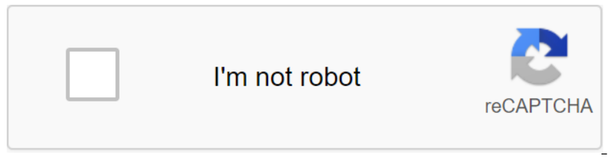
Eu guidelines patient information leaflet



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Based on an analysis of current practices, risks and benefits for patients, the Commission believes that the time has come to improve the quality of information available to patients about medicines. The balance between the benefits and risks of providing information points to the need for clear rules that apply to information that ensure its objectivity and avoid any advertising nature. Today, patients are playing an increasingly active role in the pharmaceutical field. Interest in health issues has increased significantly over the years with patients becoming more health conscious and wanting to be informed about the existing medicines that are available, the grounds on which they have been approved, and how they are monitored. The Commission fully recognizes the right of patients to access information about medicines. To meet current and future needs, a political response to various questions related to the provision of information to patients is needed. The information available on medicines should be accurate, evidence-based, accurate and objective. In addition, with the increased use of the Internet in recent years, the need to consider reliable and quality information available on websites has become essential. As a result of the revision of EU pharmaceutical legislation, which came into force in 2005, a number of measures have been taken to promote patients' access to information on medicines, namely by improving the quality of patient leaflets and publishing brief reports on the evaluation of permitted medicines. In addition, the revision of EU pharmaceutical legislation provided the basis for access to information on pharmaceutical and clinical trials, as well as for the creation of the European drug database - EudraPharm. The legislation has fundamentally preserved the rules applicable to the advertising of medicines in the European Union. However, the current legal framework (Directive 2001/83/EC, amended to the 2004/27/EC Directive) does not provide sufficient agreed rules for providing patients with information about medicines. This situation has led to different approaches and understanding in Member States regarding the provision of information on medicines. Information provided by public authorities is now very different between Member States, and media such as the Internet are not always able to provide reliable or understandable data. This situation does not provide a level playing field for all EU citizens, while allowing risks associated with unreliable or even illegal sources of information to be publicly available. To address this issue, on 10 December 2008, the Commission adopted two legal proposals for patient information within the framework of the Package. Common goal is to harmonize existing practices throughout the EU and ensure that all EU citizens have equal access to reliable and quality information about existing medicines. For more information on legal proposals see below: Summary of the Proposals Of the Commission Proposal on the Directive of the European Parliament and the Council for amending the Directive 2001/83/EC regarding public information on medicines subject to medical prescription, Directive 2001/83/EC on the Community Code, the human-made drug use was adopted on 10 December 2008: The Text of the Proposal (Directive) - COM (2008) 663 final proposal of the European Parliament Regulatory Commission and the Council for Amendments, concerning information for the public on medicines for medicines for Human use according to a medical prescription, Regulation (EC) No. 726/2004, establishing community procedures for the authorization and supervision of drugs for human use and veterinary medicine and the establishment of the European Medicines Agency was adopted on December 10, 2008 : The Text of the Proposal (Regulation) - COM (2008) 662 final public consultations Public Consultation on key elements of the legal proposal for patient information was launched by the Commission on February 5, 2008: The Impact Assessment Report Commission conducted a study to assess the economic, environmental and social impact of the proposal. The final impact assessment report was adopted by the Commission on 10 December 2008 and is available here: Volume 1 - Volume 2. The next steps of the Proposal have been