EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication to patients, consumers and healthcare professionals

Belgrade, 23 June 2014

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Stakeholders and Communication, European Medicines Agency (EMA)

European Medicines Agency's (EMA) main responsibilities

- evaluation of marketing authorisation applications of medicines;
- coordination of pharmacovigilance in the EU;
- provision of scientific advice during drug development;
- evaluation for orphan designation and paediatric investigation plans.

But also...

Provides information to patients, consumers and healthcare professionals (HCPs) on the medicines that the Agency evaluates.

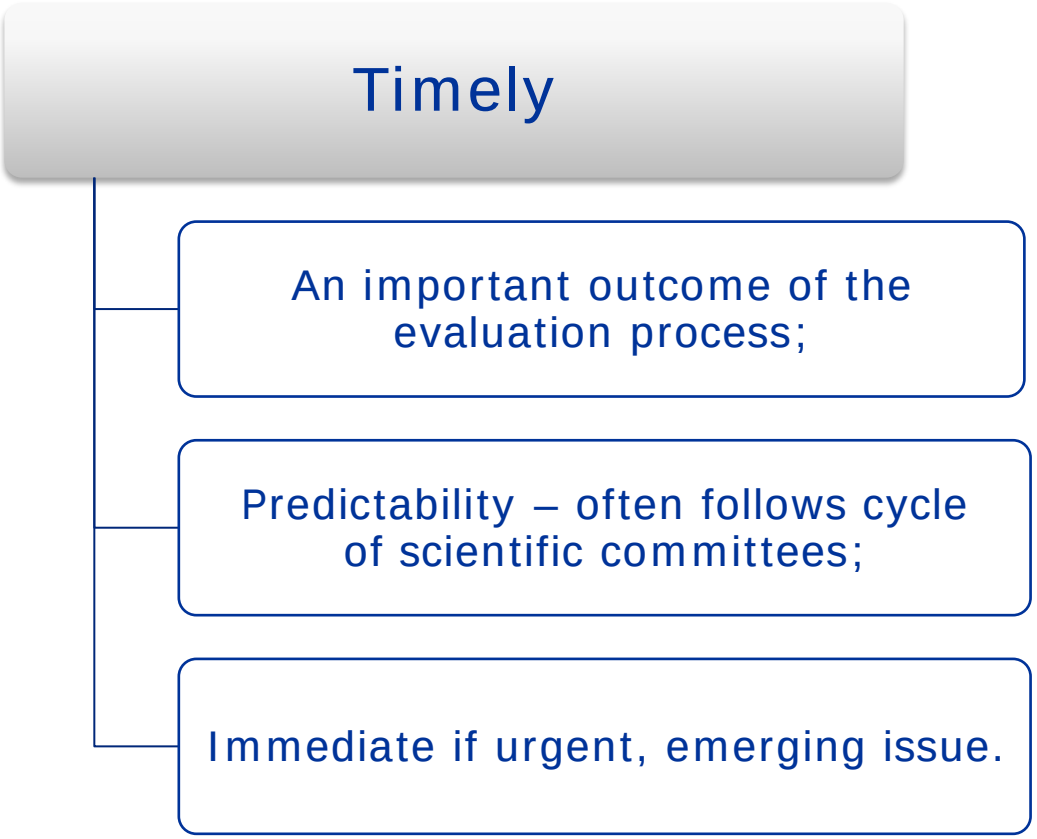
- Good quality;
- Science/ evidence – based;
- Unbiased, independent;
- Timely;
- Up-to-date;
- Adapted to the target audience.

EMA information on medicines

Good quality – evidence/ science based

- Done in parallel to the scientific assessment;
- Written by experts in communication, but reviewed by the assessors;
- Consistent with the scientific conclusions.

EMA information on medicines



EMA information on medicines

EMA information on medicines

Adapted to the target audience

- Specific tools/communications for patients and healthcare professionals;
- Information is prepared by specialists in writing for lay public and user- tested by patients and healthcare professionals;
- (Key information) available in all EU languages.

