EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How could social media data be relevant to regulatory decision-making?

Social Media Workshop

PCWP and HCPWP Joint meeting

19 September, 2016

June M Raine, MHRA UK

Social media data & regulatory decision-making

EUROPEAN MEDICINES AGENCY

Who – are patients & healthcare professionals listened to in regulatory decision-making?

Why regulatory interest in social media?

How might social media add value in pharmacovigilance?

What next for regulators to move forward from here?

Patients and HCPs expect of regulator...

EUROPEAN MEDICINES AGENCY

Access to safe and beneficial medicines without unnecessary delay

Prompt identification of **signals** of harm in use and risk-proportionate action

Favourable **benefit-risk** of medicine throughout product life-cycle

Quality of manufacture and security of supply chain

Full, comprehensible and up to date **information** to support safe use

EU Regulatory approaches and objectives....

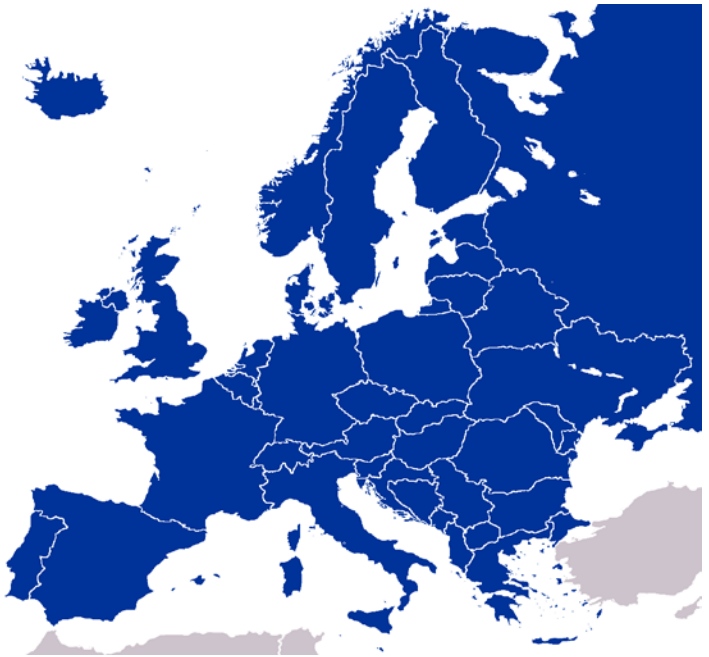
EUROPEAN MEDICINES AGENCY

Monitoring benefit risk throughout product lifecycle in near real-time

Timely decision-making as evidence accrues

