FOCUS ON INNOVATION
Industry perspective

EMA Veterinary Medicines Info Day, 15 March 2024

Joint industry presentation

Access VETMED

Committed to animal well-being in Europe

AVC

Association of Veterinary Consultants

animalhealth europe

THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

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Regulatory tools to support innovation and availability

- **Limited market procedure (Art 23)**
  - Gaining experience with classification and the supporting GLs - too early to see the impact
  - Is not an option for multispecies product combining one major species (i.e. vaccine for chicken, geese, duck, turkey) : impact on availability

- **Exceptional Circumstances (Art 25)**
  - Less than the standard comprehensive documentation + Post auth studies + Benefit /risk balance(*)
  - Admin burden: ie: Valid for a 1 year (re-exam 9month after approval)
  - No longer any scope for NAT conditional licenses so need to utilise the tools we have

- **CVMP flexibility with scientific justification for a full MA under Art 8**
  - Terminology “unless justified” in many sections Annex II : door open to support the flexibility within the GL on requirements and justifications for products (i.e. and not only for unmet need but do not qualify for Art 23 or 25)
- **Data protection -Art 40 (5) : uncertainty on how it will enhance innovation and availability**
  - Aimed at supporting life cycle innovation, now 5 years since Regulation was finalised – Is time sufficient to see any impact on innovation?

Note: Draft Human Heath legislation proposes conditional licensing pathway as well as phase review option (missed opportunity in Vet Med?)

*Corrigendum to Commission Notice - Guidance to Applicants - Veterinary Medicinal Products (Official Journal of the European Union C, C/2024/1443, 14 February 2024) (europa.eu)

Innovation Opportunity to Leverage from existing data for quickest availability

Annex II - Section V= certain adaptation to the standard Comprehensive technical documents

V3-Multi-strain dossier

Single dossier containing the relevant data for a unique and thorough scientific assessment of the different options of strains/combinations of strains permitting the authorisation of inactivated vaccines against antigenically variable viruses or bacteria for which rapid or frequent change in the composition of vaccine formulations …According to the epidemiological situation where the vaccine is intended to be used, a number of strains could be selected from those included in the dossier to formulate a final product. Each multi-strain dossier is applicable only to **one** virus species, bacteria genus or vector for a given disease.

- Since 2022 :extended to any relevant virus or bacterial antigenically variable – No MA yet (only FMD – BTV approved products)
- Addition new strains : VRA timing
- UPD could be simplified

V4-Vaccine platform technology master files (vPTMF)

Vaccine platform technologies have the potential to lead to the development of multiple vaccines with the same 'backbone carrier'. Therefore, it is expected that this procedure will allow for the omission of already certified information in future dossiers and consequent reductions in data to be submitted by the applicant. This avoids the re-evaluation of parts of the dossier already assessed and certified in the first vPTMF; in turn speeding up subsequent authorisations and also helping to increase the availability of vaccines.

- Introduced 2019/6 EEC Reg – GD data 2022 procedure 2023

"Certification of the backbone carrier"

- No MA yet
- Opportunity for vectored vaccines but not only
- Need Confirmation if can be used in art 23 application.

Delegated regulation - 2021/805 - EN - EUR-Lex (europa.eu)

Guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines (europa.eu)

*Guideline on data requirements for vaccine platform technology master files (vPTMF) (europa.eu)

Vet GMP - Clinical Trials

Industry challenge : need Pragmatism in interpretation and predictability

Vet-GMP : preparation of the implementing act according to Reg.2019/6 article 93-2 - GMP principles for novel therapy veterinary medicinal products

Implementation of the new annex I

VICH GL60 draft for comment (except immuno): Section 19 : API for development batches not under full GMP can be used in clinical trial (veterinary investigational medicinal products) GMP concepts approach.

Clinical Trial : Requirements sized with stages, appropriate expectations for the submission package, pragmatic approach for the data assessment , predictable timelines

Industry have not seen the benefits of EU harmonization.