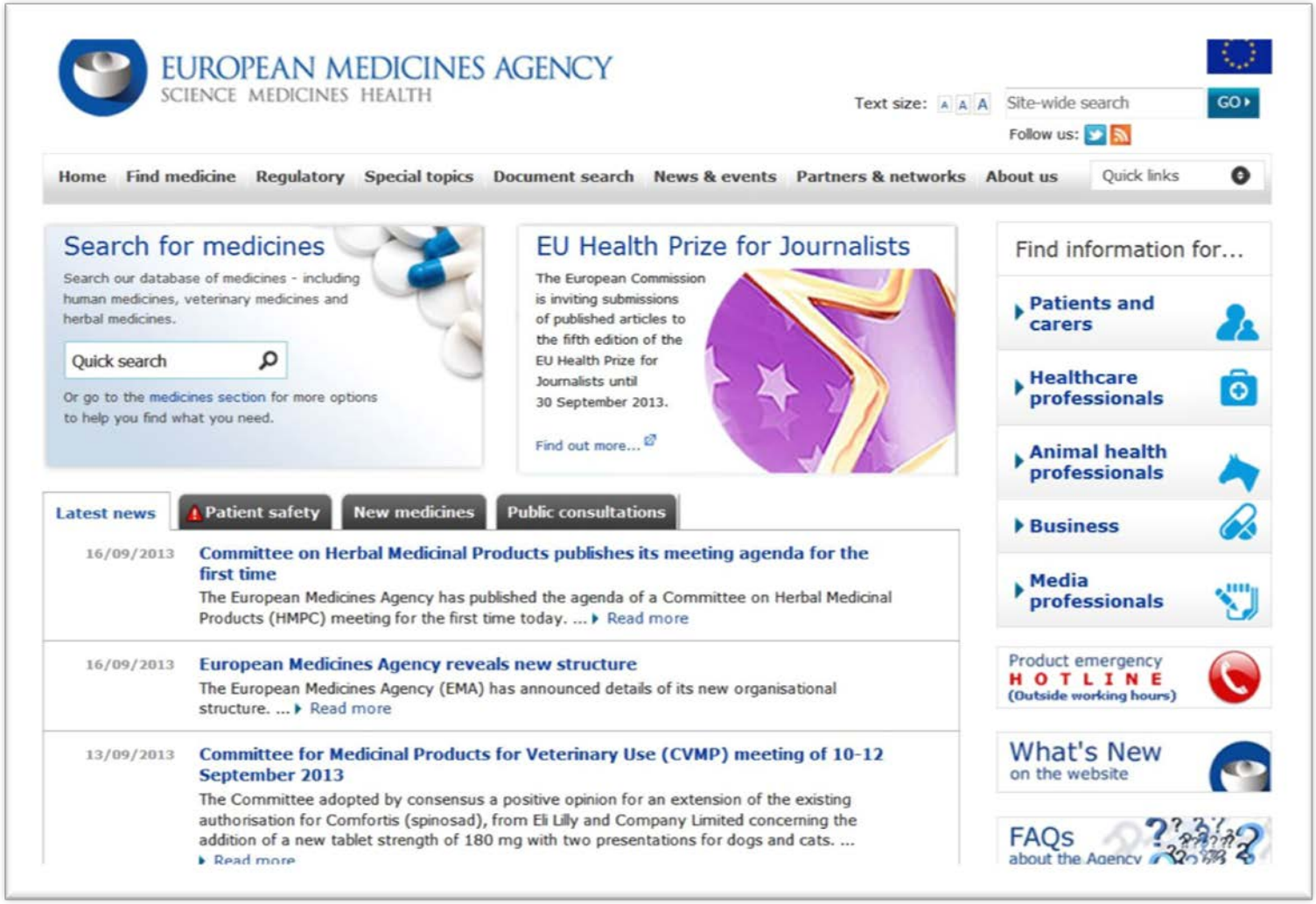
What information on medicines does EMA provide?

- EMA holds a database with comprehensive information on all medicines authorised centrally (via EMA);

- DOES NOT include full information on medicines authorised via decentralised/ national procedures;

- Also communicates on emerging safety issues (for all medicines authorised in EU) – 2012 PhV legislation.

