

# Transferable exclusivity vouchers for medicines: FACTSHEET disrupting markets, unfair to consumers

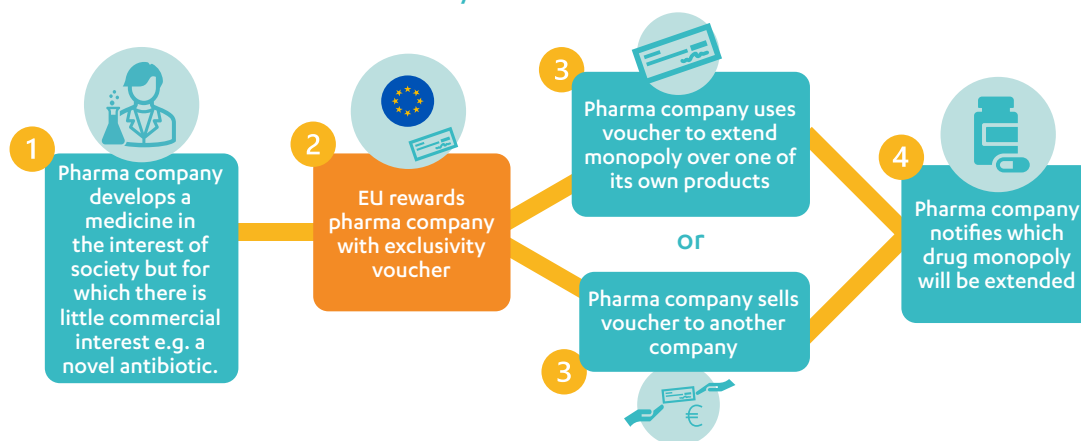
We are on the cusp of a major societal problem – bacteria are developing greater resistance to the antibiotics we use when we get infected. This means we urgently need to develop new, effective antibiotics if we want to avoid routine infections getting out of control.

To address a lack of commercial interest from the pharmaceutical industry in investing in and developing certain antibiotics which are essential but might not have a large market, and as part of a major review of its pharma legislation, the European Commission is considering creating **transferable exclusivity vouchers**. Although we need to find ways to encourage research and development in antibiotics, we believe these vouchers would be a **big mistake** which would end up harming patients and markets.

## How would transferable exclusivity vouchers work?

A company which has developed a new medicine, for which there is a societal need but little commercial interest for example, receives a voucher. This voucher allows the company to extend the period during which it has a monopoly on selling another, more lucrative product, or to sell it to another company. These vouchers are meant to incentivise the pharma industry to work on medicines with a societal interest. However, they would cause greater harm to state healthcare budgets and competition in the medicines industry, in turn negatively impacting patients and consumers.

### Process for Use of a Transferable Exclusivity voucher



## What would be the effects of these vouchers?

### 1. Bad for public health budgets

They would come at a **huge cost** to healthcare systems around the EU. This is because pharmaceutical companies are likely to apply the voucher to their most profitable medicines.

For example, granting one extra year of exclusivity to the pharma company responsible for producing Adalimumab (Humira®), which helps treat several immune system conditions, would have represented an **extra bill of €1billion** for EU healthcare systems because of the delayed entry of a highly similar medicine by a generics company. Similarly, an extra year of exclusivity for the cancer drug Trastuzumab (Herceptin®) would have caused an **extra €600m** in extra healthcare expenditure in the EU<sup>1</sup>.

<sup>1</sup> Medicines for Europe, '[Note on Transferable Vouchers](#)', April 2022 (accessed on 14 Sept 2022).



## 2. Bad for competition

It will become **harder** for companies which produce cheaper versions of the original medicine to prepare their market launches if that medicine is protected by a voucher (generics or biosimilars). The **lack of clarity** as to when a pharmaceutical company's period of exclusivity over a medicine expires, combined with the possibility of it choosing to extend its period of exclusivity through the purchase of other vouchers, could discourage generics companies from investing in alternatives to the original, and generally more expensive, medicines. In effect, this would create legal uncertainty in the generics sector and harm competition in the market for medicines. As a consequence, it would very likely drive up prices, and/or keep them at high levels, and reduce consumer choice.

The vouchers could also harm **innovation** because the incentive for pharma companies will be to extend their exclusivity over an existing, profitable medicine rather than to prioritise medicine development in other areas. In other words, these vouchers could replace one problem (lack of novel antibiotics) with another (reduce innovation in other areas).

## 3. Bad for consumers

Transferable exclusivity vouchers will **delay** the entry in the market of copies (generics), or medicines that use similar components (biosimilars), of the original pharma company's product. This means that patients will have to **wait longer** to access cheaper medicines and run the risk of not being able to afford an expensive medicine if state health budgets have decided to prioritise reimbursements of other, cheaper types of medicines.

Because pharma companies do not necessarily make their products available at the same time in all EU Member States – smaller countries or less wealthy ones are often less of a priority because they are seen as less profitable – the vouchers would also further **delay** the availability of treatment in certain EU countries.

### BEUC RECOMMENDATIONS:

Rather than put in place transferable exclusivity vouchers, there are more effective mechanisms to improve people's access to medicines, including:

- 1. REVISIT THE INTELLECTUAL PROPERTY INCENTIVES SYSTEM AND PUT IN PLACE SAFEGUARDS TO PREVENT EXCESSIVE PROFITS AND PRICES:** At present, when pharmaceutical companies bring a new medicine to the market, they benefit from ten years of data and market protection over it. Current rules do not distinguish between types of medicines based on their commercial potential and the extent to which they address unmet medical needs.

Instead, the revised general pharmaceutical legislation should lay down different periods of data and market protection, according to the type of product, and include safeguards to prevent abuses in relation to prices and profits, which in turn requires companies to share data on research and development costs.

- 2. SUPPORT THE DEVELOPMENT AND AFFORDABILITY OF NOVEL ANTIBIOTICS THROUGH PUBLIC RESEARCH FUNDING THAT INCLUDES ACCESS CONDITIONS.** Public research funding plays an important role in promoting medicine development. However, to maximise their societal benefit, funding should go hand in hand with conditions on product availability and affordability:

- Horizon Europe should prioritise public health needs and deploy a combination of push and pull mechanisms that include access-related conditions, for example, inducements in exchange for meeting some milestones along the R&D chain and developing products that meet specific requirements.
- Research funding should go hand-in-hand with access-related conditions, such as intellectual property-sharing to enable earlier market entry of generics and lower prices. Data and market protection should not be a barrier.
- The European Health Emergency preparedness and Response Authority (HERA) should become an effective 'medicine R&D coordinator' steering research in the EU to speed up the development of novel antibiotics.