Incentive for developing innovation and timely availability of medicine in the EU :
Pragmatic assessment, Right level of quality

Opportunities for innovation - Vaccines

Claims for reduction of antimicrobial use/antimicrobial resistance

- **Vet vaccines can reduce AM use and reduce the risk of AMR development (in some conditions)**
- Acknowledged by EMA/CVMP[1,2]
- Demonstrated:
  - In poultry (eg vaccine against *E. coli*)
  - In pigs (eg vaccines against *Lawsonia*; PCV2; PRRSv)
- Industry view: whenever data support, it should be possible to have a claim granted for specific vaccines (along the same line as "body weight losses reduction" claims, for example)
- Should best be mentioned in the benefit/risk guideline (as an example of "additional benefits")

Allowing for specific claims would be an incentive for Industry and would fit the goal of developing and authorizing ATAMs in the EU

[1]EMA-EFSA Opinion, 2016 [2]Reflection paper on promoting the authorisation of alternatives to antimicrobial veterinary medicinal products in the EU EMA/CVMP/143258/2021

Opportunities for innovation - Vaccines

Claims of association for authorized vaccines

- **Industry highly welcomes the re-opening of the current guideline**
- Association of vaccines is *also* innovation
- Revision of the Guideline should allow for a more pragmatic approach from a potential interference/efficacy standpoint

- Could further facilitate strict(er) adherence to SPC instructions in the field (should association claims be allowed with full safety but limited efficacy dataset)

Industry is prepared to provide its concrete views in the next steps of the revision

Opportunities for innovation - Vaccines

Guidance to Applicants

Industry welcomes the following clarification

4. **New active substance**:

A new chemical, biological or radiopharmaceutical veterinary active substance includes:

(i) a chemical, biological or radiopharmaceutical substance not previously authorised as active substance in a veterinary medicinal product in the European Union, and

(ii) a chemical, biological or radiopharmaceutical substance previously authorised as active substance in a veterinary medicinal product in the European Union provided that the following conditions are met:

— For chemical substances: an isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously authorised as active substance in a veterinary medicinal product in the European Union but differing significantly in properties with regard to safety and/or efficacy from that chemical substance previously authorised.

— For biological substances: a biological substance previously authorised as active substance in a veterinary medicinal product in the European Union but differing significantly in properties with regard to safety and/or efficacy which is due to differences in one or a combination of the following: in molecular structure, nature of the source material or manufacturing process.

