

Focus on access in EU-JAMRAI 2

Our main activities and progress

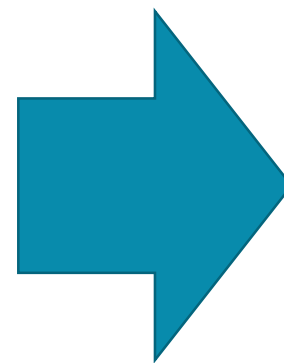
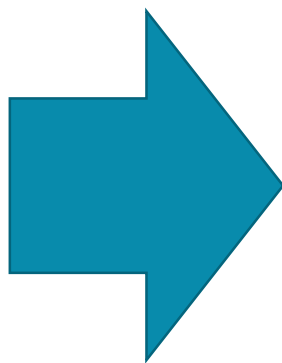


Strengthening Access through EU-JAMRAI 2

**IDENTIFY
PRODUCTS**

**UNDERSTAND
BARRIERS**

**TAILOR
INTERVENTIONS**



Sustainable Access to Benzylpenicillin for Veterinary Use

Cristina Muñoz Madero

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Why Benzylpenicillin for veterinary use?

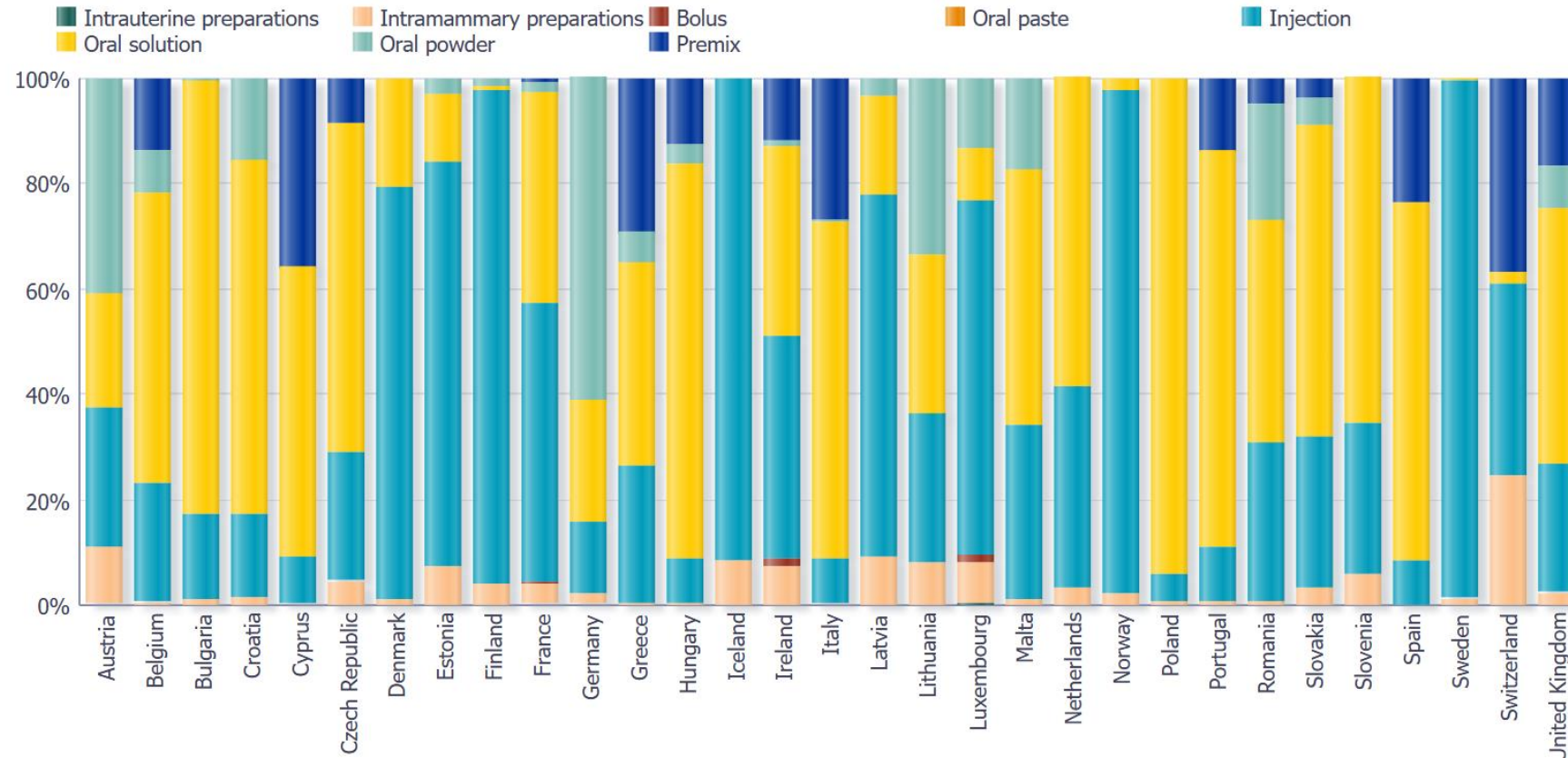
- ✓ Benzylpenicillin is a **narrow-spectrum** β -lactam antibiotic belonging to the AMEG category D that should be used as a first line treatment, whenever possible.
- ✓ These products have been **used for decades** against various diseases caused by bacteria, affecting different organ systems in the target species cattle, horses, sheep, goats, pigs, dogs and cats.
- ✓ All are **injectable** veterinary medicines products.

Use of Benzylpenicillin in veterinary field (ESVAC)



Distribution of sales by available pharmaceutical form for Penicillins, in mg/PCU, by country, for 2022

Time run: 03/03/2025 10:57:38



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Article 106.1 of VMP Regulation 2019/6



- This article of the Regulation, mandates that VMPs must be used in accordance with their marketing authorisation.
- This ensures that veterinarians adhere to the approved conditions of use, including dosage, administration route, and target species, thereby safeguarding animal health and public safety.

