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ReCent medical news

somewhat different

The development of medically effective drug ingredients is becoming increasingly complex.

Medication cover: Risks and risk management aspects

Did you know?

7,000

drugs are currently in the R&D pipeline of drug manufacturers and laboratories.

In recent years we have seen some astounding medical breakthroughs, not only but especially in drug development. In the last 10 years the U.S. Food and Drug Administration (FDA) approved almost 300 novel drugs to treat everything from psoriasis to hepatitis C to cancer. It can be observed that prices of more than USD 1,000 per dosage are no longer just theory but reality. Although it is reassuring to see that the money invested in research pays off with life-changing medications, who is actually prepared to pay for the cure if it comes at an extremely high price? And how can the industry and society handle increasing medication expenses in future?

Price of medical achievements and the risks for the insurance industry

Usually the insurance industry has no insights in the future price for novel drugs prior to approval. The possible consequences of a new development on the financials of a health insurer are hard to estimate. If risks associated with medication covers and medical inflation are underestimated, the launch of a new cure can have a severe impact on health insurer's claims. Recent trends show that the pace in medical innovations is accelerating and health insurers may face even more volatility in medication covers in years to come.

The development of medically effective drug ingredients is becoming increasingly complex, evolving from chemically synthesised medications towards high-tech products using biotechnology and genetic engineering for their medical effectiveness.

Currently, 7,000 potential new drugs are in the research and development pipeline of pharmaceuticals companies and laboratories. How many of these will come to market at extreme prices is a big unknown. Pharmaceutical companies are of course keen to recuperate their R&D costs, especially as some drugs never succeed in attaining approval. Thus, new drugs are frequently sold at a very high price.

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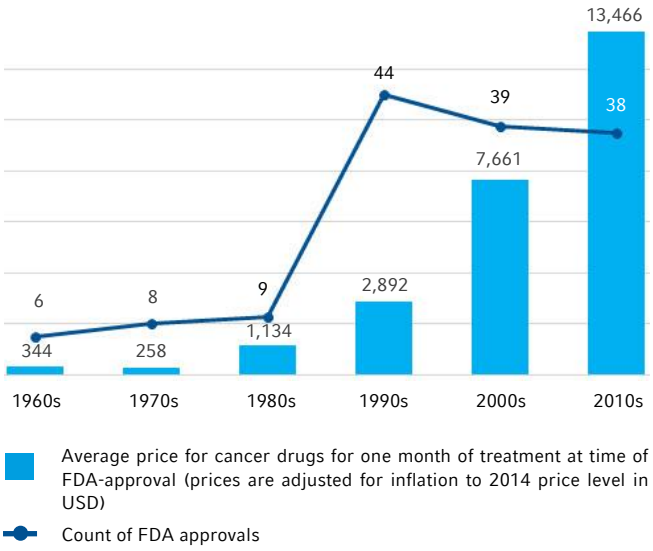
The long-term development of inflation-adjusted prices for newly FDA-approved cancer drugs in the USA for example clearly depicts the strong increase over the last decades.

Long term cost development
Average price for cancer drugs for one month of treatment at time of FDA approval[1]



Consumer protection also has a high priority. R&D costs are further boosted by complex research on side effects of new substances and interactions with other medications.

Instead of investing massively in own R&D, an attractive and frequently used alternative for pharmaceutical companies is to acquire small laboratories on the verge of receiving approval for a promising new drug. Such acquisition can significantly spur their chances of successfully launching a new drug short-term. In such cases, it is likely that this new drug will be priced so that sales will exceed the acquisition cost, maybe already in the first year.

