EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 779 b

PHARMACEUTICAL COMMITTEE
7 November 2019

Subject: Development of antimicrobials: how to address market failures [1]

Agenda item 4b

1. BACKGROUND

'New business model' has been a buzzword in many recent political discussions, albeit so far without bringing a sizeable and sustainable solution to the problem of lack of development of new antimicrobials. No new classes of antibiotics have been discovered for decades. Pharmaceutical companies are unwilling to invest in the development of new antibiotics because of concerns about (non-) profitability.

This has often been labelled "a market failure" and has led many to blame the lack of financing and the non-appropriateness of the public payment models for this type of products.

The classic research and innovation (R&I) model relies on the idea that pharmaceutical companies recuperate research and development investments selling large volumes of their medicinal products. However, when any new antimicrobial treatment enters the market and is sold and used in large quantities, resistance can be expected to develop quickly. As the use of new antimicrobials needs to be restricted to minimise the risk of resistance development, there is a commercial disincentive to invest in antimicrobials.

In addition to the failure of the R&I model to deliver new antimicrobials, there is also a worrying lack of availability and shortages of old molecules.

New approaches are required to encourage research and development, to give public authorities a stronger role in guiding R&I, to delink profits from the volume of antibiotics sold, and to address public health needs. Any new economic model should also ensure that a marketing authorisation holder continues its commercial interest in maintaining the existing portfolio of well-known antibiotics. Different parties, including European Parliament (that advocates for a dedicated legislative proposal), Council, and industry are asking for Commission action in this field.

[1] This document does not reflect an official position of the European Commission. It is only meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.

There are two primary means of economic incentives, so called push and pull. Push incentives subsidise the overall development cost while pull incentives reward successful development, providing some guaranteed return on investment. Examples of push incentives include direct funding of targeted research, placing conditions on public grants and prizes, or public-private partnerships to share costs and risks. Push incentives require extra input of public budget (possibly through a guarantee fund) and therefore should be coupled with funding mechanisms such as specific fees, levies or taxes (e.g. the "pay or play" approach advocated by Sir O'Neill or taxes on sales of other products, or possible levies collected at the time of market authorisations of other products; financial conditions and sanctions on actions that are not "prudent use"; etc). Examples of pull incentives include market entry rewards, transferable exclusivity extensions and/or extended market exclusivity. Experts suggest that a combination of push and pull incentives are needed and that for a holistic approach[2]. Policymakers are often asked to consider whether pull incentives could encourage development of new therapies.

In the past, we have seen the same problem in the orphan and paediatric areas. The Commission is finalising an evaluation of the orphan and paediatric legislation and the related incentives. While the Orphan regulation focuses on rare diseases, it may also be applicable to life-saving products that without specific incentives in form of market exclusivity are unlikely to generate sufficient return on investment. The findings of the evaluation of the orphan and paediatric regulations could be useful elements in the reflection of possible solutions for the development of effective and affordable antimicrobial therapies.

In January 2018, the EU project "DRIVE-AB" published its final report[3] on their main findings and incentive recommendations. The main pull incentive proposed by the DRIVE AB is the market entry reward i.e. a series of financial payments (around $1 billion per antibiotic) to an antibiotic developer for successfully achieving regulatory approval.

While reflecting on the need of incentives, any new model for the development of antimicrobials should be underpinned by principles that promote the appropriate use of antimicrobials and minimise the use of new and old antibiotics. Shortages and withdrawals of old antibiotics should be also addressed.

2. AIM OF DISCUSSION

The objective of the meeting is to discuss the issue, collect ideas, identify gaps and explore specific short- and long-term solutions. In particular, the following questions could give food for thought for the discussion:

- What would be the main policy aspects/incentives that in your opinion would solve the problem?
- How could we design a system that would on the one hand incentivise developers of new antimicrobials, but on the other hand address challenges such as availability and appropriate use of antibiotics?
- Due to similarities in the market failure for orphan, paediatric medicines and antibiotics. Do you see a common solution that could address problems identified in these three areas?

[2] https://academic.oup.com/cid/article/65/8/1378/3862465
[3] http://drive-ab.eu/wp-content/uploads/2018/01/DRIVE-AB-Executive-Summary-Jan2018.pdf