



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The ESVAC project. Main deliverables and results

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Outline

- ESVAC – background and mandate
- Approach
- Main deliverables
- Trends in the sales in 9 European countries (2005-2009)
- Next steps



Background: Mandate ESVAC project

[SANCO/E2/KDS/rz D(2008) 520915]

- Requests the EMEA to take the lead in collecting data on the use of antimicrobial agents in animals
- To identify the existing data/surveillance systems established for collection of sales and use of antibacterial drugs in the Member States;
- To develop a harmonised approach for the collection and reporting of data



Mandate ESVAC project cont

(Ref. doc.: EMEA/507682/2008)

- In order to guarantee an integrated approach, the ECDC, the EFSA and the CRL* should be consulted

Request from Commission to EMA

(Ref doc. Appendix to letter from Commission:C.8/MN/sx. D(2009)42527)

5. Cooperation with other agencies and committees of the Commission

As indicated above, the Commission would like to see more details in the EMA proposal on cooperation with other agencies and committees of the Commission, for example the ECDC and EFSA. One deliverable in phase II of the project could be a draft working agreement between relevant parties on how the data would be collected and used and specifying in detail the responsibilities and output of each party.

*EURL-AR



Stepwise approach – partly overlapping

- Collect harmonised overall sales data (pilot phase)
- Collect harmonised data by species
- Development of Defined Daily Doses (DDD) or similar unit to correct for differences in dosages between the various antimicrobial agents



ESVAC project launched 1 September 2009

– major deliverables

- ESVAC network on national representatives (ongoing)
- ESVAC protocol/ESVAC data collection template/ESVAC database developed in order to collect harmonized data and detailed data at package in the future
 - For protocol and template see link:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580153a00
- Call for data for 2010 according to ESVAC protocol and template sent to 22 countries willing to participate