EMA website – main channel of communication



What information on medicines does EMA provide?

Information on:

- Clinical Trials
- Orphan designation
- Paediatric investigation plans

Comprehensive info on the medicine:

- benefit-risk evaluation
- conditions of use

- Any variation
- Other relevant (safety) info

Pre-authorisation

Orphans and paediatrics

Information on:

- medicines under development which have been designated as orphan;
- review of orphan designation at the time of the medicine's authorisation;
- opinions and decisions on paediatric investigation plans.

Information available only in English.

Public summary of opinion on orphan designation

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Home | Find medicine | Regulatory

- Human medicines
- European public assessment reports
- Patient safety
- Pending EC decisions
- Withdrawn applications
- Paediatrics
- Rare disease designations
- Medicines under evaluation
- Medicines for use outside the EU
- Referrals
- Veterinary medicines
- Herbal medicines for human use

EMA/COMP/536533/2013
Committee for Orphan Medicinal Products

Recommendation for maintenance of orphan designation at the time of marketing authorisation

Defitelio (defibrotide) for the treatment of hepatic veno-occlusive disease

During its meeting of 3 to 4 September 2013, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/04/212 for Defitelio (defibrotide) as an orphan medicinal product for the treatment of hepatic veno-occlusive disease. The COMP assessed whether, at the time of marketing authorisation, the medicinal product still met the criteria for orphan designation. The Committee looked at the seriousness and prevalence of the condition, and the existence of other satisfactory methods of treatment. The COMP recommended that the orphan designation of the medicine be maintained[1].

Life-threatening or long-term debilitating nature of the condition

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Defitelio for:

Pre-authorisation

Clinical Trials

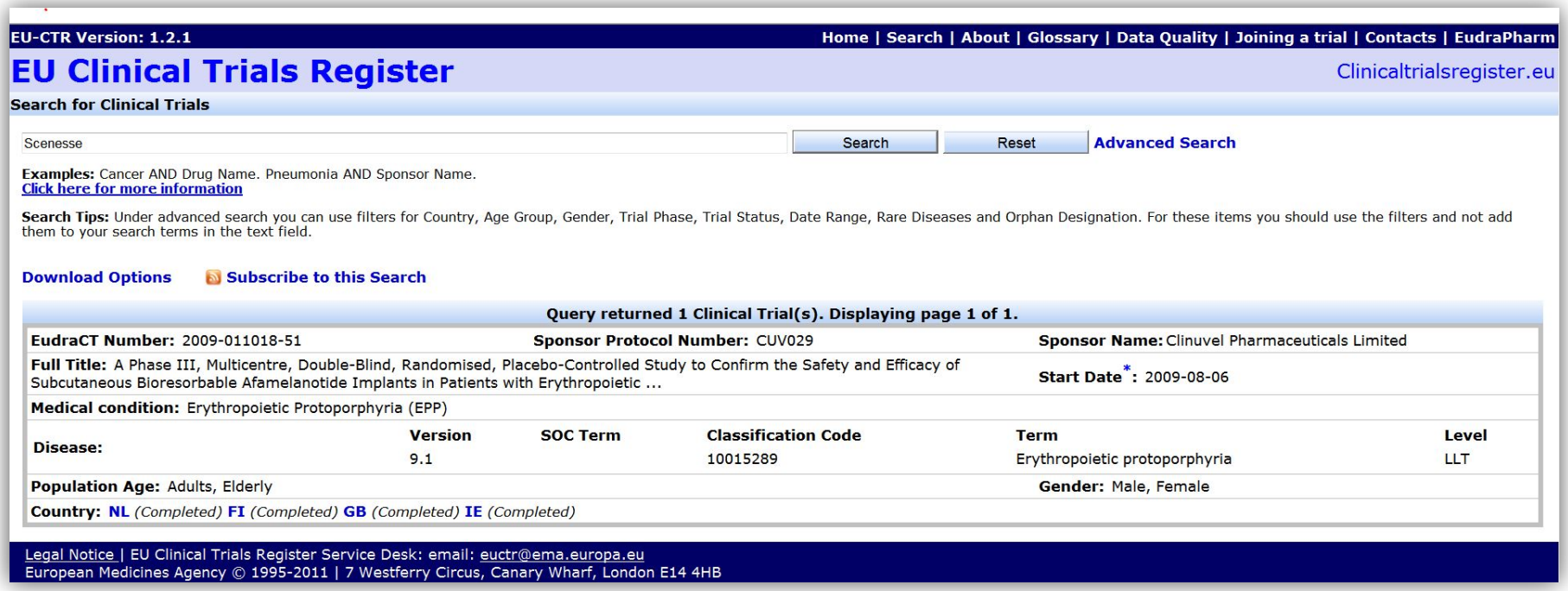
•Information on CT – the EU Clinical Trials Register website: https://www.clinicaltrialsregister.eu/

