EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication on medicine shortages

Inga Abed
PCWP/HCPWP joint meeting
5 June 2013

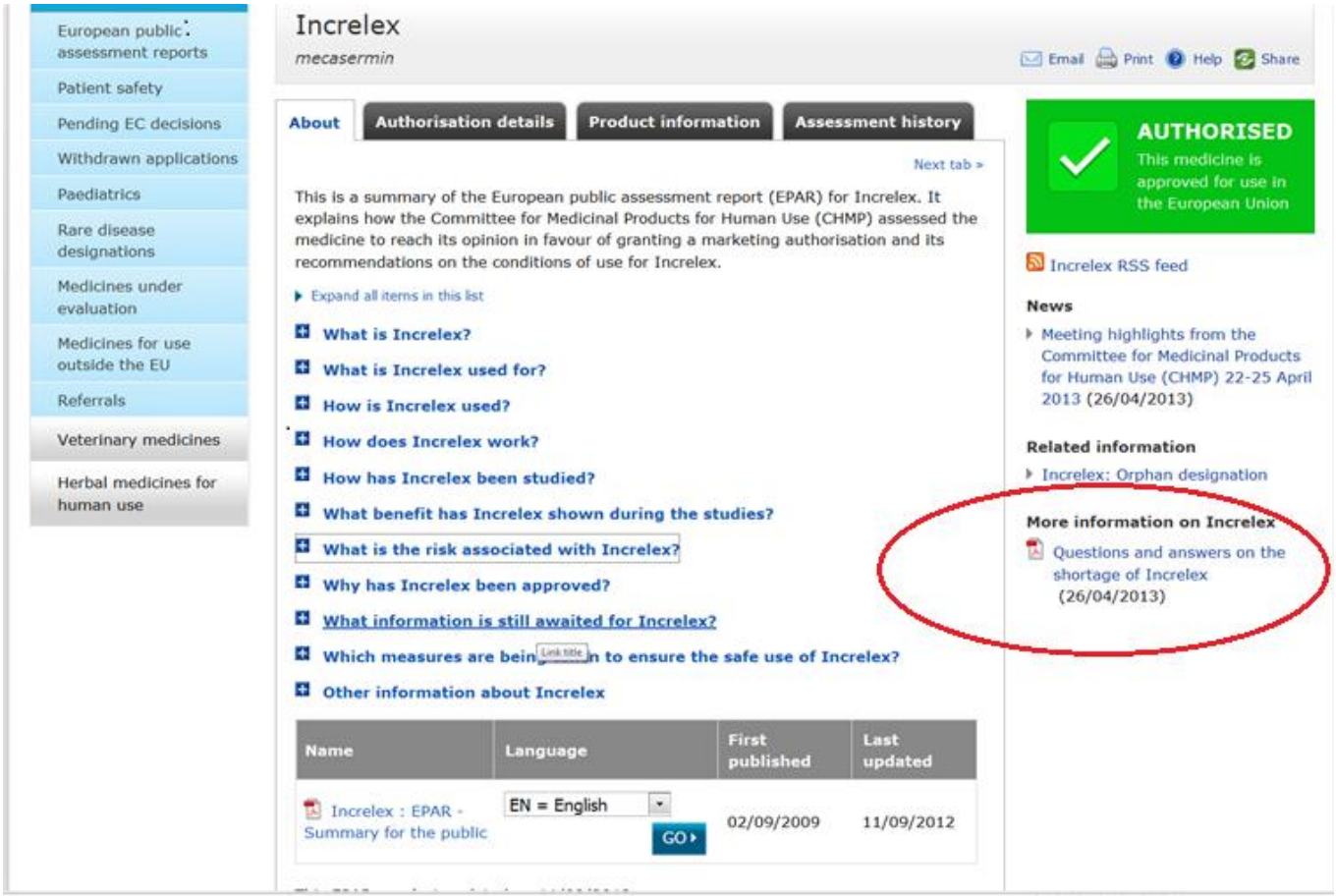
Introduction

Review of EMA communication on shortages was part of the EMA initiative on medicine shortages

Current situation

- Agency communicates on shortages using existing high-profile communication tools (PRs and Q&As)

- Communication is decided on a case by case basis and not always consistent


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Withdrawn applications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
Increlex
mecasermin
Email
Print
Help
Share
About
Authorisation details
Product information
Assessment history
Next tab »
This is a summary of the European public assessment report (EPAR) for Increlex. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Increlex.
Expand all items in this list
What is Increlex?
What is Increlex used for?
How is Increlex used?
How does Increlex work?
How has Increlex been studied?
What benefit has Increlex shown during the studies?
What is the risk associated with Increlex?
Why has Increlex been approved?
What information is still awaited for Increlex?
Which measures are being taken to ensure the safe use of Increlex?
Other information about Increlex
Name
Language
First published
Last updated
Increlex : EPAR - Summary for the public
EN = English
GO
02/09/2009
11/09/2012
AUTHORISED
This medicine is approved for use in the European Union
Increlex RSS feed
News
Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 April 2013 (26/04/2013)
Related information
Increlex: Orphan designation
More information on Increlex
Questions and answers on the shortage of Increlex (26/04/2013)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2013
EMA/250270/2013
EMEA/H/C/000704

Questions and answers

Questions and answers on the shortage of Increlex (mecasermin)

The European Medicines Agency has been notified of manufacturing problems with Increlex and stocks will run out in all EU Member States where it is marketed[1] from early August 2013. While existing stocks last the Agency's Committee for Medicinal Products for Use (CHMP) is recommending that Increlex should be reserved for patients already receiving treatment with Increlex and that no new patients should be started. Once stocks have run out, patients may have to be regularly reviewed by their treating physicians while they are not receiving Increlex. Every effort is being made to ensure that normal supply is resumed as soon as possible in the interest of patients.