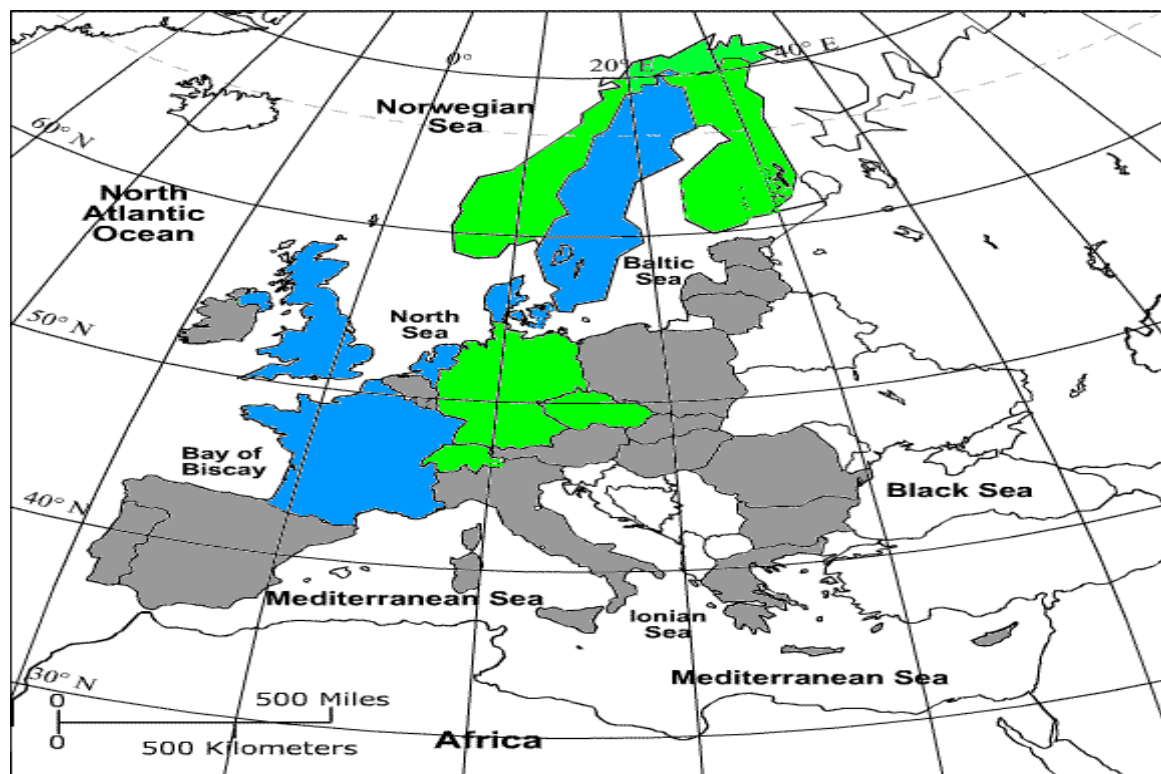
ESVAC project launched 1 September 2009

– major deliverables cont

- Draft working agreement between ECDC, EFSA and EMA under development
- **The existing data/surveillance systems** established for collection of sales and use of antibacterial drugs in the Member States **identified and evaluated**





Identification of the **existing** surveillance systems and the data published (2009)



10 countries had published overall sales data – of which **9** for several years

5 countries published by species

-  Total sales
-  Total sales + by species



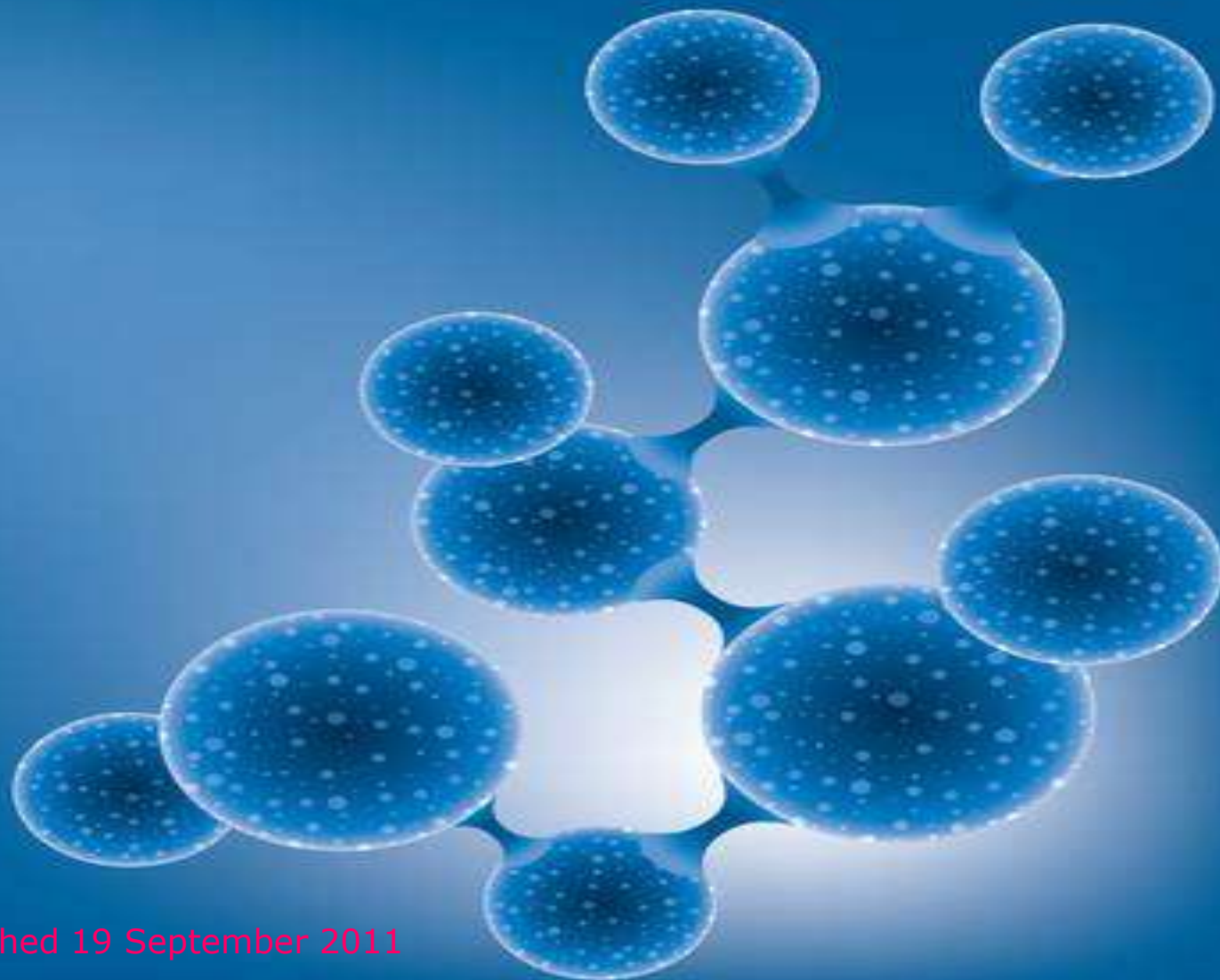
Main results of evaluation of surveillance systems