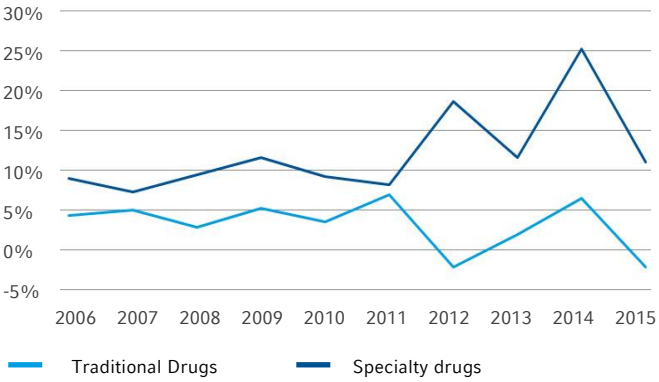
Such was the case when a pharmaceutical giant acquired a small pharmaceutical laboratory that developed an active medical substance able to cure several genotypes of hepatitis C, which were previously considered incurable. Millions of hepatitis C patients could suddenly be treated. The launch of the drug shook up the insurance industry as well as the public and triggered an emotional public debate about the ethics and fairness of profits gained at the expense of the sick.

Remarkable increase in pharmaceutical costs

For the top 4 therapy classes – inflammatory conditions, multiple sclerosis, oncology, hepatitis C – the average inflation adjusted cost per prescription increased from approx. USD 1,300 in 2005 to nearly USD 8,000 in 2015.

The chart below depicts the 10-year development of the price increase for traditional drugs and so-called specialty drugs. The price for the latter has recently increased dramatically. A further increase can be expected: the annual increase for expenditure on specialty drugs is forecast at 17% for the next two to three years.

Increase in drug price and specialty drug price[2]



Risk management measures

How can the exposure to the cost of newly approved specialty drugs be managed?

A first line of defence in risk management is a thorough understanding of regulations and their potential impact on medication prices as elaborated in more detail later. In addition to this, a thorough analysis of the own insured portfolio is as essential as up-to-date information on the development pipelines of pharmaceutical manufacturers in order to detect possible impacts as early as possible.

[1] For further information see: Memorial Sloan Kettering Cancer Center's Web; "Cancer drug costs for a month of treatment at initial Food and Drug Administration approval"

[2] For further information see: Express Scripts, "Drug Trend Report 2006-2015"

While prudent policy wordings can limit the impact of newly approved drugs to an existing portfolio, suitable reinsurance cover can protect the insurer from volatility.

Some risk management measures are applicable worldwide, whereas others may be limited by local insurance regulations or data protection requirements.

Portfolio monitoring and what-if analysis: If the data is available, insurance companies can actively monitor severe diagnoses that are prevalent in their own portfolio of insureds. By matching these conditions with respective cures on the late stage approval list of pharmaceuticals, insights can be made into the potential exposure of the portfolio. It is necessary to focus on the drug development pipeline of some of the largest pharmaceutical players to keep the effort manageable. Observation of the movements within the pharmaceutical M&A market can also provide useful indicators of future breakthroughs. Although the prices for a new drug won't be known, a what-if analysis on selected conditions and with varying assumptions for prices can prevent unpleasant surprises. When own resources are sparse, specialised consulting firms can support with tailored analysis.

Careful wording of policy terms and conditions can defer the short-term impact of highly priced new drugs and allow repricing on the basis of improved information. Measures protecting insurers, without drastically reducing medication benefits for insureds, are possible in many countries and include the following:

- Defining a "positive list" with clear definition of covered medication – all other medication would not be covered. Interestingly, in some markets this has been common practice for some or new medical procedures but so far not for medications.
- Setting appropriate limits and specific sub-limits for new drugs that have been approved less than a given number of months prior to the policy anniversary. Such temporary limits can allow for just enough time as is necessary for appropriate repricing.
- Deferred coverage for newly approved drugs until several years post approval, including final proof that the treatment is indeed more effective long-term than existing medications.

Traditionally, reinsurance cover has always been a means to protect from volatility caused by extreme claims events. Medication covers were often not reinsured in the past as they were considered less volatile than other components of medical insurance. Given recent developments and future expectations regarding medication cost, excess of loss or even quota share reinsurance for medication covers may become more valuable. In some markets, Hannover Re has been the first to offer reinsurance cover for products that covered prescription drugs only.

