European Medicines Agency

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Pharmaceutical Forum
Working Group on Information to Patients

Report on Pillar II: Statutory Information on Medicines

I Introduction

At the initiative of the Pharmaceutical Forum, the Information to Patients Working Group decided to establish a three-pillar work programme with the objective of developing the elements that could form a European strategy for information on medicines and related areas for patients.

The purpose of this document is to address Pillar II: Statutory Information on Medicines. The document takes as a basis the outcome of the discussions at the level of the EMEA/CHMP[1] Working Group with Patients' and Consumers' Organisations, hereafter called the EMEA/CHMP Working Group. After an external consultation phase, the EMEA/CHMP Working Group finalised the document "Recommendations and Proposals for Action from the EMEA/CHMP Working Group with Patients' and Consumers' Organisations".

Four areas for further improvement were identified by the EMEA/CHMP Working Group:

(1) transparency and dissemination of information,

(2) product information,

(3) pharmacovigilance, and

(4) interaction between the EMEA/CHMP and Patients' Organisations.

The recommendations and proposals for action made by the EMEA/CHMP Working Group fall into three categories:

(1) recommendations which can be implemented as such by the EMEA,

(2) recommendations which require a harmonised approach at European Union (EU) level before implementation, and

(3) recommendations which require amendments to the current legal framework.

Only those recommendations which fall within the scope of the Information to Patients project will be considered in this document.

[1] CHMP: Committee for Medicinal Products for Human Use.

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II General Comments on Statutory Information to Patients

The recommendations described in this document address only one aspect of information on medicines to the general public, i.e. the statutory information to patients. This document does not address other reliable sources of information which are available to the patient and which are acknowledged by the EMEA/CHMP Working Group, in particular the patient-specific advice and information given by physicians, pharmacists and other healthcare professionals.

It should be noted that, in the context of this document, “product information” refers to the “Package Leaflet” (PL). The recommendations listed in this document specifically address the PL, which is included in the medicinal product package and reflects the agreed use of the product as reviewed by the Competent Authority that has licensed the product. Similar recommendations should be drafted for the outer and inner labelling of medicinal products.

It should be noted that the purpose of this exercise is not to preclude physicians and pharmacists from their professional duties or to interfere in the patient-doctor or patient-pharmacist relationship. However, patients are empowered to get information in order to make their own opinion. It is the role of all the Regulatory Authorities (i.e. the EMEA and the National Competent Authorities (NCAs)) to provide additional information for patients on medicines. The objective is to encourage the dialogue between healthcare professionals and better-informed patients. Moreover, the need to provide better information to healthcare professionals is addressed in the EMEA Road Map and the Heads of Medicines Agency (HMA) Strategy Paper, especially in the context of the safety of medicines as detailed in the European Risk Management Strategy (ERMS).

Every patient has the right to access information and there should be no language barriers. Further discussion with NCAs is necessary in order to find the appropriate channels to relay the information. It is important that the information is conveyed in a language and a format understandable by all patients.

A further increase in transparency is one of the most important topics addressed in both the EMEA Road Map and the HMA Strategy Paper and further discussion with the stakeholders will take place prior to the implementation of additional measures. The boundaries between confidentiality and transparency will be further considered in the light of the new rules on access to documents as laid down in Community legislation.

The roles and responsibilities of all the partners involved will have to be defined and adequate resources will have to be secured in order to implement the proposed measures.

III Recommendations from the Working Group

III.1 Availability of Information

Proposed recommendation*:* Information on all medicines authorised in the EU should be made available.

Current status*:* This will be addressed in the context of the establishment of the EudraPharm database according to article 57(2) of Regulation (EC) No 726/2004.

Proposed recommendation: The EMEA should include a link to the future EudraPharm database on its website to allow access by the European patients to accurate and up-to-date information about the availability of medicines across Member States (MSs).

Current status: This should be addressed in the context of EudraPharm and national databases.

Proposed recommendation: Data sources include EudraVigilance (database on pharmacovigilance), EudraPharm (database on information on all authorised medicines) and databases of NCAs. Patients organisations should provide input on their expectations on what information should be publicly available from these databases.

Current status*:* The EMEA/CHMP Working Group is part of the EudraPharm user group.

Proposed recommendation*:* Information on withdrawal or premature cessation of a product under development, which is not validated by a scientific assessment, highlights an area that requires review.

Current status*:* The current pharmaceutical legislation only foresees the publication of withdrawals of Marketing Authorisation Applications for the Centralised Procedure. It is suggested that this issue is referred for consideration by the European Commission in the context of the discussion on EudraCT and EudraPharm.

Proposed recommendation*:* The concept of 'tear-off fact sheets' to support prescribers in informing patients on drug safety[1]should be encouraged.

Current status*:* This recommendation needs further discussion at European level.

[1] For example, the UK's Medicines Healthcare Products Regulatory Agency (MHRA) issues fact sheets called "Key Information for patients receiving treatment with medicines known as x" (http://medicines.mhra.gov.uk/ourwork/monitorsafequalmed/currentproblems/currentproblems.htm).