- Data collection harmonized? – this was not possible to identify because e.g. for most countries because
 - Information on which veterinary AM agents included in the surveillance programs and on the data coverage was missing
- Data reporting not harmonised between countries
 - Not possible to compare the data

Following this it was decided to collect historical (2005-2009) standardized data from 9 countries and report these in a standardized manner in order to make use of already existing data

Trends in the sales of veterinary antimicrobial agents in nine European countries

Reporting period: 2005-2009



Intended to be published 19 September 2011



Trends in sales of veterinary antimicrobial agents in 9 European countries: 2005-2009

- Main aim of study
 - To identify trends and patterns of sales of veterinary antimicrobial agents by use of already existing data in order to document the situation
- Material (defined by protocol) and methods
 - Harmonized **aggregated** sales data of clearly defined classes of veterinary antimicrobial agents were collected retrospectively for the years 2005-2009. *Note that some countries had to reanalyse the data in order to meet the criteria*
 - Countries had to describe any deviation from protocol
 - Data coverage to be reported by each country
 - Data normalized by taking into account the animal population



Material and comparability

- Material

- All countries included AM agents for systemic, intramammary and intrauterine use for terrestrial animals
- All but two countries included AM agents sold for farmed fish – for these two countries farmed fish not included in denominator
- 2 countries included also dermatologicals and preparations for eyes and ears - contribution was estimated to be minimal

- Coverage

- 7 countries reported 100% coverage, 2 countries reported 98% coverage

- Concluded that sales **data (in tonnes) are valid and comparable** between the 9 countries



Normalising sales data by animal population

- The population correction unit (PCU) is used as term for the estimated weight of livestock and slaughtered animals
- PCU is introduced as a proxy for the animal biomass at risk of being treated with antimicrobial agents
- The annual sales figure in each country was divided by estimated weight at treatment of livestock and of slaughter animals in the corresponding year
- Data source for livestock and slaughtered animals: **Eurostat** used as it is public available and based on same methodology for collection of data from all MSs



Normalising sales data by animal population cont

- Animals transported for slaughter or fattening in another MS
 - likely to have been treated with AM agents in the country of origin
 - but is reported in figures on numbers of slaughtered animals in Eurostat for the receiving country
- This was accounted for in the calculation of PCU – i.e. net balance
 - Data on animals transported obtained from TRACES – reliable as based on health certificates which are obligatory for any animal passing any border

