



**From:** [REDACTED]  
**Sent:** 15 September 2020 13:30  
**To:** [REDACTED]  
[REDACTED]  
**Subject:** Thank you and follow up on the meeting between EUCOPE and SANTE B5 re OMP and Pharmaceutical strategy

Dear all

Thank you for your time and the positive exchange yesterday.

As mentioned in our call we will be in touch to organise an exchange around the preliminary outputs and discussions held within the European Expert Group on Orphan Drug Incentives in the next month. Please find below, for your convenience, a brief summary of the information provided on the initiative during our call.

The **European Expert Group on Orphan Drug Incentives** is composed of members of the rare diseases community including research, academia, patient groups, rare disease companies, trade groups and others. This group aims to become a source of ideas and potential solutions on OD incentives that can inform and contribute to the current evaluation of the OMP Regulation. The initial meetings focused on establishing a governance structure and identifying areas of focus. The below areas of focus for our recommendations were chosen by the experts:

- Measures to modulate or provide additional incentives to **enable prioritization of research investments** into remaining 95% of rare diseases without any treatments and to support delivery of continued innovation for rare disease where treatments exist.
- Measures to **optimize and accelerate regulatory pathways** for orphan drugs, including application of novel biomarkers, acceptance of new trial design and leveraging of RWE generation.
- Measures tailored to **support the OD development process**, based on experience from US, as well additional ideas to trigger collaboration between academia, industry and regulators in Europe.

With reference to our focus on real world evidence (RWE), as mentioned yesterday, we would like to share some updates on our ongoing work as part of the **RWE4Decisions initiative** (Project website now available [here](#)).

- Next week, on **22 September from 14:00 to 17:30**, the initiative will hold an event entitled 'Realising the Potential of Real-World Evidence for Learning Healthcare Systems'. The objective is to analyse concrete case studies, discuss the critical challenges and solutions needed to enable the use of RWE to support decision-making across products life cycle. Please find [at this link](#) agenda and registration details.
- Building on the results of this event, as part of the [associated programme](#) of the German Presidency of the Council of the EU, the initiative will hold another event entitled 'Health Innovation – the European Health Data Space and Real-World Evidence' on **10 November from 14:00 to 18:00**. The event will explore how a multi-stakeholder EU Learning Network could be established to foster learnings from the use of real-world evidence within the context of the European Health Data Space in order to inform deliberations between

payers/HTA authorities. Registrations are yet to be opened - initial details can be found [at this link](#) – we would be happy to follow up with the full agenda in the next days.

- Discussions will be informed by the paper the **RWE4Decisions initiative recently published in the International Journal of Technology Assessment in Health Care**, with lead author Karen Facey: "Real-world evidence to support Payer/HTA decisions about highly innovative technologies in the EU-actions for stakeholders". The paper aims to provide recommendations each stakeholder could take to improve use of real world data (RWD) in this challenging setting. You can find the publication [at this link](#).

EUCOPE looks forward to a continued fruitful cooperation.

Please let us know of any questions.

Thank you

Best



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