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Health & Consumer Protection
Directorate-General

Update from the Commission

EURL-AR workshop
4.-5.4.2011 Lyngby

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Outline of activities

1. The Commission strategy on AMR
2. Reviews of VMP and medicated feed rules
3. Requests for EFSA and EMA
4. International activities
   - Codex
   - TATFAR
   - WHO
5. EU-RL evaluation

1. The Commission strategy on AMR

- A communication from the Commission on AMR
- A 5-year strategy to be presented on European Antibiotic Awareness Day 18 November 2011
- Based on Council Conclusions and Recommendations as well as activities following the staff working paper 2009
- Including concrete actions
- A holistic approach: public health, food safety, consumer safety, environment, animal health and welfare as well as non-therapeutic use of antimicrobials

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Six pillars the strategy will be based on:

- To develop new tools to fight microbial infections
- To promote the practices that are known to reduce antimicrobial resistance
- To reduce the practices that may contribute to increase of antimicrobial resistance
- To further elaborate the phenomenon of antimicrobial resistance and its sources/causes/consequences
- To improve communication among those involved
- To promote international cooperation in tackling AMR

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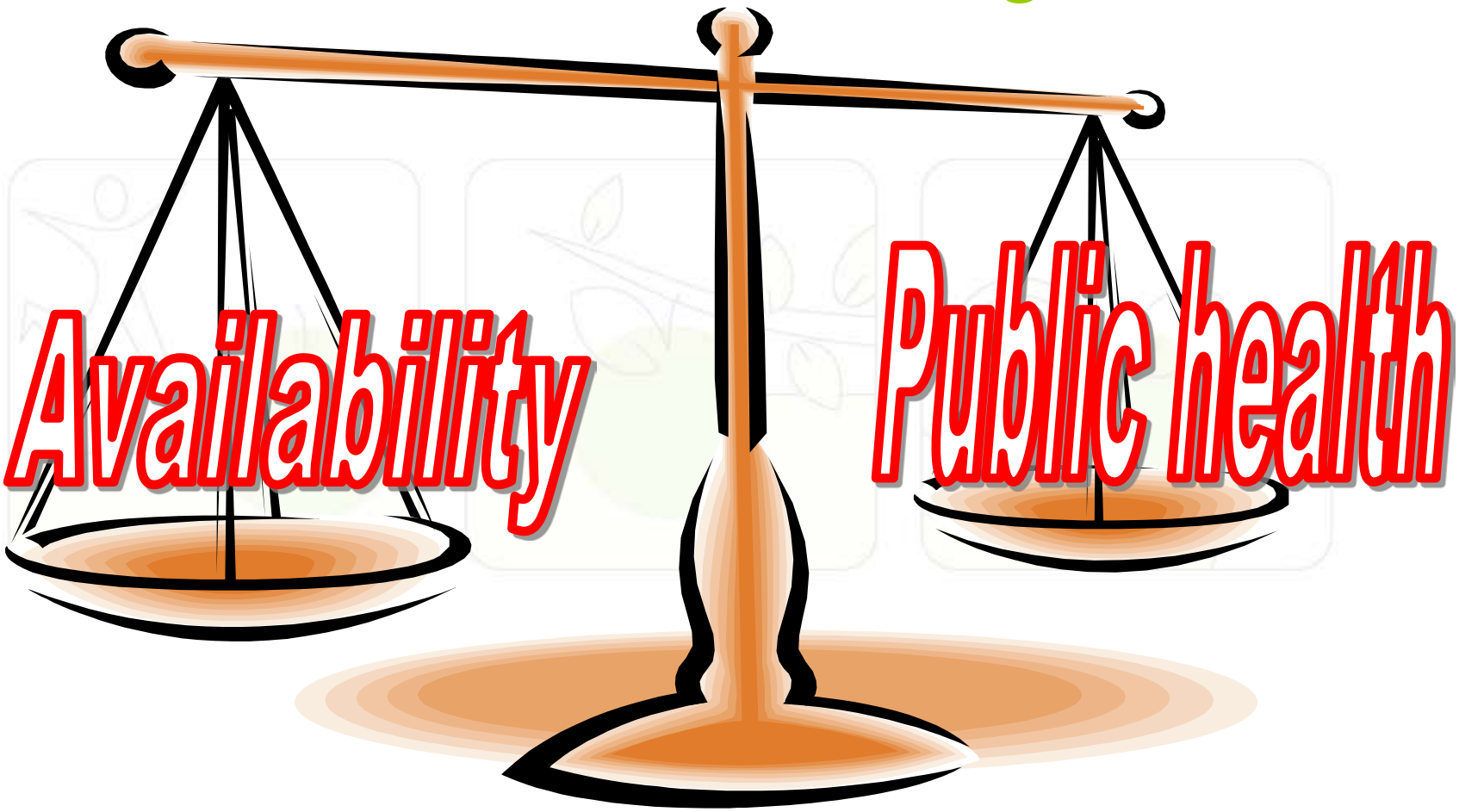
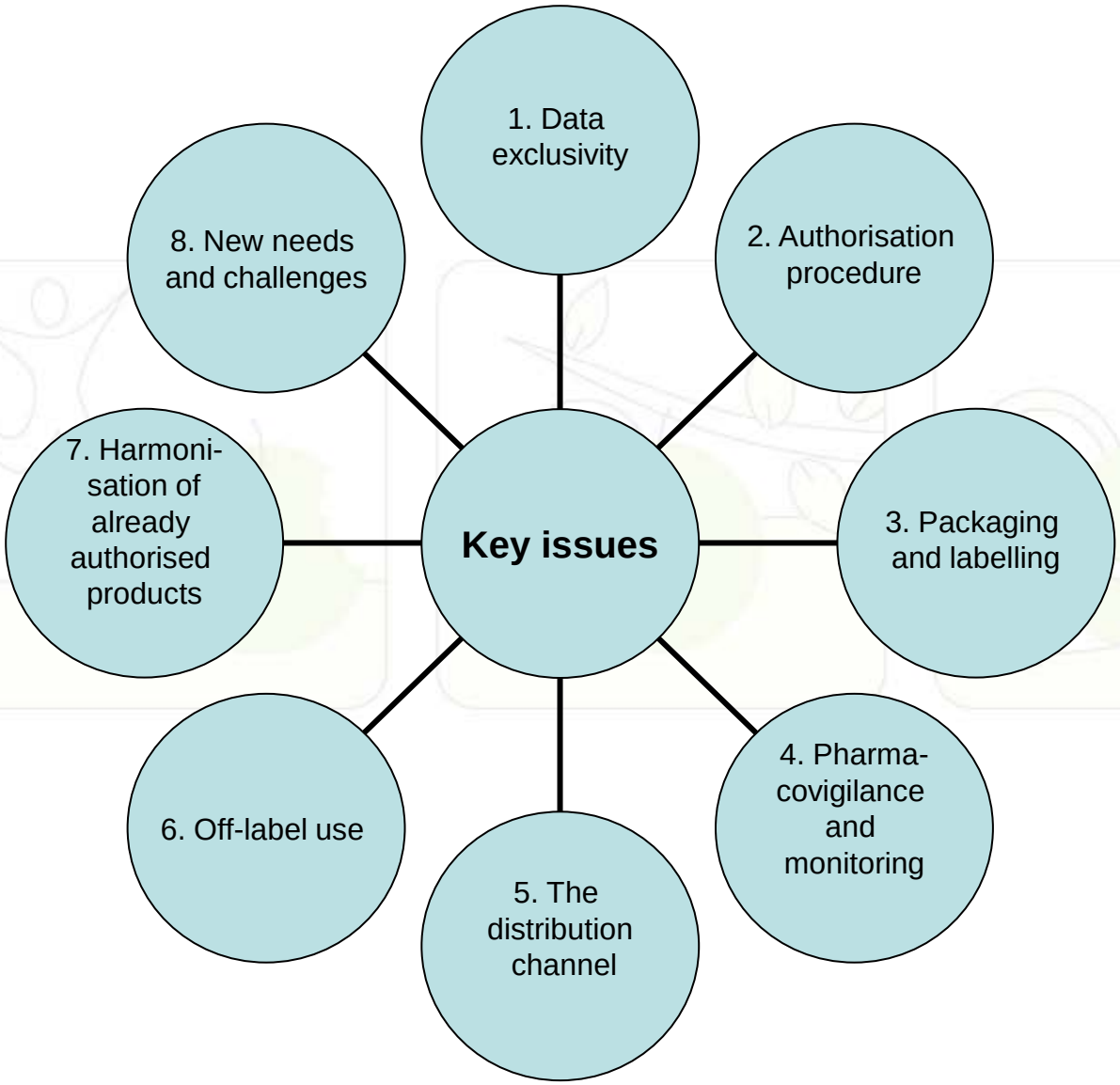
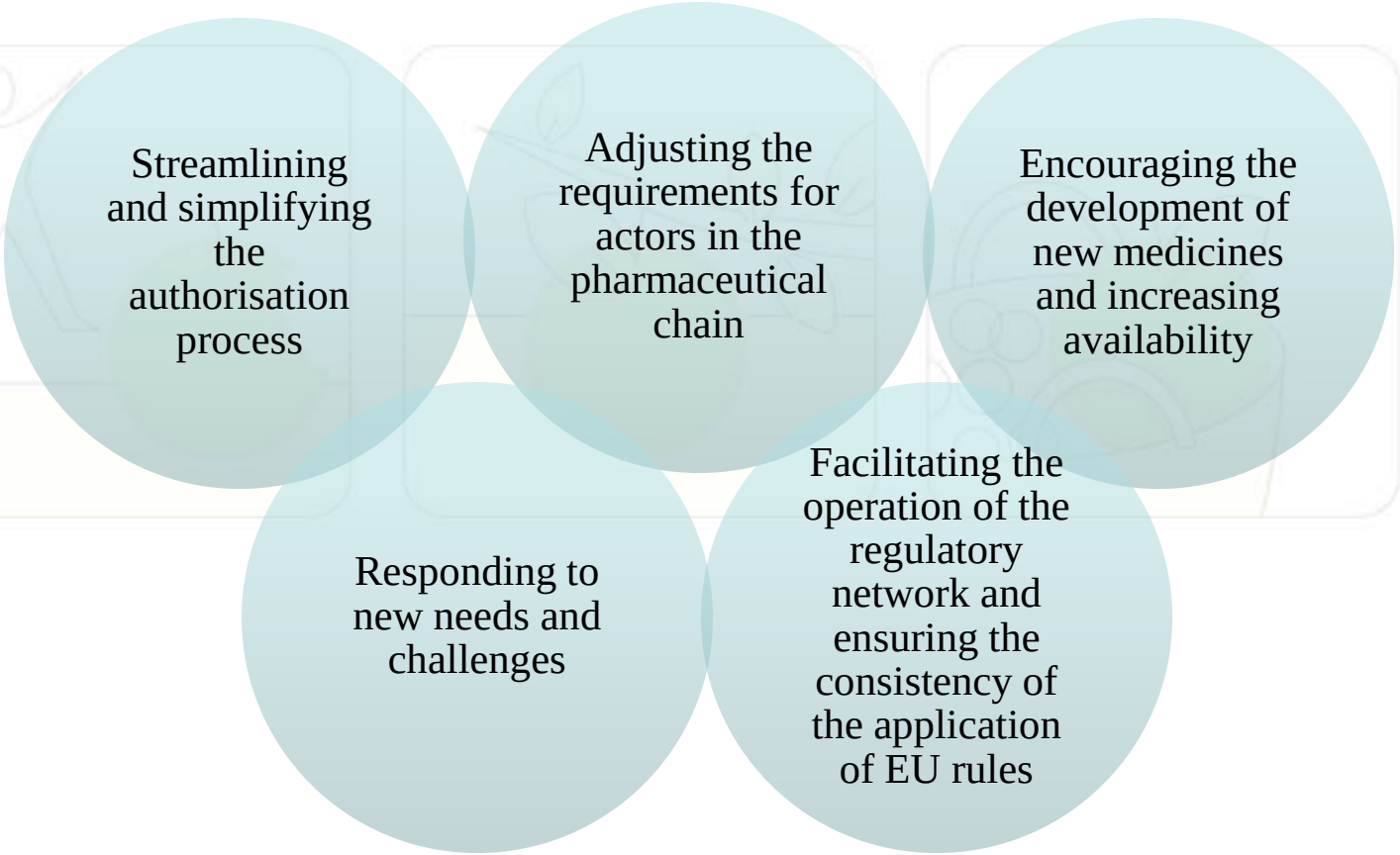
2. Review of VMP legislation