The impact of local regulation on drug prices

Understanding the regulations and their potential impact on medication prices is obvious when acting in local markets. This can however be a challenge when entering new markets or when including medication cover in international private medical insurance, where the insureds not only travel but also relocate from one country to another under their policy. The possibilities for health insurers to prepare for (and to a certain degree protect themselves from) sudden extreme costs caused by a newly launched drug, strongly depend on local regulations. Here the regulations for setting drug prices are just as important as insurance regulation.

- In the USA, health insurers have no influence on the drugs they cover, at which price, and at which point in time. As soon as a medication is FDA-approved, it is included in the benefits of insurance products that cover prescription drugs, no matter the price. On the other hand, pharmaceutical companies are free to set the price of a new medication.
- In Germany, the freedom of setting a price for a new medication is limited to the first 12 months after approval. Following this period, a suitable price has to be negotiated between the public health funds and the pharmaceutical company.
- In Canada, manufacturer prices for patented drugs are regulated by a specific price-review board to ensure that the prices are not excessive. If prices are found to be excessive, a mandatory price reduction is imposed.
- In France, drug prices are in essence determined by a specific public commission and a committee after negotiations with pharmaceutical companies according to the (added) therapeutic benefit and once a reference pricing assessment has taken place.
- In Italy, the national medicines agency is responsible for setting prices for inpatient drugs. This is based on

negotiations with the pharmaceutical manufacturers and follows a specific set of criteria.

- In The Netherlands, the Ministry responsible determines the maximum wholesale price for all outpatient prescription drugs in a central price setting.
- In countries where the health system is organised and carried out by state bodies, such as national health systems, the treatment with expensive drugs is steered centrally and can be restricted to the most severe medical cases. Thus, the effect on health insurance companies can be expected to be small.
- Some countries may reject patent approval. Consequently, generics are produced and sold at a fraction of the price of the original drugs.

The examples above show the wide range of regulatory interventions possible, each with a different role and intention. In some regions the free market economy rules on the supply side, whereby the highly regulated insurance industry is forced to pay for the demand. In other countries protectionism prevails. And generally, purchasing power plays an important role.

What to expect in the future?

Given the number of potential new drugs in the R&D pipeline, the majority of them targeting cancer, neurologic disorders and infectious diseases, it is highly likely that many of them will never be launched. Those that will however can be expected to be highly priced.

Keeping close track of R&D pipelines of large pharma companies and their acquisitions is vital. However, it is not sufficient to focus on well-known pharmaceutical giants and their development pipelines. The M&A development in the pharmaceutical industry can give important information and should be observed.

In August 2016, another pharmaceutical giant acquired a competitor for USD 14 billion. Together with the existing portfolio of drugs, the pharmaceutical development pipeline of the smaller competitor was taken over containing three “late-stage assets”. One of those promising drugs is targeting breast cancer. Its active substance seems to be one of the most potent medicines in the respective class of cancer drugs and is estimated to reach Blockbuster status. This drug is in Phase 3 of the FDA approval process with clinical trials, the final phase before market launch.

It is an undisputed fact that the next big impact from an expensive medication is just around the corner; when and where this will happen is uncertain. Hopefully, the insurance industry is well-prepared for the next big medical breakthrough.

The risk management measures mentioned above in combination with tailored reinsurance solutions should help to prepare for the unknown and unexpected.

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Sources

MEMORIAL SLOAN KETTERING CANCER CENTER’S WEB; “Cancer drug costs for a month of treatment at initial Food and Drug Administration approval”; date of retrieval 6th of April 2017 under https://www.mskcc.org/sites/default/files/node/25097/documents/chemo-prices-table-20150304.pdf

EXPRESS SCRIPTS, “Drug Trend Report” (reports 2006-2015); date of retrieval 6th of April 2017 under http://lab.express-scripts.com/