•The Register allows to search for information on CT in the EU Member States.

- Information on:
  - trial design
  - sponsor
  - investigated product and therapeutic area
  - the status of the trial
  - trial summary results

Pre-authorisation

Clinical Trials



EU-CTR Version: 1.2.1 Home | Search | About | Glossary | Data Quality | Joining a trial | Contacts | EudraPharm

EU Clinical Trials Register Clinicaltrialsregister.eu

Search for Clinical Trials

Scenesse Search Reset **Advanced Search**

Examples: Cancer AND Drug Name. Pneumonia AND Sponsor Name.
Click here for more information

Search Tips: Under advanced search you can use filters for Country, Age Group, Gender, Trial Phase, Trial Status, Date Range, Rare Diseases and Orphan Designation. For these items you should use the filters and not add them to your search terms in the text field.

Download Options **Subscribe to this Search**

Query returned 1 Clinical Trial(s). Displaying page 1 of 1.

EudraCT Number: 2009-011018-51			**Sponsor Protocol Number:** CUV029		**Sponsor Name:** Clinuvel Pharmaceuticals Limited
Full Title: A Phase III, Multicentre, Double-Blind, Randomised, Placebo-Controlled Study to Confirm the Safety and Efficacy of Subcutaneous Bioresorbable Afamelanotide Implants in Patients with Erythropoietic ...					**Start Date*:** 2009-08-06
Medical condition: Erythropoietic Protoporphyria (EPP)					
Disease:	**Version**	**SOC Term**	**Classification Code**	**Term**	**Level**
	9.1		10015289	Erythropoietic protoporphyria	LLT
Population Age: Adults, Elderly				**Gender:** Male, Female	
Country: **NL** *(Completed)* **FI** *(Completed)* **GB** *(Completed)* **IE** *(Completed)*					

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At the time of authorisation: EPAR

EPAR summary	• Information in lay language on the benefits and risks of medicine and how it was assessed
Product Information	• SmPC - for health professionals • Package leaflet (info on the use of medicine) - for patients
Summary of risk management plan	• Summary of the medicine's safety profile and the measures taken to prevent or minimise its risks.
Assessment report	• The full scientific evaluation

EPAR summary

EPAR summary

- EMA 'landing' page for each medicine (centrally) authorised;
- Written in lay language for lay audience;
- Available in all EU languages;
- Constantly kept updated;
- Summarises the evaluation of each medicine:
  - Explains the reasons why the medicine is approved (why its benefit/risk is positive);
  - Briefly describes what it is used for.

EPAR summary

- Provides access (links) to the 'product information' (SmPC and Package Leaflet) and, if the reader wants to know more, to:
  - Summary of RMP;
  - Scientific assessment report.
- Undergone a recent update (format and content):
  - More user-friendly and better explain the reasons leading to the medicine's approval.
- Prepared by specialists, in close collaboration with assessors and always user-tested by patients, consumers and HCPs during preparation.

Example: Sirturo

RMP summary

- First published in March 2014 - 1 year pilot phase;
- Increased transparency and access to relevant (safety) information;
- Complements and links to the EPAR summary and Product Information;
- Target audience:
  - Primarily – stakeholders with professional interest in medicines;
  - Secondary – useful resource for any member of the public who wants to know more about his/her medicine.

