

# **Convention on Health Analysis and Management**

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### **How can the patients accede to Health products?**

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#### **1. The theory: the vicious circle of healthcare product development**

In theory, the process of accessing health products is established. Manufacturers develop health products, which patients then buy. Manufacturers then use the profits to develop new health products. This virtuous cycle is not so simple. Customisable devices present significant costs and high risks. As a result, manufacturers are not necessarily inclined to develop them and would need greater profits to do so. But are these acceptable to civil society?

#### **2. The complex route from marketing authorisation to setting the price**

Access to the French market is very closely circumscribed. After the benefit/risk evaluation and prior to marketing authorisation, discussions are initiated and lead to the economic committee for healthcare products setting a price. The time period before products become available is so considerable that it sometimes harms patients' access to innovation.

While the time period between the marketing authorisation and setting the price is fixed by the European Union at 180 days, in reality the average time of access to the market is 360 days.

#### **3. Restrictions linked to inappropriate use of medicines**

When complex products are used inappropriately, the regulator may be required to revise their authorisation. This also has the effect of increasing the number of questions raised between the marketing authorisation and setting the price.

#### **4. The difficulty business of setting the price of the medicine**

The price of the medicine, in addition to the expenses incurred in making the discovery and manufacture, must include the financial room for manoeuvre needed by manufacturers to undertake new research and develop new medicines. It may be necessary to take into consideration the requirements of the manufacturer, but sustainability for the payer cannot be ignored. Of course, this debate raises societal questions regarding the correct use of profits on medicines.

## **5. Interdependence between players and the consensus for the benefit of patients**

Manufacturers may have an interest in bringing to market the most plus innovative products for patients. To be recognised, this innovation must be measured. In the end, all the players involved are interested in moving in the same direction.

## **6. Shared interests in real life**

For patients, quality of life is the main interest of medicine. This interest is not limited to patients, but relates to society as a whole. Because society has an interest in citizens being well in their lives through the use of medical treatments. This interest for society must be included in the reflection on funding methods. It is therefore fundamental to assess the interest of medicines in real life.

## **7. A practical example: Belatacept, a medicine that is still inaccessible in France**

Kidney dialysis costs 80,000 euros per year. Transplants cost the same in the first year, then 20,000 euros in subsequent years. The immunosuppressant drug Belatacept makes it possible to improve kidney function, leading to fewer side-effects, in particular on a cardiovascular level. To date, it is inaccessible on the French market. However, in most European countries and the United States, it is accessible and funded. An open letter was sent to the Minister for Health, highlighting the huge interest in this medicine for transplant patients. Lack of access means a loss of opportunity. Following the open letter, a five-year evaluation was carried out, but did not result in the block being lifted.