EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Outcome of consultation on additional monitoring of medicines and ADR reporting – impact on the product information

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG) Joint Meeting
28th February 2012

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# Outcome of the consultation
# Impact on the product information

- Introduction
- Consultation on the draft proposals
  - Feedback from consultation with stakeholders
  - Feedback from internal consultation
- Next steps

# Introduction
# Implementation of the PhV legislation

- There are certain aspects of the implementation of the new pharmacovigilance (PhV) legislation, which have an impact on the product information:
  - **Additional monitoring of medicines:** Black symbol and standardised explanatory sentence to be included in the summary of the product characteristics (SmPC) and in the package leaflet (PL) for medicinal products subject to additional monitoring.
  - **Encouragement of side effects reporting for all medicines:** Standardised text to encourage adverse reactions reporting to be included in the summary of the product characteristics (SmPC) and in the package leaflet (PL).

# Introduction
# Steps taken to develop the draft proposals

- The Quality Review of Documents (QRD) group, together with the Medical Information Sector at the EMA, has worked on the **draft proposals** to be implemented in the product information.
  - First draft agreed in November 2011.
- December 11 - Consultation on the draft proposal with patients, consumers and healthcare professionals organisations.
- January/February 2012 – Further internal consultation on the draft proposals.
- 28 February 2012 – Status update PCWP/HCP WG Joint meeting.

# Introduction
# List of participants in the consultation

## Patients and consumer's organisations

- FIN – Fabry International Network
- Eurordis – Rare Disease Europe (2 representatives)
- ENFA - European Network of Fibromyalgia Associations
- EMP – European Myeloma Platform
- BEUC – The European Consumer's Organisation

## Healthcare professionals' organisations

- EUGMS - European Union Geriatric Medical Society

## Internal consultation

- 1 EMA and 9 Member States

# Black symbol and explanatory sentence on additional monitoring

# Draft proposal

Draft proposal to cover the following aspects:

- Selection of a **black symbol**.
- **Location** within the product information of the symbol + “This medicinal product is subject to additional monitoring” + the standardised explanatory sentence.
- **Definition of the standardised explanatory sentence**; which should follow the statement “This medicinal product is subject to additional monitoring”.

# Selection of the black symbol
# Summary draft proposal

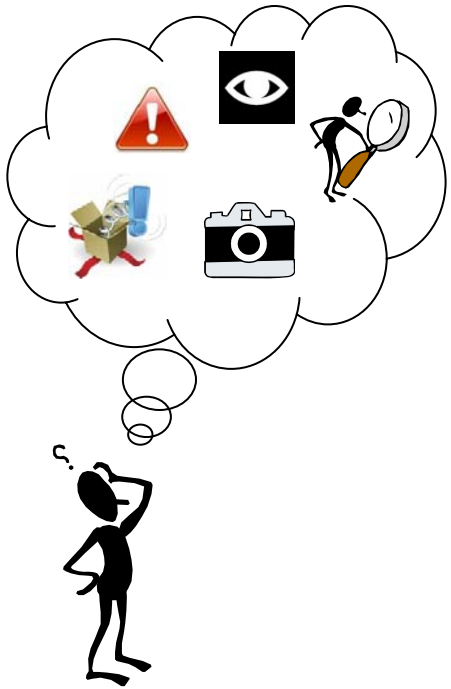
PRAC will receive the following information:

- Draft proposal:
  - The Member States endorsed the UK symbol (inverted black triangle), as the **preferred choice** of the Group.
  - If an alternative proposal is to be developed, the magnifying glass was considered the **second best option**.
- General information provided by the Member States
  - Symbols already in use to identify products under intensive surveillance.
  - Examples of established symbols, which may pose a risk of confusion.
  - Alternative symbols proposed by the Member States.

# Selection of the black symbol
# Points for consultation

The following feedback has been requested as part of the consultation:

- **Feedback on the use of the inverted black triangle** (▼), as per the Member States preferred choice.
- **Feedback on the use of other alternative symbols** proposed by the Member States.
- **To provide alternative symbols** which could be developed to identify products under additional monitoring.



# Selection of the black symbol
# Outcome consultation with the stakeholders

(1) Would you have any objections to use a '**black inverted triangle'**?

- One organisation supports the black inverted triangle (1/7).
- No comments (1/7).
- Maybe (1/7).
- Objections (4/7):
  - 'Too vague', 'no immediate meaning' and no 'eye catching'.
  - It does not suggest the action of 'monitoring'.
  - Such symbol has been previously used in another context rather than to identify PhV activities.

# Selection of the black symbol
# Outcome consultation with the stakeholders

(2) Would you agree to use any of the **alternative symbols** proposed by the Member States?

