The IFPMA Geneva Pharma Forum on 7 April was arranged to coincide with the World Health Organization’s World Health Day, which this year took antimicrobial resistance as its theme. Antimicrobial resistance (AMR), commonly termed antibiotic resistance, is an increasingly serious global problem. Resistant organisms can withstand attack by antimicrobial (antibiotic) medicines, rendering standard treatments ineffective, so that infections persist and may spread to others. While AMR is a natural phenomenon, it is being made worse by inappropriate use of medicines. A multi-stakeholder approach is needed that promotes behavioural changes as well as new medicines.

Welcoming participants from UN member-state missions in Geneva, health-related intergovernmental organizations and public-private partnerships, and the pharmaceutical industry, Dr Jean Freymond, Director of Geneva Dialogues, said AMR was a major health issue that needed to be addressed by all concerned. “Everyone is in charge, starting with the patient,” he said. Combating AMR required a holistic package of policies and measures focused on the need for behavioural changes and the necessity for new medicines.

As an example, Dr Freymond noted that every year there were 440,000 new cases of multidrug-resistant tuberculosis (MDR-TB), which would result in at least 150,000 deaths. “This might be just the beginning,” he warned.

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AMR – The Healthcare Professional Perspective

Prof Didier Pittet, Director, Infection Control Program and WHO Collaborating Center for Patient Safety, University of Geneva Hospitals and Faculty of Medicine, warned that the “good times of antibiotics have passed”. Since the discovery of penicillin in the 1940s, society had come to assume that infectious diseases could be cured. Now there was a real concern that in future there would be no antibiotics to treat common infections such as streptococcus pneumonia and urinary tract infections.

“...The benefit of antibiotics is individual but the risk is collective.” Prof Pittet

Third, doctors and patients were also culprits. It might take a three-minute consultation to prescribe antibiotics to a patient and 30 minutes to explain why such a prescription would not be appropriate. Patients may demand antibiotics and will see other doctors until they receive the required prescription. Once prescribed, they may not complete the course of treatment because they are feeling better, or they may forget to take the pills sometimes, all of which increases the risk of developing drug resistance. “The benefit of antibiotics is individual but the risk is collective,” Prof Pittet noted.

Finally, globalization facilitated the spread of drug-resistant infections around the world. One example was NDM1, a multidrug-resis-
Dr Rex pointed out that discovery of new antibiotics is hard. Scientists have to find something that kills living organisms (bacteria) without harming the patient. Bacteria are “armoured”, requiring high concentrations of an antibiotic in the blood to be effective. These high concentrations “really stretch the safety margin”. In addition, there is a hierarchy of resistance mechanisms that new drugs need to tackle, making development a slow and iterative process.

Regulatory and ethical constraints also hinder drug development, Dr Rex noted. For instance, if a company wanted to test a new antibiotic to combat MRSA (methicillin-resistant staphylococcus aureus), it could not do a clinical trial in which the control group would be given the ineffective methicillin. In these cases, companies are obliged to use a “non-inferiority” design that tests the new drug against another effective drug. This requirement makes it harder to envision value of the new agent against future resistance to the currently effective drug. “We must not let the perfect be the enemy of the good,” Dr Rex urged.

These constraints make it a less viable proposition for companies to develop new antibiotics. However, since new antibiotics can take a decade to bring to market, they will not be there when needed. The paradox was that drugs have to be developed before the need for them becomes apparent, Dr Rex pointed out. “You have to start early. You can’t just open the taps,” he said.

Industry recommendations to tackle these barriers included the creation of conditions for a diverse long-term pipeline, recognising that this requires continuous innovation, better regulatory procedures, and improved incentives for research and development (R&D). Rapid diagnostic tests would provide valuable support both for drug development and for appropriate drug selection and use in practice. Dr Rex concluded on an optimistic note, pointing to recognition of the need for action on R&D in the European Union and the United States, as well as by the World Health Organization.
World Health Day 2011 – Raising Awareness of AMR

Dr Diana Weil, Coordinator, Policy & Strategy, Stop TB Department, World Health Organization outlined why WHO had made AMR the theme of World Health Day 2011 and the thinking behind its six-point AMR policy package. There was a need not only to raise awareness of AMR but to galvanize governments to take action, as stewards of the health of their citizens.

AMR was a global concern, Dr Weil said. It threatened effective control of infectious diseases, greatly increased treatment costs, and jeopardised healthcare gains for individuals and societies. Drawing attention to the spread of multidrug-resistant tuberculosis (MDR-TB) and the emergence of extensively drug-resistant TB (XDR-TB), now reported in 64 countries so far, she noted that it costs USD 2,000 to USD 3,000 to treat each MDR-TB patient compared with USD 20 to USD 25 for patients responsive to first-line drugs. Resistance had already been discovered in Asia to the new artemisinin-based combination therapies for malaria. Lethal infections in hospital settings were becoming increasingly frequent as were other multi-drug-resistant infections including foodborne Escherichia coli (E.coli) and pneumonia. New data on antiretroviral therapies for HIV/AIDS also showed worryingly high resistance levels in some cases.

Various factors were blocking progress, Dr Weil said. AMR was a complex problem requiring a comprehensive response across different sectors. Although the actions needed were clear, there was a failure of commitment, implementation and accountability. Preventing AMR was a “public good” which strengthened health security, but financing was insufficient. WHO hoped making AMR the focus of World Health Day 2011 would engage its 193 member states and the global health community to foster action for change worldwide.

In 2001, WHO had put out a strategy on AMR containing 94 recommendations, addressed to everyone, but this time it had decided to concentrate its recommendations in a six-point policy package designed to make explicit what governments should be doing, both in taking action themselves and in getting others to take action. Combating AMR suffered from the lack of a vocal civil society lobby for more resources, such as those on HIV/AIDS and TB. Still, there was scope to “piggy-back” on surveillance measures, diagnostic facilities and medicine supply chains established for specific diseases such as HIV/AIDS or TB, to ensure both proper access to antibiotics and their correct prescription and use. Simple actions like handwashing could reduce the risk of infections in hospitals. WHO also wanted better incentives and faster regulatory decisions to encourage development of new antibiotics.

WHO’s approach was intended not only to boost awareness but also to enhance understanding of what was needed for governments and other stakeholders to take effective action on this issue, Dr Weil said.