Addressing AMR: Innovation and best practices for infection control, use of medicines and technology development

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An international response is required

- World Health Assembly May 2014 requests WHO
  - ... To develop a draft global action plan to combat AMR ... to ensure that all countries ... have the capacity to combat AMR.

- The Draft Global Action Plan to be submitted to the WHA in 2015
  - ... To apply a multisectoral approach to inform the drafting of the global action plan, by consulting Member States as well as other relevant stakeholders....
    FAO, OIE.....
Guiding Principles for the Global Action Plan (GAP)

• Whole-of-society engagement
• Actions based on best available knowledge and evidence
• Prevention first
• Access not excess
• Sustainability – more likely when integrated into health systems or practices in other sectors (animal, agriculture)
• Incremental targets for implementation that recognise the different priorities and capacities of Member States
GAP has 5 strategic objectives

1. Improve awareness and understanding of AMR through effective communication, education and training
2. Strengthen the knowledge and evidence base through research and surveillance
3. Reduce the incidence of infection through effective hygiene and infection prevention measures
4. Optimize use of antimicrobial medicines in human and animal health
5. Develop the business case for investment in new medicines, diagnostic tools, vaccines and interventions
Use of medicines
Variability in antibiotic consumption in Europe 2011

Total antibiotic use in 2011, expressed in number of DDD per 1000 inhabitants per day in 12 European countries and Kosovo as compared to 29 ESAC-Net countries.

Source: WHO-EURO and ESAC-Net
Some issues identified

- Variability in levels of use: range 15.3 - 42.3 DDD/1000/day
  - Turkey highest – has stimulated interventions towards rational use
  - Armenia lowest – underuse may be related to poor availability
  - High levels of outpatient injectable antimicrobials in some countries

- Lack of information systems: rely on sales data; however will include antibiotics procured without a prescription

- Self-medication common: >50% sold OTC in most countries in spite of antibiotics being prescription drugs

- Choices vary:
  1. underuse of first line treatments;
  2. overuse of combination amoxicillin+β-lactamase inhibitors and respiratory quinolones, high use of amphenicols - some countries (chloramphenicol had been widely used for diarrhoea treatment)
How do we achieve better use of antibiotics?

- Need political commitment, intersectoral involvement & coordination (e.g. human health, animal health, agriculture)
- Availability of reliable data on use, of policy guidance and best practices
- Action at different levels – from national policies to facility level coordinated interventions
- Build and strengthen partnerships:
  a) Ministries of Health & Agriculture (human and veterinary sectors)
  b) Other countries and regional networks
  c) International agencies
  d) Organisations & institutions involved in promoting rational use
  e) Civil Society and patient organizations
  f) Others
Quality of antimicrobial agents: challenges and actions to address them

• Substandard and counterfeit antimicrobials
   E.g. in 2014, reports of “fake” artemether & lumefantrinein combination (Coartem) without active ingredient

• Public health responses and interventions
   Strengthen medicines regulatory authorities (MRAs)
   Enforce regulations relating to registration, production, and distribution; enhance national laboratory capacity for quality control and monitoring; enhance capacity for inspection of manufacturing facilities
   Eliminate irrational antibiotic combinations and irrational pack sizes; regulate the pharmacy and drug sellers to only sell antibiotics with prescription; regulate veterinary market (no antibiotics as growth promoters, separate types of antibiotics to be used in human and veterinary medicine)
   Organize campaigns aimed at the public at large to reduce use of antibiotics
Development of new antimicrobials
Discovery of new classes of antibacterial drugs (1930s to 2000s)

In recent decades, only 2 new classes of antibiotics have come to market, and there is a dearth of novel antibiotics in the pipeline.

Need for development of therapies that do not drive resistance!

* Penicillins were the first beta-lactams. This class includes cephalosporins and carbapenems, developed in the 1960s and 1980s, respectively.

Current Situation

EU, US or other investors
$300M/project

IMI

Bioventures, R&D companies
(generate IP)

Company A

sub-license to
Agrobusiness
Subsidiary Y

ANTIBIOTIC X

Market

Irrational use of antibiotics
market fall off in few years with resistance

Health Systems and Innovation
Proposed Initiative: Innovation for AMR

- Innovation
- Development
- Registration & Production

Academics
Biotechs
Biotechs
R&D Pharma
Companies

- e.g. prizes, grants
- R&D & generic manufacturers
- Approx $2-5B

Managed Market

ANTIBIOTIC X, Y, Z...

Initiative Consortium
PDP

IP

Health Systems and Innovation
Towards a new initiative in support of the development and rational use of new antibiotics

WHO & DNDi Technical consultation, 8 - 9 Dec 2014, Geneva

Vision: Establish a *product development partnership* which, in collaboration with public and private partners in high-, middle and low-income countries, researches and develops new antibiotics and ensures their rational use and their preservation globally.

Participants: WHO, governments, academia, civil society, industry…

Expected result:
- draft concept for a PDP on antibiotics
- draft Mission statement
- roadmap for setting up, fundraising and convincing partners & donors