submitted to the European Parliament and the Council, which will participate in the joint decision-making process. To follow the proposal at various stages of the procedure, please consult with the Legislative Observatory of the European Parliament or PreLex, the EU database on inter-situational procedures. Additional information: The European Medicines Agency (EMA) provides recommendations and templates for giving applicants permission to market practical advice on how to compile information on a product for human medicines, which includes a summary of product characteristics, labeling and packaging of flyers. The EMA manual clarifies the content to be included in these documents, as well as the standard headlines and the most commonly used standard statements and terms in all official languages of the European Union (EU) plus Icelandic and Norwegian languages, as well as the format and layout of product information. EMA Guidance Without Prejudice: Any Final Positions of the Agency, The Committee on Medicines for Human Use (CHMP) European institutions dealing with the content of documents; The mandatory nature of the relevant legislation; any legal interpretations given by the European Commission or the Court of Justice of the European Union. Union. published: 23/04/2020 First published: 23/04/2020 First published: 29/11/2019 First published: 28/11/2019 First published: 18/10/2019 Last updated: 27/11/2019 First published: 11/11/2019 Last updated: 14/11/2019 First published: 18/11/2019 First published: 15/10/2019 Last updated: 21/10/2020 First published: 04/01/2019 First published: 04/01/2019 First published: 30/05/2018 Last updated: 30/05/2018 First published: 18/04/2018 Last updated: 18/04/2018 First published: 23/01/2018 Last updated: 31/01/2018 First published: 13/02/2018 Last updated: 13/02/2018 First published: 25/10/2017 Last updated: 25/10/2017 First published: 20/10/2017 Last updated: 20/10/2017 First published: 21/08/2017 Last updated: 21/08/2017 First published: 10/08/2017 Last updated: 04/10/2017 First published: 05/07/2017 Last updated: 18/04/2018 First published: 18/05/2017 Last updated: 18/05/2017 First published: 05/05/2017 Last updated: 29/10/2019 First published: 25/01/2017 Last updated: 26/01/2017 Corr. 1 First published: 17/01/2017 Last updated: 19/01/2017 First published: 23/01/2017 Last updated : 23/01/2017 First published: 11/10/2016 Last updated: 11/10/2016 First published: 23/09/2016 Last updated: 23/09/2016 First published: 12/04/2016 Last updated: 08/11/2016 First published: 07/03/2016 Last updated: 07/03/2016 First published: 27/01/2016 Last updated: 27/01/2016 First published: 11/01/2016 Last updated: 11/01/2016 First published: 18/05/2015 Last updated: 18/05/2015 First published: 18/05/2015 Last updated: 18/05/2015 First published: 18/05/2015 Last updated: 18/05/2015 First published: 06/10/2014 Last updated: 06/10/2014 First published: 26/08/2014 Last updated: 19/12/2017 First published: 29/03/2011 Last updated: 18/05/2015 First published: 29/03/2011 Last updated: 18/05/2015 First published: 18/05/2015 Last updated: 18/05/2015 First published: 29/03/2011 Last updated: 08/11/2016 First published: 29/03/2011 Last updated: 08/11/2016 First published: 29/03/2011 Last updated: 22/05/2013 First published: 29/03/2011 Last updated: 18/05/2015 First published: 29/03/2011 Last updated: 22/05/2013 First published: 29/03/2011 Last updated: 26/09/2017 First published : 21/05/2012 Last updated: 18/09/2015 First published: 25/03/2013 Last updated: 18/05/2015 First published: 25/03/2013 Last updated: 22/05/2013 First published: 17/04/2013 Last updated: 22/05/2013 First published: 29/03/2011 Last updated: 18/05/2015 First published: 29/03/2011 Last updated: 18/05/2015 First published: 23/06/2015 Last updated: 23/06/2015 First published: 23/06/2015 Last updated: 23/06/2015 First published: 22/05/2013 Last updated: 08/11/2016 First published: 29/03/2011 Last updated: 28/03/2017 First published: 24/02/2009 Last updated: 18/05/2015 First published: 22/05/2013 Last updated: 22/05/2013 First published: 10/11/2008 Last updated: 22/04/2015 First published: 25/03/2013 Last updated: Originally published: 29/03/2011 Last updated: 18/05/2015 First published: 29/03/2011 Last updated: 18/05/2015 This guide sets the legal basis for patient information leaflets described in EU law and national legislation and best practices in information design. Is this page useful? Useful?