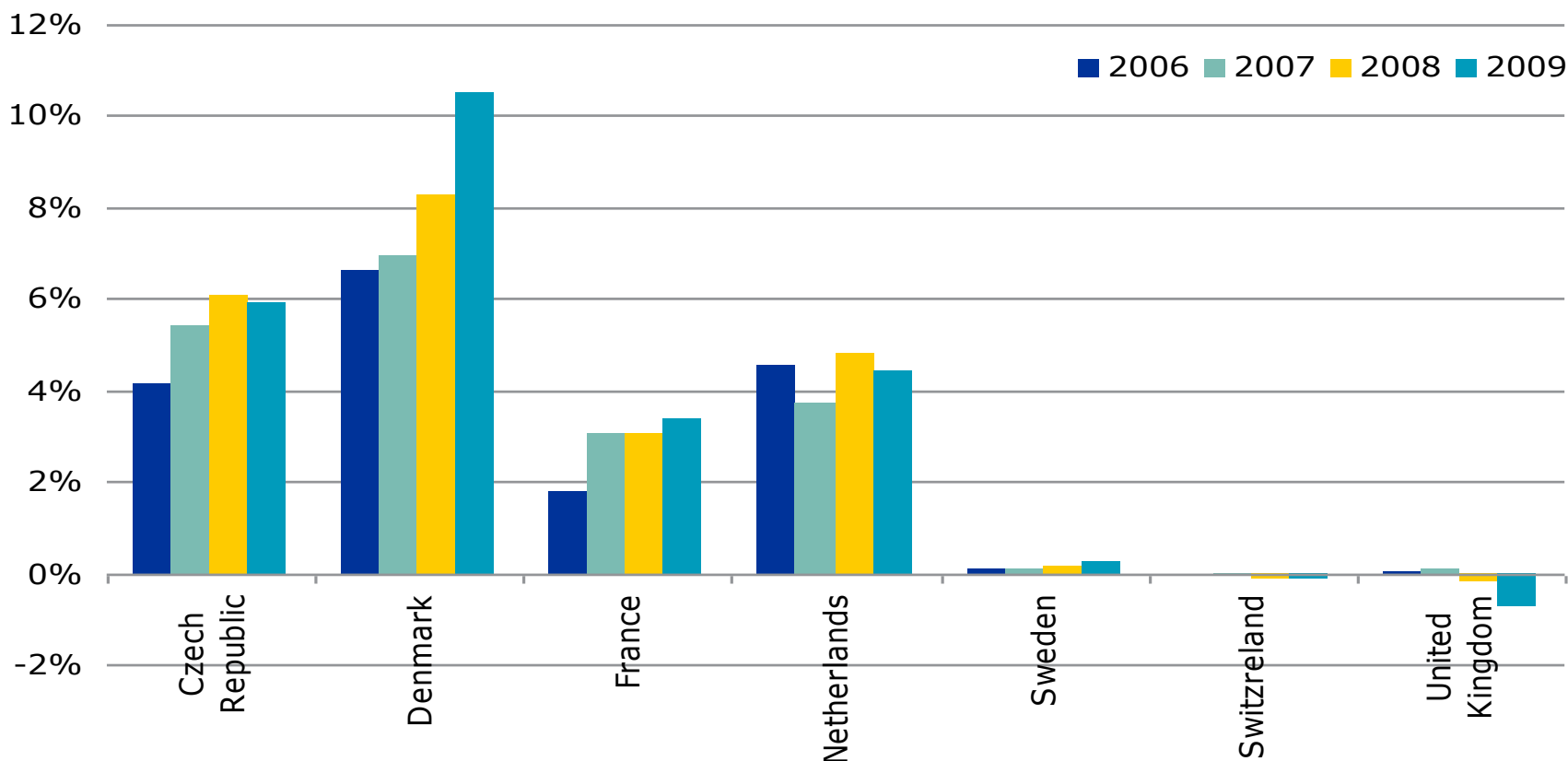


Normalising sales data by animal population cont.

- As sales data covers all animal species also the estimated PCU should cover all species
 - Two countries did not include sales to farmed fish – for these countries farmed fish were not included in PCU
- Data had to be available for all countries for the various animal species to be included in the calculation of PCU
 - Data on numbers of cats and dogs were not available for all countries, these species were therefore excluded from the calculation of PCU