Using all available evidence supported by suitable methodologies

Patients & **healthcare professionals'** views integrated throughout



Listening to patients' and HCPs' views

PRAC members

Public hearings

Receiving ADR reports from patients and HCPs

EUROPEAN MEDICINES AGENCY

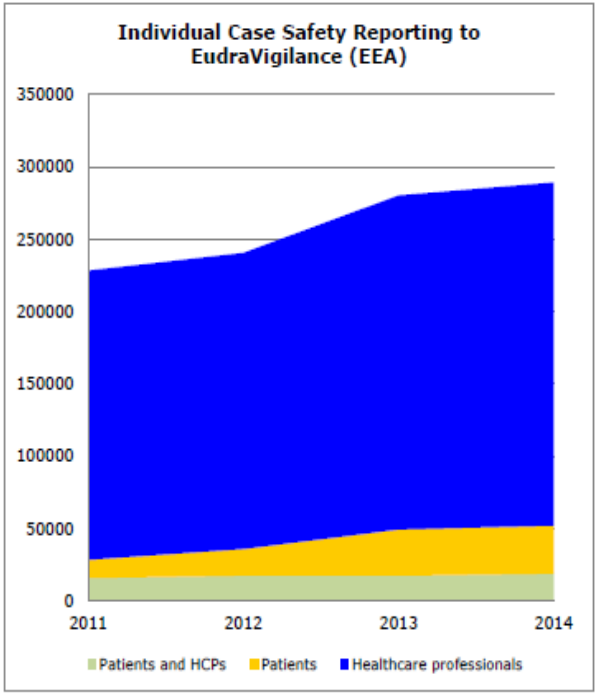
EUROPEAN
COMMISSION

Brussels, 8.8.2016
SWD(2016) 284 final

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

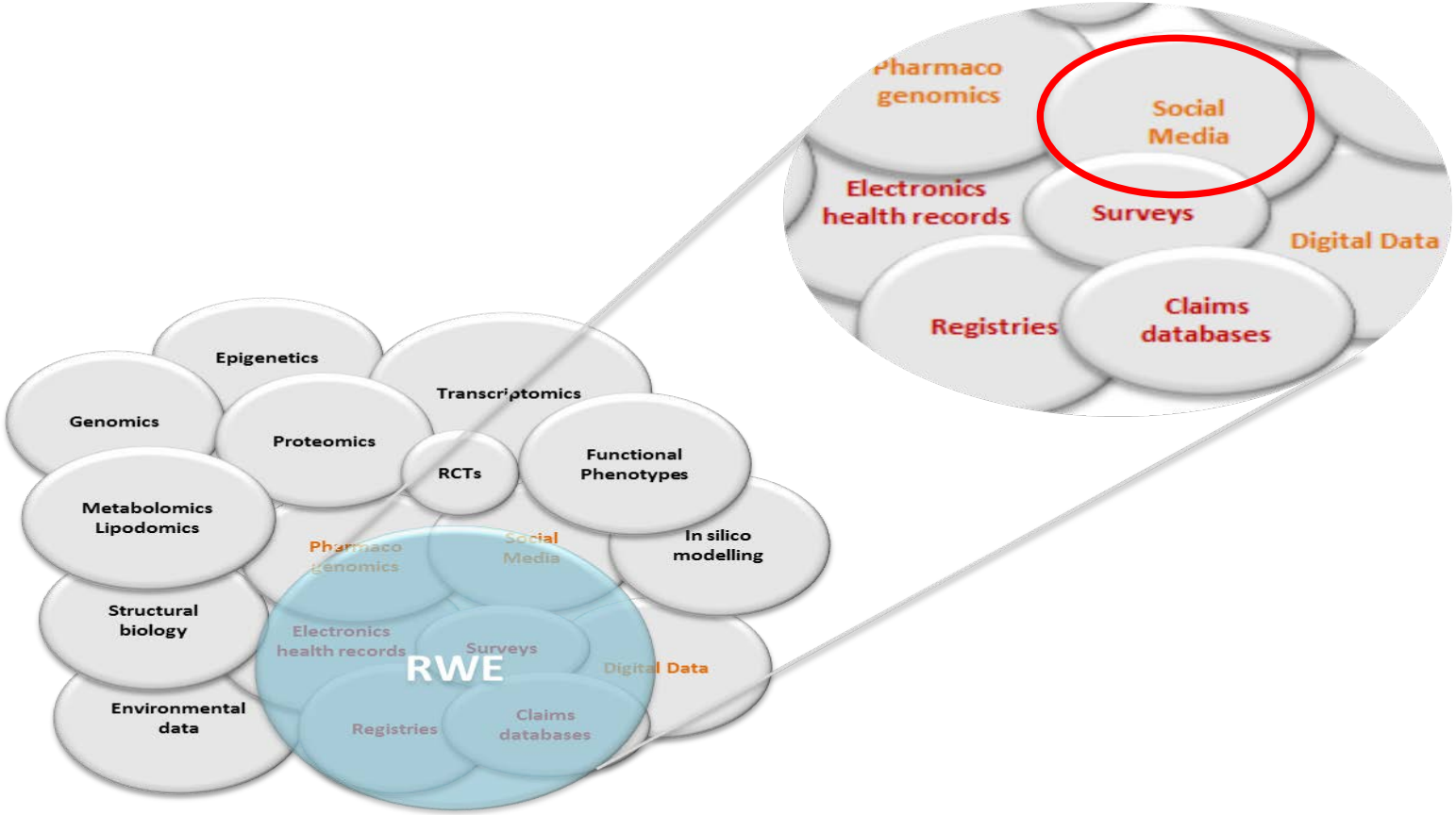
Commission Report

Pharmacovigilance related activities of Member States and the European Medicines Agency concerning medicinal products for human use (2012 – 2014)



Focus on evidence in real world clinical use

EUROPEAN MEDICINES AGENCY



Why interest in social media?

Patients don’t report ADRs because they don’t know they can or should

Physicians don’t report ADRs because reporting is time-consuming

The information available to regulators on harms in use is incomplete

96% adverse drug reactions are unreported

Timeliness of sharing information

3.26pm take-off

3.27pm engine trouble

9 min

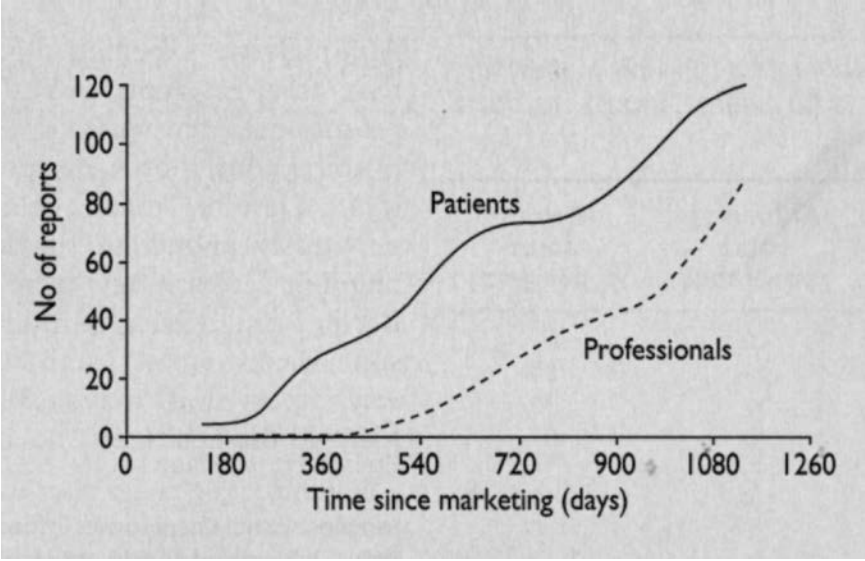
3.36pm first picture onTwitPic

> “There's a plane in the Hudson. I'm on the ferry going to pick up the people. Crazy.”

