making the technology base a ubiquitous asset for the industry. One has to evaluate the technological assets and processes, the process of their acquisition, and the access to important technologies. Focusing on acquisition, most experts would agree that the industry is quickly shying away from its previous intrapreneurial, self-sufficiency, “not-invented-here” syndrome towards the entrepreneurial spirit of forming as many strategic alliances as possible. The latter is also called the “anything invented anywhere” syndrome. Hypothetical Pharma frequently uses a variety of technology acquisition benchmarks, for example the number of strategic alliances, technology supplier base, new technology introductions, as well as personnel training and competency.

The industry has recently been involved in a wave of activity outsourcing, indicating the need for pharmaceutical organizations to focus on their core competencies, and minimize costs. The phenomenon has been increasingly evident within the R&D field, which traditionally has been viewed as a critical and internal-only industry activity. Due to this increasing trend, contract research and site management organizations have enjoyed a phenomenal growth in the last decade. Indeed, the decision to outsource or maintain the internal control of pharmaceutical R&D is a critical one. Some of the factors influencing Hypothetical Pharma’s decision are listed in Figure 3.

R&D partnering has also been called boundary spanning or virtual R&D. Industry players are evaluating their efforts by looking at their partnering strategy, policy, and activity. Partnership policy, on the other hand, calls for a centralized contract process, standard operating procedures, preferred provider status, monitoring and the establishment of an internal database. Activity evaluation focuses on the number, type, duration, and future potential of formed alliances and also the ratio of royalties paid to royalties received over a period of time.

Measuring the quantity, type, quality, and impact of R&D outputs and outcomes is one of the most commonly used evaluation methods. Hypothetical Pharma has even gone as far as benchmarking their patenting intensity. For example, since the beginning of 2000, top management now requests all R&D project funding requests to be accompanied by the number of patents filed per capita R&D personnel, the product or process patents granted, and the ratio of patents to total R&D expenditures. In addition, they will soon imitate major competitors who have recently introduced benchmarks such as the number of patents granted per $1 million of sales revenues, the percentage of sales covered by patents, and the age of patents. Obviously, in an ever more increasing competitive industry environment, Hypothetical Pharma is trying to ensure that most of its products and processes receive intellectual property protection.

Another aspect of pharmaceutical R&D that needs to be quantified is its long-term public impact. That impact goes beyond the influence on other research fields, or technology itself. In fact, it goes beyond the medical care systems and even medical education, eventually influencing the patients’ quality of life, and their families’ coping with the disease. Those influences are inevitably transferred to the general public, via the media.

How do you award Olympic medals to R&D winners?

R&D performance can be evaluated through a variety of parameters. Let’s take another look at our trusted industry example, namely Hypothetical Pharma. Its specialized R&D project managers have always been paying close attention to their R&D portfolio financial returns, costs, time, asset utilization, and goal attainment. Furthermore, increased transparency and accountability resulting from an intensifying competitive environment, have led them to closely monitor researcher productivity (comparing their outputs and results), departmental
effectiveness (to reach previously agreed goals), quality (measured via ethics committees’ and regulatory agency comments), and customer satisfaction. Furthermore, cycle time is of paramount importance in determining R&D performance, due to the increasingly competitive healthcare environment, and the growing regulatory grip of governments around the globe. It has been said, “only time is irrevocable”, and thus special effort has been afforded to the continuous reduction of the company’s R&D times.

Pharmaceutical R&D involve, among other things, an intense battle of minds, namely among bright scientists with a plethora of backgrounds, experiences, and talents. The previously existing organizational structures in Hypothetical Pharma varied widely, although the prevailing trend of cycle time reduction through extensive use of concurrent engineering has given a boost to the formation of open, multidisciplinary teams that have significant decision-making authority and accountability in bringing an R&D project to commercialization.

Outlook

Third-generation management of pharmaceutical R&D calls for the visionary, skilful, transparent, and accountable management of a company’s tangible assets and intellectual capital in achieving a sustained and balanced, high R&D productivity. Therefore, the continuous, objective, fair, and improvement-focused evaluation of the external and internal R&D environments is not only a privilege of an industry’s few, but also a responsibility of every pharmaceutical firm wishing to remain competitive and in existence throughout the 21st century.

The plethora of existing R&D evaluation benchmarks provided in this analysis are not a part of an elaborate mechanical model that would allow industry leaders to enter variables and come up with decisions. Instead, they have been presented in an effort to provide the industry with the tools in asking the right questions for each situation at any environment. Evaluating those benchmarks would offer R&D managers the necessary insight in adjusting their strategic intent, selecting and prioritizing among various projects, allocating finite resources in a balanced manner, and ensuring their company’s R&D productivity, effectiveness, and efficiency. The vision of everyone involved is clear – improving the quality of patient lives.

E-mail: dimitri.dogramatzis@serono.com