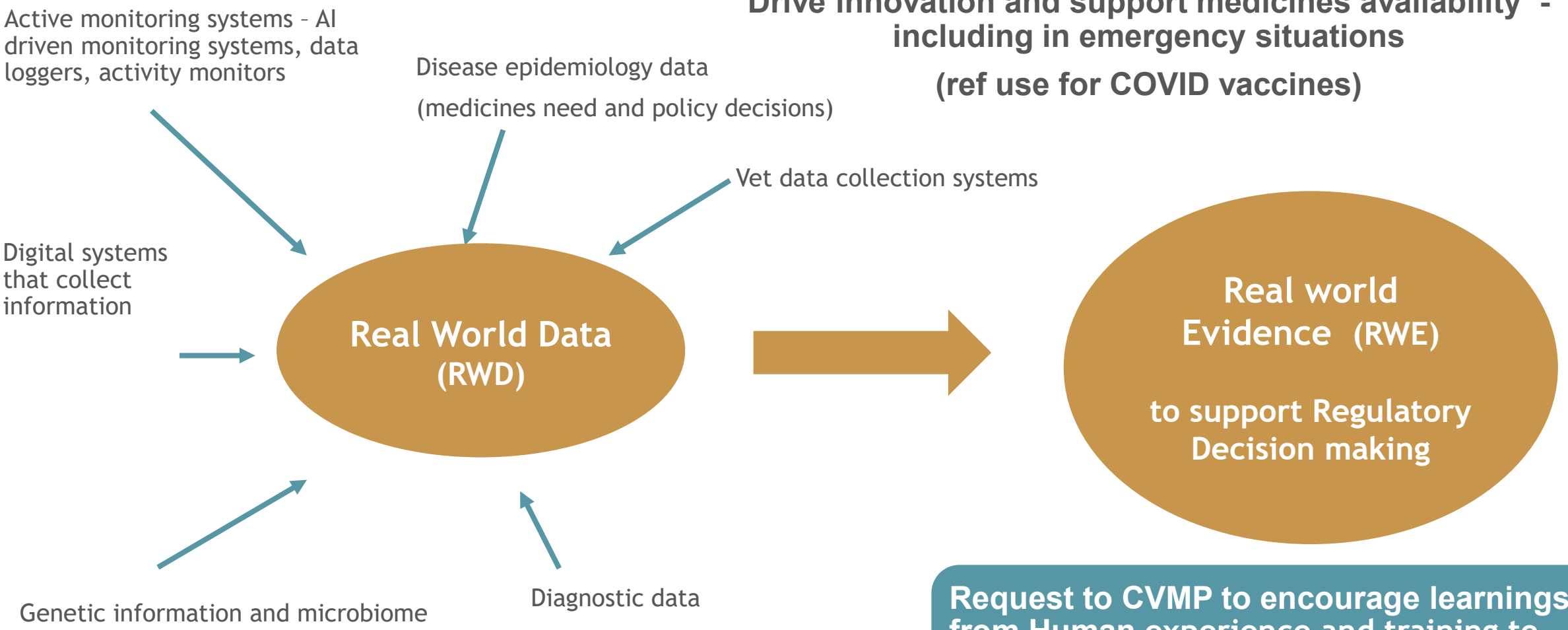
For immunological veterinary medicinal products: The replacement or addition of a new antigen or a new strain in the case of already authorised immunological veterinary medicinal products should not be considered as replacing/adding a new active substance. New isolates or variants of microorganisms that have been authorised in an immunological veterinary medicinal product are likewise not to be considered as new active substances.

Will be beneficial for fish vaccines (MAs only for a very few EU Member States) ,but not only,

Innovation in use of Data

Drive innovation and support medicines availability - including in emergency situations

(ref use for COVID vaccines)



Request to CVMP to encourage learnings from Human experience and training to adapt, streamline and support innovation in Veterinary Medicine

Multi-stakeholder workshop on Real World Data (RWD) quality and Real World Evidence (RWE) use | European Medicines Agency (europa.eu)

Day 2_Session 4_1 Measuring vaccine performance under emergency situations case studies and learnings for RWE generation Mathijs Goossens.pptx (europa.eu)

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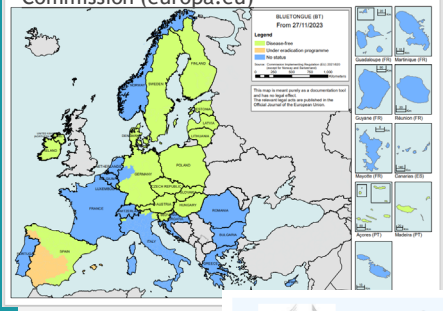
Emerging diseases

How to enhance the EU ambition moving from reactivity to preparedness

Europe Recognize the benefit of Vaccine availability in EMERGENCY -Recent experiences

EU Parliament -Committee on Agriculture and Rural Development 02/2024: Exchange of views with the Commission regarding animal diseases: Bluetongue, African swine fever and Epizootic haemorrhagic virus

Specific info one Bluetongue - European Commission (europa.eu)



EFSA coordination
CVO network

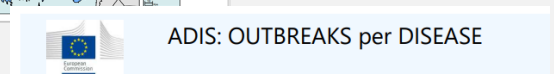
Vet Industry provide concrete supports in emergency situations