- No comments (1/7).
- Magnifying glass (4/7).
  - One of the organisations stated that the magnifying glass expresses well that the product is under surveillance but should be tested to avoid confusion i.e. symbol to identify medicines for ophthalmic use.
- Triangle with exclamation mark (1/7).
- Magnifying glass or eye (1/7).

# Selection of the black symbol
# Outcome consultation with the stakeholders

(3) Would you have any **other suggestions** for the 'black symbol'?

| | |
|---|---|
| Black triangle with an eye inside |  |
| Traffic lights |  |
| Capsule behind magnifying glass |  |
| Non-inverted triangle with capsule inside |  |
| Vigilant eye with capsule inside |  |
| Banner (indicating 'work in progress') |  |
| Traffic cone (indicating 'work in progress') |  |
| Video surveillance |  |
| Hand icon |  |

# Selection of the black symbol
# Outcome internal consultation

(1) Would you have any objections to use a '**black inverted triangle'**?

- No comments (2/10).
- No objections (5/10).
- Objections (3/10).
  - 'Not self-explanatory', it does not suggest any 'monitoring action' and it is not 'eye catching'.
  - To develop a unique symbol with a close link to the additional monitoring.
    - Symbol to be user tested!
  - Based on the views expressed by patients organisations.

# Selection of the black symbol
# Outcome internal consultation

(2) Would you agree to use any of the **alternative symbols** proposed by the Member States?

- No comments (3/10)
- No (1/10)
- Yes (6/10)
  - But black triangle is the preferred choice (1/10)
    - Magnifying glass as second preference (1/10)
  - Magnifying glass as first preference (4/10)

    - Symbol to be user tested!
    - To implement an additional frame around the symbol to further highlight it.
    - Magnifying glass but without a man holding and without showing any pharmaceutical form inside.

# Selection of the black symbol
# Outcome internal consultation

(3) Would you have any **other suggestions** for the 'black symbol'?

- '*A person with a magnifying glass in hand*' would be self-explanatory.
- Magnifying glass in black <u>without</u> a person, capsule or hand but with black outline (black handle and clear glass).
- The identified preference for a magnifying glass after the consultation with patients, consumers and healthcare professionals is appreciated.
- Important to consider that the symbol is not alarming and meaningful for patients.

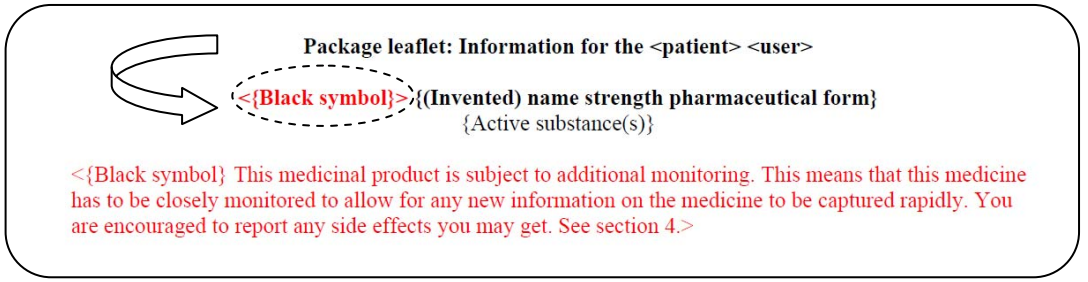
# Selection of the black symbol
# Summary consultation

PRAC will receive the following information:

- **Stakeholders consultation (PCWP and HCP WG)**
  - The consulted stakeholders **did not endorse** the inverted black triangle (only one organisation endorsed it).
  - The preference of the consulted stakeholders would be to develop the magnifying glass, as the **preferred option**.
  - Provision of a list of alternative symbols provided by the stakeholders.
- **Internal consultation**
  - Inverted black triangle: no objections (5/10)/objections (3/10).
  - 3 out of 10 endorsed the magnifying glass, as the preferred option.

