Pharma R&D: getting personal

Gupta Strategists studied the R&D costs of medicines. Results of this study will be discussed during four round table discussions with all stakeholders.

About Gupta Strategists

Gupta Strategists is a strategy consulting firm with full focus on healthcare. We provide independent, expert advice on everything related to healthcare – from hospitals and insurance companies to pharmaceutical companies and inspectors. We transform complex issues into innovative ideas and practical solutions, using our expertise to make an impact. Next to our project work we regularly publish independent research that provides socially relevant insights and highlights important trends.

Executive summary of the study

In recent years, the global discussion on healthcare expenditures increased. The most critics are on medicine spending and prices of individual medicines. Pharmaceutical companies, in return, explain high prices by R&D costs of innovative medicines.

Many reports have been published on R&D costs showing a large spread in R&D costs per medicine. In this study we objectivize current discussion on R&D costs of medicines and will take a look in the near future. In this study we show that:

- There is a trend of growing R&D costs per New Molecular Entity (NME)
- Sector wide relative spend on R&D has remained stable on 23% this century
- Personalised medicines will break the trend of growing R&D costs per NME

There is a trend of growing R&D costs per NME

In previously published studies, estimates of developing one single New Molecular Entity (NME)vary widely (from 100mln USD to 2.600mln USD), but comparison is difficult because definitions and methodologies also vary widely. Furthermore, to gain meaningful insight into what drives developments in cost of R&D, we should also subdivide into the cost of specific types of medicines, for example orphan vs. non-orphan, or by therapeutic area. Published studies rarely do so. Finally, the most recent and most widely cited study is based on data from the period 1995-2005.

To provide a detailed and more recent view, we developed a model that is based on the fundamental cost drivers of pharmaceutical R&D costs. This model shows that R&D costs per NME have been increasing and amount 3.5 to 4 bln USD for medicines that came to market recently (between 2012-2017).

Sector wide relative spend on R&D has remained stable on 23% this century

R&D spend has doubled from 77 bln USD (inflation corrected) in 2000 to 160 bln USD in 2017. However, R&D expenditures have been a fairly stable proportion (~23%) of total industry revenue over the past few decades, suggesting that the two are correlated. If we zoom in to individual companies and even further to individual medicines, we show that R&D expenditure as proportion of 5-year revenue varied between 2% and 46% for the top 20 medicines that came to market after

2001. All-in-all, there is ample evidence that medicines, just like many other goods and services, are priced not on a cost-plus basis, but on value and the basis of willingness-to-pay.

Although, R&D costs for rare diseases are much lower than for other diseases. For such diseases, it is typically impossible to run large scale trials, and regulations for medicines that target such diseases are more relaxed. When officially approved as 'orphan drugs', such medicines benefit from substantially relaxed requirements for the development process, as well as from longer market exclusivity.

Personalised medicines will break the trend of growing R&D costs per NME

While it is perhaps not too useful to attempt to predict the future too precisely, if trends from the past few years continue, we will see a continued decline of R&D costs per NME over the next few years. With the novel model we show that R&D costs per NME have peaked in 2007 (the average year of research for medicines that came to market recently). We predict that thereafter they will decline by ~4% per year. This is driven by the change towards medicines for orphan diseases.

Better knowledge of interindividual differences shifts the focus from a one-medicine-fits-all approach to specific development for smaller patient groups. Thus, the movement towards personalized medicine means that R&D will look more like that of current orphan drugs, which treat a small, very specific patient population. Already, we see that orphan drugs are increasingly targeted at small subpopulations of much more common diseases.

Further evidence that R&D expenditures are decreasing comes from income statement projections, which are based on global pharmaceutical portfolios and R&D pipelines. These projections show that in the next 5 years, revenues will increase by 6% per year, while R&D costs as a percentage of revenue will decline.

Roundtable discussion

It is unknown how the sector will react to the latter. With all stakeholders we explore the different reactions the market might have on this change.

During the round table we elaborate on various options and discuss these with pharma's stakeholders. The options we currently see, are:

1. **Discovery of more new medicines**: Budgeting in the sector will be performed in the same way as last decennia: 22%-25% of revenue will be spend on R&D, so more NME's will be discovered.
2. **Entry of other players to the market**: With personalized medicine, it pays less to be big. Much smaller firms and other initiatives can successfully bring portfolios of medicines to market than was historically the case.
3. **Lowering of prices**: Pricing will change from value pricing to cost pricing: decreasing revenues.
4. **More emphasis on value**: Under scrutiny for high profits, the pressure to demonstrate value grows substantially.