



**Directive 2010/84/EU and REGULATION (EU) No 1235/2010  
Amending the EU Pharmacovigilance legislation**

**Recommendations  
for a patient-centred implementation**

**Introduction**

These recommendations have been developed by the European Patients' Forum and its member organisations representing the interests of patients with chronic diseases throughout the European Union. They aim to provide the authorities and bodies in EU Member States tasked with the transposition and implementation of Directive 2010/84/EU with a set of recommendations to ensure that this Directive, as intended, will lead to a strong, open and transparent pharmacovigilance system that ensures the confidence of patients, health professionals and regulators alike and represents a step forward for safety, high quality, and patient-centred healthcare.

Patients and their organisations have a wealth of expertise and experience that can contribute to higher patient safety, and quality of medicines in Europe. They are committed to sharing this expertise and contribute both at national and European levels to the successful implementation of the Directive. The pharmacovigilance framework encourages patient involvement at national and European level. This document therefore highlights areas where patient organisations can provide valuable input and support to the national authorities.

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*Note: The Directive 2010/84/EU amends Directive 2001/83/EC on the Community code relating to medicinal products for human use. The text below refers to the articles as numbered in the amended community code*

## Adverse Drug Reaction definition

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The Directive amends the definition of Adverse Drug Reaction included in the community code [Article 1(a).11]. The inclusion of mis-use and medication errors is an important aspect that is now addressed in the new rules. This is a step towards better patient safety and protection of public health, as it will lead to the collection of more information on the real-life working of medicines when they are used in different circumstances by different people.

### Recommendation

1. We recommend that Member States indicate clearly through the national medicines web-portals and other means that adverse reaction reporting also encompasses medication errors and misuses, and all types of adverse reactions, not only severe or serious, should be reported.

## Article 11: Information on medicines packaging and leaflets

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Products which are subject to additional monitoring (e.g. products with new active substances, biologicals and other products if required under the terms of the marketing authorisation) will be identified by a black symbol and a standard explanatory sentence on the packaging.

While it is key to ensure that patients are not alarmed and do not stop their treatment unnecessarily, they should be aware that their medicine is under additional monitoring, what such monitoring entails, and the reasons behind this. We believe this transparency is paramount to ensure patients' trust in the functioning of the pharmacovigilance system.

Article 11 also specifies that Member States *should develop a standard text expressly asking healthcare professionals to report any suspected adverse reaction*. While we believe that the relationship of trust between the patient and health professional should remain central, patients often cite a perceived lack of interest, or lack of listening, by health professionals as the reasons for wanting to report directly. It is therefore important that a relationship of trust is established and patients are encouraged to turn to their health professional in the first instance concerning any suspected adverse reactions.

Patient organisations are strongly involved in ongoing work at European level (through the European Medicines Agency) in the review of the package leaflet template and summary of product characteristics, to ensure this information is user-friendly and accessible for patients and the public, and corresponds more to their needs.

### Recommendations

1. We recommend that Member States in cooperation with patient organisations design the appropriate measures and messages to inform patients and the public about the meaning of the black symbol, including through the national medicines web-portal, to avoid creating unnecessary alarm as regards the medicinal products subject to additional monitoring.

2. We recommend that Member States develop information encouraging patients to be vigilant and report any suspected adverse drug reactions and indicating where they can get additional information, in cooperation with patient organisations to ensure the information meets patients' needs.
3. We recommend that Member States involve both national patients' and health professionals' organisations in discussions on the importance of reporting adverse reactions, and to explore how the different stakeholders can work together to support the patient-health professional relationship – including patient empowerment and building health professionals' listening and communication skills towards patients.

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### **Article 21: Information by National Competent Authorities**

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Article 21 lists information that national competent authorities should make available to the public.

This includes marketing authorisation, package leaflet, summary of product characteristics and information on eventual conditions to which the medicinal product is subjected in order to be granted a marketing authorisation. It also includes the assessment report for the marketing authorisation, with the reasons for the opinion of the NCA, as well as a summary that is understandable to the public, with a section relating to the conditions of use of the medicinal product.

### **Recommendations**

1. We recommend that Member States and NCAs involve patient organisations in the drafting and/or reviewing of information addressed to the public. Patient organisations are experts in communicating medical concepts in an understandable way and know the information needs of the patient communities.

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### **Title IX Pharmacovigilance: General provisions**

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Underreporting of adverse reactions is a serious issue which undermines the safety of medicines within the European Union: It is estimated that only 10% and 25% of all cases of adverse drug reactions are reported. The Directive amends the community code on medicinal products for human use to remedy to this problem.

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### **Article 101: Pharmacovigilance audit**

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Member States are required to conduct an *audit of their pharmacovigilance system* and report on the results to the Commission by 21 September 2013, then every two years [Article 101.2]

## Recommendations

We recommend that Member States consult patient organisations to gather information about the functioning of the pharmacovigilance system in general, and regarding the implementation of this legislation and patient 'organisations involvement by the NCA or Member State in this process – in particular for the provisions concerning direct patient reporting, information to the public, and the national medicines web-portal. This will help assess the impact of the measures to increase transparency and safety, while encouraging patient and citizen involvement at policy level.

### Article 102: Direct patient reporting

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Member states are requested to take *all appropriate measures to encourage patients and healthcare professionals to report suspected adverse reactions* to the national competent authority. Member States shall also facilitate **direct patient reporting** through the web based format and alternative formats [Article 102(b)].