12 min

3.48pm: NY Times ‘breaking’

Patients may identify adverse reactions quicker



Patient reports of suspected adverse reactions associated with SSRIs preceded those of healthcare professionals

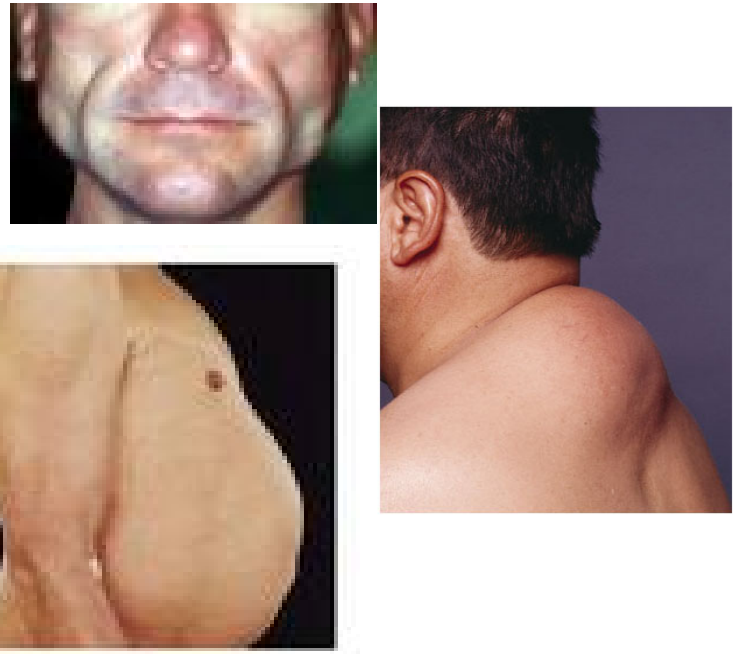
Egberts AC et al. Br Med J 1996; 313 (7056): 530-1

Patients may identify adverse reactions quicker

EUROPEAN MEDICINES AGENCY

Lipoatrophy associated with certain anti HIV medicines

"Crix belly"

