



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication to patients, consumers and healthcare professionals

Belgrade, 23 June 2014

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An agency of the European Union





European Medicines Agency's (EMA) main responsibilities





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

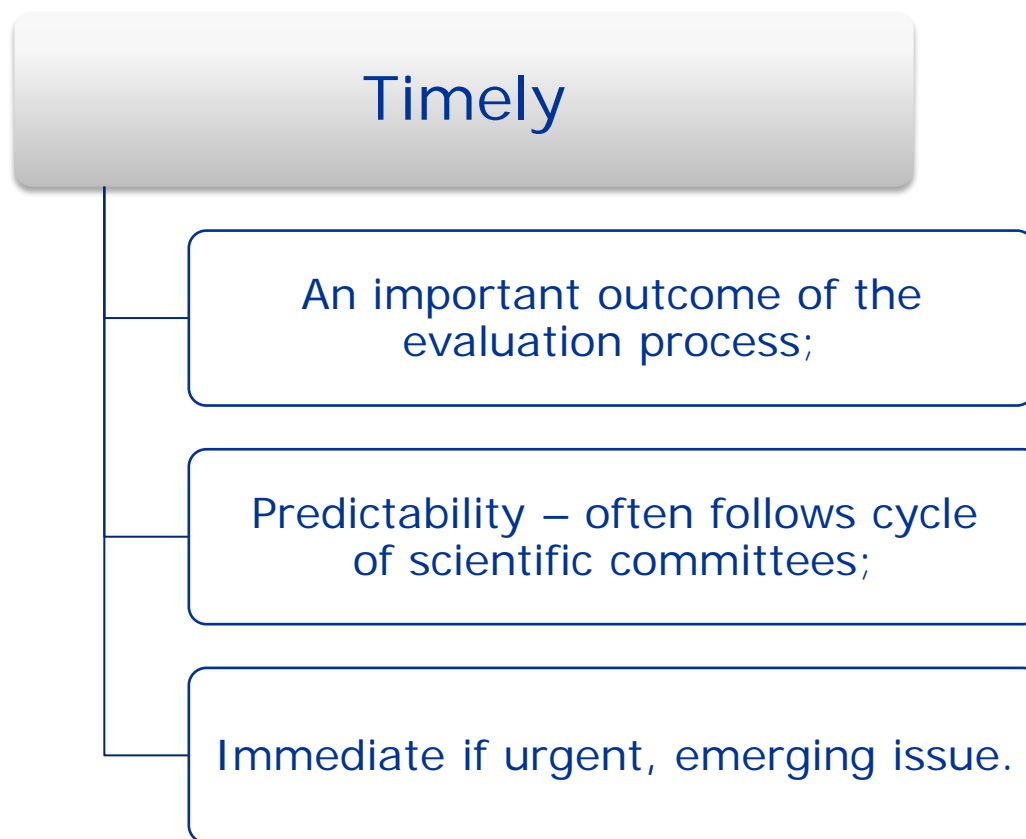
Done in parallel to the scientific
assessment;

Written by experts in communication,
but reviewed by the assessors;

Consistent with the scientific conclusions.

