EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP/HCPWP presentation on update on work in the area of pandemic preparedness

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Ad-hoc core group of patients, consumers and healthcare professionals' organisations – pandemic preparedness activities

- **January 2014** – Call for expressions of interest to all eligible organisations
  - European Union of General Practitioners (UEMO)
  - The European Consumers' Organisation (BEUC)
  - European Institute for Women's Health (EIWH)
  - European Forum for Primary Care (EFPC)
  - Pain Alliance Europe (PAE)
  - Pharmaceutical Group of the European Union (PGEU)
- **April 2014** – initial teleconference
- **May-June 2014** – written consultations
- **September 2014** – report to PCWP/ HCPWP

Activities

1. Outcome of feedback on potential new names for different types of centralised influenza (pandemic) vaccines

2. Current status & next steps

3. Need for feedback from group on update of EMA website

1. Feedback on new vaccine names

a) Vaccines for use during a pandemic (currently mock up vaccines)

b) Vaccines for use against a zoonotic strain e.g. to immunise poultry or lab workers / for government stockpiling (currently pre-pandemic vaccines). Use can be independent of a pandemic or product could potentially be used if the contained strain shows sufficient homology to an emerging human pandemic strain.

Why change?

The name 'mock up' appears to inaccurately suggest a skeleton / sub-standard MA. It is also not mentioned in the legislation. The name 'pre-pandemic' does not accurately convey that it is actually a vaccine directed against an animal influenza virus infecting humans.

Conclusion on names

- Pandemic preparedness vaccine is the EMA's new name for the former mock up vaccine. Upon variation to introduce the actual pandemic strain, this MA becomes a pandemic vaccine. Similarly, an MAA submitted and approved during a pandemic would be authorised as a pandemic vaccine. The term 'pandemic vaccine' is mentioned in the legislation and EMA considers that 'pandemic preparedness vaccine' accurately reflects the fact that it is a vaccine approved in readiness of a pandemic. This was supported by the PCWP/HCPWP sub group.

- Zoonotic vaccine is the EMA's new name for pre-pandemic vaccines. There was mixed feedback from the group about this name and concern over its interpretation. Following discussion with EC and EMA management, it has been agreed that the name is agreed since it is scientifically correct. However, the EMA website (and PI) will explain the name i.e. zoonotic vaccine (vaccine for human use containing an animal influenza strain).

2. Current status of pandemic activities

- EC and EMA management agreement on new pandemic names obtained.
- CHMP influenza guideline- quality module finalised and published May 2014. Non-clinical/ clinical module published for consultation July 2014. Note: new names are not being consulted upon but are mentioned in the non-clinical/clinical module.
- Procedural guideline to be published Q3/4 2014 for consultation
- Consultation period on non-clinical/clinical and regulatory modules to be completed by end 2014.
- Stakeholder meetings (EMA and industry) in Nov 2014 to obtain industry comments/ feedback on non-clinical/clinical guideline.
- Website updating- by end 2014

3. Update of website

- To ensure adequate communication of the new pandemic names, the EMA website requires updating. This will be a medium term project and at first the linked page* will be updated to give more information about pandemic and zoonotic vaccines. A few sentences will also be placed onto the pandemic influenza landing page to acknowledge that many linked documents will be updated in due course to remove the reference to the old names and replace with the new names.
- The sub group of the PCWP-HCPWP will be asked to assist in improving this webpage as first step. Stakeholder meetings (EMA and industry) in Nov 2014 to obtain industry comments/ feedback on non-clinical/clinical guideline.
- Website updating- by end 2014

*(http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000462.jsp&mid=WC0b01ac058004b9ac)

Other preparedness activities - Ebola

- EMA has put in place an ad-hoc group of EU regulators with expertise in vaccines, infectious diseases and clinical trial design. Their main tasks are:
- Serve as a hub to support European Commission, WHO and other regulators as needed
- Provide support to drug and vaccine manufacturers on regulatory aspects
- Define best regulatory pathways to ensure that potential treatments and vaccines are assessed as swiftly as possible

Other preparedness activities - Ebola

- Effective medicines against Ebola requires international collaboration

- **4 September 2014: a joint statement published by the International Coalition of Drug Regulatory Authorities *"Medicines regulators to work together internationally to find innovative solutions to facilitate evaluation of and access to potential new medicines to counter Ebola outbreaks"***

- Signed by medicines regulators from 13 countries; published on their websites