

PRICING VACCINES AND DRUGS IN EUROPE: WORTH DIFFERENTIATING?

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EDITORIAL



Pricing vaccines and drugs in Europe: worth differentiating?

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Introduction

The COVID-19 pandemic has recently brought to the forefront the vital importance of vaccines, of which Europe is the world leader in both development and manufacturing [1]. Although vaccines are considered pharmaceuticals from a regulatory viewpoint, there are substantial differences between vaccines and other pharmaceutical products in terms of both health and economics.

Here we compare drugs and vaccines using a sort of '6P scheme', adding Patient and Patent to the well-known 4P (Product, Place, Promotion, Price) business tool [2] for casting light on the major differences between the two types of products. The final aim is to put forward an original proposal for pricing vaccines in European countries.

Comparative analysis

Patent

exceed the private ones [4]. Conversely, because vaccines can cause a (small) risk of serious adverse effects in healthy individuals—often infants and children—not suffering the targeted diseases, they may be more open to criticism than drugs [4]. This can favor campaigning against them by the so-called 'anti-vax' movements, especially in highly developed countries which have not experienced pandemics for decades before COVID-19.

Patent

Patents are crucial for maximizing financial returns on drugs' research investments, even after the first invention, which is part of a harsh debate in the pharmaceutical literature [5]. To limit the turnover of off-patent medicines, pharmaceutical companies often recur to secondary patenting for dramatically prolonging protection (the so called 'evergreening' strategies). Secondary patents on drugs are usually applied to new indications and 'me-too' drugs. Besides patent on products, complex historical issues such as the

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INTRODUCTION

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INTRODUCTION

Here we **compare drugs and vaccines** using a sort of '**6P scheme**', adding Patient and Patent to the well-known 4P (Product, Place, Promotion, Price) business tool for casting light on the major differences between the two types of products

The final **aim** is to put forward an original proposal for **pricing vaccines in European countries**

COMPARISON

1) PATIENT

Drugs are usually **administered** to patients, i.e. ill/injured subjects **in need of treatment** regardless of the severity of their health problems

Many drugs can coexist in the same therapeutic class because each of them **may have different effects on specific sub-groups of patients**

COMPARISON

1) PATIENT

In contrast, the **same vaccines** are administered to otherwise **healthy individuals**, to prevent the same diseases

Wherever high coverage rates are achieved, unvaccinated subjects may benefit too, by reducing the risk of transmission and circulation of pathogens due to the so called '**herd immunity**'

Therefore, the **social benefits** of vaccines can **exceed the private ones**

COMPARISON

1) PATIENT

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This can favor campaigning **against** them by the so-called **‘anti-vax’ movements**, especially in highly developed countries which have not experienced pandemics for decades before COVID-19

COMPARISON

2) Patent

Patents are crucial for maximizing financial returns on drugs' research investments, even after the first invention, which is part of a harsh debate in the pharmaceutical literature

To limit the turnover of off-patent medicines, pharmaceutical companies often recur to **secondary patenting for dramatically prolonging protection** (the so called 'ever greening' strategies)

COMPARISON

2) Patent

Secondary patents on drugs are usually **applied to new indications and 'me-too' drugs**

Besides patents on products, **complex biological drugs, such as the recent monoclonal antibodies (mABs), can be further protected** on production phases that affect their final mechanism

Differently, **patents are less relevant for vaccines**, mainly protecting manufacturing processes rather than antigens

COMPARISON

2) Patent

In fact, **patents on products cannot prevent other companies from using different strains** to supply competing vaccines

Because most **vaccines are biological agents** to date - awaiting the forthcoming mRNA synthetic vaccines - their **outcomes can vary a lot on account of the biological variability** in raw materials and the steps involved in purification processes

Thus, **patents on processes may help prolong their life cycles**

COMPARISON

3) Product

Research and promotion have always been the **major cost items** for developing and marketing **drugs**, whereas **manufacturing costs** hardly ever account for a substantial proportion of total costs, with the last generation of sky-high priced mABs no exception

In general, **it is difficult to estimate single cost items per product in a research-oriented industry like pharmaceuticals**

