EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Assessments for maximum utility:

Transparency supporting our work

Presented by Juan Garcia Burgos on 15 September 2015

- New legislation - unprecedented level of openness and transparency
- High level of communication between the network, stakeholders and wider public
- Real time communication - new tools - additional information:
  - to promote safe use of medicines
  - to support further our work within the network

Recent steps in communication

- Stronger coordination
- New information on Risk Management Plans (RMPs)
- New information on Periodic Safety Update Reports (PSURs)
- New information on signals

Stronger coordination

- An ‘Early Notification System’ operates to inform national competent authorities, the EC and other network partners
  - Early warnings on safety concerns which will require timely and consistent communication
  - Coordination with the MAH concerned
- Adequate and timely information to relevant patients, consumers and HCPs groups

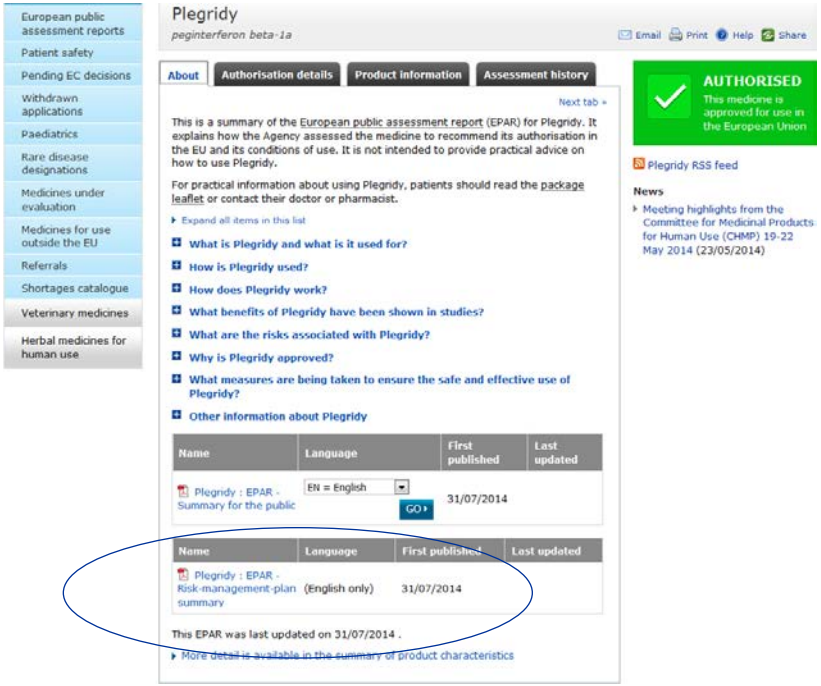
→ Ultimate purpose is to ensure that the public gets consistent, clear and timely messages on safety

→ Basis for operation – described in GVP Module XV

New information on Risk Management Plans (RMPs)

- Publication on summaries of RMP
- 1 year pilot phase - *started in March 2014*
- All new medicines centrally authorised ever since
- Over 80 RMP summaries have been published so far
- CMDh working on a similar project to publish the list of safety concerns per active substance (for NAPs)
- Content, presentation and value of these documents have been reviewed to help improvement

Summary of risk management plan



EMA/329000/2014

Summary of the risk management plan (RMP) for Plegridy (peginterferon beta-1a)

This is a summary of the risk management plan (RMP) for Plegridy, which details the measures to be taken in order to ensure that Plegridy 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 Plegridy, which can be found on Plegridy's EPAR page.

Overview of disease epidemiology

Plegridy is used to treat the relapsing-remitting form of multiple sclerosis (MS). MS is a disease in which the body's immune system malfunctions and attacks parts of the central nervous system (the brain and spinal cord). This causes inflammation and destroys the protective sheath around the nerves, leading to progressive disability. Onset of MS is usually between the ages of 20 and 40 years, and rarely occurs in children or in adults 60 years and older. Approximately twice as many women than men have MS. About 85% of people with MS initially have the relapsing-remitting form, characterised by occasional flare-ups of the disease, called relapses, in between periods when the disease is inactive. About half of patients with MS relapses go on to develop progressive MS within 10 to 20 years after diagnosis. The total number of people with MS worldwide is estimated to be between 2 to 2.5 million, and approximately 93 of every 100,000 persons in Europe have MS.

