No cure, no pay

Claus Møldrup

Not paying for a drug unless it works sounds great for patients and healthcare funders, but it could also benefit manufacturers.

Department of Social Pharmacy, Danish University of Pharmaceutical Sciences, Universitetsparken 2, DK-2100 Copenhagen Ø, Denmark
Claus Møldrup *associate professor*
cm@dfuni.dk

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Tensions between the pharmaceutical industry and health authorities over drug marketing have increased in recent decades. The authorities want to get the most possible drug for their money whereas drug companies want to get the most money for their drugs.[1 2] The current situation is untenable first and foremost for the industry but also for the authorities, and, in the end, the patients. This article proposes how a no cure, no pay strategy could meet the needs of all parties and contribute to a sustainable future for the medical environment as a whole.

Collision course

Marketing tensions are neither new nor odious, but two factors in particular have put the two opposing sides on a collision course. On one side, the authorities have fewer financial resources at their disposal relative to the many drug options available and the increasing need for treatment caused by a swell in the ageing population. Fewer resources naturally lead to increased focus on how money should be spent and what the return is in practice. This has caused the authorities to focus more on clinical evidence and relevance in the choice of drug treatment. In turn, this has led to the introduction of the concept of rational pharmacotherapy as a political tool for ordering priorities (box 1).[3 4]

Box 1: Rational pharmacotherapy

Rational pharmacotherapy is defined as drug treatment that provides the greatest effect with the least serious and fewest side effects at the lowest possible price.[5] The following equation is used to illustrate the idea:
Effect (clinical studies)+extent of side effects/price = extent of rational pharmacotherapy

On the other side, drug companies have had to become more competitive as a result of the falling number of new chemical entities,[6 7] "me too" strategies,[8] generic production, and parallel imports. Mergers of major drug companies have also increased competitiveness.[9] The consequence is the use of sales, marketing, and public relations strategies that constantly challenge, and in some cases exceed, the limits of legislation and the moral integrity of recipients.[10]

The industry cannot do much about dwindling resources, but it can shift its sales behaviour to meet the buyers' needs. The authorities want rational pharmacotherapy—that is, the best treatment at the cheapest price—and the individual drug company will have to honour that request to beat the competition. So how can a no cure, no pay strategy help?

An early example of no cure, no pay

No cure, no pay strategy

A large percentage of all prescribed drugs do not have the desired effect on patients' problems. The many influences on this poor outcome include wrong choice of drug, genetic factors, interactions, non-compliance, and poor drug quality.[11 12]

A no cure, no pay approach can counter these problems by optimising the effect yet still making the treatment economically feasible. If the drug does not cure, relieve, or prevent the patient's symptoms based on specific clinical measures or visible results, the healthcare system and the patient get their money back. A money back guarantee might also be applicable if the patient suffers adverse effects. This is a previously unseen dimension of rational pharmacotherapy.

Obviously, if a drug company risks repaying substantial sums for a treatment that seems efficacious

in clinical studies but does not have the desired effect in daily use, it is an incentive for the company to find programmes that improve compliance, in particular. Programmes to increase compliance are another new dimension that can make a positive contribution to rational pharmacotherapy.

Examples of no cure, no pay

A search of the literature turns up eight cases where the no cure, no pay strategy has been used (box 2). The first case is ten years old. So why is this strategy not more widespread? The answer is simple: there has been no need. More traditional marketing initiatives have been successful in areas where purchasing authorities have not had rational pharmacotherapy as their first priority, and thus drug companies have not needed to take large financial risks. However, now that drug representatives' access to doctors is being limited, and doctors are increasingly reluctant to accept direct marketing initiatives, the pharmaceutical industry will have to start considering alternative business models.

The earliest examples are from the United States. The valsartan initiative in Denmark was the first in Europe, and Novartis has expanded it to other countries.

Optimal product candidates

Product candidates for a no cure, no pay strategy must be effective, preferably for a large proportion of patients. Otherwise, the strategy could become very expensive for drug companies, not to mention unethical. However, the examples in box 2 show that the optimal product candidates for a no cure, no pay strategy also have one or more of the following characteristics:

- Simple methods can be used to measure the effect—for example, blood pressure and blood glucose or cholesterol concentration
- The patient or general practitioner can see the effect for themselves—for example, on stopping smoking, erectile dysfunction, infections, baldness, problems that would require surgery if left untreated
- The product is a market leader but facing heavy competition from several "me too" products or generic drugs
- The product has a smaller market share than its potential warrants.

Box 2: No cure, no pay strategies

1994: Merck-Frost offered refunds to patients who had been prescribed finasteride if they required surgery for benign prostatic hyperplasia after one year of treatment[13]
1995: Sandoz introduced a money back guarantee for clozapine for treatment resistant schizophrenia. The reimbursement covered the costs of the drug, dispensing fees, and pharmacy mark-ups[14]
1998: Merck promised to refund patients and insurers up to six months of their prescription costs if simvastatin plus diet did not help them lower LDL cholesterol to target concentrations identified by their doctors.[15] The guarantee still applies.[16]
2004: Novartis launched a no cure, no pay initiative for valsartan and valsartan hydrochlorothiazide as part of a "take action for healthy blood pressure" programme in the United States.[17] In addition to a money back guarantee for the patient only, the programme also provides the option of a 30-day trial product package, the opportunity to buy a blood pressure measuring device cheaply, and various on-line compliance systems
2004: Novartis launched a no cure, no pay initiative for valsartan in Denmark, independent of the initiative in the US[18]
2004: Lilly ICOS launched a no cure, no pay on tadalafil for erectile dysfunction in the US. Patients who were not satisfied with the treatment were issued with a voucher for the oral treatment of their choice[19]
2005: Novartis launched a money back initiative in Denmark for nicotine chewing gum. If the patient does not like the taste (four tastes to chose from), a refund is offered
2005: Bayer launched a no cure, no pay initiative on vardenafil for erectile dysfunction in Denmark. Patients who are not satisfied with the treatment can get the cost refunded.[20]