Example: Sirturo

RMP summary – an example

EMA/16634/2014

Summary of the risk management plan (RMP) for Sirturo (bedaquiline)

This is a summary of the risk management plan (RMP) for Sirturo, which details the measures to be taken in order to ensure that Sirturo is used as safely as possible. For more information on RMP summaries, see here.

This RMP summary should be read in conjunction with the EPAR summary and the product information for Sirturo, which can be found on Sirturo's EPAR page.

Overview of disease epidemiology

Tuberculosis (TB) is an infectious disease that is caused by a bacterium called *Mycobacterium tuberculosis*. TB usually infects the lungs but can also affect other parts of the body such as the brain, kidneys and spine. There are two forms of the disease: latent TB and active TB. Latent TB is when the human immune system, the body's natural defences against germs and other substances that cause infection, fight the bacteria causing TB and prevent it from causing disease. The bacteria remain hidden or inactive without causing symptoms. Active TB is when the bacteria causing TB become active and make you sick. This can happen when the immune system is weakened, e.g., due to infection with the human immunodeficiency virus (HIV).

Patients with drug-susceptible TB (DS-TB) respond well to the medicines most commonly used to treat TB, which are called first-line anti-TB medicines. In patients with multidrug-resistant tuberculosis (MDR-TB), the TB bacteria have become resistant to first-line anti-TB medicines, and patients must be

RMP summary – an example

Summary of safety concerns

Important identified risks

Important potential risks

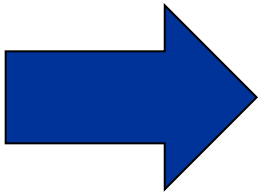
Risk	What is known
Serious liver side effects (Severe hepatotoxicity)	During clinical trials, side effects involving the liver were seen more often in patients who received bedaquiline than in patients who did not. Most of these side effects were related to changes in the amount of liver enzymes, which speed up essential chemical reactions in the liver. Other medicines used to treat MDR-TB, including pyrazinamide, ethambutol, prothionamide, p-aminosalicyclic acid and linezolid, can cause side effects that involve the liver. During clinical trials, these medicines were often given together with bedaquiline, so it is not known in each case whether the liver side effects were due to bedaquiline, another anti-TB medicine, or a combination of anti-TB medicines .
	that increase the QT interval, potentially life threatening); patients with a family history of increased QT

Missing information

Risk	What is known
Long-term effects of bedaquiline treatment on death (mortality)	There is limited information on the long-term effects of bedaquiline on the rate of death among patients taking bedaquiline.

