Communications at the heart of the European Medicines Agency

Session III: Communication of national and international regulatory bodies and pharmaceutical industry with external public and media

Meeting Challenges and Perspectives: Networking and Communication of National Regulatory Bodies and Pharmaceutical Industry
Kragujevac, Serbia, 20 – 21 October 2017

Presented by Martin Harvey-Allchurch, 20 October 2017
International Affairs
“Once upon a time there lived an emperor who had three sons and three daughters…”
Why should regulators communicate?

“As a regulator we can only have an impact on public health if citizens trust and follow our recommendations. Open, accurate, relevant and timely communication is essential to establish trust and confidence in the Agency’s work.”

EMA Communications Strategy 2016-2020
Strategic (‘planned’) communications

- Aligned with and supports corporate strategy
- Written and agreed document, regularly reviewed by management
- Sets the baseline for how others perceive you and expectations
- Transparency and openness are key parts of building trust and reputation
- Dedicate resources and build this into the corporate governance structure
Strategic (‘planned’) communications

Typical questions when doing a communication strategy:

- What do we want to achieve? What are our communication goals? Image, trust, reputation, openness, etc.
- Who are our partners and stakeholders (patients, HCPs, industry, politicians, etc.)?
- What do we want them to know or do? What are our messages?
- What are the best channels to reach them?
- Is the media our friend or foe?
- How do we know we’ve achieved our goals?

Communication perception surveys

- Useful to know how we are progressing with communications strategy
- Establish whether we are reaching our partners and stakeholders
- Assess how our communication is perceived
- Understand how our communication is valued by partners and stakeholders
- Assess and measure satisfaction levels of the services provided
- Establish baselines and targets to measure progress, analyse trends and improve communication activities
- EMA first survey done in 2015, next one in preparation
Areas of current EMA communication efforts

- **Corporate website optimisation** to improve findability, general usability and reduce complexity
- **Greater stakeholder engagement** across the different groups via targeted information and more active dialogues
- **Increased use of social media channels** to create a better awareness of EMA and its work
- **Simplified content** to make information more accessible
Transparency

- Actively managed website
- Outcomes and outputs published (EPARs)
- Public hearings (Valproate, September 2017)
- Agendas and minutes of all meetings
- Publication of clinical data (first in world)
- Public access to databases
- Broadcast key workshops and events
- Social media channels
Trust and reputation

- Trust is hard to build, easy to lose and tougher to regain
- Part of planned strategic communications, not by accident
- Transparency is key component of trust
- Trust builds confidence in what you do and how you do it
- Build goodwill for a rainy day

EMA perception survey 2015
Reputation management building blocks

- Trust
- Reputation
- Legitimacy
- Engagement
“Do your partners and stakeholders know you are a public health authority?”

All agencies have struggled with lack of understanding of their role, common issues:

- Benefit-risk communication, understand risk tolerance
- Communications must have credibility
- Decisions must be science based and must have integrity according to rules
- Transparency underpins this, be open to legitimate external questions

“...it has been said that the FDA has just two speeds of approval — too fast and too slow.” Dr Margaret Hamburg, US FDA Commissioner, 2009-2015

Engage with partners and stakeholders

EMA has developed frameworks for engaging with patients, healthcare professionals, academia and industry (especially SMEs)

- Working parties for patients and healthcare professionals engagement
- Involvement in Agency committees and outputs
- Improves Benefit-Risk communication

Increases likelihood that recommendations will be followed and acted on = **public health benefit**
Why effective benefit-risk communication by regulators is vital

- Impartial and reliable information from a trusted source to enable informed decision-making
- Promote the rational and safe use of medicines
- Counteract misconceptions or biased claims from interested parties
- Transparency
- Preparedness for crisis communication
Communicating under stress

- These are some examples of EMA corporate communications
- But EMA also communicates as part of the European medicines network
- Role is to bring together different voices and perspectives to ultimately develop an EU (regional) response across the network
- One critical example of this is incident management communication, e.g. shortages, quality defects, etc.
- How do we do this?
Managing incidents so they don’t become a crisis

- EU approach described in Incident Management Plan (revised August 2017)
- Global approach for consistent and systematic action by all authorities in EU
- **Proactive** incident management: Review information to assess public health impact, use of routine measures (PhV, routine regulatory action, communication tools, etc.)
- **Reactive** incident management: Routine measures not adequate, urgent and coordinated action needed (precautionary suspension or withdrawal, etc.)
- Management structure for decision-taking (‘Incident Review Network’ and Executive Task Force), Rapid Alert and Non-Urgent Information systems to support information sharing
Early notification system