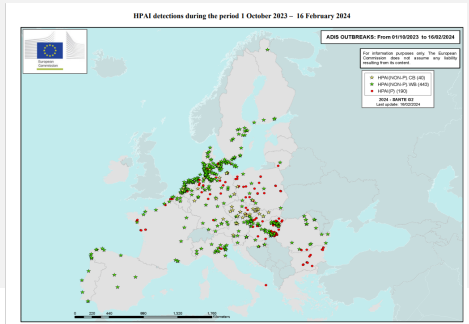
- EU Stakeholder communications
  - Joint meeting with all parties concerned (CVOs, Companies, Perm. Reps, EMA, AnimalhealthEurope (i.e. BTV3 12/23 - HPAI 07/22)
  - HPAI Survey EMA Feb 2023 (published in EFSA report 09/23)
- Governmental experiments : publicly available for vaccine matching and efficacy and mutualized by species

HPAI

New Digital platform

(Reg2020/2022)
ADIS2023





Human Covid lesson learned : Reg 2022/13 and Emergency Task Force (ETF)

- to increase resilience and solidarity across the Union
- Union-level advice and recommendations with regards to the use of medicinal products in the fight to overcome public-health emergencies.

- EN - EUR-Lex (europa.eu) (Regulation - 2022/123- (27)

Pragmatism is legally permitted for vaccine Supply in EMERGENCY

Article 110

Use of immunological veterinary medicinal products

2. By way of derogation from Article 106(1) of this Regulation, and in the absence of a veterinary medicinal product as referred to in Article 116 of this Regulation, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EU) 2016/429 or an emerging disease as referred to in Article 6 of that Regulation, a competent authority may allow the use of an immunological veterinary medicinal product not authorised within the Union.

3. By way of derogation from Article 106(1) of this Regulation, when an immunological veterinary medicinal product has been authorised but is no longer available within the Union for a disease which is not referred to in Article 5 or 6 of Regulation (EU) 2016/429 but which is already present in the Union, a competent authority may, in the interest of animal health and welfare and public health, allow the use of an immunological veterinary medicinal product not authorised within the Union on a case by case basis.

- **Each Country is responsible to operate (biosecurity-vaccination)**
  - under EU Animal Health law 2016/429 and WHOAH standard
  - Select a fit for purpose vaccine * and vaccination
  - Use of UPD to check if existing suitable EU vaccine,
  - list of Vaccine candidates

- **Quick Administrative process (weeks):** Variety of situation at discretion of each
  - When necessary, import permit, national use permit by agency
  - Upon request applicant provide confidential Data Evidence
  - EU MA, EU GMP, Dossiers are not mandatory
  - National public tender laws- when public budget

- **Emergency supply:** supply with Existing stocks and labels as is: vaccination can be immediate

Future Joined analysis of available data evidence by National agencies / Union-level advice recommendations to possibly mutualize the efforts in Animal Health ?

* *Order of preference (when not time contraint, no emergency): MA in EU> MA in one EU country> MA in non EU > local special permit>no MA*

Use of Art 25 = after emergency

Article 25

Applications in exceptional circumstances

By way of derogation from point (b) of Article 8(1), in exceptional circumstances related to animal or public health, an applicant may submit an application which does not meet all requirements of that point, for which the benefit of the immediate availability on the market of the veterinary medicinal product concerned to the animal or public health outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided. In such a case, the applicant shall be required to demonstrate that for objective and verifiable reasons certain quality, safety or efficacy documentation required in accordance with Annex II cannot be provided.

