EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

PRODUCT INFORMATION
Recommendations and Proposals for Action

TOPIC LEADER: Mrs Mary Baker (EFNA)

Presentation by:-
Mrs Lesley Greene: Eurordis and Climb
Mrs Hilde Boone EMEA

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⌘ Recommendations are divided into three sections

- Those that can be implemented by the EMEA within the current legal framework
- Those requiring a harmonised approach at EU level
- Those that would require amendments to the current legal framework before implementation

⌘ Here "product Information" refers to "Package Leaflets". These recommendations are directed at the Package Leaflet which reflect the product's agreed use by the competent authority that licensed the product
⌘ Other reliable sources of information, while recognised and valued, are not addressed in these recommendations

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Recommendations implementable within the current legal framework

- Companies using the centralised licensing route should involve patients associations in drafting the PL at an early stage
- Patient Associations could be involved in Readability Testing
- Patient Associations could be involved in the work of the Quality Review of Documents Group of the English PL at the Day 150 meeting

To do that

- o EMEA website include list of European Patient websites and NA website links
- o A national organisation or consumer group representative would be invited where there is no EU equivalent. All representatives would sign confidentiality agreement
- o A voluntary trial period to test process with companies

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Current framework (Contd)

- The PL of a centrally authorised product should refer to EMEA website which contains latest information on product (EPAR)

To do that

- o Place reference to EMEA website at end of PL
- The PL for Orphan Drugs only, where appropriate, should include reference to Eurordis website as well as EMEA website.

To do that

- o Include a statement e.g." General information on rare diseases is available from Eurordis at www. eurordis.org"

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Current framework (contd)

- There should be a mechanism enabling patients to send comments to EMEA on the readability/quality of its PLs (e.g. There could be a statement saying "to send your opinion, click here) Relevant feedback will be compiled and provided to the MAH

To do that

- The EMEA should review and filter feedback received, liaising with MAH and relevant Patient Associations.

- Changes made to the PL should be identified clearly

To do that

- Add tabulated tracking sheet to EPAR with overview of chronology of PL and its revisions
- Have clear, simple indication at end of PL indicating which sections last revised (e.g. Section 2:Pregnancy)-amend PL template

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Current framework(contd)

- Only Local Representative(s) relevant to MS(s) where pack is marketed should be listed at end of printed PL. Inclusion of all member state MA holders is not considered helpful or a valid use of space.
- Only the manufacturer responsible for the release of the actual batch should be included in the printed PL. This avoids confusion in the case of different manufacturers being authorised.

To do that

- Amend PL template

- New, updated draft guidelines on the EMEA website that are relevant to Product Information, should be flagged to patient and health care professional associations

To do that

- An electronic mailing list should be set up and a system to identify which guidelines should be sent.

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Recommendations requiring a harmonised approach at EU level before implementation

- The PL of a specific product should give same information to all patients in EU, both for those products approved via Mutual Recognition Procedure as well as the Centralised procedure
- Standardised requirements should apply across EU

To do that

- Available guidance on standardised structure and format of PL could be further developed
- Different language versions of the same PL should allow for flexibility of regional translation while maintaining the core meaning
- Companies, authorities (patient organisations?) should work together to ensure good quality translations

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Harmonised approach (contd)

- The readability of the PL should be increased

To do that

- Companies should be encouraged to perform readability testing and increase the font-size of printed PLs
- Guidance on such issues should be developed when reviewing the Guideline on Readability

- To provide a good balance between BENEFIT and RISK;

To do that

- the benefits to be more prominent, expanded and better explained without promotional claims to improve concordance, especially for long term treatment/prevention

- The text should distinguish between PREVENTION &TREATMENT

To do that

- PL should explain need to discuss potential results of stopping treatment with doctor/pharmacist first and also when expected benefit of product is not achieved

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Harmonised approach(contd)

- Review the Commission's Guidelines on Readability (1998) with involvement of patient associations at an early stage.

To do that

o Working group to be set up involving people with different expertise

- Develop further the specified aim that "Results of consultations with target patient groups should be reflected in the PL" (Directive 2001/83)

- The inclusion in the PL of clear unambiguous symbols harmonised across the EU to aid visual navigation should be investigated

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Harmonised approach (contd)

- Products available through exceptional circumstances or pre-authorisation programmes should include a patient friendly statement in the PL alerting patients to this fact.
- Presentation of side effects should be reviewed and patients encouraged to discuss with doctor/pharmacist
- Inclusion of information on interaction with recreational drugs should be considered
- Inclusion of information on interaction with herbal/alternative therapies should be given where necessary

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Recommendations Requiring Amendments to Current Legal Framework

- The term Patient Information Leaflet should replace the term Package Leaflet in the EU legislation as it reflects better the purpose of the leaflet

- The current and revised legislation (Dir 2001/83) gives a specific order for the PL information points which should be reviewed

To do that

o Relevant feedback on the validity of this order should be kept and analysed as evidence for future recommendations when amending the Directive.