EMA identifies emerging issue

EMA warns the Network and international partners of upcoming communication

EMA shares communication material ‘under embargo’ in advance of publication

- Suspension, withdrawal or revocation
- Start or end of a safety review
- Restrictions of indications
- Major changes in safety labelling (contraindications)
- Dissemination of a DHPC (‘Dear Doctor’)
- Emerging safety concerns giving rise to public or media interest

- Press release
- Safety communications
- Lines-to-take
Pfusch bei Zulassung von Medikamenten

Skandal um Arzneistudien erreicht Main

Fünf Unternehmen aus der Region dürfen einige ihrer Medikamente von den Markt entfernen. Das Bundesinstitut für Arzneimittel hat die Zulassung von Medikamenten geführt.

Fälschungsverdacht gegen Studien: 176 Medikamente womöglich vom Markt

EU nations yank drugs over GVK data scandal

Some European Union states have suspended the approvals of drugs tied to a data falsification scandal at CRO GVK Biosciences, and the European Medicines Agency is investigating whether to recommend a continental halt.

According to the EMA, irregularities at GVK’s Hyderabad lab have cast doubts on bioequivalence data used to support the approval of an undisclosed number of drugs, and some countries have withheld their marketing authorizations until sponsors redo the studies.
Germany suspends some drug approvals on concern over Indian data

HYDERABAD, Oct 1, 2014

The European Medicines Agency (EMA) has started a review in connection with findings of alleged non-compliance with good clinical practice (GCP) at a facility owned by GVK Biosciences, a city-based Contract Research Organisation.

The European body's action follows an inspection by the French medicines agency (ANSM) which included a visit to the GVK Bio facility in Hyderabad.

The quality of Indian pharmaceuticals has come under fire this year, with regulators in Europe and the United States citing problems ranging from data manipulation to sanitisation and banning the import of certain products from several firms.

Germany's Federal Institute for Drugs and Medical Devices (BfArM) said on Friday it was investigating drug approvals based on clinical trials meant to show that the generic drug was superior to the original brand-name drug marketed by GVK Biosciences.
A case study: GVK Biosciences, 2014

- Story ‘broke’ on German primetime TV news in November 2014 – despite already being in public domain since September 2014
- Worked with German TV to give them as much information as possible – but there were many unanswerable questions + CHMP review was still ongoing
- Close liaison with European Commission, Germany and France (the inspectors)
- Prepared ‘lines-to-take’ for whole network to ensure consistent messaging
- Challenges: we didn’t know how many medicines were potentially concerned, we didn’t know the outcome or public health impact, etc.
- Member States started taking precautionary action to suspend the medicines
What we did when Member States started suspending medicines (December 2014)

- Press release
- Respond to media queries
- Lines to take for the network
January 2015 - Conclusion of the review

Outcome:

- EMA looked at over 1,000 medicines for which studies were conducted at GVK Biosciences
- No evidence of harm or lack of effectiveness observed
- Medicines that have other, non-GVK clinical studies can remain on the market (around 300 medicines)
- For medicines without data from other studies (around 800), EMA recommended suspension unless they are of critical importance for patients because there are no alternatives
What we did at the end of the review (January 2015)

- Press release – public health communication
- Respond to media queries
- Lines-to-take and Q&A documents for the network to help press offices in the Member State national agencies
**Media coverage by month**

- September: 2
- October: 9
- November: 2
- December: 177
- January: 189

**Media requests**

- E-mail requests
- Phone requests

**Unique media interactions**

- 28.9.2014: 2
- 28.10.2014: 9
- 28.11.2014: 2
- 28.1.2015: 189
EU regulator recommends suspension of drugs over Indian data

(Reuters) - Europe's drug regulator said EU’s GVK Biosciences gets harsh accusations from EMA on fake generic trials

January 26, 2015 | By EJ Lane

SINGAPORE—In a no-holds-barred action, the European Medicines Agency has accused India-based CRO GVK Biosciences of systematically faking clinical trials for about 700 generic drugs marketed throughout the world. The products of dozens of generic makers are among the drugs involved, including popular antidepressants.

EMA Recommends Hundreds of Drugs to be Suspended Over ‘Flawed Studies’
Some lessons learned

- Be prepared – know the ‘hot button’ issues for your agency, Ministry and country (in health: vaccines, children, globalisation of clinical research, etc.)
- Provide facts and figures
- Be honest about what you know and what you don’t know
- Respond accurately and timely
- Watch out for the longer-term implications, e.g. public concern in medicines where trials are done outside your country or region
And finally...

Efforts in communicating openly

Transparency

Involving patients and healthcare professionals

Trust + Better outcomes
Any questions?

Further information

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