III.2 Harmonisation-Standardisation-Translation

Proposed recommendation*:* The PL of a specific product should give the same information to all patients in the EU. There should be no differences between MSs and between patients. Whereas this objective is already achieved in the Centralised Procedure, harmonisation of the PL text for products approved via the Mutual Recognition Procedure would be desirable.

Current status*:* Since 30 October 2005, products approved via the Mutual Recognition Procedure or the Decentralised Procedure have the same product information (Summary of Product Characteristics (SPC) and PL) in all the Member States where it has been approved. This is in accordance with Article 28 (4) and (5) of Directive 2001/43/EC as amended.

Proposed recommendation*:* Standardised requirements should apply across EU. This should ideally also apply to the content of PLs of products containing the same active substance(s).

Current status*:* This recommendation needs further discussion. It would imply the harmonisation of the SPC and PL across EU in MSs where the product is marketed. Article 30 of Directive 2001/83/EC provides the MSs and the European Commission with a tool to harmonise the SPC and the PL. It would also imply harmonisation of product information (SPC and PL) between originators and generic products. The issue of patent usage needs to be addressed.

Proposed recommendation*:* The issue of good-quality translations should be addressed. Even if a PL should have the same content in all language versions, strict literal translations may lead to unnatural, unreadable PLs that are difficult to understand. Therefore, different language versions of the same PL should allow for regional translation flexibility, whilst maintaining the same core meaning. In addition, companies and authorities should work together to ensure good-quality translations, possibly involving Patients Associations.

Current status*:* The EMEA is currently putting a procedure in place to involve Patients/Consumers in the revision of the PL as part of the Centralised Procedure (Quality Review of Documents (QRD) activities). A similar initiative could be introduced at MS level.

Proposed recommendation*:* The legislation and PL guidance provide for a standardisation of structure and format of a PL, but the available guidance could be further developed and optimised (e.g. QRD Group recommendations, review of Commission guidelines).

Current status*:* see Chapter III.3 “Readability”.

Proposed recommendation*:* Rather than using the term “Package Leaflet”, the term “Patient Information Leaflet” would be preferred as this reflects better the purpose of the leaflet. It is noted that “Package Leaflet” is however the term used in the European pharmaceutical legislation. Even though flexibility of this term in translations exist, it would be better if the ‘official’ English term in the EU legislation would be Patient Information Leaflet, because ‘package’ refers to the product and not to the purpose of such leaflet.

Current status*:* The current pharmaceutical legislation refers to the Package Leaflet.

III.3 Readability

Proposed recommendation: The readability of PLs should be increased as to improve the quality of the leaflets to a level that is understandable to most patients. Companies are strongly encouraged to perform readability testing and to increase the font size of printed package leaflets.

Current status: The European Commission guidance concerning "consultations with target patient groups" for the PL provides guidance to Industry on how to implement Articles 59.3 and 61.1 of Directive 2001/83/EC, as amended.

The EMEA, NCAs and pharmaceutical industry will work together to analyse how these provisions have been implemented and to draw more practical recommendations to industry and to the assessors regarding user consultation.

Proposed recommendation: It is recommended to review the European Commission's Guideline on Readability (1998), with active involvement of Patients' Associations at an early stage. The EMEA should co-ordinate this task and should set-up a working group involving people with different expertise (Patients' Associations, QRD experts, industry representatives, experts on readability and information design, etc…). Appropriate benchmarks and standards against which to judge the leaflets and tests performed should be established, based on adequate PL performance requirements.

As part of the general review of the Guideline, the following points should also be addressed:

i. In the Review of the pharmaceutical legislation (Directive 2001/83) it is specified that: "Results of consultations with target patient groups should be reflected in the PL". The EMEA/CHMP Working Group welcomes this new provision. Further details however on what is required and when should be developed.

ii. The inclusion in the PL of clear and unambiguous signs/symbols/pictograms harmonised across the whole EU to aid visual navigation and highlight important sections or statements should be investigated.

iii. Where a product has been approved with conditions, or under exceptional circumstances, or is available under a pre-authorisation programme, a patient-friendly statement should be included in the PL to alert patients to this. The EMEA has introduced statements in the PL QRD template.

iv. The presentation of side-effects should be looked at: quantification, usefulness, comprehension, understanding and patients should be encouraged to talk to their doctor or pharmacist for advice if they have any problem with side effects.

v. The inclusion of information on interaction with 'illicit/recreational drugs' should be considered. Interaction with herbal or alternative therapies should be addressed in the PL where necessary.

vi. More information on teratogenicity needs to be included in the PL, where available (e.g. from databases in the MSs).

Guidance on the provision of a good balance between information on benefits versus risks should be developed when reviewing the Guideline on Readability (see Chapter III.4 "Information on Benefits Versus Risks").

Current status*:* The comments have been forwarded to the European Commission in the context of the public consultation on the Readability guideline.

Proposed recommendation: It was noted that the current and revised legislation (Dir 2001/83) provides for a specific order for the PL particulars. As experience with this order is currently lacking, relevant feedback should be kept and analysed for future recommendations to amend the Directive accordingly.