EPF welcomes this provision. In those Member States where direct patient reporting already exists, it has not overburdened the national competent authority; on the contrary, studies and pilot projects have shown the added value of direct patient reporting.

Patients are in the best position to report a reaction, as they have a unique personal knowledge and experience of the effects of the medication they take, on their body as well as their daily lives. Patients are able to give more details on the circumstances surrounding the reaction; their reports are more nuanced and descriptive in nature, often yielding important new information concerning reactions.

While EPF believes the patient-healthcare professional relationship should remain central, patients may have difficulty in reporting through healthcare professionals in some situations: e.g. if the adverse reaction is of intimate nature, or if it results from an error. In addition, health professionals may be reluctant to report, whether for lack of time or other reasons (such as in cases where the medicine is prescribed off-label).

The possibility to report directly will lead to more crucial safety information being collected, and therefore to better medication safety. A user-friendly system, and raising awareness of patients on the importance of reporting reactions, is in our view essential to harness this benefit to improve public health.

The article also contains specific provisions to ensure that the public is provided important **information on pharmacovigilance concerns** relating to the use of medicinal products through the web-portals and possibly other means. It also requires that Member States establish a *follow-up* of suspected adverse reaction reports. It is essential for the individual patient who reports an adverse reaction to have feedback and further information about the medicine that provoked the adverse reaction, as it can play a role for adherence to their treatment, or the choice for an alternative therapy. Low adherence is another important public health problem, and adverse drug reactions may be a factor in this.<sup>1</sup>

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<sup>1</sup>See for example: <http://www.eu-patient.eu/Documents/Press/PressReleases/EPF-Press-Release-Adherence-2011.pdf>

## Recommendations

1. We recommend that Member States establish systems of reporting which capture the richness and added value of patient reports, in consultation with patient organisations. Patient involvement in the setting-up and user testing of the reporting systems (both web-based and alternative formats) will ensure the system is fit for purpose and user-friendly.
2. We recommend that Member States put in place guidelines for the follow-up procedure of reports, in consultation with patients' and health professionals' organisations. This will enable the collection of more high-quality data, to provide feedback (on how the information will be used, usefulness of the reports) and also serve to provide patients with further information or indicate to them where it is available (e.g. through the publicly accessible part of the EudraVigilance database).

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## Pharmacovigilance: Transparency and communication

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Chapter 2 of title IX contains crucial provisions from the patients' perspective concerning transparency and communications regarding medicines and pharmacovigilance, including through establishing a national medicines web-portal.

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### Article 106

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The following information has to be made available through a national web-portal, at a minimum:

- Publicly available versions of the assessment reports with their summaries
- Summaries of product characteristics
- Package leaflets
- Summaries of the risk management plans for authorised medicinal products
- The list of medicinal products that are subject to additional monitoring
- Information on the different ways of reporting suspected adverse reactions to the national competent authorities by healthcare professionals and patients

The active involvement of patient organisations can ensure the information provided is comprehensive, relevant, meets the real-life needs of patients, and is presented in an understandable, accessible format. High-quality information will empower patients to play their role in the pharmacovigilance system, for better patient safety and high quality of care.

Furthermore, a successful implementation of the new rules will depend upon effective dissemination of information to patient communities about: what pharmacovigilance is; how the new rules will improve medicines safety; why it is important that patients report suspected adverse reactions; and what avenues are available to do it. This will help to ensure that the pharmacovigilance system fully benefits from the added-value of patient reporting and patients' expertise.

While information campaigns can raise awareness in the short term, patient organisations play a key role in supporting patient awareness in the long term, as they are in regular and close contact with grass-roots patient communities.

### Recommendations

1. We strongly recommend that Member States consult *on regular basis* patient organisations in the setting-up and development of the national web-portals on medicines, to ensure that information is patient friendly and corresponds to the needs of users.
2. We recommend that national authorities to organise *joint campaigns* with patients' organisations to raise awareness in the patient community and among the general public about the pharmacovigilance rules and reporting of adverse events.
3. We recommend that Member States and NCAs cooperate with patients' and health professionals' organisations on a regular basis to raise awareness in the long term about pharmacovigilance, and set up appropriate training and capacity-building initiatives for both patients and healthcare professionals. (See also Article 11, recommendation 3 above.)

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### Urgent Union Procedures

Section 4 of Chapter 3 of the Pharmacovigilance title [Article 107i to k] establishes the procedure for *urgent actions* by Member States concerning the change or suspension of a marketing authorisation for a product, the coordination of the announcement, and the verification procedure for the safety concerns that led to taking these actions.

### Recommendations

1. We recommend that Member States involve patient organisations as appropriate to provide the right messages and advice in case of urgent safety measures such as suspensions or recalls. Patient organisations are an effective conduit of information to the grassroots patient communities. We further recommend that Member States consult patient organisations as well as healthcare professionals on the appropriate temporary measures to take.

The European Patients' Forum (EPF) was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of the EU patients' movement. EPF currently represents 54 member organisations, which are chronic disease-specific patient organisations working at European level, and national coalitions of patients organisations. Collectively they reflect the voice of over 150 million patients living with various chronic diseases in the European Union. EPF's vision for the future is high quality, patient-centred, equitable healthcare throughout the European Union.



These *recommendations for a patient-centred implementation* arises from the European Patients' Forum 2012 Work Programme, which has received funding from the European Union, in the framework of the Health Programme.

Disclaimer: The content of these *recommendations for a patient-centred implementation* reflects only the author's views and the Executive Agency is not responsible for any use that may be made of the information contained therein.