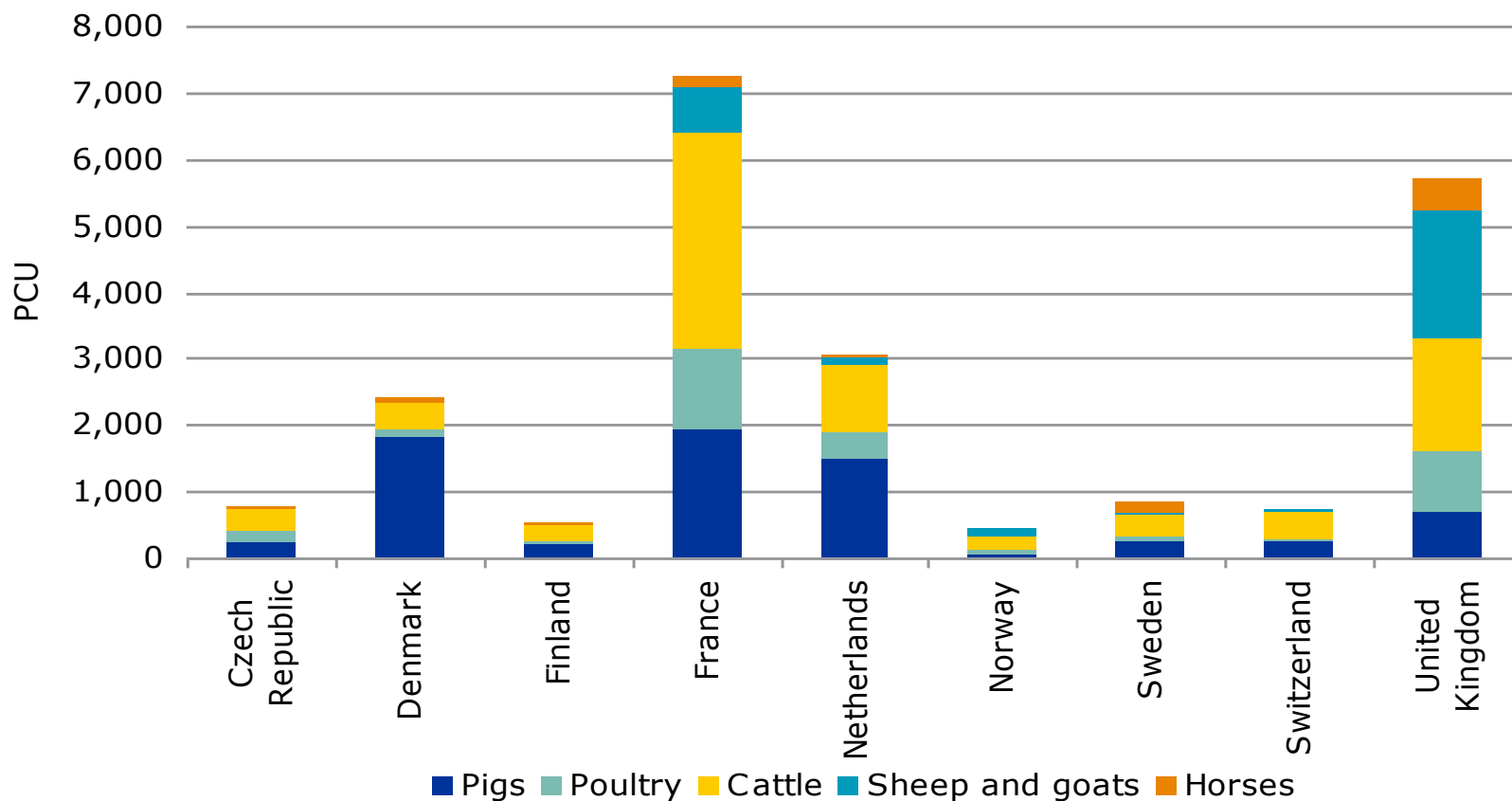
% PCU (of total PCU) for animals exported or imported (net balance) for fattening or slaughter in another MS*