Post-authorisation

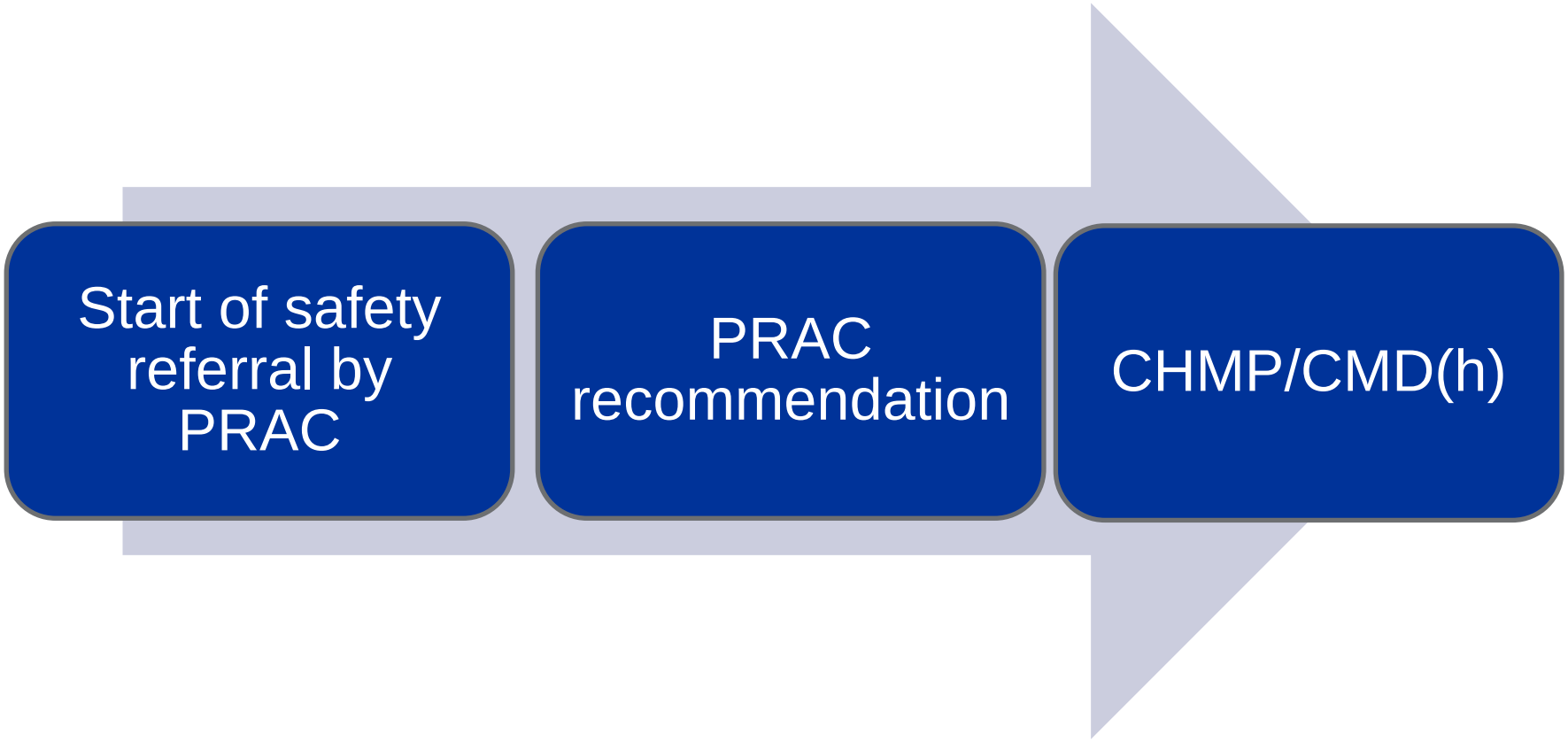
- New therapeutic indications;
- New contraindications;
- Other variations.



- Update of EPAR summary;
- Update of Product Information;
- Update of RMP summary;
- Publication of relevant assessment report.

Emerging (safety) communication

Example of safety referrals



Human medicines Highlights Newsletter

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HUMAN MEDICINES
HIGHLIGHTS

Key information for patients, consumers and healthcare professionals
Published monthly by the European Medicines Agency

An agency of the European Union

IN THIS ISSUE

This newsletter is addressed primarily to organisations representing patients, consumers and healthcare professionals. It provides a summary of key information relating to medicines for human use published during the previous month by the European Medicines Agency.

Information is selected based on recommendations from consulted patients, consumers and healthcare professionals, and does not necessarily cover all relevant information published by the Agency.

To receive an e-mail alert when each new issue of the newsletter is published, send a request to: HMHnewsletter@ema.europa.eu

Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- Ebilfumin (*oseltamivir*)
  Treatment and prevention of influenza
- Olysio (*simeprevir*)
  Treatment of chronic hepatitis C