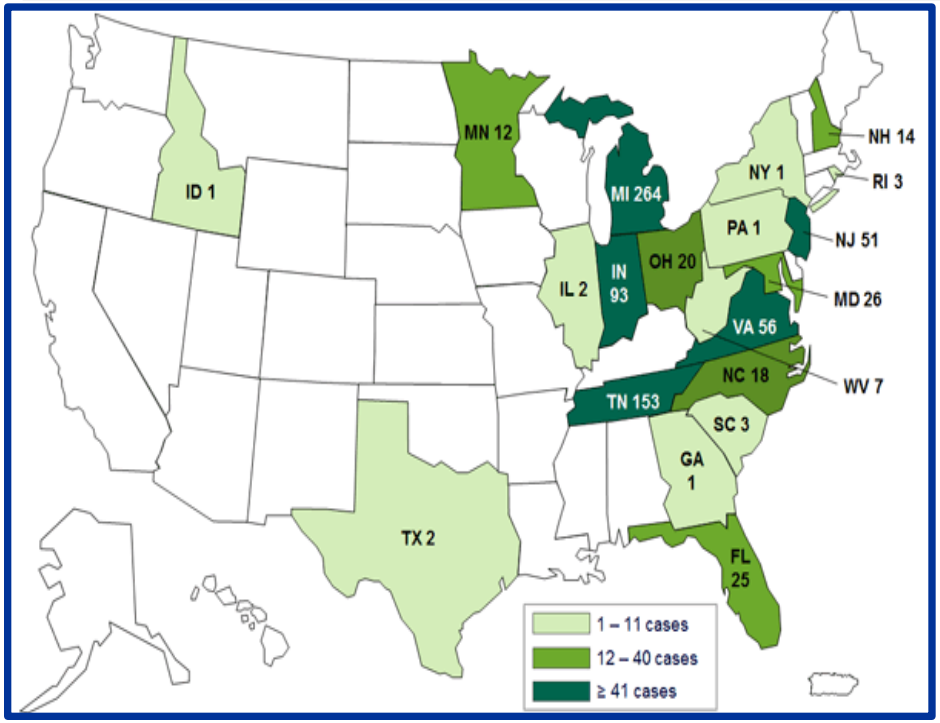


Henghel et al, Lo et al Lancet 1997, 1998

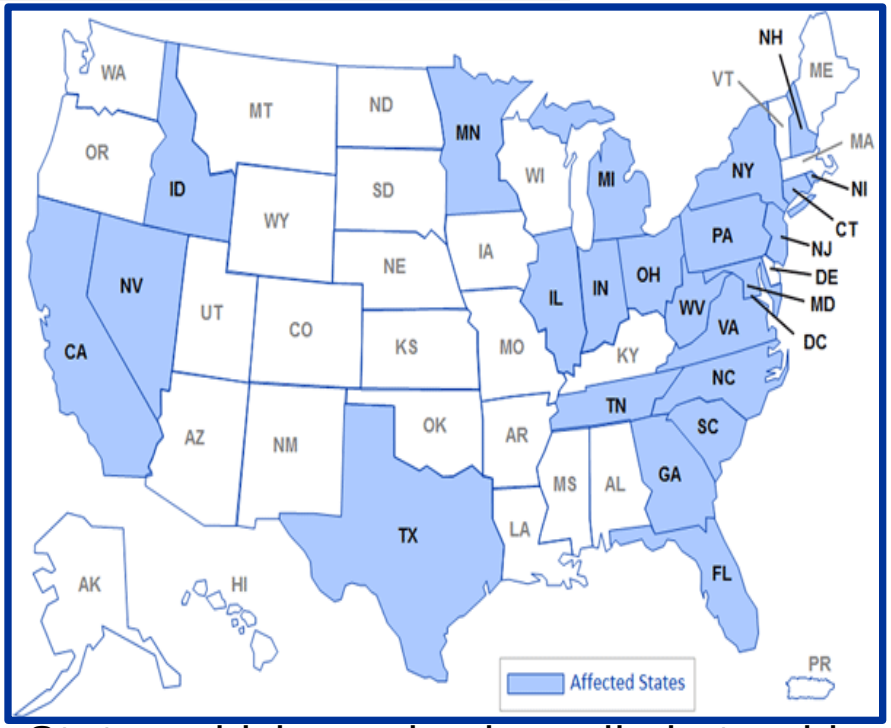
Information on location

EUROPEAN MEDICINES AGENCY

Meningitis Cases Are Linked to Steroid Injections in Spine



Total of 753 cases and 64 deaths from fungal meningitis

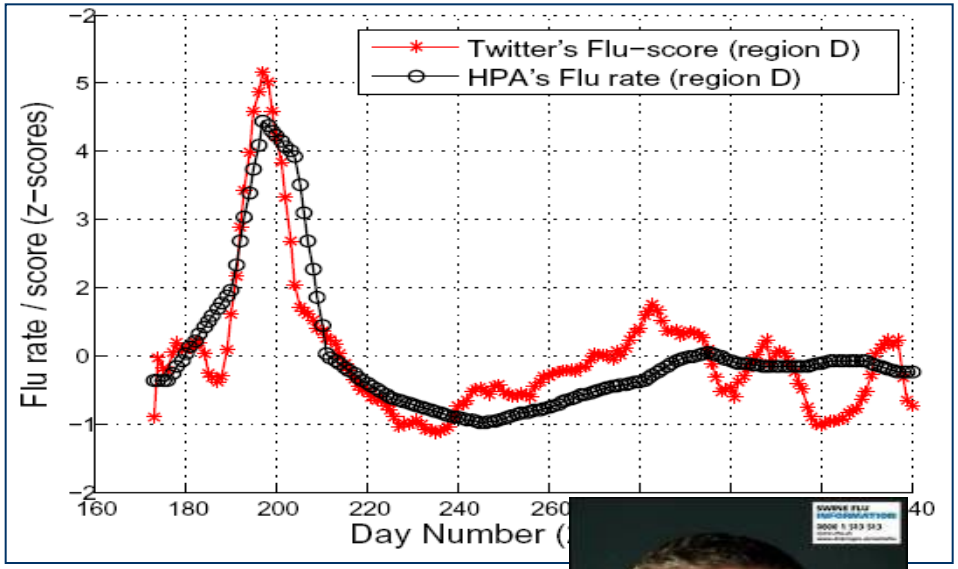


States which received recalled steroid from New England compounding centre

Usefulness of social media data

During 2009 flu pandemic, mentions of symptoms on Twitter correlated closely with number of cases recorded over same time period

Social media conversations could be used to predict the impact of outbreaks in future



How could social media be relevant to pharmacovigilance?