1. Data exclusivity
2. Authorisation procedure
3. Packaging and labelling
4. Pharma-covigilance and monitoring
5. The distribution channel
6. Off-label use
7. Harmoni-sation of already authorised products
8. New needs and challenges
Key issues

Priority themes for impact assessment



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Policy options on antimicrobials in IA*

- The usage of critical antimicrobials for humans is prohibited in the veterinary sector (including use under the cascade)
- Potential impact on AMR is specifically addressed as part of the authorisations procedure
- Veterinarians are prohibited from selling antimicrobials
- A system is established for the recording and collection of data on sales and usage of antimicrobials
- Stricter rules governing the advertising and marketing of antimicrobials to veterinarians

*Please note that these are policy options for consideration as part of the process of impact assessment and do not present the official position of the EC; the IA will prepare evidence for the EC on the advantages and disadvantages of possible policy options by assessing their potential impacts.

3. Requests for EMA and EFSA

- EMA: European Surveillance on Veterinary Antimicrobial Consumption (ESVAC)– on-going
- EFSA: mandate on ESBLs in food and food producing animals – publication in July

4. International activities

- CODEX alimentarius *ad hoc* Intergovernmental Task Force
  - Guidelines for Risk Analysis on Foodborne AMR – adoption in July 2011
- TATFAR = transatlantic task force on AMR
  - Aim to identify areas for further collaboration between the EU and the US
  - Report will be published after endorsed on both sides of Atlantic
  - Subgroup: Appropriate use of therapeutic AM in veterinary communities
- WHO-EURO strategy on AMR
  - Booklet: Tackling AMR from food safety perspective in Europe will be published on WHD 7 April

5. Evaluation of the EU-RLs

- The Commission launched an evaluation of EU-RLs in 2010
- All 26 food and feed safety EU-RLs evaluated (2006-2010)
- Evaluation performed by CIVIC consulting in 2010

Objectives of the evaluation

- Evaluate functioning and performance of the labs
- Obligations and duties laid down in Regulation 882/2004, working programmes
- Assess relevance of tasks, possible overlaps or synergies, appropriateness of current mandate

Methods

- Desk research
- Exploratory interviews (Com, EU-RLs, NRLs)
- Surveys: EU-RLs, NRLs, Commission (AMR –21 replies from NRLs)
- In-dept evaluation interviews – EU-RLs
- Complementary interviews
- Assessment criteria

Evaluation themes

1. Adequacy of assistance to NRLs
2. Appropriateness of analytical methods and techniques
3. Extent of coordination and training activities
4. Extent of support to the Commission
5. Extent 882/2004 requirements and other legislation are fulfilled

Results – EU-RL AMR

- **Overall assessment A = excellent!**

1. Assistance to NRLs = A
2. Analytical methods = A
3. Coordination and training = A
4. Support to the Com = A
5. Fulfillment of legislation = A

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A recommendation to EU-RL AMR

- Collection of feedback from the participants in workshops

A special acknowledgement

- Co-operation with EURL for staphylococci in MRSA survey

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Thank you for your attention!

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