Geneva Pharma Forum

forum highlights

7 April 2011

IFPMA International Federation of Pharmaceutical Manufacturers & Associations

How to Combat Antimicrobial Resistance?

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.[1] 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.

1 World Health Day – 7 April 2011, Antimicrobial resistance: No action today, no cure tomorrow: http://www.who.int/world-health-day/2011/en/

IFPMA position on Antimicrobial resistance (AMR)*

- A continuous pipeline of new classes of antibiotics that can overcome increasing bacterial resistance is essential. Barriers to new drug development must be tackled through creative partnership between the pharmaceutical industry and other stakeholders.
- Effective antibiotic stewardship is required to ensure antibiotics are prescribed and used responsibly. This also requires a multi-stakeholder approach involving governments, the pharmaceutical industry, the World Health Organization and healthcare professionals.

* IFPMA Position on Antimicrobial Resistance (AMR): http://www.ifpma.org/fileadmin/webnews/2010/pdfs/IFPMA_Position_on_Antimicrobial_Resistance_7April2011.pdf

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.

Prof Pittet listed four contributory factors to the growth of AMR, but stressed that none was solely responsible. First, the bacteria themselves were "smart", constantly changing to fight off antibiotic medicines. Second, antibiotics were widely used in the food processing industry, for example, to prevent mass infections in aquaculture and chicken batteries. But consumers had a shared responsibility. "Are we prepared to pay higher prices for food that has not been fed with antibiotics?", Prof Pittet asked.

> "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-resistant infection originating in the Indian subcontinent that had now travelled to North America, Europe, east and south-east Asia and Australia. Meanwhile, methicillin-resistant staphylococcus aureus (MRSA), responsible for several difficult-to-treat "staph" infections, had become a "silent epidemic", Prof Pittet said.

Antibiotics were among the best drugs there were but they had to be used properly. Using, over-using and misusing antibiotics were creating not only resistance but also a reservoir for resistance. Prof Pittet described a number of important measures to reduce and optimize antibiotic use in hospital settings. However, while hospitals had been an initial source of AMR, due to the combination of very sick patients and use of broad spectrum antibiotics, today only 10 % of antibiotics used in human medicine were used in hospitals and 90 % were used in the community.

There was now increasing recognition of AMR as a growing problem but effective action would not be possible unless people realised that it was a global issue that required global solutions, Prof Pittet concluded.

Presentation:
http://www.ifpma.org/fileadmin/templates/Events/2011/PharmaForum_AMR/pdf/HUG_Presentation.pdf

Good times of antibiotics have passed.

The Search for New Tools: The R&D Challenge

Dr John Rex, Vice-President, Clinical Infection, AstraZeneca explained the scientific, regulatory and financial factors that have led to a reduction in research into and development of new antibiotics. He argued that society fundamentally undervalues antibiotics, which are essential to modern medicine. Without reliable antibiotics heart surgery, care of premature infants, hip replacements and cancer treatments would all be impossible.

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.

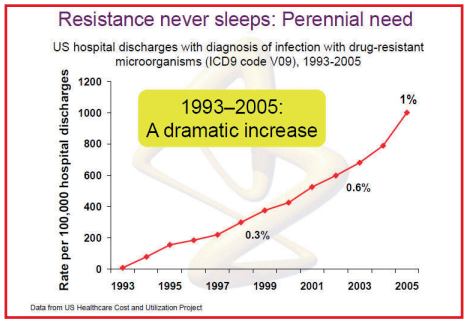
Regulatory and ethical constraints also hinder drug development, Dr Rex noted. For instance, if a company wanted to test a new antibiotic to combat MRSA (methicillin-resistant staphylococcus aureus), it could not do a clinical trial in which the control group would be given the ineffective methicillin. 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.

> "Without reliable antibiotics heart surgery, care of premature infants, hip replacements and cancer treatments would all be impossible." Dr Rex

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.

Presentation:
http://www.ifpma.org/fileadmin/templates/Events/2011/PharmaForum_AMR/pdf/HUG_Presentation.pdf



Participant contribution
"Do developing countries require different solutions?"

A representative of the Permanent Mission of Congo in Geneva pointed out that many developing countries suffer from infrastructure and capacity constraints and suggested that tackling AMR might require different solutions that take these constraints into account. In response, Dr Pittet said there were many simple actions, such as handwashing by hospital staff, that applied in all countries. If water shortages made handwashing difficult, the same result could be achieved using alcohol, which was very cheap. It was true that there was also a need for better nutrition, improved infrastructure and so on in many developing countries but the greater the global effort to tackle AMR, the more the global health community would find appropriate solutions.
Dr Pittet drew attention to the African Partnership for Patient Safety. Better surveillance of AMR could be achieved through extending the surveillance and detection network already being put in place for TB, he argued. Exploiting commonalities and synergies was a point taken up by Dr Weil in her response to the same question. There was likely to be more opportunity to move forward on AMR if it was tackled as part of other health agendas such as HIV/AIDS, TB and malaria, rather than as a stand-alone issue, she said.

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 multidrug-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.

Presentation:
http://www.ifpma.org/fileadmin/templates/Events/2011/PharmaForum_AMR/pdf/WHO_Presentation.pdf

WHD 2011 Core Product: Six Point Policy Package

1. Commit to a comprehensive, financed national plan with accountability and civil society engagement
2. Strengthen surveillance and laboratory capacity
3. Ensure uninterrupted access to essential medicines of assured quality
4. Regulate and promote rational use of medicines including in animal husbandry and ensure proper patient care
5. Enhance infection prevention and control
6. Foster innovations and research and development for new tools

IFPMA
International Federation of Pharmaceutical Manufacturers & Associations

About the IFPMA
The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical industry, including the biotech and vaccine sectors. Its members comprise 26 leading international companies and 45 national and regional industry associations covering low, middle and high income countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/ClinicalTrials), the IFPMA's Ethical Promotion online resource (www.ifpma.org/EthicalPromotion) and its Developing World Health Partnerships Directory (www.ifpma.org/HealthPartnerships) help make the industry's activities more transparent. The IFPMA supports a wide range of WHO technical activities, notably those relating to medicine efficacy, quality and safety. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

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