Summary of treatment benefits

Plegridy is a medicine that contains the active substance peginterferon beta-1a. It is available as a solution for injection under the skin. The peginterferon beta-1a in Plegridy is a 'pegylated' interferon (a protein naturally produced by the body), which is removed from the body at a slower rate than other interferons, allowing the medicine to be given less often.

Plegridy was investigated in 1,516 patients in one main study, in which it was compared with placebo (a dummy treatment). Plegridy showed about a 30% reduction in the number of relapses in patients with relapsing-remitting MS compared with placebo, which is comparable to the effect of other MS

At the time of the authorisation

Summary of risk management plan

Summary of safety concerns

Important identified risks

		Preventability
ir ı) ıic ıgue,		Patients should not use peginterferon beta-1a if they are allergic to peginterferon beta-1a, interferon beta-1a, or any of the other ingredients of Plegridy. Patients should contact a doctor immediately if they experience symptoms of an allergic reaction. Peginterferon beta-1a should be discontinued if serious hypersensitivity reactions occur.
in less than ent with		Patients should call a doctor immediately if they get yellowing of the skin or eyes (jaundice), itch all over the body, bruise easily or feel sick or vomit. These may be signs of a possible liver problem. Doctors may do blood tests from time to time to make sure that the patients liver and blood values are within the normal range.
ly, patients white blood 0 people) or in 100 increased		The doctor may do blood tests from time to time to make sure that a patient's blood count is within the normal range. Patients should speak with their doctor, pharmacist or nurse before injecting peginterferon beta-1a if they experience infections or bleeding. They may get worse while using peginterferon beta-1a.

Important potential risks

Risk	What is known
Cardiac (heart) disorders	Worsening of cardiac disease has been reported in patients receiving interferon beta. If patients develop heart problems, which can cause symptoms such as chest pain (angina), particularly after any activity; swollen

Missing information

Risk	What is known
Use in paediatric patients	Plegridy has not been studied in patients under 18 years of age.
Use in older patients	Plegridy has not been studied in patients over 65 years of age.
Effects on pregnancy and use in breastfeeding women	Treatment with Plegridy should not be started in pregnant patients. Patients who could get pregnant should use contraception during treatment with Plegridy. Patients planning to have a baby, or who become pregnant while using Plegridy, should tell their doctor to discuss possible treatment discontinuation. Patients wishing to breastfeed while using Plegridy should speak with their doctor first.

Results from pilot testing

Suggested interest

Media interest

- Press release on first publication
  14088 viewings.
- **Followed by various media mentions**
  industry-focused media

External request for RMP summaries

- From generic companies
- From consultancy and regulatory intelligence companies

Requests for access to documents

- ***27*** **requests** (Jan-Sep 2013)
- ***84*** **requests** (Jan-Sep 2014)
- ***144*** **requests** (Jan-Aug 2015)

