



Towards EU guidelines on prudent use of antimicrobials in human health

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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 spectes 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:
 - Council recommendations on the prudent use of antimicrobial agents in human medicine (2002/77/EC)
 - “One Health” approach
 - Existing EU policy on antimicrobial resistance
 - Commission guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04)
- Two parts:
 - Clinical practice
 - 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

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