EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Transparency at EMA (1)

interaction with the public and external stakeholders

Francesca Cerreta

Senior Scientific Administrator – CNS section, Safety and Efficacy of Medicines

European Medicines Agency

In this presentation:

- Transparency in involving stakeholders in decision processes
- Types of information available to the public
- Interaction meetings for companies
- Transparency of regulatory decision
- Making clinical trial data publicly available

Transparency

Transparency is an important feature of the European Medicines Agency's operations. As for any public authority, the Agency strives towards being as open as possible about how it works and how it comes to its decisions.

Since its formation in 1995, the Agency has published detailed information on its scientific assessment work, through the publication of **European public assessment reports**, a unique tool among medicines regulators in describing the basis for its opinions.

Over the subsequent years, it has worked towards **increasing** the level of openness over how it works, through publication of information on its scientific and non-scientific operations and a continuous effort to explain its decisions and procedures.

European Union (EU) law sets the minimum level of transparency that the Agency must apply. However, in many areas, the Agency has decided to go beyond what law requires, so that it can provide as much information to the public as possible. In all cases, it takes care to balance this with the protection of commercially confidential information and personal data.

This page summarises the types of information that the Agency releases proactively on its activities. In addition, the public has the right to request information and documents from the Agency in accordance with its rules on access to documents and on access to information. The Agency is also developing a transparency policy, which will set out how the Agency intends to provide for greater clarity and openness in all areas of its operations in the future.

The medicine authorisation process

The Agency releases information on the medicines it is evaluating at various stages during the marketing-authorisation process.

Evaluation
The Agency publishes a list of the international non-proprietary names (INNs) and therapeutic areas for all human medicines under evaluation by the Committee for

Related information

- Access to documents
- Information on medicines
- Scientific committees
- Handling conflicts of interests
- Transparency policy
- European database of suspected adverse drug reaction reports
- EU Clinical Trials Register
- Article 45 paediatric studies database
- EudraGMP

What can be found on our website

EUROPEAN MEDICINES AGENCY

- Access to documents policy
- Information on medicines (EPARs, Product information, registration status)
- Scientific committees (composition, minutes and agendas)
- Handling conflicts of interests (+DoI committee memb.)
- Transparency policy
- European database of suspected adverse drug reaction reports
- EU Clinical Trials Register
- Article 45 paediatric studies database
- EudraGMP

EMA Transparency Policy (EMEA/232037/2009)

Draft Transparency Policy launched for public consultation on 19 June 2009 until 25 September 2009

Project currently put on hold

- Priority to EMA Access to Documents Policy (EMA/110196/2006, 01 Dec 2010)

- Incorporate, where relevant, elements resulting from the 2012 Pharmacovigilance legislation

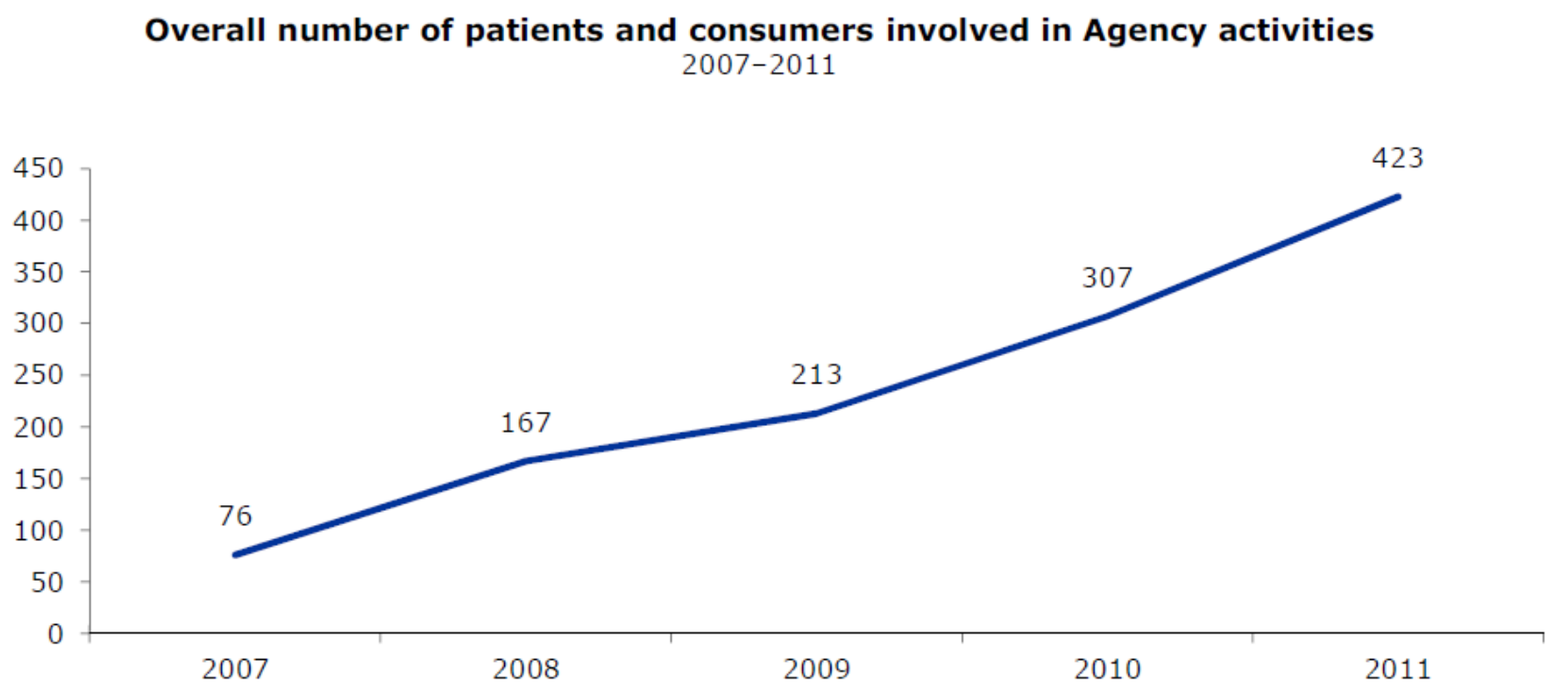
Involvement of stakeholders in decision process. Some examples