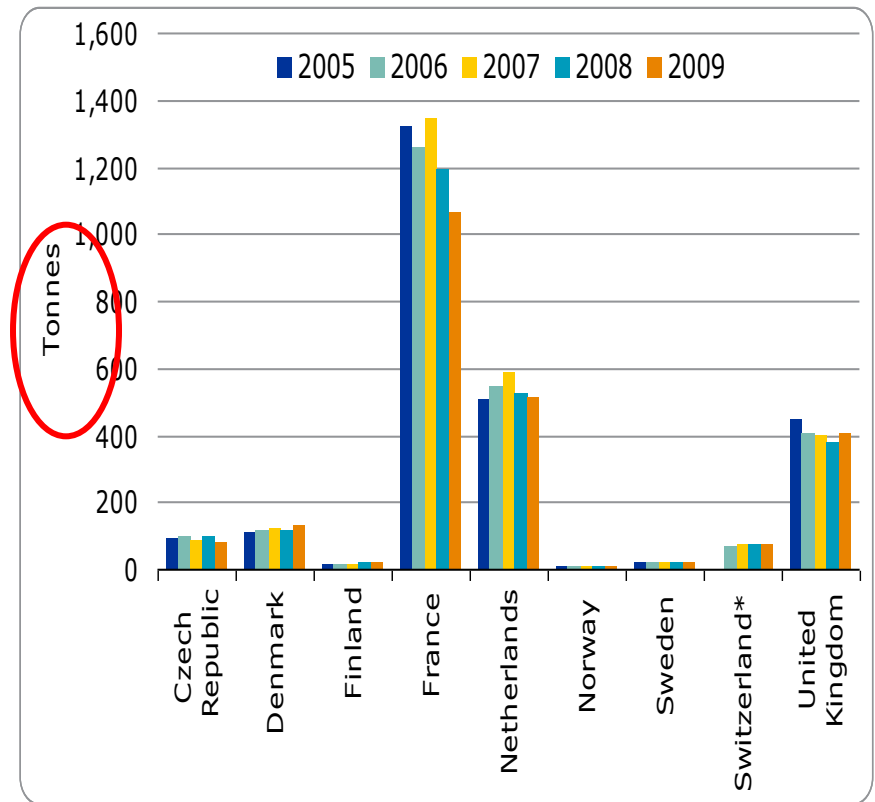
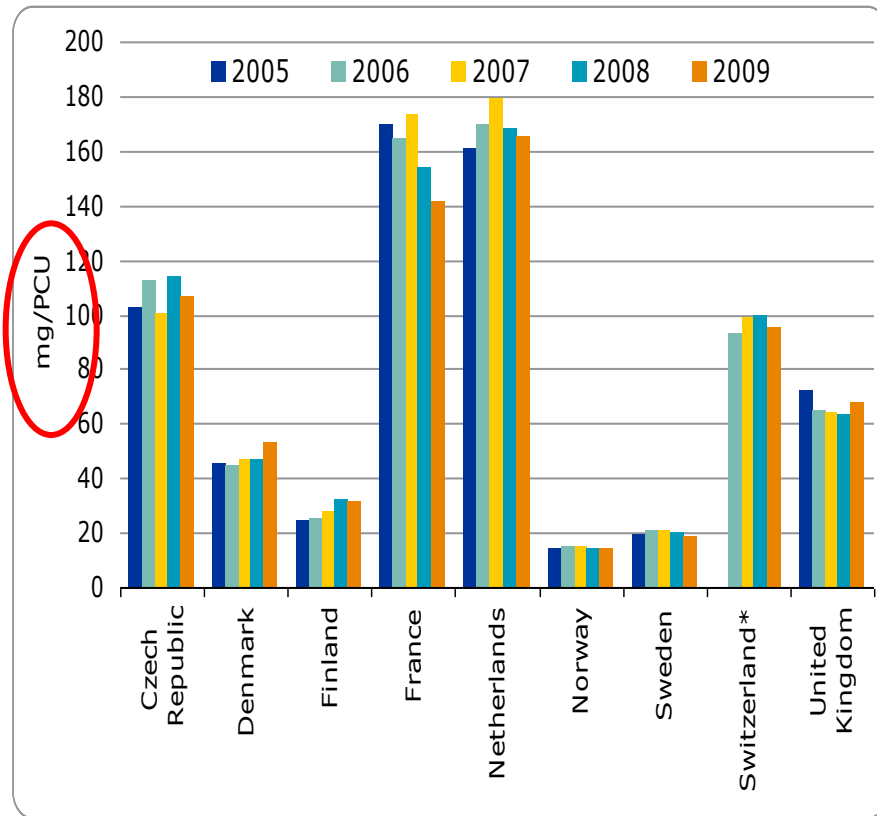
2005 data not included as TRACES data not valid



Estimated PCU (1,000 tonnes) in the 9 countries for 2009. A substantial difference is observed between the countries



- Sales given as mg/PCU 12 fold difference while when given in tonnes 190-220 fold differences between the least- and most selling countries
- Shows the importance of correcting the sales figures by animal population

