

From ADVANCE to VAC4EU

Opening of the Meeting

June M Raine
Scientific Advisory Board Member

Brussels
March 6th 2019

Why is ADVANCE a major milestone for EU vaccine safety?

Where have we come from? – learnings from last 10 years

What are the information needs of regulators?

How – collaboration for a future sustainable system?



Why is there a measles outbreak in Europe?

Cases of measles in Europe have reached the highest this decade, according to the World Health Organization. So what's going on?



ADVANCE





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Pandemrix triggers antibodies to a receptor that's involved in sleep regulation. INA FASSBENDER/REUTERS/CORBIS

Why a pandemic flu shot caused narcolepsy

By **Gretchen Vogel** | Jul. 1, 2015, 2:15 PM

27 August 2023 September 2010
EMA/543435, EMA/CHMP/588294/2010
Press Office Press Office

18 February 2011
EMA/CHMP/130422/2011
Press Office

15 April 2011
EMA/CHMP/297822,
Press Office

27 July 2011
EMA/CHMP/568830/2011 corr*¹
Press Office

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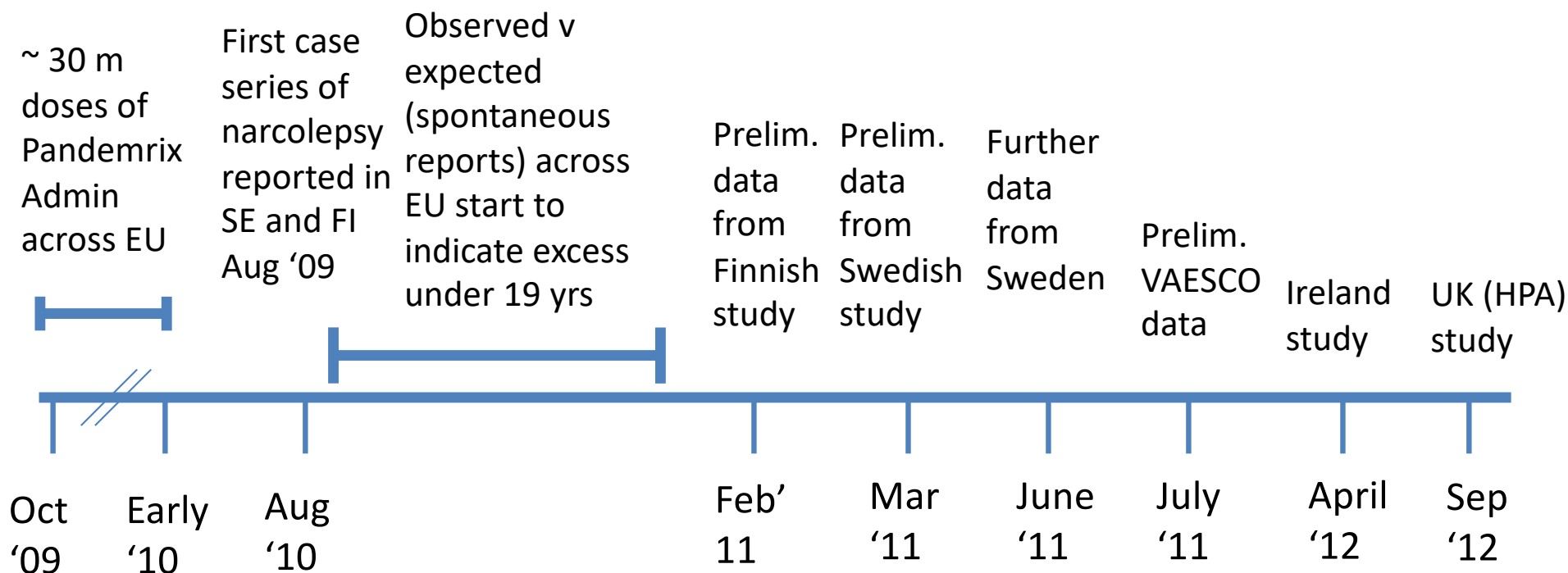
[Press release](#)

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Agency is Pandemrix and reports o narcolepsy and pc
narcoleps Available evidence does not conf Causal relationship not

European |
measures
Updated pres
epidemiologic

European Medicines Agency recommends restricting use
of Pandemrix

In persons under 20 years of age Pandemrix to be used only in the absence
of seasonal trivalent influenza vaccines, following link to very rare cases of
narcolepsy in young people. Overall benefit-risk remains positive.