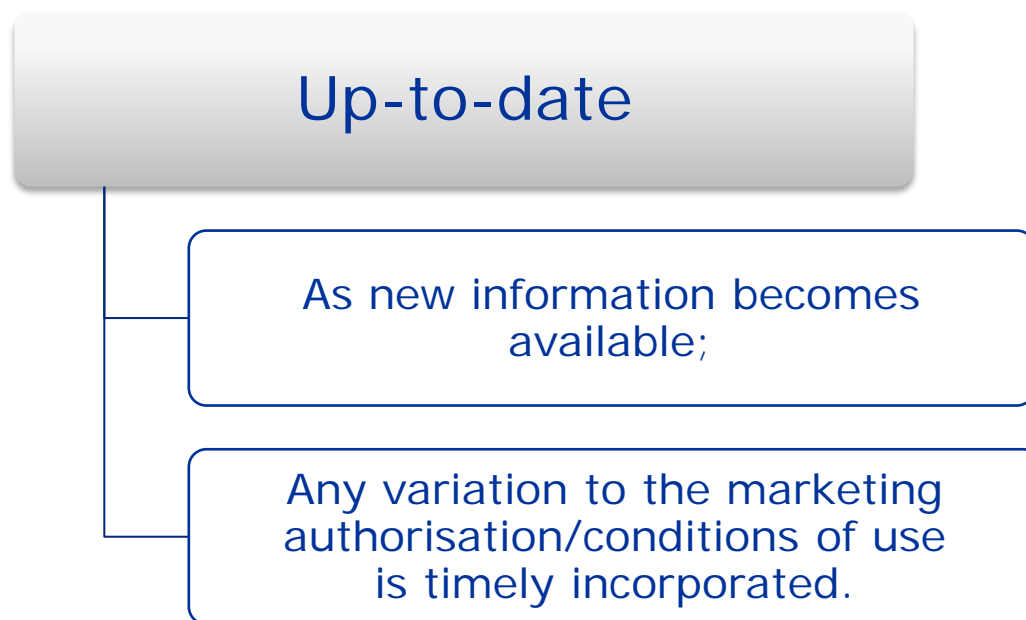


EMA information on medicines





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

The screenshot displays the EMA website homepage with the following elements:

- Header:** EMA logo and name, "SCIENCE MEDICINES HEALTH", text size controls, site-wide search bar with "GO" button, and social media follow icons for Twitter and RSS.
- Navigation:** A horizontal menu with links: Home, Find medicine, Regulatory, Special topics, Document search, News & events, Partners & networks, About us, and Quick links.
- Main Content Area:**
 - Search for medicines:** A section with a search box and text: "Search our database of medicines - including human medicines, veterinary medicines and herbal medicines. Or go to the medicines section for more options to help you find what you need."
 - EU Health Prize for Journalists:** A promotional banner for the fifth edition of the prize, with a deadline of 30 September 2013.
 - Find information for...:** A vertical list of categories with icons: Patients and carers, Healthcare professionals, Animal health professionals, Business, and Media professionals.
- Latest news:** A section with three news items:
 - 16/09/2013 Committee on Herbal Medicinal Products publishes its meeting agenda for the first time**: The European Medicines Agency has published the agenda of a Committee on Herbal Medicinal Products (HMPC) meeting for the first time today. ... [Read more](#)
 - 16/09/2013 European Medicines Agency reveals new structure**: The European Medicines Agency (EMA) has announced details of its new organisational structure. ... [Read more](#)
 - 13/09/2013 Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 10-12 September 2013**: The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for Comfortis (spinosad), from Eli Lilly and Company Limited concerning the addition of a new tablet strength of 180 mg with two presentations for dogs and cats. ... [Read more](#)
- Product emergency HOTLINE (Outside working hours):** A red telephone icon.
- What's New on the website:** A section with the EMA logo.
- FAQs about the Agency:** A section with question mark icons.



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

The screenshot shows the EMA website interface. At the top left is the EMA logo with the text "EUROPEAN MEDICINES AGENCY" and "SCIENCE MEDICINES". To the right is the European Union flag. Below the logo is a navigation menu with "Home", "Find medicine", and "Regulatory". A sidebar on the left lists various categories such as "Human medicines", "Patient safety", and "Rare disease designations". The main content area features the EMA logo and the text "EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH". The central text reads: "6 November 2013", "EMA/COMP/536533/2013", and "Committee for Orphan Medicinal Products". The main heading is "Recommendation for maintenance of orphan designation at the time of marketing authorisation" followed by "Defitelio (defibrotide) for the treatment of hepatic veno-occlusive disease". The text below states: "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 maintained¹." Below this is a section titled "Life-threatening or long-term debilitating nature of the condition" which begins with "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 [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.