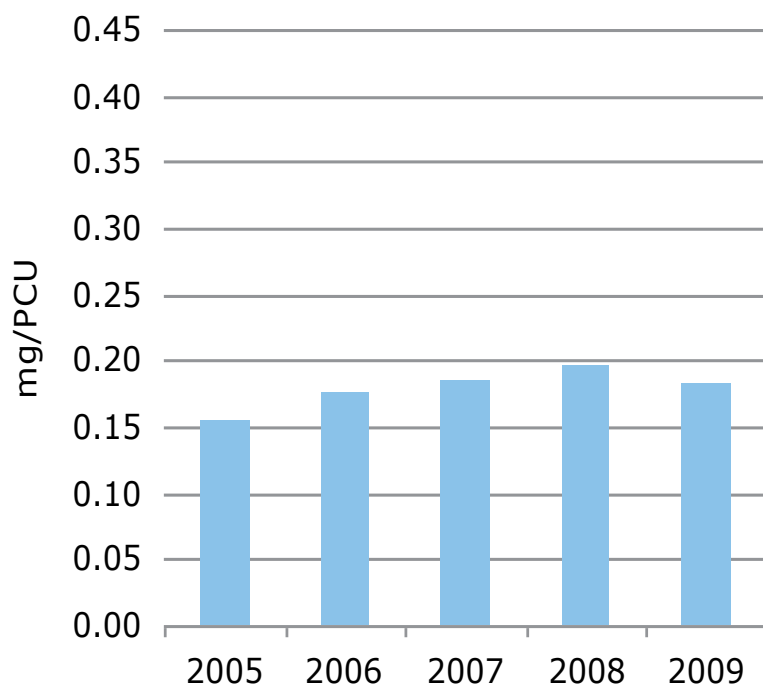


*Switzerland: 2006-2009

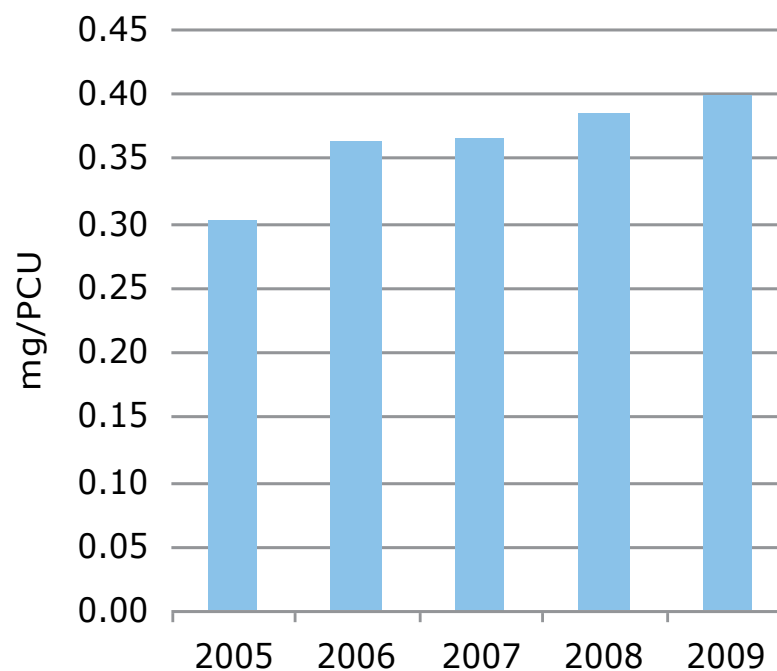


Increase in sales of AM agents critical important to human medicine

Cephalosp.-3rd and 4th gen.



Fluoroquinolones



- 3rd and 4th-generations cephalosporins aggregated for DK, FR, NL, SE, UK
- Fluoroquinolones aggregated for DK, FI, FR, NL, NO, SE, UK



Summary

- Sales data **in tonnes** valid and comparable between countries
- Substantial differences in
 - prescribing patterns between countries
 - mg sold of AM agents/PCU between countries observed
- Differences cannot be described by differences in animal demographics alone



Summary

- Increase in use of 3rd and 4th generation cephalosporins and fluoroquinolones observed
- In 8 countries (Switzerland not included)
 - tonnes sold declined by 11.2%
 - PCU declined by 3.1%
 - mg/PCU declined by 8.3%



Next Steps/Meetings

- Publication of the report on the EMA web page on 19 September, report embargoed until then
- 13-14 October 2011 workshop on
 - establishment of DDD_{animal} or similar units to correct for differences in dosage
 - collecting data by species
- Analysing and reporting data from Member States for 2010
- Next ESVAC network meeting – 14-15 February 2012



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Thank you for the attention!