Monitor risk minimisation effectiveness

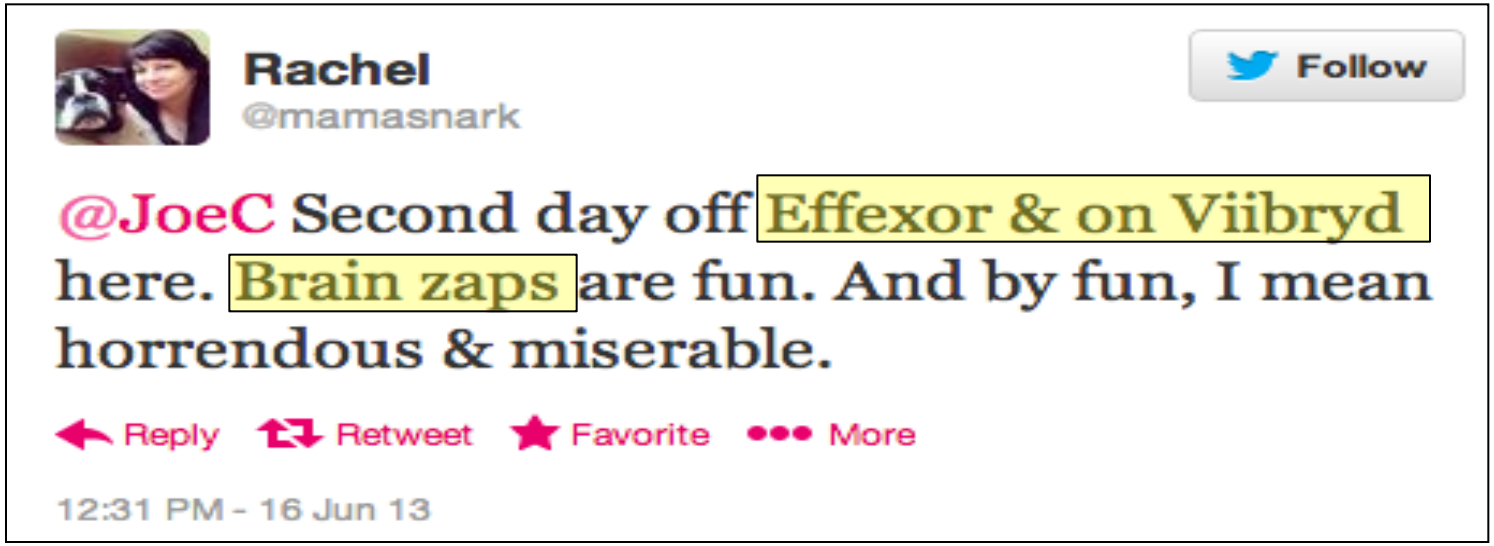
Signal detection in real world use

Better characterised risks of medicine

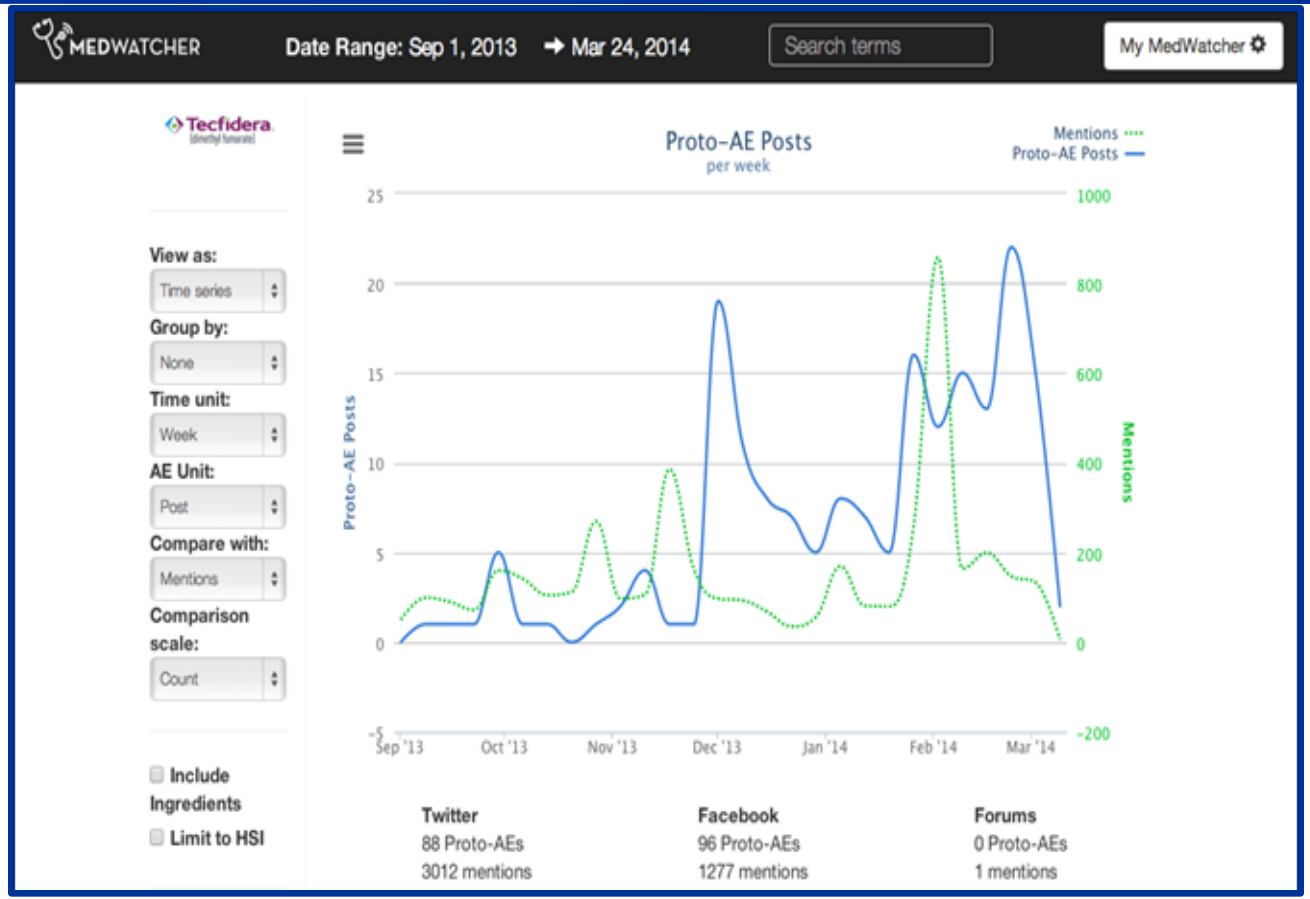
Ongoing evaluation of benefit risk

Risk minimisation, communication, maintain favourable benefit risk

