



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Progress report to PCWP/HCPWP

What has happened since April 2018

Presented by Donald Singer, 25 September 2018
PCWP/HCPWP joint meeting

An agency of the European Union



Innovation

Q1 2018 – [Joint PCWP/HCPWP meeting](#) includes a day themed around digital media and health

- **The agenda was driven by the PCWP and HCPWP participants**
- *This emerged as the discussions developed, with input from all of the different stakeholders*
- **The establishment of thematic groups (RWE; mHealth; social media) helped to focus on specific points which could be developed individually**
- *The event was coordinated by a series of teleconferences with pre-defined agenda to ensure that the time was used optimally*
- **It was important to have specific outcomes (such as a real world data Q&A document) so that there would be a lasting outcome from the meeting**
- **We stressed the importance of knowing what EMA departments are doing with regards to digital health to prevent duplication, but also to share experience and best practice**

Innovation

Q1 2018 – [Joint PCWP/HCPWP meeting](#) includes a day themed around digital media and health

- We experienced a greater willingness of EMA to open up to society.
- **This is reflected not only in the move to open up in social media but also to engage more in digital health**, however this new openness requires a culture shift across all depts. of EMA.
- It was good that **representatives of EMA depts. that do not often interact with the PCWP/HCPWP were involved in the debate about digital health, so that both can get a feeling of the needs and attitudes of the other.**
- **These efforts should continue as well as a presentation of the activities of each of the org. participating in the PCWP/HCPWP so that EMA officials not often present at the groups' meetings get to know who we are, what we do, what we aim to do.**
- **Considering that EMA is a regulatory body with strict rules, all we have been discussing requires a whole new culture shift across the organisation.**

Early access to medicines

Q1 2018 - WPs, through their topic group on digital media and health:

- Identify **general points of concern** from patients, consumers and healthcare professionals around generation and use of real world evidence (e.g. validity, reliability, transparency, security, ethics) in the evaluation and supervision of medicines
- Reflect on how to address identified concerns and best communicate to patients, consumers and healthcare professionals in a clear and comprehensible manner

- ‘Patient data Q&A’ – document under development
 - What is “real world evidence”?
 - What is a patient registry?
 - What can RWE be used for?
 - Are there problems associated with the use of RWE?
 - How can you get involved in a patient registry?
 - What are the limitations for the use of RWE?
 - Can additional data be collected?
 - What are the challenges in the use of RWE data?
 - What are the communications challenges associated with the use of RWE and the development of patient registries?

Pharmacovigilance

Q1 2018 - WPs, through their topic group on digital media and health:

- **Identify points of concern from patients and healthcare professionals around mHealth apps** for real world clinical use (e.g. validity, reliability, transparency, interoperability, safety, effectiveness and efficacy)
- **Reflect on the need for a guideline for patients** on how to assess open mHealth apps and solutions: privacy, transparency, usability

- 'Patient data Q&A' – document under development
- Gaining a better understanding of distinctions around mHealth apps
 - Identify and explain aspects that are unclear and have the potential to undermine trust in possible uses of these technologies in the evaluation of medicines
- EC speakers for upcoming PCWP/HCPWP meetings:
 - A representative from DG Connect could present preliminary results on the study on the safety of non-embedded software in the health sector (expected by end Nov 2018)
 - On the other hand, DG Sante could provide an update on the new joint action on eHealth (eHAction) where Member States will look at the issue of mHealth

Social media

WPs suggest that EMA continues to work towards clear and consistent messages cross-media and to move from broadcasting information towards an interactive dialogue with EMA stakeholders

Progress from EMA:

- Social media strategy under development
- Editorial plan developed focusing on retweeting and re-posting and organisations with any campaigns are encouraged to inform EMA at least 2 weeks ahead in order to prepare own materials
- Mapping of influencers - progress is underway
- Hashtags - EMA already has a database, which can be enriched with contributions from organisations



Next steps

- Patient data Q&A document – open for consultation until 25 October 2018
- Once PCWP/HCPWP meetings can be resumed following EMA's relocation to Amsterdam, invite European Commission to present on mHealth related activities
- Develop case studies to illustrate how organisations can engage with EMA on social media campaigns
- Direct efforts towards developing specific case studies related with the other work streams (RWE and mHealth)



Thank you for your attention

