EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scientific guidance on post-authorisation efficacy studies

ENCePP Plenary Meeting, 22 November 2016

Presented by Kevin Blake
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Points of interest

- April 2014 Delegated Regulation, 1st PAES imposed CHMP June 2014)
- *Not* a recipe-book but more philosophical
- *Not* procedural, separate Q & A*
- However, clear indication that there is an openness on the part of EU regulators to accept findings from observational research to be used to address requirements for post-authorisation efficacy studies imposed as conditions of a marketing authorisation
- Avoid use of the terms 'efficacy' v's 'effectiveness' in favour of 'demonstration of benefits'

* http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000150.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580979eae.

Points continued

- Avoid use of the terms ‘interventional’ v’s ‘non-interventional’ as legal interpretations
- Emphasise need for quality, standards, methods..
- Aligned with EMA initiative on registries
- Section on vaccine as within scope
- Innovation is encouraged but supportive scientific justification
- Consideration of CHMP Scientific Advice
- Proactive planning
- Reporting in the EU PAS register

Thank you for your attention

Further information

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