Patients and Consumers organisations

23 out of **36** responses

Healthcare professionals' organisations

26 out of **29** responses

Feedback from patients and healthcare professionals

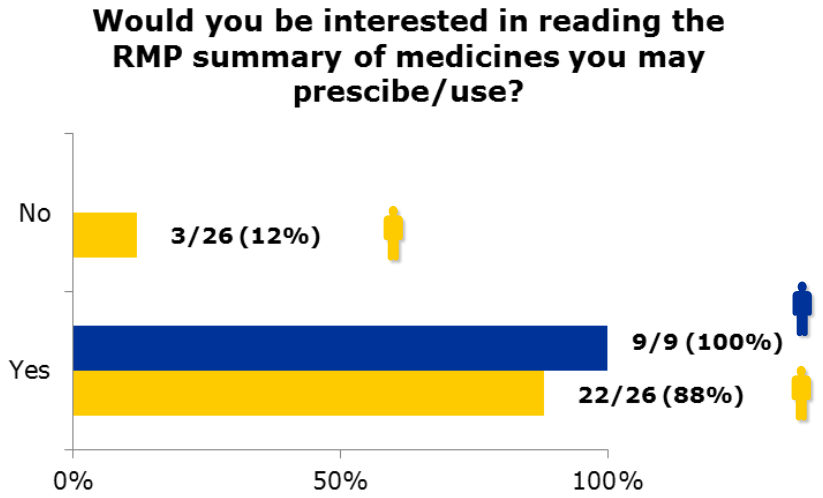
Individual patients

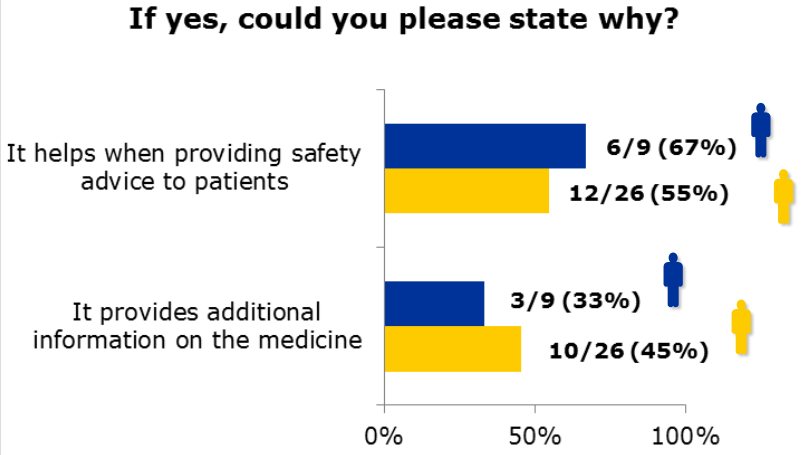
8 responses

Individual healthcare professionals

9 responses

Healthcare professionals' interest in RMP summaries

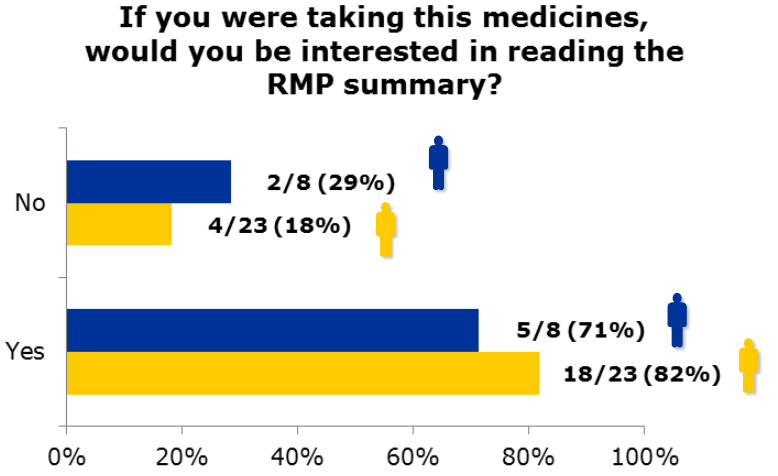


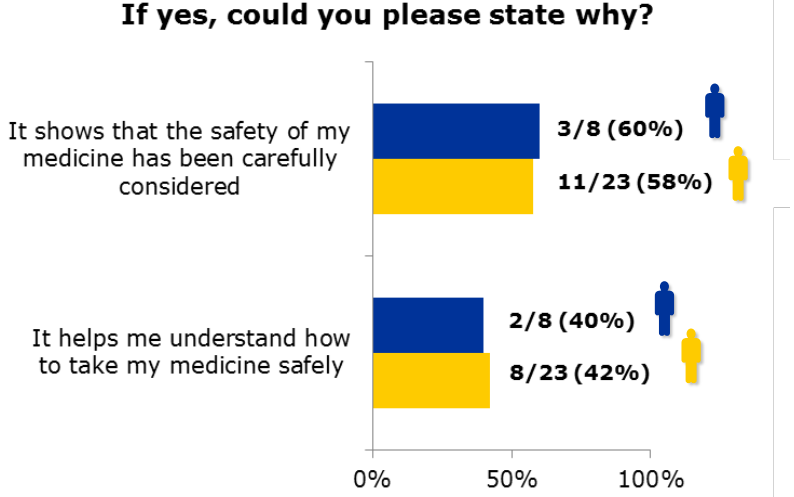


Healthcare professionals' organisations

Individual healthcare professionals

Patients' and consumers' interest in RMP summaries





Patients and Consumers' organisations

Individual patients

Feedback for industry

- Overall, industry welcomes transparency
- Divergent views on usefulness (innovative *vs* generics)
- Welcomes process improvement (simplification)