New medicines authorised

- Sirturo (*bedaquiline*)
  Treatment of multi-drug resistant tuberculosis

New information on authorised medicines

Information on adverse drug reactions

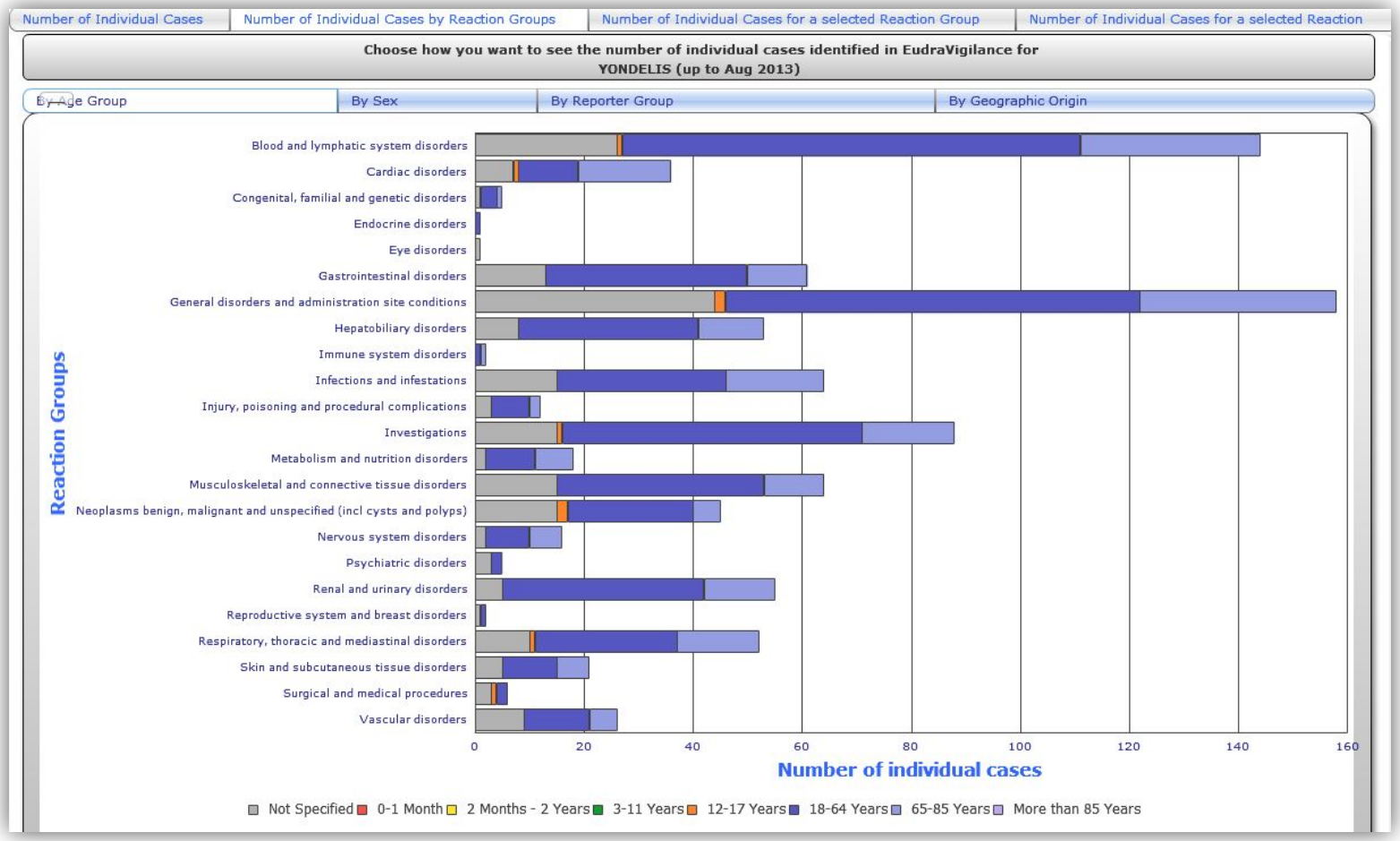
http://www.adrreports.eu

- EU database with information on 'suspected adverse drug reactions' for medicines authorised in the EU.

- A phased development:
  - so far, only for medicines approved via centralised procedure.

- The reports are constantly updated.

EU database of suspected adverse drug reactions reports - http://www.adrreports.eu/



Conclusions

- Patients, consumers and healthcare professionals – key stakeholders for EMA;

- Important steps in recent years in adapting and focusing our communication to them
  - Producing specific information and tools for them

- In order to succeed:
  - Strong collaboration with Patients and healthcare professionals' organisations;
  - Working in the context of EU Regulatory Network (EU Member States, European Commission and EMA).

Conclusions

•Progressively more regulatory authorities in the EU target their communications to medicine users;

•Website is the main tool for EMA communication;

•Predictability and coordination of emerging (safety) information is paramount:

- Among regulatory authorities while involving patients and healthcare professionals.

Thank you for your attention.