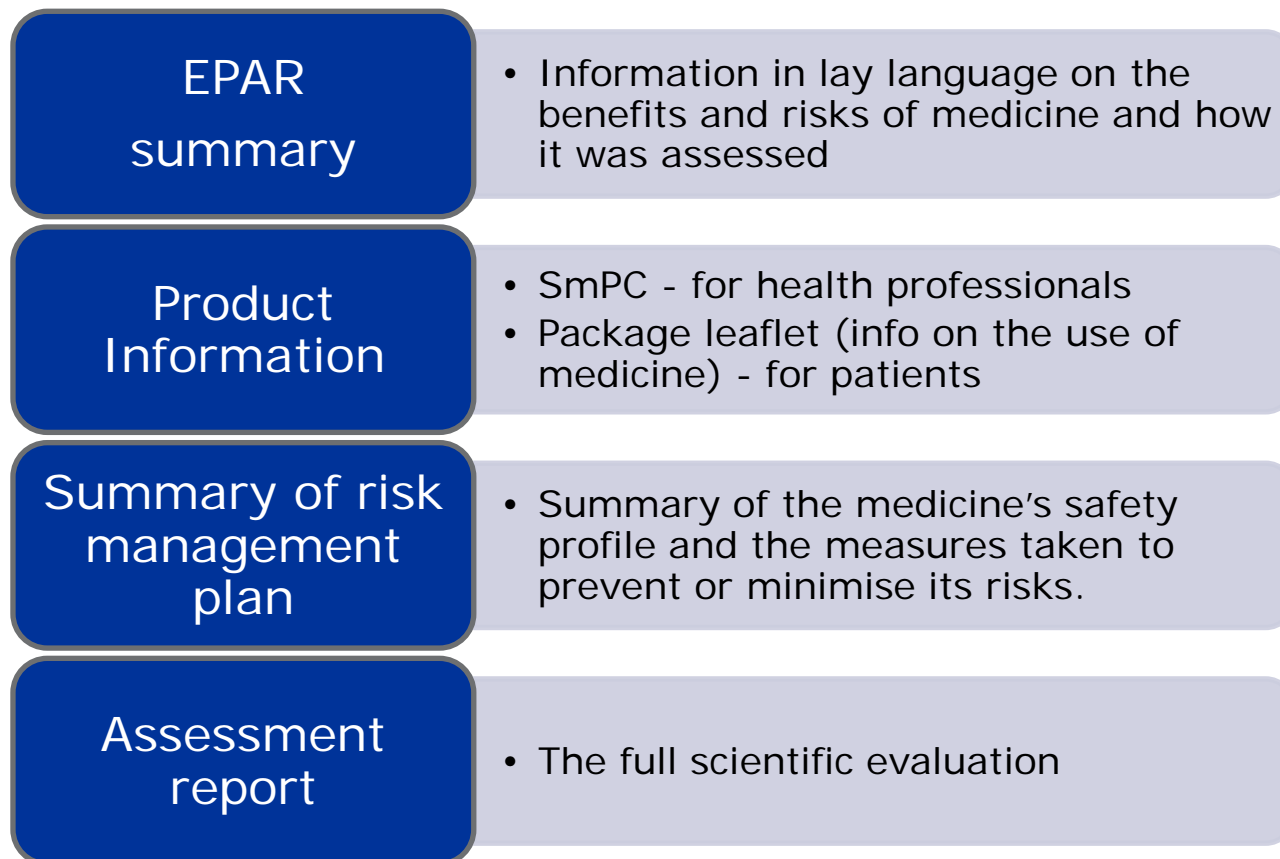
[Download Options](#) [Subscribe to this Search](#)

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 Protoporphyrria (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)					



At the time of authorisation: EPAR





EPAR summary

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/807654/2013
EMA/H/C/002614

EPAR summary for the public

Sirturo bedaquiline

This is a summary of the European public assessment report (EPAR) for Sirturo. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Sirturo.

For practical information about using Sirturo, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sirturo and what is it used for?

Sirturo is a tuberculosis medicine that contains the active substance bedaquiline. Tuberculosis is an infection caused by the bacterium *Mycobacterium tuberculosis*. Sirturo is used in combination with other tuberculosis medicines in adults with tuberculosis that is affecting the lung and that is multi-drug resistant (resistant to at least isoniazid and rifampicin, two standard tuberculosis medicines). It is given when combinations without Sirturo cannot be used, either because the disease is resistant to them or because of their side effects.

Because the number of patients with tuberculosis is low in the EU, the disease is considered 'rare', and Sirturo was designated an 'orphan medicine' (a medicine used in rare diseases) on 26 August 2005.

How is Sirturo used?

Sirturo can only be obtained with a prescription. Treatment should be started and monitored by a doctor who is experienced in the treatment of multi-drug resistant tuberculosis. In addition, it is



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



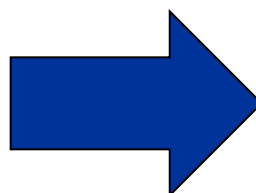
RMP summary – an example

Summary of safety concerns	
<i>Important identified risks</i>	
<i>Important potential risks</i>	
Risk	What is known
Serious liver side effects (Severe hepatotoxicity)	<p>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.</p> <p>Other medicines used to treat MDR-TB, including pyrazinamide, ethambutol, prothionamide, p-aminosalicylic 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 .</p>
	that increase the QT interval, potentially life threatening); patients with a family history of increased QT
<i>Missing information</i>	
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.

