EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

Pharm 786

PHARMACEUTICAL COMMITTEE
17 December 2019

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

Agenda item 4

1. BACKGROUND

On 7 November, Pharmaceutical Committee had a preliminary debate on the market failure. The discussion on development of new antimicrobials showed that the matter needs a multifaceted strategy and incentives under the pharmaceutical legislation may not be sufficient to address the market failure.

Member States were asked to share with the Commission their ideas on how to address the market failure. We did a cluster analysis and grouped them into five main categories: I. Incentives, II. Measures to facilitate development and authorisation, III. Measures to facilitate manufacturing process and IV. Measures to facilitate the life cycle of antimicrobials.

2. AIM OF THE DISCUSSION

The objective of the meeting is to discuss ideas under two clusters: I. Incentives and II. Measures to facilitate development and authorisation (please see detailed table below). Several measures may be compatible with the current legislation; however, some of proposed mechanisms would require changes in the framework. Finally, some of them may be considered as pure financing instruments that are independent from the regulatory framework. During the meeting, we would like to discuss the ideas and take a decision on next steps.

In addition, Commission asked the Public Health Agency of Sweden (PHAS) to present its national pilot on a new reimbursement model to ensure availability of new approved antibiotics of special medical value. The new reimbursement model implies that the state guarantees a minimum annual revenue to the pharmaceutical company. In return, the company delivers a certain amount of antibiotics within specified time limits. In the pilot, Sweden will investigate whether the model is efficient and effective. The project will run until 2022. The pilot study includes a public procurement process, which is planned to be completed in spring 2020.

[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.

<table>
<tr><th colspan="3">Mechanisms to address AMR</th></tr>
<tr><th colspan="2">I. Incentives</th><th>II. Measures to facilitate development and authorization</th></tr>
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<td>Better use of existing incentives

✓ Orphan (like) incentives
• What would be the benefit? May it lead to improvements in the antibiotics pipeline
• Further examination of this option may also inform the orphan/paediatric evaluation</td>
<td>New Incentives (legislative and non-legislative)

✓ Priority review vouchers
• Example: the American Creating Hope Act
• Can be allocated to any medicinal product in sponsor’s portfolio or transferred via sale to another developer

✓ Transferable exclusivity vouchers
• 6 month extension of SPC to be allocated to any medicinal product in sponsor’s portfolio

✓ Market entry reward (MER)
• Partially or totally delinked from sales

✓ Innovative reimbursement models

✓ Stay on the market reward

✓ Social Impact Bonds
• Pay-for-success financing</td>
<td>✓ Fees waiver for the EMA Scientific Advice

✓ Fees waivers for a Marketing Authorization
• EMA fees for CAP
• RMS/CMS fees for DCPs/MRPs

✓ Candidacy for PRIME programme/automatic inclusion for the PRIME scheme for antimicrobials

✓ Target Product Profiles
• At EU level, MS to specify the type of products that they would be willing to support with specific incentives

✓ Old antibiotics with National Authorisation could benefit from the Centralized Procedure

✓ Use of Conditional Marketing Authorisation (CMA)
• If there is any evidence that this would help? Would it provide sufficient proof of efficacy and safety?

✓ Use of public marketing authorisation holders</td>
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