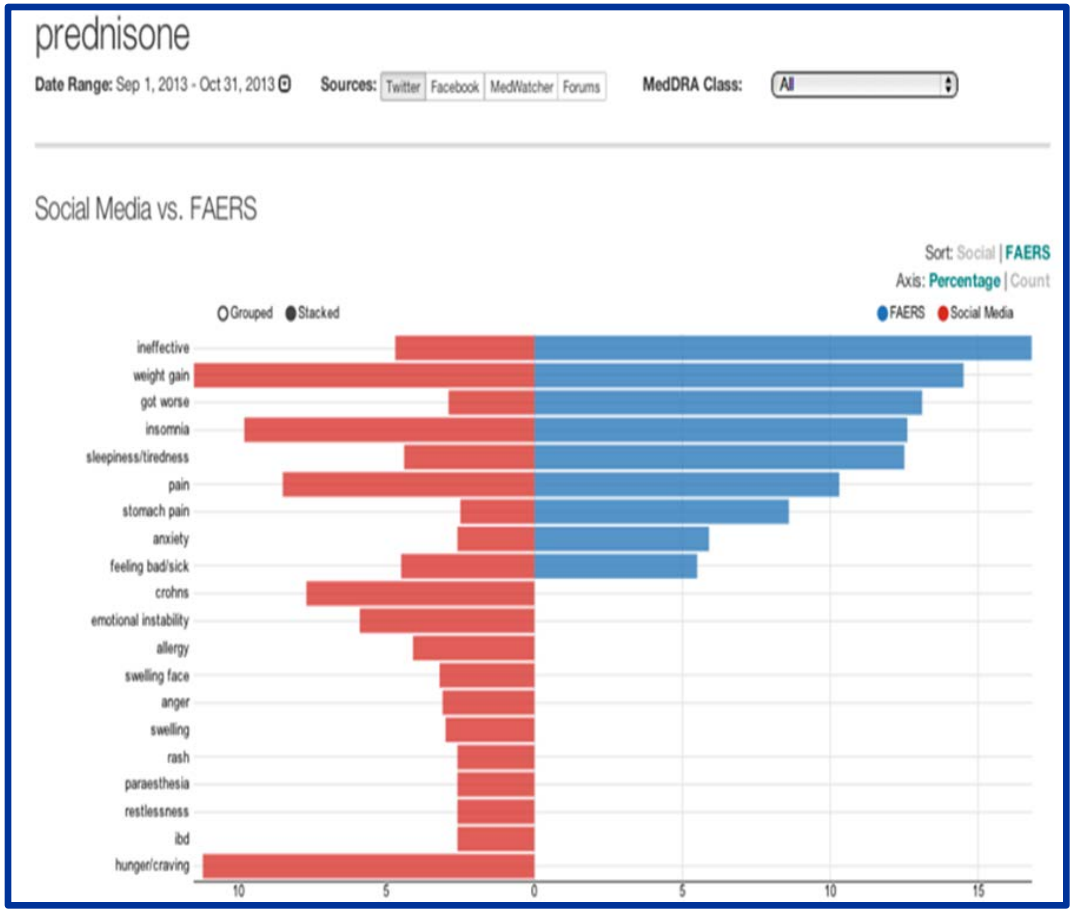
Signal detection?



Signal analysis?



Signal strengthening?



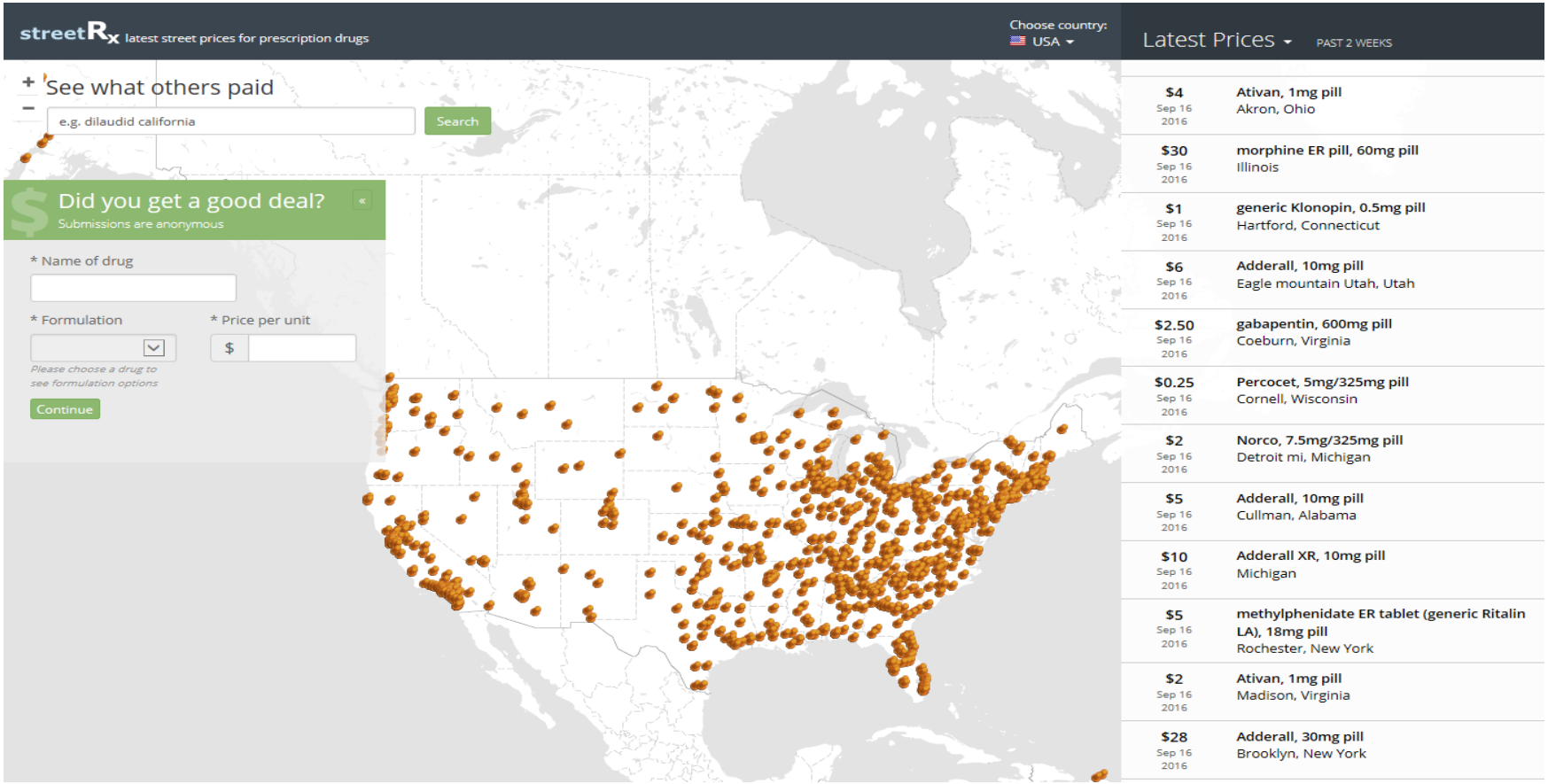
Social media may supplement evidence from spontaneous reports of suspected adverse drug reactions

