**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.**

## 1. 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.**

## 2. Challenges to overcome

**Lack of systems to assure quality: Many countries do not have adequate systems to assure the quality of essential medicines.**

**Gaps in legislation for drug regulation: Without comprehensive legislation to support drug regulation, some areas of pharmaceutical activity may not be covered by the regulations.**

**Poor implementation of drug regulations: Inadequate infrastructure, fragmented drug regulatory functions and a lack of overall accountability lead to lapses in implementation and to duplication of efforts.**

**Absence of regulatory tools: Without regulatory tools, such as documented operating procedures, erratic application of legislation and lack of transparency of law enforcement will result.**

**Inadequate planning and resources: Poor availability of essential medicines in the public sector is often due to lack of resources or under-budgeting, and inefficiencies and wastage can result from inadequate planning, managing and monitoring the supply of medicines.**

**Insufficient financial control: Lack of price controls, non-transparent price mark-ups, lack of competition, and taxes and tariffs on medicines all tend to raise prices and lower access to essential medicines.**

**Deficient management of procurement and distribution: Poor estimation of needs, uneven distribution, misuse, lack of effective coordination, and poor storage conditions throughout the distribution system lead to wastage and jeopardize quality.**

**Countries which have successfully tackled these problems have done so through a series of core actions (see below) guided by well-defined national medicines policy.**

## 3. Core actions

**(A) Reinformce the system for supply of essential medicines**

**Set up a national body to coordinate (a) the development and regular updating of an Essential Medicines List based on national standard treatment guidelines, (b) setting priorities for supplying essential medicines in the public and private sectors, and (c) targeted quality assurance and reimbursement schemes.**

**Improve the forecasting of quantities needed in the country based on accurate national data, and ensure adequate and timely ordering, procurement and distribution of essential medicines.**

**Ensure sufficient public financing for essential medicines; review the impact of current health care financing on access to essential medicines; and introduce broad-based insurance schemes to cover essential medicines1.**

**Formulate pricing policies, including those on relevant tax and mark-ups, in collaboration with authorities in ministries of finance, trade and commerce; encourage higher margins for affordable generic medicines and lower margins for expensive brand-name medicines.**

**Institute adequately resourced mechanisms to monitor prices of medicines, with participation of civil society and consumer groups.**

**(B) Assure the quality of drugs according to international standards**

**Structure the drug regulatory authority (DRA) as an independent central coordinating body in the ministry of health with overall responsibility and accountability for all aspects of drug regulation, involving other relevant ministries where necessary; and ensure that its functions are separated from those of drug supply and management to avoid conflicts of interest.**

**Review and revise relevant legislation to ensure that the DRA has an adequate legal basis and functions effectively to cover all activities associated with manufacture, importation, distribution, dispensing and promotion; and rectify regulatory gaps by modifying existing legislation or introducing new legislation.**

**Develop standards and documented guidelines to be used as tools for applying all drug regulatory functions; and make these guidelines publicly available to ensure transparency of the regulatory process.**

**Set up programmes on staff development to provide appropriate training and qualification of personnel engaged in drug regulation.**

**Establish mechanisms for systematic monitoring of the regulatory process.**

**Ensure that medicines available in the public and private sectors have been registered by the DRA.**

**Thursday 9th of May 2024 05:12:45 AM**