GL rev 2022 :

- Absence of vaccine against a listed disease is by itself a significant risk
- Outbreak and threat of outbreak

Gained from previous waves : No fees for maintenance of HPAI if full MA without sales

Consider :

- Site transfer timing : Need EU GMP +Controls located in EU
- For new EIDs (Lumpy Skin Dis., Schmallenberg at the time) : no way out of a CP, which raises complications as the EID may be limited to just a restricted area and have no relevance at all for many MS
- Admin Burden
  - Time to perform Dossier >>full MA (all parts data+ summaries +Justifications each data gaps)
  - Procedural :
    - Eligibility acceptance on a case-by-case basis
    - standard timing 210 d- reduced 150d
    - The QRD v9 applicable

→ Art25 Vaccine availability = x years

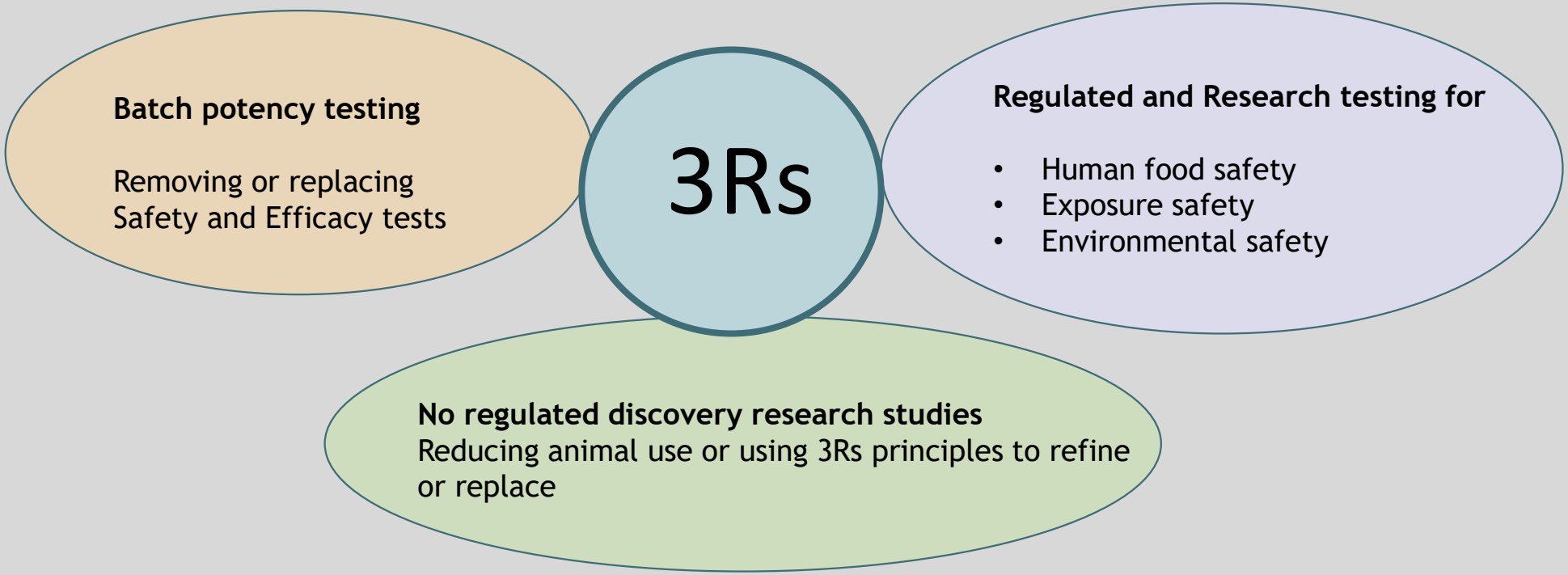
    - Valid 1 year- renewal 9months post approval
- Commitment to conduct post-authorisation studies, fill the gap.

Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances - Scientific guideline | European Medicines Agency (europa.eu)

3Rs

3 Key focus areas supporting innovation in New Approach Methodologies

3 Key focus areas in New Approach Methodologies



- ❑ Work with EMA 3Rs TF on targeted 3Rs topics and guidance in addition to cross-sectorial collaboration
- ❑ Leverage 3Rs dedicated topics for Innovation Task Force (ITF)

Conclusion

Regulatory tools to support competitive innovation
and
Product availability in Europe

predictability -pragmatism –dialog-resilience