What is Increlex?

Increlex is used as an injection under the skin for the long-term treatment of patients aged two to 18 years who are of short stature due to a condition known as 'severe primary insulin-like growth factor-1 deficiency'. Patients with this condition have low levels of the hormone insulin-like growth factor-1 or IGF-1, which is required for normal growth.

Increlex received a marketing authorisation valid throughout the European Union on 3 August 2007. It is available in the following Member States: Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxemburg, the Netherlands, Poland, Portugal, Slovakia, Sweden, Spain, the United Kingdom, as well as Norway.

[1] Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxemburg, the Netherlands, Poland, Portugal, Slovakia, Sweden, Spain, the United Kingdom, as well as Norway.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

What is the cause of the supply problem and how long will it last?

The company that markets Increlex, Ipsen Pharma, informed the Agency that problems at the manufacturing site in the USA have led to an interruption in the manufacture of the active substance and will lead to a worldwide shortage in the supply of Increlex. Existing stocks are expected to run out by early August 2013 in all EU member states where Increlex is marketed. The problems are linked to equipment failures at the site which are currently being addressed by the company. Although the duration of this shortage is unknown, new supplies are not anticipated before the end of 2013.

What are the recommendations of the CHMP during the shortage period?

The CHMP has agreed that the company should provide a letter to healthcare professionals in the countries where Increlex is marketed, informing them of the shortage in their country and that there are no alternative treatment options available in the absence of Increlex. Treating physicians are advised to review patients as appropriate when their treatment has to be interrupted. Limited data suggest that it is possible to stop and restart treatment with Increlex without significant concerns. Treatment interruption of short duration is not expected to have relevant long-term consequences (such as an impact on the final height).

The Committee is working closely with the company to ensure that normal supply is resumed as soon as possible in the interest of patients.

What are the recommendations for patients?

- Patients are informed of an upcoming shortage of Increlex.
- There will be a period during which Increlex will be unavailable. During this period you may have to be regularly reviewed by your doctor. Available evidence suggests that it is possible to stop and restart treatment with Increlex without significant concerns. A treatment interruption of short duration is not expected to have relevant long-term consequences (such as an impact on the final height).
- Patients who have any questions should speak to their doctor or pharmacist.

What are the recommendations for prescribers?

- Healthcare professionals will receive detailed information on the shortage of Increlex in their country.
- No new patients should be started on Increlex until normal supplies are re-established. While existing stocks last Increlex should only be given to continue the treatment of patients already being treated with Increlex.
- There are no alternative treatment options for 'severe primary insulin-like growth factor-1 deficiency'. When stopping treatment hypoglycaemia could re-occur in patients (especially young children) who experienced hypoglycaemic episodes before starting treatment with Increlex. Patients may therefore have to be monitored as appropriate.
- EMA will be working closely with the company and will keep the supply situation under review. Any further advice will be communicated, as appropriate.

The current European public assessment report for Increlex can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

Q&As/PRs are not optimal tools

- Situation does not always justify a Q&A/PR
- No systematic follow-up and communication for resolution of shortages

Proposal for optimising communication on shortages

- Public catalogue on dedicated webpage with links to/from EPAR page
- For centrally authorised medicines and medicines involved in referrals
- Information will be up-dated when shortage is resolved

Criteria for communication

In cases where all of the following conditions are met:

- Shortage affects centrally authorised medicines or nationally authorised medicines in a referral procedure
- Shortage affects more than one EU Member State
- Assessment by PRAC and CHMP/CMDh with recommendations via DHPC

NOT all shortages will be listed in the table

Information to be included:

- Brand name
- Indication
- Reason for shortage (raw materials, supply chain issues, business decisions)
- Likely extent (which presentations are affected, in several Member States/ all Member States;)
- Information to HCPs (based on DHPC)
- Information to patients (based on DHPC)
- Status of shortage (ongoing or resolved)

Example

Simponi (golimumab) prefilled pen and syringe 50 mg	
Indication	Treatment of adults with: • active rheumatoid arthritis, • active and progressive psoriatic arthritis • severe active ankylosing spondylitis
Reason for shortage	February 2011: Reduced manufacturing capacity due to manufacturing defect of the device affecting some batches of pre-filled pens which led to a partial recall of a batch in Germany.
Presentations and Member States affected* * This information is accurate at time of last update and may change. For accurate information about the status of a medicine shortage in a particular member state the national competent authority should be contacted.	Shortage of cartridges and prefilled pens affected all EU countries where Simponi is marketed.
Information to HCPs	• In countries affected by a shortage, HCPs to receive a letter from MAH. • During shortage, no new patients should be started on the prefilled pens and patients currently on pre-filled pens may need to be switched to the pre-filled syringe or alternative treatments. • Additional advice may be available from your national competent authority.
Information to patients	• There are no safety or quality concerns for products remaining on the market • Patients will be informed by their HCP if their treatment is affected by shortage. • In these cases doctors will prescribe alternative treatments. • Additional advice may be available from your national competent authority.
Status	• Resolved
Date of last update	• May 2012

Publication and dissemination of information

- Information published once nationally tailored DHPCs have been sent out in one or more Member States
- Information disseminated to relevant PCOs and HCP organisations using newsletter

Conclusion

- Catalogue will replace the need for PR and Q&A in most cases
- Catalogue will ensure a more consistent approach and information provided will be:

➢ Concise

➢ Relevant

➢ Up-to-date

➢ Easy to find when needed