Vaccine 31 (2013) 4961–4967



ELSEVIER

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Bivalent human papillomavirus vaccine and the risk of fatigue syndromes in girls in the UK

Katherine Donegan, Raphaele Beau-Lejdstrom, Bridget King, Suzie Seabroke, Andrew Thomson, Philip Bryan*

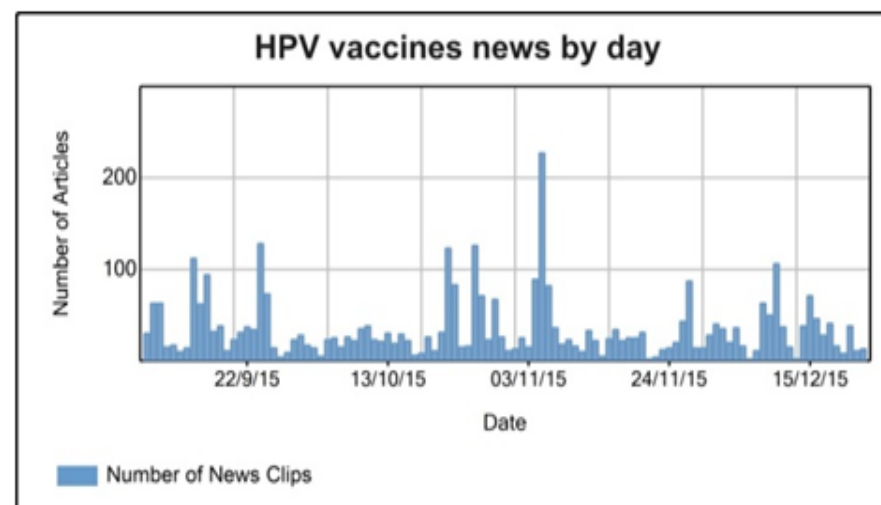
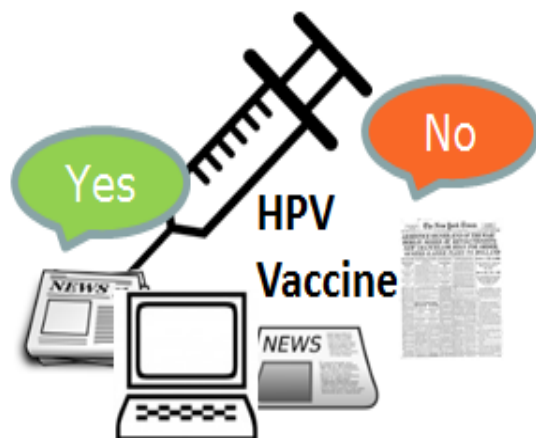
Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency, London, UK



Media Monitoring of the HPV Vaccines Debate

– What the public wants to know and experts should address

Priya Bahri, Julianna Fogd, Irina Caplanusi, Andrej Segec, Xavier Kurz, *European Medicines Agency (EMA)*, on behalf of the IMI-ADVANCE consortium. For more information email: priya.bahri@ema.europa.eu



What are the regulator's information needs?

- Access to real world data for product life-cycle vigilance
- Support for robust regulatory decision making
- Marketing authorisations for products that can support evolution of immunisation programmes
- Support for innovation in vaccine development

Our goal - public health and public trust



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HOW WILL WE MOVE FORWARD?

A sustainable European system to generate
rapid and reliable data on vaccines

**Best evidence at the right time to support decision-
making on vaccination in Europe**