COMPARISON

3) Product

Conversely, **manufacturing costs** are **the major ones for vaccines**, which can have batch-to-batch variability and substantial changes in manufacturing processes requiring extensive analyses to show bioequivalence even after marketing approval

Vaccines imply large-scale productions, which have traditionally **discouraged the launch of off-patent and 'me too' vaccines**

COMPARISON

3) Product

High fixed manufacturing costs are **diluted over many doses** and are quite easy to post to each vaccine given their limited number

Recent trends have been **to launch combination vaccines**, including more than one antigen for reducing administration processes and new adjuvants for potentiating immune responses and/or sparing doses

COMPARISON

4) Place

General practitioners (**GPs**) are traditionally the **major prescribers of drugs**

Although the prescription of a **growing number of new and expensive agents** (e.g. mABs) may now be **limited** to the hospital settings in many European countries, most drugs are still prescribed by GPs and thus **dispensed through community pharmacies**

COMPARISON

4) Place

Somewhat differently, **the delivery of vaccines is more uneven throughout European countries**, varying a lot according to the type of health care systems -e.g. Beveridge-type like in Italy and the UK, or Bismarck-type such as in France and Germany- and the national framework within the same type

For instance, **in Italy**, the **vaccines recommended for children are administered in local health districts by public health professionals** and those for adults by GPs in their cabinets, whereas in the UK all vaccines are mainly provided by general practices

COMPARISON

4) Place

Because most vaccines are still injectable, a common **issue** is that of **storage and preparation**

Hence, beyond **reducing injection overcrowding** in health facilities, **combo vaccines** help **contain storage and shipping costs**

COMPARISON

5) Promotion

In a typical '**market failure**' situation like **pharmaceuticals**, **physicians** (working as the patient's agent) fill the information gap of patients in medicine and take on their behalf the final **decisions about how many and which drugs to prescribe** among those available

Hence, **as prescribers, physicians** are conventionally the **major marketing target of pharmaceutical companies** and aggressive strategies may raise financial conflicts of interest, eventually leading to drug overconsumption and bribery

COMPARISON

5) Promotion

In contrast, **vaccines** do not normally require intensive **promotion by industry**

Campaigns to achieve high rates of coverage are mainly a task of health authorities, with manufacturers obviously interested in backing them up

Activities may consist of specific trainings for healthcare professionals and awareness campaigns for patients, except where vaccinations are mandatory, which is hardly ever the case in European countries nowadays

Final **results are** substantially **affected by public perception of vaccines values**, with single physicians playing an important role in influencing vaccine hesitant families

COMPARISON

6) Price

Prices of new drugs have dramatically **increased** all over Europe in the last decade, making **pharmaceutical expenditure** somewhat **unsustainable** even in the (wealthier) Western countries

The **most recent** and ambitious **price schemes** (e.g. **value-based pricing** and **outcome-based agreements**) have shown **intrinsic limits** despite their scientific attractiveness, whereas sound strategies such as **reference pricing** and **competitive tendering** do not seem to be enough to **stop the present trend** of **sky-rocketing prices**

COMPARISON

6) Price

At present, the **leading strategy** for cost containment among European health authorities is **to negotiate confidential prices** directly **with companies**, an approach which inevitably lacks transparency

Although many European **health authorities** have conventionally **recurred to public procurement for buying vaccines**, so as to exploit at most their purchasing power, the **recent tendencies** for **pricing vaccines** tend to **follow those for drugs**

Since any 'competitor' is (obviously) expected to be **against price competition**, nowadays the few (multinational) companies which market vaccines strive for **undermining competitive tenders by differentiating their vaccines and launching the new ones** (e.g. HPV and PCV) at prices which were unthinkable only a few years ago

POLICY IMPLICATIONS

Vaccines are merit goods in public health aimed at safeguarding people, no matter where they live

Historically, vaccines have **alleviated human suffering** and prevented the loss of countless lives

A very important lesson from COVID-19 is that there is **no reason to assume Europe will be spared from pandemics** requiring **new vaccines in the future**

POLICY IMPLICATIONS

The number of recommended **vaccines** has substantially **increased in the last decades**