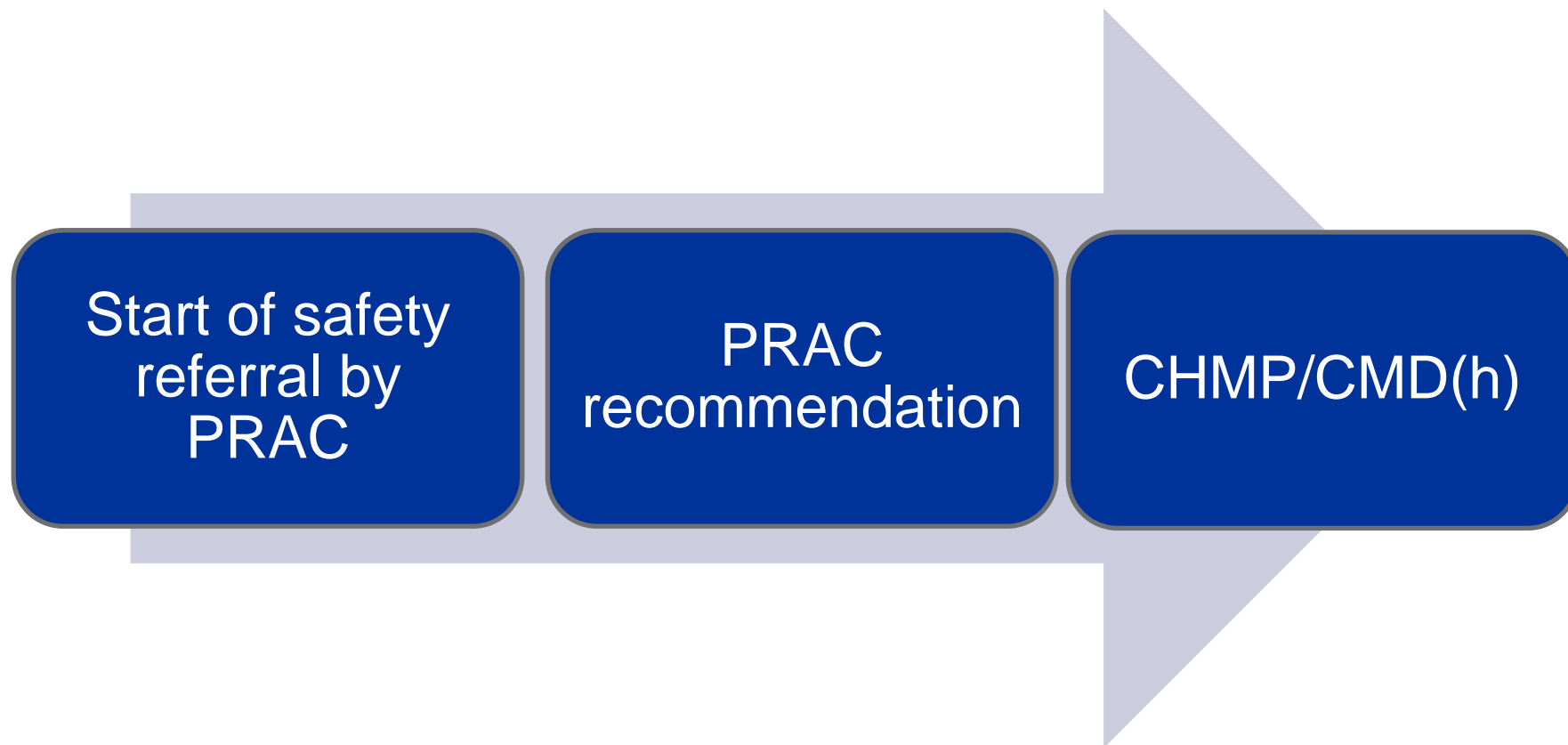


- Update of EPAR summary;
- Update of Product Information;
- Update of RMP summary;
- Publication of relevant assessment report.