EMA Referral of Procaine Benzylpenicillin



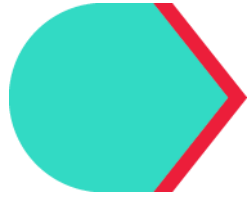
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Procaine benzylpenicillin - referral

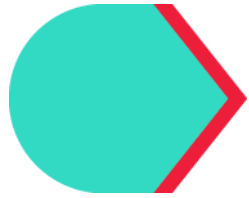
There were concerns that the dosage regimen for injectable veterinary medicines containing procaine benzylpenicillin might not be appropriate to ensure effective use of these veterinary medicines, which could also contribute to the development of antimicrobial resistance.

To ensure an effective use for the proposed indications whilst minimising the risk of antimicrobial resistance development, the Committee concluded that **the dose rate and treatment duration for some of the concerned veterinary medicines should be increased.**

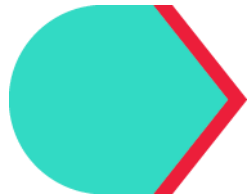
Challenges for sustainable access to Benzylpenicillin



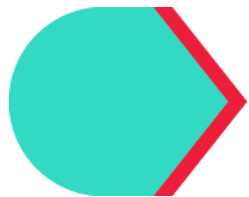
Benzylpenicillin is a globally critical medicine. It serves as the primary treatment against various bacterial diseases, affecting different organ systems in the target species cattle, horses, sheep, goats, pigs, dogs and cats.



A competitive market with low profit margins have resulted in a decreased number of active pharmaceutical ingredient (API) manufacturers.



There are few API manufacturers left to supply the global market.



As a result of imbalances between supply and demand, shortages may occur that require mitigation strategies.



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Thank you!

Cristina Muñoz Madero



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**BUILDING A
ONE HEALTH
WORLD** 

to reduce Antimicrobial Resistance (AMR)



Scan and submit your question to the panellists



Panel discussion: The case of access to benzylpenicillin for veterinary use

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**3- Focus on human products:
Improving the availability of “access”
antibiotics for human use.**



Which WHO “access” antibiotics for human use are EU-JAMRAI 2 focusing on?

The efforts of EU-JAMRAI 2 regarding **access** are in line with the 2023 EU Council Recommendation



Council of the European Union

Brussels, 1 June 2023
(OR. en)

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Interinstitutional File:
2023/0125(NLE)

SAN 250
PHARM 90
VETER 61
ENV 509
PHYTOSAN 32
RECH 186

NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (legal basis proposed by the Commission: Article 168(6) TFEU) - <i>Adoption</i>

- On 26 April 2023 the Commission submitted to the Council the proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance (AMR) in a One Health approach, based on Article 168(6) TFEU.
- The proposal includes a series of actions to: strengthen national action plans against antimicrobial resistance; reinforce surveillance and monitoring of AMR and antimicrobial consumption (AMC); strengthen infection prevention and control as well as antimicrobial stewardship and prudent use of antimicrobials; recommend targets for AMC and AMR in human health; improve awareness, education and training; foster research and development, and incentives for innovation and access to antimicrobials and other AMR medical countermeasures; increase cooperation; and enhance global actions.

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EU Council 2023 recommended target for antimicrobial consumption

“Take appropriate national measures aimed at ensuring that, by 2030, **at least 65 % of the total consumption of antibiotics in humans belongs to the Access group of antibiotics** as defined in the AWaRe* classification of the WHO” (n16)

WHO's AWaRe* classification

Access antibiotics

- First or second choice antibiotics
- Offers the best therapeutic value, while minimizing the potential for resistance

*Access, Watch, Reserve

To reach these targets, the antibiotics must be available and prescribed



- Countries have identified **14 substances*** from the WHO Access antibiotics to focus their EU-JAMRAI 2 efforts on
 - Older products of **clinical importance** with a **national vulnerable supply**
 - **Hospital and primary care** products
 - **Different formulations**; iv., tablets, oral suspensions etc., and strengths
- WHO "access" antibiotics of **common interest** to several countries
 - Potential for **multi-national/regional interventions** and collaboration
 - For example, **11 countries** want strengthened access to **phenoxymethylpenicillin**

*Amikacin, Amoxicillin, Amoxicillin and beta-lactamase inhibitor, Ampicillin, Benzathine benzylpenicillin, Benzylpenicillin, Temocillin, Diclloxacin, Flucloxacillin, Piperacillin/tazobactam, Mecillinam, Phenoxymethylpenicillin, Pivmecillinam, Procaine benzylpenicillin

Common interest in strengthening availability to WHO "access" penicillins for pediatric use

- Three or more countries are focusing their efforts on strengthening access to **pediatric formulations** of **Amoxicillin, Dicloxacillin, Flucloxacillin** and **Phenoxymethylpenicillin**
- **Oral liquid** dosage forms (e.g. suspensions, solutions) and small, lower strength tablets
- **Narrow-spectrum** products
- Known for **frequent shortages**
- Difficult to find **treatment alternatives**
- Are at risk of **leaving markets**





Scan and submit your question to the panellists



Moderator
Christine Årdal,
EU-JAMRAI 2, Norway

Panel discussion: Improving the availability of “access” antibiotics — the case of pediatric penicillins

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Michael Borg

Chair: National
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Boumediene Soufi (Bo)

Global Head AMR at Sandoz
Representing Medicines For
Europe for AMR topics



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Medicines and Medical Devices
Shortages Specialist at TRS-SAM
European Medicines Agency (EMA)





4- Wrap-up



Looking ahead to next year and general questions



Thank you!

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