World Health Organization

6. FOSTER INNOVATIONS AND RESEARCH AND DEVELOPMENT FOR NEW TOOLS

Efforts to avoid the emergence and spread of antimicrobial resistance will prolong the useful life of antimicrobial medicines, but inevitably their effective lifespan will be limited. New medicines and other tools to control infections will still be needed in the future.

WHY ARE MORE RESEARCH AND NEW PRODUCT DEVELOPMENT ESSENTIAL TO COMBAT ANTIMICROBIAL RESISTANCE?

> The microbes that cause infectious diseases are able to adapt to the antimicrobial medicines used for treatment. With exposure to an antimicrobial, particularly if it is not used correctly, resistant microorganisms will emerge. These resistant organisms can survive and proliferate, causing persistent infection which may spread to others. This process gradually erodes the efficacy of the drug and ultimately it become useless.

> For some diseases, resistance can be slowed down by using a combination of antimicrobials, to avoid exposure of microbes to one single drug. But despite such measures, the emergence of resistance cannot be entirely prevented.

> Therefore, there is a pressing need for new products to be brought to market for the prevention, diagnosis and treatment of infectious diseases.

CHALLENGES TO OVERCOME

> **Insufficient operational research:** research to identify the main factors that contribute to the emergence and spread of antimicrobial resistance (AMR) is lacking in most countries.

> **Lack of incentives to develop new tools:** few new antibiotics have been brought to market in recent years, largely due to increasing competition within the pharmaceutical industry and the perceived poor financial attractiveness of the market. Even where new public–private research and development (R&D) partnerships exist, the pipeline for new infectious disease diagnostics, drugs and vaccines is still too small.

> **Delays in access to new tools:** some recently developed diagnostics and medicines have been slow to reach intended users due to delays in regulatory review, limited financing and weak logistics. Furthermore, decisions on priority distribution of supplies when resources are limited may not always favour those most in need, often the health facilities and patients in the poorest communities.

CORE ACTIONS

A. IMPROVE THE USE OF CURRENT DIAGNOSTICS AND ANTIMICROBIALS

1) Pursue operational research on local use and misuse of antibiotics and other antimicrobials and on the effectiveness of the relevant regulations.

2) Assess how to improve access to diagnostic testing in order to better equip health providers and patients in making decisions on the use of antimicrobials.

B. CREATE INCENTIVES FOR NEW PRODUCT DEVELOPMENT

1) Advocate for global and national commitments to develop diagnostics, drugs and vaccines for infectious diseases, and share information on the national costs of inaction.

2) Offer "push" incentives to encourage researchers and financing partners by reducing the inherent risks in the initial phases of R&D; such incentives could include government financing for basic research and clinical trials, prioritizing investment in anti-infection research, and providing R&D tax credits.

3) Offer "pull" incentives to offset the risks of a limited or volatile market, such as advance market commitments, prizes for research breakthroughs or finished products, and patent buyouts to accelerate affordable access in countries and communities most in need.

C. ENABLE RAPID REGULATORY PROCESSES FOR NEW TOOLS AND EQUITABLE ACCESS

1) Eliminate regulatory bottlenecks to facilitate rapid review and licensure of new diagnostics, drugs and vaccines.

2) Prepare plans for rapid procurement and distribution of new products, with special attention to overcoming constraints to access by the poorest regions, communities and at-risk groups.

3) Monitor access to new products and the results of uptake and use.

The antimicrobial research & development pipeline

- Drug research and development is expensive and time-consuming. The average cost per each new drug that is developed is estimated to be US$ 800 million to 1.7 billion.
- There is a decrease in discovery research efforts and in antibacterial trials, reflecting a diminishing industry focus on antibacterial drug research and development.
- There are few antibacterial agents in the pipeline. A study in 2004 showed that only 6 out of 506 drugs in development by 15 large pharmaceutical companies and 7 major biotechnology companies were antibiotics.
- A report from the European Centre for Disease Prevention and Control and European Medicines Agency in 2009 showed that there are only two new antimicrobials under development, both being in the early stages when the failure rates are high.
- There is also a decrease in diversity of new antibiotics. Most of the antibacterial agents that entered the market were modifications of existing molecules.
- In 2008, a study of antibiotic development covering small firms as well as big pharmaceutical companies revealed that only 15 antibiotics out of 167 under development had a new mechanism of action.
- A growing number of pharmaceutical companies are withdrawing from the market of antibiotic development, and the trend has accelerated since 2000. Eight of the 15 major pharmaceutical companies that once had antibiotic discovery programmes have left the field, and two others have reduced their efforts.

[1] *A useful source on related issues: The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) can be accessed at http://who.int/phi/implementation/phi_globstat_action/en/*

For more information, go to: **http://www.who.int/world-health-day/2011**