INVENTING FOR LIFE

A NEW INCENTIVE TO SUPPORT R&D FOR ANTIMICROBIALS

"There are no market failures, but failures to understand how markets work."

Background

The COVID-19 pandemic has made it very clear that the world needs to be better prepared for global threats posed by infectious diseases. Antimicrobial resistance (AMR) is one of these threats. Drug resistant infections are estimated to cause approximately 700.000 deaths each year[i], and have the potential to cause a level of economic damage similar to that caused by the 2008 financial crisis.

Governments need to support a sustainable innovation ecosystem that will invest in the R&D for new antibiotics and other antimicrobials. This requires new economic incentives, tailored antibiotic value assessments, and prices that reward R&D efforts.

Among the various policy options that are called for, it is time to consider the creation of a tailored incentive that will harness the power of intellectual property rights to drive R&D into novel treatments.

Transferable Exclusivity Extension

Experience has shown the value of tailored incentives in the form of ad hoc market exclusivity rights (eg, legislation promoting R&D for rare diseases). In order to incentivize R&D in novel antimicrobials, we propose the implementation of a Transferable Exclusivity Extension (TEE), which would reward successful R&D efforts by a company bringing a new, priority antimicrobial product to the market. Because of the specific hurdles attached to the limited use by clinicians of novel antimicrobials and the depressed price levels offered by payers, the simple extension of intellectual property rights granted on this new product would not provide an effective reward mechanism. To overcome this hurdle, it is proposed to allow the innovating company to transfer such exclusivity extension to any other product within its portfolio or even auction this TEE to other companies.

This TEE could take the form of a supplementary protection certificate (SPC) or time extension of regulatory data protection (RDP). It would provide a more direct and timely financial reward to the developer of a new antibiotic and serve as a powerful incentive tailored to the unique features of antibiotic development and use.

Policy makers would establish a list of priority pathogens that would open the right to a TEE. The additional exclusivity period should be set at a level likely to attract R&D investments and support a sustainable antibiotic R&D ecosystem. A TEE of 18 months would be deemed reasonable compared to the 6-month SPC extension granted for paediatric development or the 10-year market exclusivity granted to orphan medicines.

This novel and innovative approach to the known hurdles facing antimicrobial research could be an effective solution to triggering a new wave of antimicrobial R&D. While an untested approach, lessons can be drawn from other tailored incentive frameworks, such as the OMP Regulation or similar initiatives in the US with FDA priority review vouchers.

For more on MSD's commitment to fight antimicrobial resistance, please visit our website (https://t.ly/DAaq).

[i] Review on AMR (2014). Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. https://t.ly/cc8Q

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