The most **recent vaccines** include an **increasing number of antigens in combination** (e.g., DPT and MPR) and **sero/genotypes** (e.g., HPV and PCV)

POLICY IMPLICATIONS

Of course, a **single dose (oral) vaccine** that immunizes children from all diseases would be **ideally** the **most efficient** solution, **minimizing the workload of health authorities for administration**

Also, **an increasing number of high-risk subtypes included in a vaccine are expected to be an efficacy improvement**, extending the protection against the targeted disease

POLICY IMPLICATIONS

From an economic viewpoint, vaccines are likely to be among the most efficient health interventions, potentially offering a **cheap alternative to prevent long-term morbidity and mortality**

The **opportunity cost** - i.e. the cost of an alternative that must be forgone to pursue a new action - of a vaccine **is expected to be low** so that even the best drug treatments would be less desired

POLICY IMPLICATIONS

Therefore, unsurprisingly, **cost-effectiveness analyses** based on **long-term models** for justifying the request of high prices for new vaccines always **conclude in their favour**

Vaccines expenditure, like anything else, is the **product of volumes and prices**

POLICY IMPLICATIONS

Unlike drugs, **volumes of vaccines are relatively easy to forecast**, whilst similarly to drugs, their **prices may go quickly out of control**, contributing to a further distortion in the allocation of financial resources in a 'market failure' context like health

Since there is no way to rank diseases according to their importance, and more generally to set a value for a human life, **we can simply assume that all recommended vaccines are equally essential for the population's health**, especially those for children whose social impact is essentially immeasurable

POLICY IMPLICATIONS

While it is the purview of **public health experts to advise decision makers on which vaccines to recommend for reimbursement** (hopefully) according to the existing epidemiological and clinical evidence, **health economists cannot really contribute to setting the right prices** of any health product, including vaccines

Instead of supporting irrational pricing, **health economists could rather contribute to rational budgeting** for managing vaccine expenditure in this apparently permanent period of economic crisis

POLICY IMPLICATIONS

Accordingly, here we put forward a **practical proposal** from the health authorities' perspective, particularly focused on pediatric vaccinations

FROM PRICING TO BUDGETING

Once the **national health authorities** have **decided the list of vaccines** (and dose schedules) to recommend for their country, their **payment procedures** could be substantially revised to **minimize the influence of** (flawed) **economic considerations** on reimbursement decisions

Our **proposal** can be broadly **summarized in three points**

FROM PRICING TO BUDGETING

1) the **yearly budget** of **vaccines** could basically **coincide** with the **national historical expenditure of the last year**, to avoid any start-up shock, varying lightly in the future years on account of inflation/deflation, or growing more substantially according to eventual increases in the number of vaccinations recommended

2) **national health authorities could reimburse to companies** the same unit price for all the doses of vaccines administered **on a monthly basis**, calculated as the broad ratio between the total expenditure of vaccines and the total number of doses administered in the previous year

FROM PRICING TO BUDGETING

According to the existing estimates on the manufacturing cost per dose of vaccines and to the prices offered to humanitarian organizations, an average **unit price over €15 per dose in Western European countries should be profitable for any vaccine** (e.g., the whole average price in Italy for vaccines recommended for children is around €35)

If a company refused the unit price per reimbursement, claiming that it is too low to cover its costs without rebutting with solid information on the real manufacturing costs, health authorities could apply for **compulsory licensing** if the firm were the only one marketing the vaccine at issue, consistently to the European regulation

FROM PRICING TO BUDGETING

3) the unit prices of **vaccines which do not achieve a high rate of coverage** (e.g. 90%) could be **lightly decreased** (e.g. -5%) from the second year until the target is achieved, in order to provide incentives for companies to support actively health authorities

A 'stick and carrot' financial incentive would address the (questionable) comment that the present price-based tenders of European countries could have negative (though unintended) effects on the rates of coverage, discouraging the provision of (unspecified) value-added services by companies

CONCLUSION

Because we share the opinion that withholding from reimbursement any effective vaccine because of its high price is ethically disturbing, here we raise a proposal to minimize the probability of such a negative event in an era of (really) finite resources

**THANKS A LOT FOR
YOUR KIND ATTENTION !**

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