



The policy context of the request for advice

Consultation meeting with stakeholders, request from the EC for advice on the impact on public and animal health of the use of antibiotics in animals

Mario Nagtzaam DG Health and Consumers European Commission

EMA, London, 28 February 2014





AMR a public health priority!

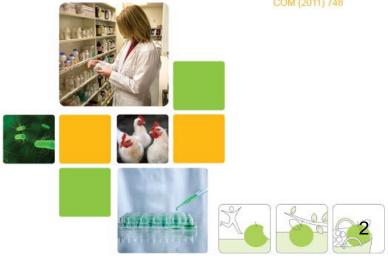
((COM (2011) 748) – 17 Nov 2011

- 5 year action plan
- Holistic approach
- 7 key areas
- 12 concrete actions

Communication from the Commission to the European Parliament and the Council

Action plan against the rising threats from Antimicrobial Resistance

COM (2011) 748





The 12 actions

Human

Veterinary

- 1. Appropriate use
- 4. Prevention of infections

6. New antibiotics

9. Surveillance

8. International cooperation

11. Research & Innovation

12. Communication, education

DG SANCO

2 & 3. Appropriate use

5. Prevention of infections

7. Need for new antibiotics

10. Surveillance



Action 2 & 3: Appropriate use antimicrobials in veterinary medicines

a) <u>Strengthen the regulatory framework on veterinary medicines</u>
→ Revision veterinary medicines legislation

- Incentives for new veterinary antimicrobials
- Cascade
- New and better legal tools for management of AMR
- Advertising
- Decoupling sales and prescription
- Monitoring sales



Actions 7: Need of new veterinary antibiotics?

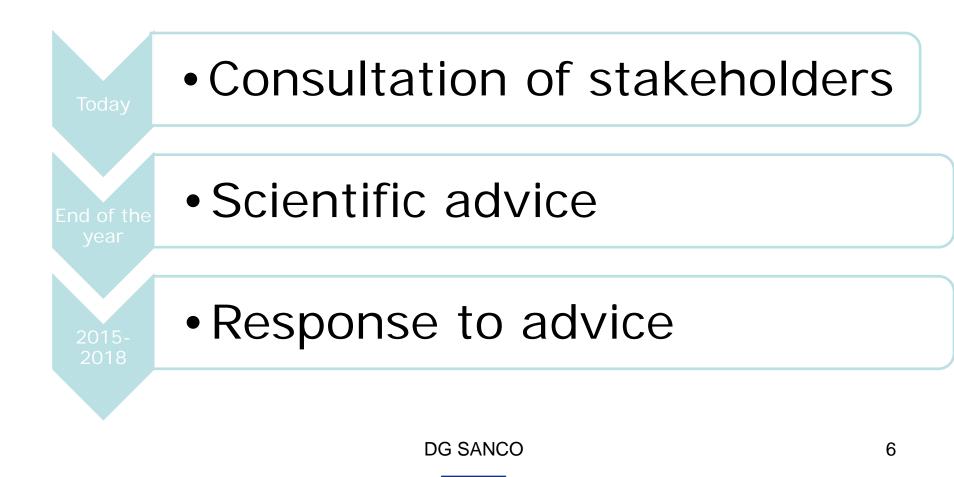
Promote efforts to analyse the need for new antibiotics into veterinary medicine and its repercussion on AMR

- request for scientific advice: Will the use of new types of veterinary antimicrobials reduce the development of resistance in animals and humans?

- **deadline**: 2014



Planning





Today – interested parties / stakeholders

Advice based on the best scientific information available and the most recent scientific results

All effort is required to collect and to evaluate information

Excellence, transparence and independence



End of the year- advice of EMA

Advice of EMA, ECDC and EFSA I dentify risks and effects Gaps in knowledge, scientific uncertainties



2015-2018 – response to advice

- **Structured approach**
- Involve interested parties and stakeholders
- What is the level of risk deemed appropriate
- Response based on current legal tools/additional tools revision legislation veterinary medicines
- Efficacy of possible options
- To do nothing is also a response



Thank you for your attention



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