No cure, no pay, and rational pharmacotherapy

Obviously, a no cure, no pay policy for a drug with poor data and little effect will not be able to influence rational pharmacotherapy. In such cases, the initiative would be considered aggressive or frivolous marketing. However, if good data are available on a drug and it is either better than or as good as the drug of first choice, a no cure, no pay strategy could be used to support a message about product benefits. In such cases, the compliance initiatives introduced as part of the no cure, no pay strategies will influence decisions about rational pharmacotherapy because the effect of daily use should be included in the calculations. The possibility of a refund should also be included. Thus the equation becomes:

Effect[clinical studies]+effect[daily use]+side effects/(price – refund) = degree of rationalpharmacotherapy

However, a no cure, no pay policy cannot be considered as part of rational pharmacotherapy unless the price of the product is unchanged and the strategy is not intended to change current treatment recommendations. Thus, it is not rational pharmacotherapy if a no cure, no pay strategy is introduced to move a drug from second line treatment to first line treatment. In other words, the strategy is only applicable for shifting market share within analogue products.

All things being equal, if these conditions are met, a drug marketed with a no cure, no pay strategy will increase its rational pharmacotherapeutic value. Naturally, this is not the same thing as automatically promoting the product to first choice. However, a no cure, no pay strategy can make a product seem more attractive than analogue products that are not marketed with this strategy.

Potential for expansion

Before the strategy can be expanded we need to ensure that it adds value to society, industry, and the patient. Several important questions need considering.

What has been the effect so far?—It is impossible to tell the effect on price or on rational prescribing because of lack of evidence. The cases described earlier are either so new that no effect has yet been reported or based on empirical data that are industrial property.

However, it is most likely there has been no effect because of the limited number of cases in highly diverse areas. Empirical evidence on the effect is needed and further research will provide it.

How do we ensure that the strategy will not be used to move drugs to first line treatment?—The informative material provided to general practitioners and patients should clearly state that it is not the intention to move drugs from second to first line treatment. Perhaps the authorities should review the wording to make sure. Nevertheless, since general practitioners can prescribe whatever treatment they want, it will not be possible to enforce compliance with the spirit of the strategy, only to recommend it. The concept can (and probably will) be misused occasionally and turned into a cheap marketing ploy. But cheap marketing will be easy to detect, and if the price is raised or the clinical data supporting the product are insufficient, it will have a boomerang effect on the company. Companies need to present a good case.

What will happen if the strategy is used for a more costly drug that is no better than others in its class?—This situation is a perfect example of why the rational pharmacotherapy equation (box 1) is such a useful part of the concept. Because price is part of the equation, higher priced products cannot justify using a no cure, no pay strategy as they would not meet the guideline for rational pharmacotherapy.

Who would be responsible for monitoring and reporting on the effectiveness of the therapy?—Each case needs its own system for reporting effect. However, it would be appropriate to use a procedure for monitoring effect similar to that used in phases III and IV clinical trials of the drug. For example, with a drug to treat hypertension, the general practitioner monitors blood pressure and for a drug to treat erectile dysfunction, patients report the effect based on experience.

Who should be reimbursed in the event of ineffectiveness?—All payers (individual patients and insurers, whether public or private) will get their money back. If this does not happen, the concept will not work as rational pharmacotherapy.

How do we ensure that companies are not rewarded if the product is ineffective?—It is well known that even if something does not work or performs poorly, some people will not report these failures even if money is involved. This is a serious problem and the only solution is motivation.

Conclusion

Widespread use of no cure, no pay policies must be the optimal goal from the perspective of insurers and other healthcare funders. Not only do they get their money back for ineffective drugs, but the concept also promotes the idea of the right pill in the right mouth because it encourages therapeutic evaluation and thus change of ineffective treatment.

The biggest barriers to expansion are the possibility of misuse as cheap marketing and thus the reservations of healthcare staff and politicians about the concept. Indeed, more evidence is needed and a good debate on the pros and cons would be helpful. Practical and ethical guidelines would also be required. A no cure, no pay strategy creates a win-win situation for the authorities as well as the drug industry, and thus patients, because in a competitive environment only the best drugs will win.

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Contributors and sources: CM is an associate professor of social pharmacy with focus on lay understanding and use of modern drugs such as lifestyle drugs and pharmacogenetics. The experiences and expert views expressed also derive from the academic thinking and research prefacing the author's practical role as the architect of a no cure, no pay initiative.

Competing interests: CM was the architect of the first three no cure, no pay initiative launched in Europe.

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Endpiece

Sensible advice for disorders of the imagination

Disorders of the imagination may be as properly the object of a physician's attention as those of the body; and surely they are, frequently, of all distresses the greatest, and demand the most tender sympathy; but it requires address and good sense in a physician to manage them properly. If he seems to treat slightly, or with unseasonable mirth, the patient is hurt beyond measure; if he is too anxiously attentive to every little circumstance he feeds the disease. For the patient's sake as well as his own, he must endeavour to strike the medium between negligence and ridicule on the one hand, and too much solicitude about every trifling symptom on the other.

Gregory J. *Lectures on the duties and qualifications of a physician*. London: W Strahan and T Cadell, 1772:24

Jeremy Hugh Baron,
honorary professorial lecturer,
Mount Sinai School of Medicine, New York