Differing value in detection/ analysis/ strengthening for different medicines or events

A “one size fits all” approach may not be the most helpful

Misuse and abuse

EUROPEAN MEDICINES AGENCY



Methylphenidate (Ritalin)

EUROPEAN MEDICINES AGENCY

Study of Twitter “proto-AEs” for Ritalin has over 5,000 records

.

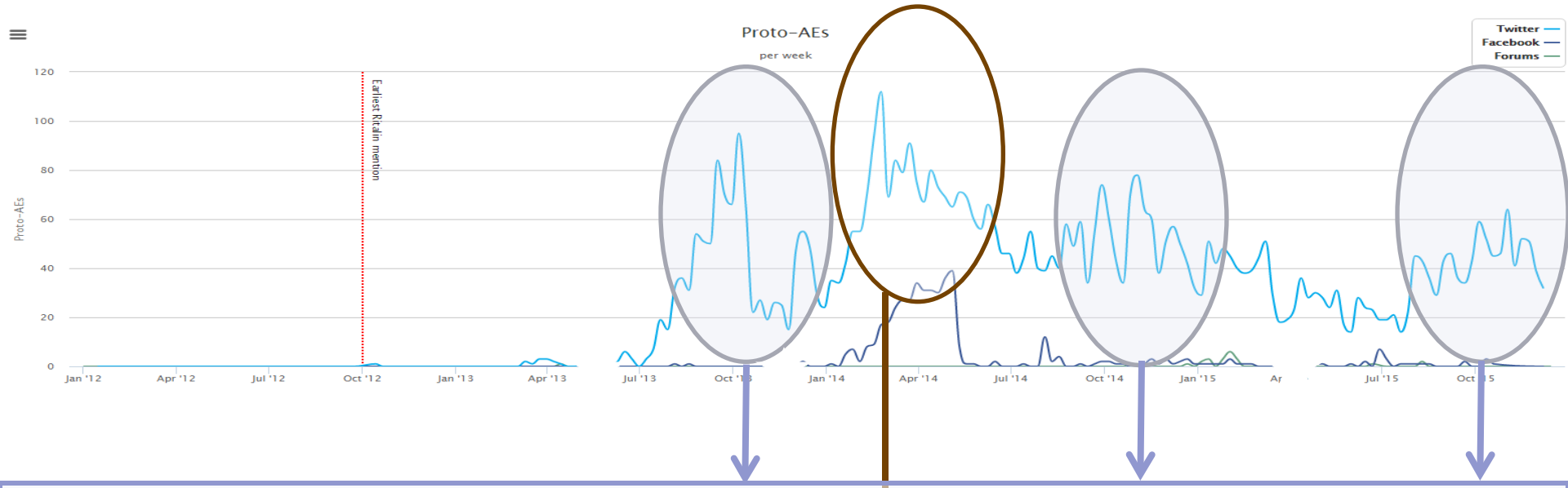
Further analysis yielded series of threads suggestive of patterns of misuse at educational institutions including colleges, universities at time of examinations

Verbatim text	Active substance(s)	Proto-AEs 08 Jan 15	Mentions 08 Jan 15	% proto AEs
Ritalin	methylphenidate	4912	117492	4.18%
Methylphenidate		130	7940	1.64%

Personal communication, D Lewis 2016

Social media conversations on Ritalin over time

EUROPEAN MEDICINES AGENCY



October → November – academic work, cold season, contributing to increase mentions

March →April– academic work contributing to increase

HPV vaccine and link with chronic fatigue syndrome

EUROPEAN MEDICINES AGENCY

Pre-planned epidemiology study using Clinical Practice Research Datalink confirmed no evidence of increased risk of chronic fatigue syndrome

Results: The number of spontaneous reports of chronic fatigue following Cervarix vaccination was consistent with estimated background rates even assuming low reporting. Ecological analyses suggested that there had been no change in the incidence of fatigue syndromes in girls aged 12–20 years after the introduction of the vaccination despite high uptake (IRR: 0.94, 95% CI: 0.78–1.14). The SCCS, including 187 girls, also showed no evidence of an increased risk of fatigue syndromes in the year post first vaccination (IRR: 1.07, 95% CI: 0.57–2.00, p = 0.84).