Proposed way forward

- Interest from stakeholders seen
- Refocus target audience
  - Not in plain language
  - Still clearly written and presented
  - For patients, priority is given to PL & EPAR summary; RMP summary to remain a secondary source of information, for those who want to know more about their medicines

Next steps

- Template update - in progress
- GVP module revision
- Imminent public consultation
- Full implementation (including publication of updates in 2016)

New information on Periodic Safety Update Reports (PSURs)

- PSUR - *a pharmacovigilance report submitted regularly by the company at defined time points following a medicine's authorisation*
- Assessed by PRAC and CHMP/CMDh
- Outcome is to be published on the EU medicines web portal
- EMA website - interim solution

New information on Periodic Safety Update Reports (PSURs)

- Outcome of PSUR assessment for **centrally approved medicines**:
  - Published as part of the EPAR
  - Brief summary of recommendation is published following CHMP meeting (as part of the CHMP meeting highlights)
  - Also, EMA may publish:
    - assessment report
    - public safety communication

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24 July 2015
EMA/38584/2015
Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 20-23 July 2015

Name of medicine	INN	Scope
Aluvia	lopinavir / ritonavir	CHMP opinion to update the section 4.4 of the SmPC to indicate that strong CYP3A4 inhibitors such as protease inhibitors may increase bedaquiline exposure and thus related adverse events. Therefore, combination of bedaquiline with these medicines should be avoided.
Filgrastim Hexal and Zarzio	filgrastim	CHMP opinion to revise the wording related to the warning for latex-sensitive individuals in section 4.4 of the SmPC to indicate that the removable needle cap of the pre-filled syringe contains a derivative of natural rubber latex. Although no natural rubber latex has to date been detected in the removable needle cap, the use of filgrastim solution for injection in pre-filled syringe in latex-sensitive individuals has not been studied and thus there is a potential risk for hypersensitivity reactions that cannot be completely ruled out.

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Recommendation to restrict the use of Protelos / Osseor (strontium ranelate)

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Press release

26/04/2013

Recommendation to restrict the use of Protelos / Osseor (strontium ranelate)

CHMP confirms recommendation from the PRAC

The European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has recommended a restriction in the use of the osteoporosis medicine Protelos / Osseor, following an assessment of data showing an increased risk of serious heart problems. The CHMP recommended that Protelos / Osseor should only be used to treat severe osteoporosis in postmenopausal women at high risk of fracture and severe osteoporosis in men at increased risk of fracture. Additional measures, including restrictions in patients with heart or circulatory problems, were also recommended to minimise the heart risks of these medicines.

The CHMP recommendation is based on the advice of the Pharmacovigilance Risk Assessment Committee (PRAC), which evaluated Protelos / Osseor as part of a routine benefit-risk assessment. During the assessment, data from clinical studies in post-menopausal women were evaluated, showing a higher risk of heart attack with Protelos / Osseor than with placebo, with no observed increase in mortality risk. Given the other serious risks (blood clots and rare serious skin reactions) previously identified with the medicine, the PRAC concluded that certain restrictions in the use of the medicine should be in place for the benefit-risk balance to remain favourable and that a further in-depth evaluation of the benefits and risks of the medicine was needed.

The CHMP agreed with the PRAC's recommendations and this opinion will be sent to the European Commission for a legally binding decision. A further wide-ranging evaluation of the benefits and risks of Protelos / Osseor will now be conducted by PRAC and CHMP. In the meantime, the current recommendations are intended to minimise the risk of serious heart problems.