III.4 Information on Benefits Versus Risks

Proposed recommendation: In order to provide a good balance between information on benefits versus risks, the benefits of taking/using the medicine should be made more prominent and better explained in the PL, without leading to promotional claims. The text should also distinguish more clearly between prevention and treatment. In this respect, the potential consequences of stopping treatment and the need to discuss this with the treating physician or pharmacist prior to reaching a decision should be addressed in the PL as appropriate. Similarly, a recommendation to consult the treating physician or pharmacist in the event that the expected benefit is not achieved could be included in the PL, where relevant.

Although the first section of a PL is "what the product is and what it is used for", the information provided in this section is usually very short. Especially for long term treatment and prevention products, further information on the demonstrated benefits for the patient should be included to give full information to patients and in order to improve compliance/concordance. However, it should not lead to the inclusion of any additional and promotional claims from the company outside the approved indications. The issue of finding the right balance between providing relevant information on benefit/risks but without overloading the PL will have to be considered.

Current status: The EMEA has made a proposal to provide better information on the benefits for centrally authorised products. This proposal will be shared with NCAs and the European Commission to reach a common approach.

Proposed recommendation: To effectively distribute new information to prescribers and patients remains a major challenge. This is in particular true for delivering information that balances the benefits and risks for individual patients appropriately. Safety information should not jeopardise therapeutic adherence.

Current status: This recommendation needs to be further discussed by the EMEA, NCAs and the European Commission to reach a harmonised approach. Contributions from pharmaceutical industry, healthcare professionals, patients and consumers will also be necessary.

IV Conclusions

Work carried out at the level of the EMEA/CHMP Working Group with Patients' and Consumers' Organisations has indicated that the current situation in relation to statutory information on medicines can be further improved. Three areas for further improvement were identified: (1) availability of information, (2) harmonisation, standardisation, translation, and (3) readability. The recommendations from the EMEA/CHMP Working Group were reviewed and agreed upon by the Working Group on Information to Patients under the umbrella of the Pharmaceutical Forum.

There are several recommendations which require a harmonised approach at EU level. This necessitates a debate in an appropriate forum involving the EMEA, the NCAs and the European Commission. In addition, there are some recommendations requiring changes to the

current EU legal framework governing information, which will also need to be discussed in a wider forum. Contributions from all the stakeholders, including pharmaceutical industry, healthcare professionals, patients and consumers should be obtained.

The EMEA Road Map and the HMA Strategy Paper already include a proposal to build a networking model in the field of transparency and information to patients. Networks are already in place in several Member States and further discussion should take place with the NCAs in order to share their experience to reinforce networks and processes and improve their adequacy across the EU. One of the tasks of the network could be to discuss the recommendations requiring a harmonised approach.

Finally, it should be mentioned that a number of recommendations made by the EMEA/CHMP Working Group fall outside the Pillar on statutory information on medicines, but should be considered in pillars I and III. These recommendations are described in Annex 1.

I Recommendations to be Discussed Within the Framework of Pillar I

The EU Regulatory Authorities (EMEA and NCAs) and Patients' and Consumers' Organisations should work together on the provision of patient-friendly information on medicines. In this respect, the EMEA and its role/activities should be made better known to the general public.

i. Patients and the general public need information on the availability of medicines in the EU.

ii. Patients and the general public need independent and validated information to help them understand and participate in the treatment decisions. This should be a collaborative process with all parties involved in the provision of healthcare.

iii. The EMEA's and NCAs' communication material should include more patient-focused items and should take into account the needs of different user groups.

iv. Patients should be taken into account in the EMEA's and NCAs' communication strategy.

v. Other tools to disseminate the information should be made available in addition to the EMEA and NCAs websites.

The collection of comprehensive information on medicines should be based on a collaborative approach between regulatory bodies, healthcare professionals, patients groups, consumers' organisations, pharmaceutical industry and other parties involved. The EMEA and NCAs should take the initiative to bring together representatives of these groups to improve the level of collection of information on medicines with regard to the interests of patients.

The MSs should make a listing of national patients associations publicly available (e.g. on their website) in line with the document "Criteria to be Fulfilled by Patients' and Consumers' Organisations Prior to Involvement in EMEA Activities" as published on the EMEA website.

Patients' Organisations should prepare patient education programmes jointly with healthcare professionals on the appropriate and safe use of medicines in general and for individual medicinal products where such education programmes are proposed by or requested from marketing authorisation holders.

II Recommendations to be Discussed Within the Framework of Pillar III

Levels of validation of information should be reflected on the information provided, including reliability of data source. Patients' Organisations should develop a template guidance against which information provided by patient groups and other external sources could be validated. Patients' Organisations could consider signing-up to some self-regulation mechanism concerning the information to be presented. Alternative tools to disseminate the PL should be put in place.

Public access to general information on pharmacovigilance safety and risks of medicinal products should be ensured.

Public access to information on product-related pharmacovigilance safety and risks should be further improved.