Vaccine 31 (2013) 4961–4967

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, Raphaelle Beau-Lejdstrom, Bridget King, Suzie Seabroke, Andrew Thomson, Philip Bryan *

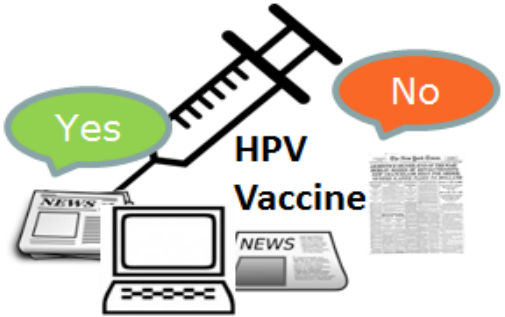
Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency, London, UK

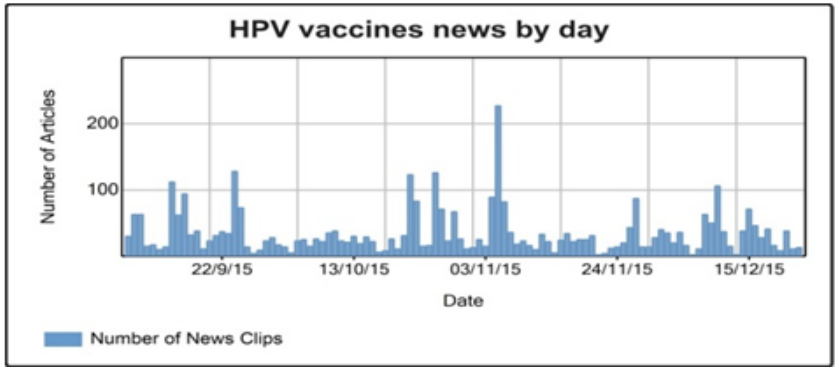
EMA initiated media monitoring – HPV vaccine

EUROPEAN MEDICINES AGENCY

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



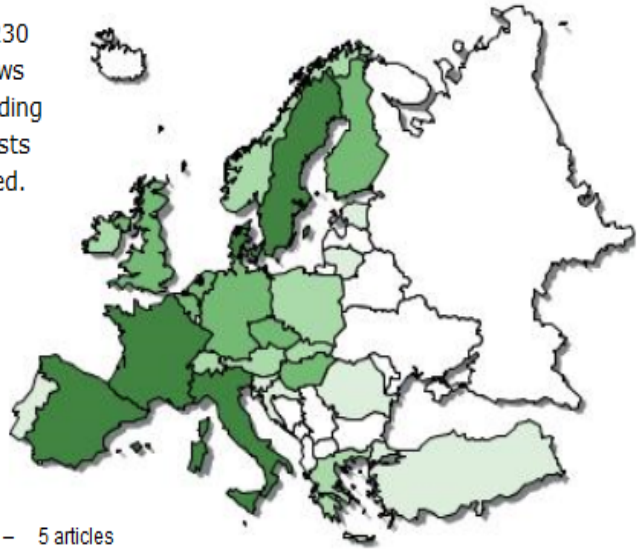


EMA Media monitoring of HPV vaccine debate

EUROPEAN MEDICINES AGENCY

4. Results

A total of 4230 articles ("news clips"), including 493 blog posts were collected.



Lighter green: 1 – 5 articles
Light green: 6 – 10 articles
Dark green: 14 – 47 articles
Darker green: 68 – 626 articles

Map depicting volume of media coverage from 7 Sep to 23 Dec 2015

MM of online news in most EU languages **60-100 items** identified daily

Analysis of topics, concerns and information gaps, translation into **"virtual questions"**

When EU review started, public debate moved from **personal** to **scientific** points

Virtual questions grouped into 12 question areas - public had **wide** information needs

MM helped **assessors** & **decision-makers** ensure that **public concerns** were covered by the EU assessment, & adequate **details** provided in public statements on outcome

Moving forward on the basis of evidence

EUROPEAN MEDICINES AGENCY

Where to look?

How collect, analyse data?

Language/terminology?

Validation?

Duplicate detection?

Etc, etc

Blogs

facebook

Email alerts

YouTube
Broadcast Yourself™

LinkedIn

flickr

twitter

Forums

Moving forward on the basis of evidence

Innovative Medicines Initiative WEB-RADR consortium

How can we make **best use** of these new technologies to enhance pharmacovigilance?

Can use of social media be harnessed to support regulatory **decision-making in PV**?

What are the **legal** & **ethical** implications?

What **policy & guidance** need to be in place to ensure that data are used appropriately?

imi

WEB-RADR

Conclusions

EUROPEAN MEDICINES AGENCY

How may social media contribute to regulatory decisions?

- Signals in certain therapeutic areas and types of harms (quality defects)
- Hard-to-reach areas outside “traditional” pharmacovigilance eg misuse & abuse
- Timeliness and geographical location
- Research tool that identifies ‘user needs’, feeding into content strategies

Helping regulators to fill the “knowledge gap” more comprehensively and quickly

EUROPEAN MEDICINES AGENCY

Patients are speaking - shouldn’t we be listening?

Meet patients where they’re at

Protect their privacy

Give them easy to-use tools