Emerging (safety) communication

Example of safety referrals





Human medicines Highlights Newsletter

61

Issue 61
March 2014

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

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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: HMnewsletter@ema.europa.eu

Information on medicines

Antivirals/anti-infectives

Positive CHMP opinions on new medicines

- [Ebilfumin \(oseltamivir\)](#)
 - Treatment and prevention of influenza
- [Olysis \(simeprevir\)](#)
 - Treatment of chronic hepatitis C

New medicines authorised

- [Sirturo \(bedaquiline\)](#)
 - Treatment of multi-drug resistant tuberculosis

New information on authorised medicines



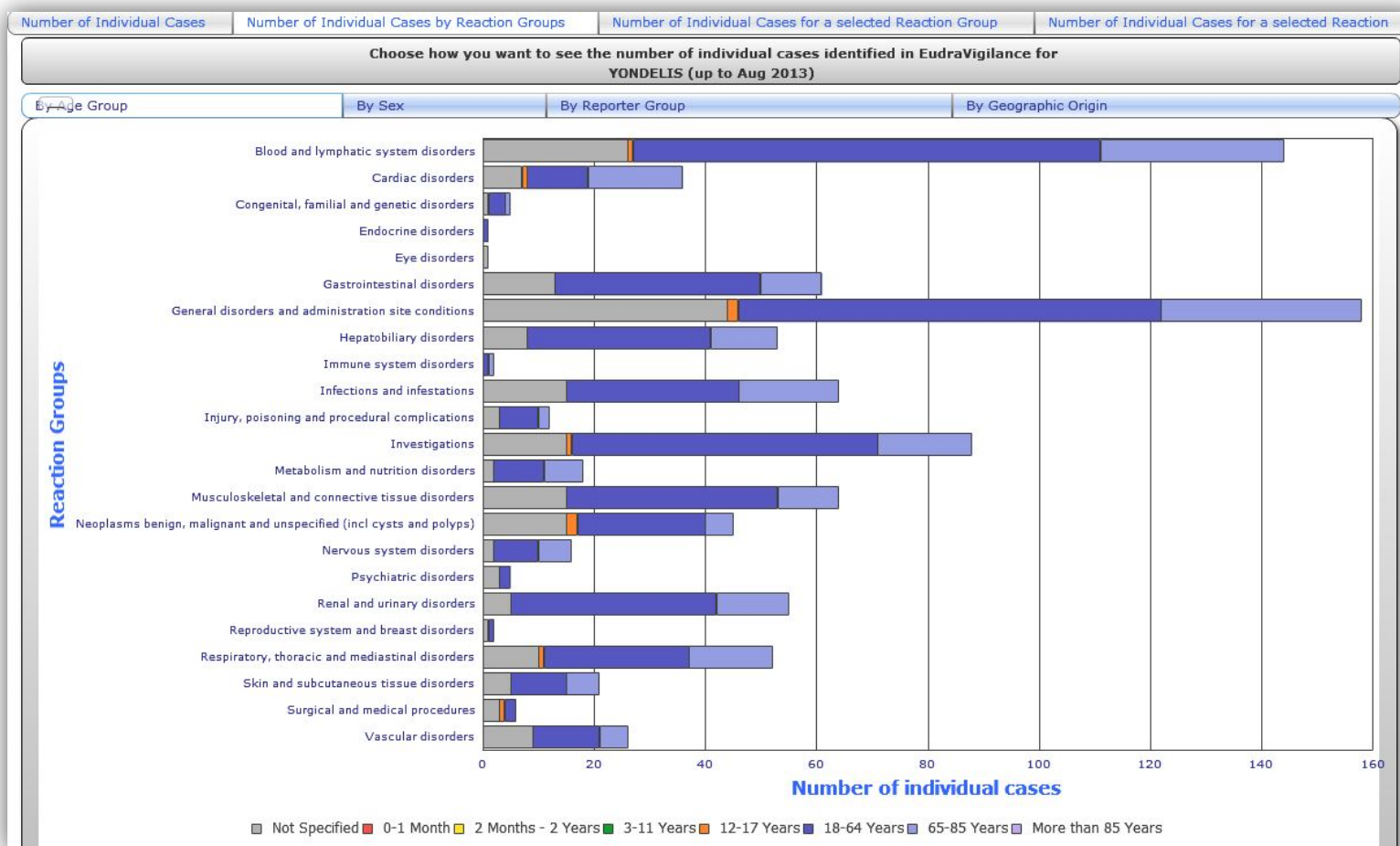
Information on adverse drug reactions

<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.