Related information

- Osseor: EPAR
- Protelos: EPAR
- Protelos: Withdrawn application
- Osseor: Withdrawn application
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 April 2013 (26/04/2013)
- European Medicines Agency confirms positive benefit-risk balance of Protelos / Osseor, but recommends new contraindications and revised warnings (16/03/2012)

Contact point:

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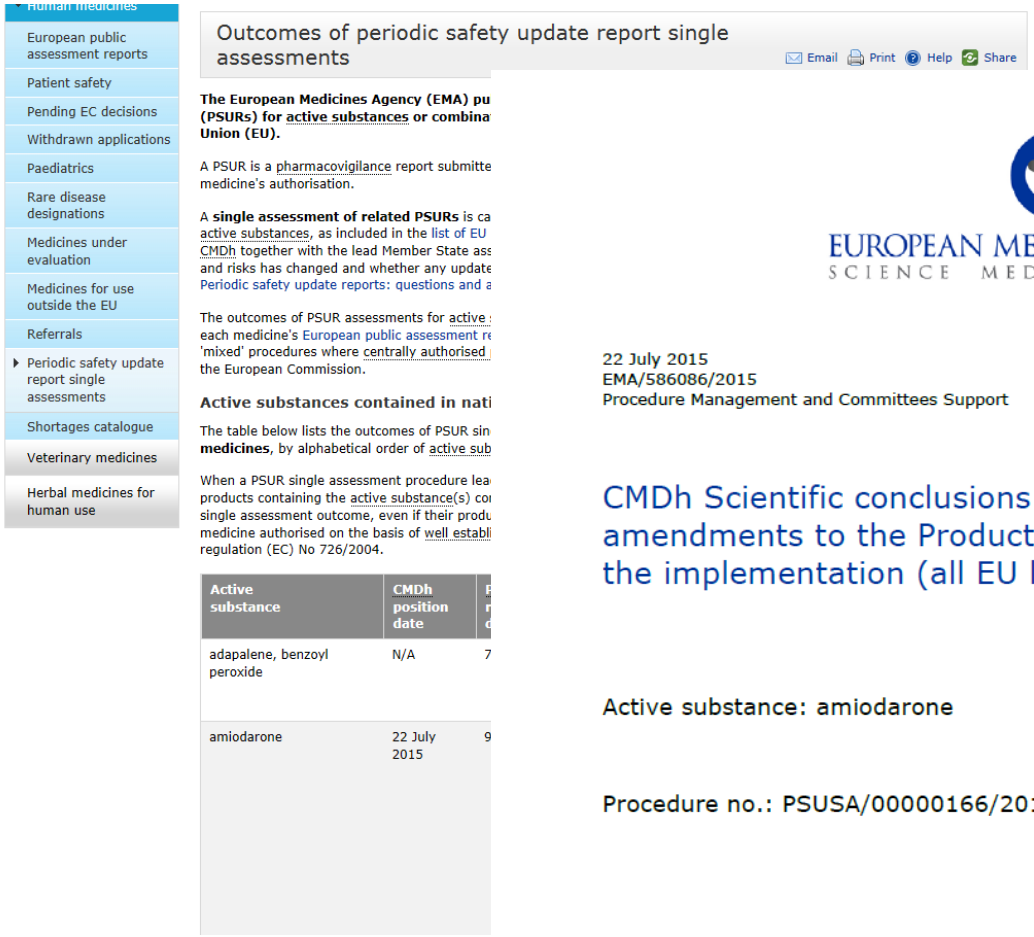
New information on Periodic Safety Update Reports (PSURs)

- Outcome of PSURs single assessment for active substances contained in **nationally authorised medicines**:
  - New EMA page created
  - Maintenance/variation
  - List of authorised medicines (in the different MSs)
  - Scientific conclusions *(in all EU languages)*
  - Product Information update *(in all EU languages)*
  - Timetable for implementation *(in all EU languages)*



- 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
- Periodic safety update report single assessments
- Shortages catalogue
- Veterinary medicines
- Herbal medicines for human use

Outcomes of periodic safety update report single assessments

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The European Medicines Agency (EMA) pu
(PSURs) for active substances or combina
Union (EU).

A PSUR is a pharmacovigilance report submitte
medicine's authorisation.