# Location of the black symbol
# Outcome consultation

- **Stakeholders consultation (PCWP and HCP WG)**
  - No comments about the location.
- **Internal consultation**
  - Placing the symbol preceding the invented name is not contemplated in the legislation. The black symbol should be followed by 'This product is subject to additional monitoring and an appropriate explanatory statement' (2/10).
    - From a legal point of view it has been confirmed that there are no particular issues in respect of the proposed location. ☑



# Definition of the explanatory sentence Overview consultation with the stakeholders

**Package leaflet: Information for the <patient> <user>**

**<{Black symbol}> {(Invented) name strength pharmaceutical form}**
{Active substance(s)}

<{Black symbol} This medicinal product is subject to additional monitoring. This means that this medicine has to be closely monitored to allow for any new information on the medicine to be captured rapidly. You are encouraged to report any side effects you may get. See section 4.>

- **Comments:**
  - To use '*recognised*' instead of '*captured*'. ?
  - To replace '*additional monitoring*' by '*surveillance*'. ✗
- **Suggestions:**
  - '*This product is under additional monitoring because <u>its safety profile isn't completely known yet</u>*' or ✗
  - '*This product is under additional monitoring in order <u>to better establish its safety profile</u>*'. ✗

# Encouragement of the reporting of suspected adverse reactions

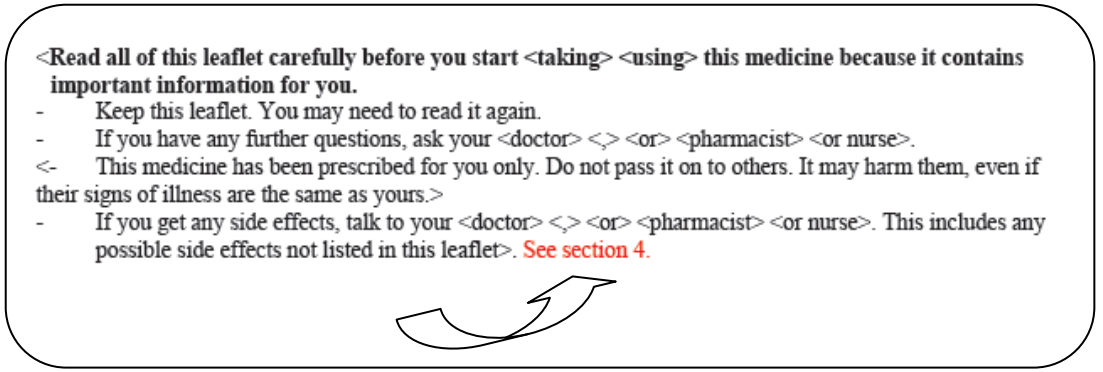
# Draft proposal

Draft proposal to cover the following aspects :

- **Location** of the standard text within the product information.
- Definition of the **standardised text** to be included in SmPC and package leaflet.

# Location standardised text
# Outcome consultation with the stakeholders

- **Stakeholders consultation (PCWP and HCP WG)**
  - One request to include a further reference regarding the reporting of side effects at the beginning of the package leaflet.
    - Implemented. ☑



**<Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor> <,> <or> <pharmacist> <or nurse>.

<- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.>

- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet>. See section 4.

# Definition of the standard text
# Overview consultation with the stakeholders

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**<Additional side effects in children <and adolescents>>**

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly to the national reporting system via <the internet at 'national reporting system website>; alternatively you can report via <alternative reporting systems to be defined at national level>. By reporting side effects you can help to make sure that medicines remain as safe as possible.

- **Comments:**
  - To change the order of the healthcare professionals. ✗
  - To also refer to the '*listed*' side effects. ✗
  - Too much choice regarding the ways of reporting i.e. to the HCP and to the reporting system. ✗

# Definition of the standard text
# Overview consultation with the stakeholders

**4. Possible side effects**

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If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly to the national reporting system via <the internet at 'national reporting system website>; alternatively you can report via <alternative reporting systems to be defined at national level>. By reporting side effects you can help to make sure that medicines remain as safe as possible.

- **Comments:**
  - '*National reporting system*' considered confusing. ☑
  - To replace '*you can help*' by '*you contribute*'. ?
- **Suggestion:**
  - 'By reporting side effects you can help *collect more information on the safety of this medicine*'. ☑

# Definition of the standard text Points for further discussion


- Additional monitoring
  - Textual changes
    - To further link the explanatory statement with the side effects reporting.
    - The use of '*expected*' or '*requested*' instead of '*encouraged*'.
    - The use of '*way*' instead of '*tool*'.
  - To merge '*This medicinal product is subject to additional monitoring*' with the explanatory statement.
- Encouragement of side effects reporting
  - Textual changes
    - To avoid using '*national reporting system*'.
    - Inclusion of the details for alternative formats of reporting also in the SmPC.
    - Re-wording last sentence standard text.
  - Location: to move the standard text at the beginning of the sections.

# Development of the proposals
# Next steps

- 1 March 2012 - Status update to the QRD group.
- April 2012 - Short external consultation (1 month).
- 24 May 2012 – Finalisation of the proposals with the QRD group.
- Final proposal and collated information to be provided to the Pharmacovigilance Risk Assessment Committee (PRAC).

# Thank you!