



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Additional monitoring – proposals on the black symbol for SmPC and package leaflet

PCWP/HCP WG Joint meeting
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An agency of the European Union





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Legal basis

Black symbol and additional monitoring

- For medicinal products for human use subject to additional monitoring:
 - The summary of product characteristics and the package leaflet shall include the statement **“This medicinal product is subject to additional monitoring”**. That statement shall be preceded by a **black symbol** which shall be selected by the Commission following a recommendation of the Pharmacovigilance Risk Assessment Committee by 2 January 2012*, and shall be followed by an appropriate standardised **explanatory sentence** (Art. 11 and 59 of Directive 2001/83/EC and Art. 23(5) of Regulation (EC) No 726/2004).

**Proposal to amend the date to 2 July 2013.*



Impact of the new legislation in the product information

- The Quality Review of Documents (QRD) group has worked on draft proposals to be implemented in the product information covering the following aspects:
 - **To identify a black symbol**
 - ✓ To assist PRAC when drafting the recommendation on the black symbol for the EC.
 - **To specify the location** of the symbol and the new standardised statements within the QRD human product information template.
 - **To define the wording** for the new standardised statements.
 - ✓ Additional monitoring.
 - ✓ Encouragement of the reporting of adverse reactions.



Identification of the black symbol

QRD proposal

- The QRD group agreed to propose the **inverted black triangle (▼)**, as the preferred choice.
 - Symbol already in use in two Member States (Belgium and United Kingdom).
 - No clash with other symbols already established.
 - Measurements and design already set up.
- As an alternative proposal, the development of a symbol resembling a **magnifying glass** was considered by the QRD group to be the second best option.
 - Design needs to be agreed and cost involved.



Identification of the black symbol

Summary feedback consultation

- **Inverted triangle**

Pros	Cons
✓ Abstract symbol (not linked to any meaning/connotation) - less likely to cause confusion or alarm to patients.	✓ 'Not self-explanatory', it does not suggest any 'monitoring action', not 'eye catching' and 'not able to convey the message of additional monitoring'.
✓ Solid representation and easy to reproduce in a consistent manner.	✓ Triangular shape used to identify other activities at national level (e.g. warnings).
✓ Symbol is already in use in two Member States for similar PhV activities.	✓ To develop a brand new symbol only linked to the concept of additional monitoring.
✓ No clash with other symbols already established for pharmaceuticals.	✓ Similar symbols have been previously used in other (non-medical) contexts.
✓ Measurements/design already set up.	



Identification of the black symbol

Examples implementation – inverted triangle

- Examples of current electronic implementation of the inverted triangle in UK and Belgium:

- Electronic Medicines Compendium (eMC)**

1. Name of the medicinal product

ELIQUIS ▼ 2.5 mg film-coated tablets

- Centre Belge d'information pharmacothérapeutique (CBIP)**

Apixaban

Eliquis (Bristol-Myers Squibb) ▼ ▲

[apixaban]
compr.

	€	20 x 2,5mg	R _x	b!	€ 49,30
	€	60 x 2,5mg	R _x	b!	€ 131,85

Posol. 5 mg p.j. en 2 prises



Identification of the black symbol

Summary feedback consultation

- **Magnifying glass**

Pros	Cons
✓ More visual and meaningful symbol to convey the 'additional monitoring' idea and support the 'explanatory sentence'.	✓ Design needs to be agreed, involving a cost.
	✓ Used to identify the search tool on websites.
	✓ Difficult to recognise by visually impaired patients: less black and less visible upon first glance.
	✓ Difficult to reproduce in a consistent manner from a technical viewpoint
	✓ The specific measurements may require more space than the inverted triangle.
	✓ In the UK, the magnifying glass is used to request leaflets with larger text (symbol user tested for such purpose).



Identification of the black symbol

Examples current use of the magnifying glass

- Search tool on websites:



- To request leaflets with larger text (UK):



If you would like a
leaflet with larger
text, please contact
01271 311257.





Identification of the black symbol

Examples implementation – magnifying glass

- Examples implementation of a magnifying glass in leaflets:



08977/0002

PATIENT INFORMATION LEAFLET FOR
♂ ASPIRIN 300MG TABLETS

This leaflet provides important information about your medicine. Please read it carefully before you start taking Aspirin 300mg tablets.

What is in your medicine?
Your medicine is called Aspirin 300mg tablets and are circular white tablets. Each tablet contains 300mg of the active ingredient Aspirin. Each tablet also contains potato starch, lactose and talc. Aspirin belongs to a class of medicines called non-steroidal anti-inflammatory drugs and has anti-inflammatory, pain relieving and temperature reducing properties.

What is this medicine for?
For the relief of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains, and the relief of the symptoms of cold and flu. Also for the relief of sprains, strains, rheumatic pain, sciatica, lumbago, muscular aches, fibrositis, joint swelling and stiffness.

Who makes this medicine?
The product licence holder: Aspar Pharmaceuticals Ltd, London, NW9 0EQ.



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Identification of the black symbol

Summary feedback consultation

- Additional comments provided during the consultation:
 - Communication
 - ✓ Awareness campaign to promote the recognition of the symbol
 - ✓ Education is crucial to ensure that the concept is well understood.
 - User testing
 - ✓ The short-listed symbols need to be tested with members of the public.



PRAC recommendation

What is the EC expecting from PRAC?

- EC expects the recommendation of the PRAC by the end of 2012.
- EC wishes to receive a concrete and mature proposal for the black symbol from the PRAC.
 - Concrete symbol and size (not a concept to be developed).



PRAC recommendation

Proposed timelines

- PRAC September 2012
 - Introduction of the two preferred options for the black symbol proposed by the QRD group and feedback from the consultations on the proposal.
- PRAC October 2012
 - Presentation of PCWP/HCP WG views.
 - Further discussion and agreement on the concept regarding the black symbol and on the specifications (shape, form, design...).
- PRAC November-December 2012
 - To finalise the PRAC recommendation and provide it to the Commission for the final selection.



PRAC recommendation

Patients, consumers and HCP's views

- It is essential to hear the patients, consumers and healthcare professionals' voice regarding the black symbol prior to finalising the PRAC recommendation.
- A representative from the PCWP and HCP WG will be invited to the PRAC meeting (1-3 October 2012) to present the views on the two proposals for the black symbol.



Thank you!