Towards EU guidelines on prudent use of antimicrobials in human health

Diamantis Plachouras, Surveillance and Response Support Unit
Dominique L. Monnet, Head of Disease Programme, Antimicrobial Resistance and Healthcare-Associated Infections (ARHAI)
European Centre for Disease Prevention and Control

Luxembourg, 25 May 2016
Background

- COMMISSION NOTICE. Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04)

- Request from DG SANTE to ECDC to draft EU guidelines for the prudent use of antimicrobials in human medicine: 21 March 2016

- Aim: To provide generic elements of good practice on prudent and appropriate use of antimicrobials for all the main aspects of human medicine in the EU

- Final draft to be delivered by ECDC to DG SANTE: 31 October 2016
Purpose of EU guidelines on prudent use of antimicrobials in human medicine

• To provide generic elements of good practice on prudent and appropriate use of antimicrobials for all the main aspects of human medicine
Scope of the guidelines

• Principles of prudent and appropriate use of antimicrobials
• Take into account:
  o Council recommendations on the prudent use of antimicrobial agents in human medicine (2002/77/EC)
  o “One Health” approach
  o Existing EU policy on antimicrobial resistance
  o Commission guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04)
• Two parts:
  o Clinical practice
  o Resources, systems and processes that EU health systems should provide
• Constructed in such a way that implementation of the guidelines can be evaluated in a straightforward manner
Principles for guideline development

Transparency and management of conflicts of interest

Evidence-based approach

- Systematic review and appraisal of existing evidence
- Existing relevant guidelines
- Expert opinion

Broad involvement of stakeholders

- Member states
- EMA
- Professional associations
- Public, patients, consumers

Public consultation

Evaluation and monitoring – indicators, auditing

Clinical practice guidelines we can trust. Institute of Medicine, 2011
Challenges

• Address all key actors
• Evaluate generalisability of recommendations
• Account for behavioural, cultural, organisational and legal variability in Europe
• Encourage adaptability
• Ensure endorsement by the target audience(s)
• Facilitate implementation
• Short deadline
Methods, roles and timeline
Definitions and elaboration of scope

• Ensure consistent definition of antimicrobials
• Define prudent and appropriate use
Review of evidence

- Review of available systematic reviews on antimicrobial prescribing
  - Cochrane database of systematic reviews
  - Pubmed
  - EMBASE
- Review of available relevant guidelines
  - National guidelines (Member States, USA, others)
- Other sources
  - Council recommendation
  - National action plans on antimicrobial resistance
  - Other grey literature sources
- Evaluation with use of assessment tools (PRISMA, AGREE)
ECDC guidelines
Content  *(first draft)*

- Definitions
- Scope and purpose
- General principles
- Responsibilities *(see next slides)*
- Awareness raising
- Education
- Surveillance and monitoring
- Research
Responsibilities (1)

• International

• National / regional

• Healthcare facilities (resources, systems and processes)
Responsibilities (2)

• Prescribers
  – General
  – Community prescribers / General practitioners / Family medicine
  – Hospital prescribers (incl. prescribing nurses)
  – Long-term care facilities

• Non-prescribers
  – Pharmacists
  – Nurses
  – Microbiologists
  – Infection control practitioners
  – Others

• Patients / Public
• Educators / Academics
• Pharmaceutical industry
For each recommended measure:

- **Description** [incl. reference]
- **Possible adaptation to suit different settings**
- **Indicators**
  - Structure
  - Process
  - Outcome (would need adjustment)
- **Enabling factors / Examples of good practice** [incl. reference]
Next steps

• **9-10 June 2016** (ECDC): Expert meeting
  - 10 experts with research and experience in antibiotic use policies and development of guidelines
  - Review of early draft of guidelines

• **July-August**: Public consultation (web)

• **12-14 September** (ECDC): Advisory Forum

• **16 September** (ECDC): Stakeholder meeting
  - professional associations
  - scientific societies
  - patients’ (users’, consumers’) associations

• **31 October 2016**: Final draft delivered to DG SANTE