A **single assessment of related PSURs** is ca
active substances, as included in the list of EU
CMDh together with the lead Member State ass
and risks has changed and whether any update
Periodic safety update reports: questions and a

The outcomes of PSUR assessments for active
each medicine's European public assessment re
'mixed' procedures where centrally authorised
the European Commission.

Active substances contained in nati

The table below lists the outcomes of PSUR sin
medicines, by alphabetical order of active sub

When a PSUR single assessment procedure lea
products containing the active substance(s) co
single assessment outcome, even if their produ
medicine authorised on the basis of well establi
regulation (EC) No 726/2004.

Active substance	CMDh position date	
adapalene, benzoyl peroxide	N/A	7
amiodarone	22 July 2015	9

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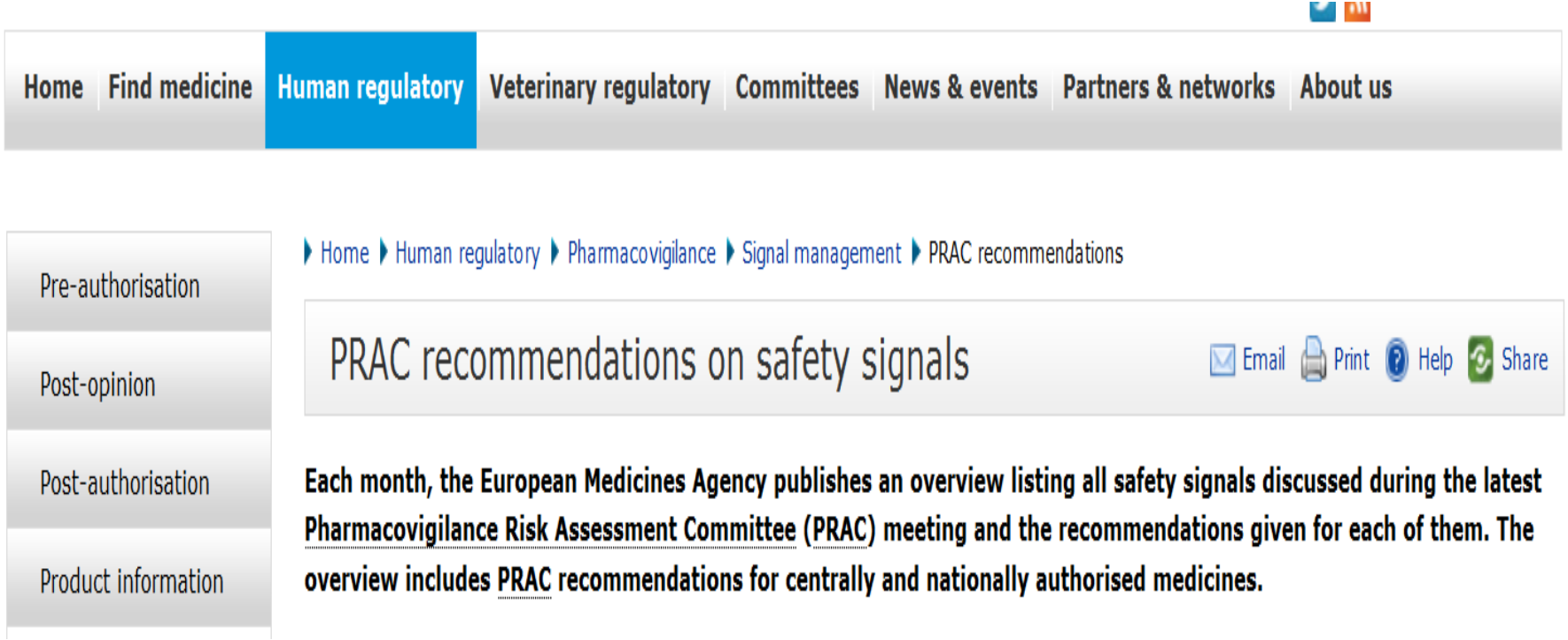
22 July 2015
EMA/586086/2015
Procedure Management and Committees Support

CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation (all EU languages included)