Public guideline consultation

Scientific advice/orphan drugs patient’ s involvement

Open workshops, including broadcast

Patients’ representatives as members of committees and SAGs



Information on authorised medicines

EUROPEAN MEDICINES AGENCY

Vistide

cidofovir

Email Print Help Share

About | Authorisation details | Product information | Assessment history

Next tab »

This is a summary of the European public assessment report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach its recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the scientific discussion (also part of the EPAR).

Expand all items in this list

- What is Vistide?
- What is Vistide used for?
- How is Vistide used?
- How does Vistide work?
- How has Vistide been studied?
- What benefit has Vistide shown during the studies?
- What is the risk associated with Vistide?
- Why has Vistide been approved?
- Other information about Vistide

Name	Language	First published	Last updated
Vistide : EPAR - Summary for the public	EN = English GO	27/01/2009	

AUTHORISED
This medicine is approved for use in the European Union

Vistide RSS feed

Patient safety

- European Medicines Agency gives final recommendations for 12 centrally authorised medicines manufactured at Ben Venue Laboratories
- European Medicines Agency recommends precautionary recall of remaining batch of Vistide manufactured at Ben Venue Laboratories

More information on Vistide

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 13-16 February 2012 (17/02/2012)
- European Medicines Agency gives final recommendations for 12 centrally authorised medicines manufactured at Ben Venue

Interaction meetings with companies at EMA

- Scientific advice presubmission meetings
- Presubmission meetings (pre-filing)
- Business pipeline meetings
- ITF briefing meetings

Opportunity to discuss the company’ s plans with EMA. No fee for these.

Even if you are on the right track, you will get run over if you just sit there.

- Are we trying to cover too different audiences at the same time?
- What level of information do we need to provide?

Did EMA have a transparency problem?

BMJ

BMJ 2011;342:d2686 doi: 10.1136/bmj.d2686

Opening up data at the European Medicines Agency

Widespread selective reporting of research results means we don't know the true benefits and harms of prescribed drugs. **Peter Gøtzsche** and **Anders Jørgensen** describe their efforts to get access to unpublished trial reports from the European Medicines Agency

Peter C Gøtzsche *professor*, Anders W Jørgensen *PhD student*

Nordic Cochrane Centre, Rigshospitalet and University of Copenhagen, Dept 3343, Blegdamsvej 9, DK-2100 Copenhagen Ø, Denmark

A change of minds and hearts- EMA position

Clinical trial data is not commercial confidential information

Access to documents – retroactive availability of trial reports

Proactive publication of trial reports (Module 5) - planned

? Public availability of ‘raw’ data ? (pre-licensing RCT, pharmacovigilance, observational data)- under discussion

Electronic Format under discussion

Transparency and the division of labor

"Historically, observation and analysis have been yoked together, the person who does the experiment analyses the data. ...

M. Nielsen. Reinventing Discovery. Princeton Press 2011

Exception: regulated products, "a new division of labor"

Playing with data: boon or bane for drug development and public health?

Cons:

Data protection issues

Phantom risks, health scares

Industry and regulators will be blind-sided

"We have entered an era of increasingly frequent publication of meta-analyses, some of which identify potential safety signals. Such publication commonly leads to urgent calls to take immediate regulatory action…."

Michele TM et al; NEJM 363:1097-1099; September 16, 2010

How many good drugs will we lose?

"… there are challenges to achieving meaningful informed consent in postmarketing trials of drugs for which there is a signal indicating the possibility of drug-related harm."

Mello MM, Goodman SN, Faden RR. Ethical considerations in studying drug safety-the Institute of Medicine report.

N Engl J Med. 2012 Sep 6;367(10):959-64.

Playing with data:

boon or bane for drug development and public health?

Pros:

"open science" could support development of:

- predictive models for patient selection to appropriate treatments/doses
- machine learning systems
- matching patient history to clin trial data set
- enable Comparative Effectiveness Research

Next steps for EMA?

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2012
EMA/406355/2012
Senior Medical Officer

Workshop on access to clinical trial data and transparency

Send your expression of interest to ctdataworkshop@ema.europa.eu

The European Medicines Agency is hosting a workshop on access to clinical trial data and transparency on 22 November 2012 from 12.30 to 17.00 in meeting room 2A at the Agency's offices in Canary Wharf, London, UK.

Next steps for EMA?

EUROPEAN MEDICINES AGENCY

Purpose of 22 November workshop:

- EMA to listen to all its stakeholders
- be informed when drafting our policy
- establish a working relationship with those stakeholders who are willing to engage

While protecting the decision making process, develop:

- standards for storing and sharing of data
- level of data to be released
- standards for protection of personal data
- quality standards
- rules of engagement

Honesty and transparency make you vulnerable. Be honest and transparent anyway.

Mother Theresa

Mitigation of reputational risk

- Harmonise methodology and evidence standards
- Explain divergent decisions on the basis of credible differences in healthcare environments
- Anticipate and manage (high-profile) divergent decisions

Thank you
for your attention

With acknowledgement and special thanks to:

Martin Harvey Allchurch

Emer Cooke

Juan Garcia Burgos

Hans-Georg Eichler