Active substance: amiodarone

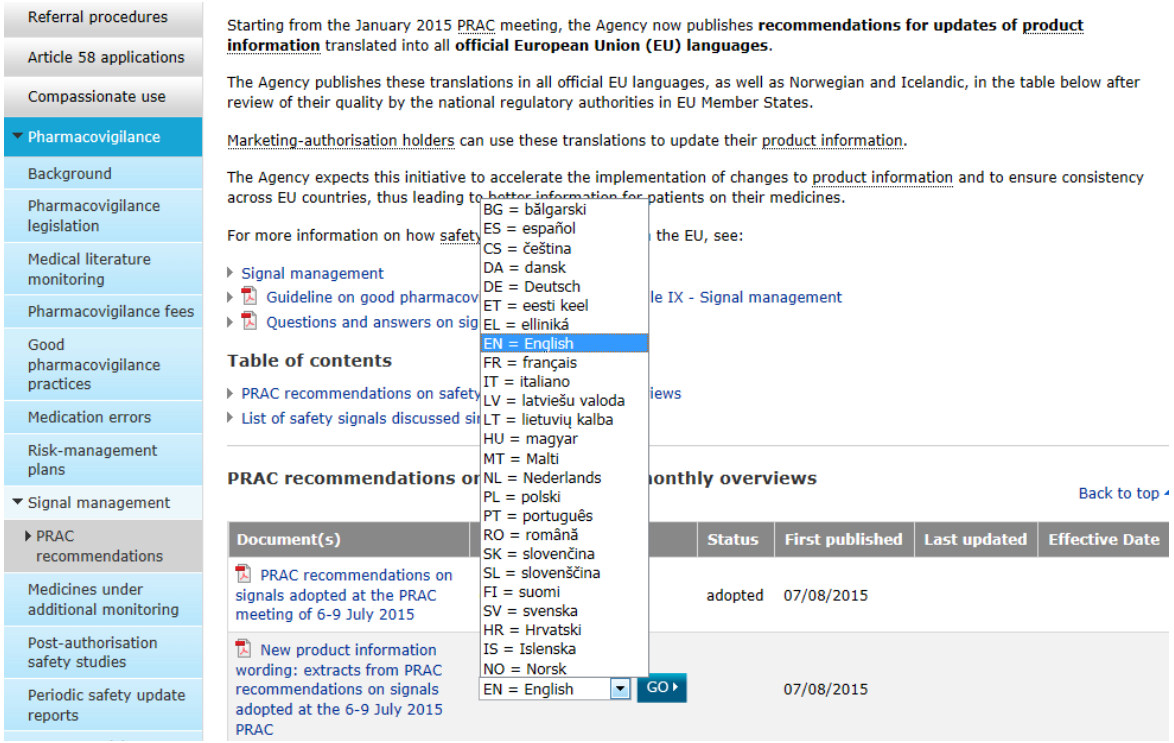
Procedure no.: PSUSA/00000166/201412

New information on signals



Translations of PRAC recommendations for PI update

- reduction of admin burden and costs to facilitate consistent implementation



Overview of all signals discussed at PRAC

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An agency of the European Union

27 February 2015
EMA/PRAC/530804/2013
Pharmacovigilance Risk Assessment Committee

List of signals discussed at PRAC since September 2012

INN	Signal	PRAC meeting	Update of product information recommended by PRAC
Abatacept	Angioedema	06-09 January 2014 PRAC meeting minutes	No
Adalimumab	Dermatomyositis	03-05 September 2012 PRAC meeting minutes	No
Adalimumab	Dermatomyositis	26-29 November 2012 PRAC meeting minutes	Yes[1]
Adalimumab	Dermatomyositis	13-16 May 2013 PRAC meeting minutes	Yes[1]
Adalimumab	Glioblastoma and other brain neoplasms	08-11 April 2013 PRAC meeting minutes	No

Conclusions

- EMA committed to full transparency (not only for pharmacovigilance)
- Aiming at achieving the best balance between transparency and good communication
- Looking both at patients' as well as at regulatory needs
- Listen to stakeholders' needs and adapt accordingly, while serving the EU network in supporting its work
- Need to continuously evaluate impact and utility

Thank you for your attention

Further information

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