How to enable patients to use information on packaging and labeling?

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Brainlinx: 9th Pharma Packaging and Labeling Innovation Forum (PPLIF)

1. **The proposal for revision**
2. Eight recommendations
3. Potential consequences
4. Conclusions: reasons to change

European Commission

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Law

Revision of the EU general pharmaceuticals legislation

In preparation

Roadmap

Feedback period

30 March 2021 - 27 April 2021

FEEDBACK: CLOSED

Public consultation

Consultation period

28 September 2021 - 21 December 2021

FEEDBACK: CLOSED

Commission adoption

Feedback period

26 April 2023 - 08 November 2023

FEEDBACK: OPEN

About this initiative

Summary

As part of the EU pharmaceuticals strategy, and drawing lessons from the COVID-19 pandemic, the Commission plans to evaluate and revise the EU's general legislation on medicines for human use to ensure a future-proof and crisis-resistant medicines regulatory system.

The revision will aim to:

- ensure access to affordable medicines
- foster innovation, including in areas of unmet medical need
- improve security of supply
- adapt to new scientific and technological developments
- reduce red tape.

Topic Public health

Type of act Proposal for a regulation

EUROPEAN
COMMISSION

Brussels, 26.4.2023
COM(2023) 192 final

2023/0132 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

(Text with EEA relevance)

{SEC(2023) 390 final} - {SWD(2023) 191 final} - {SWD(2023) 192 final} -
{SWD(2023) 193 final}

Article 76

Approval of the labelling and package leaflet information

1. One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.

2. The competent authority shall refuse the marketing authorisation if the labelling or the package leaflet do not comply with the provisions of this Chapter or if they are not in accordance with the particulars listed in the summary of product characteristics.

Compiled by:
Karel van der Waarde
July 2023

Bibliography: European Package Leaflets

[August 6, 2023: This list is 'work in progress' and unlikely to be ever complete.]

This bibliography contains references to 245 publications about the mandatory European package leaflets. Each entry is annotated and contains a DOI or website link.

Please inform waarde@glo.be if there are any omissions or mistakes.

2023

Berg LN van den, Chavannes NH, Aardoom JJ. **'Using animated videos to promote the accessibility and understandability of package leaflets: retrospective observational study evaluating the first year of implementation'**. *Journal of Medical Internet Research*. 25: e40914. [DOI]. The Netherlands, 4926 questionnaires: web-based library with animated videos increase the understanding and accessibility of medication information.

Bergmo TS, Sandsdalen V, Manskow US, Småbrekke L, Waaseth M. **'Internet Use for Obtaining Medicine Information: Cross-sectional Survey.'**. *JMIR Form Res*. 7, e40466. [DOI]. Norwegian survey (n=303): 42% used package leaflet (physician 63%, pharmacy: 47%).

Davis C, Wagner AK, Salcher-Konrad M, Scowcroft H, Mintzes B, Pokorny AMJ, Lew J, Naci H. **'Communication of anticancer drug benefits and related uncertainties to patients and clinicians: document analysis of regulated information on prescription drugs in Europe'**. *BMJ*. 380, e073711. [DOI]. A UK analysis of 29 package leaflets for anticancer drugs (2017-2019): Drug benefits and uncertainties were not included.

Espírito-Santo M, Nascimento T, Pinto E, Dulce Estêvão M. **'Patient information leaflets of drugs used in cardiometabolic disorders: suitability for use by older persons.'**. *Portuguese Journal of Public Health* [DOI]. An analysis of 69 Portuguese package leaflets: information specifically for older persons is relatively scarce.

1. The proposal for revision
2. **Eight recommendations**
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Not: legible, understandable, comprehensible

The ibuprofen dose depends on the patient's age and body weight. The maximum single daily dose for adults should not be greater than 800 mg of ibuprofen. The recommended dose is:

Rheumatic diseases

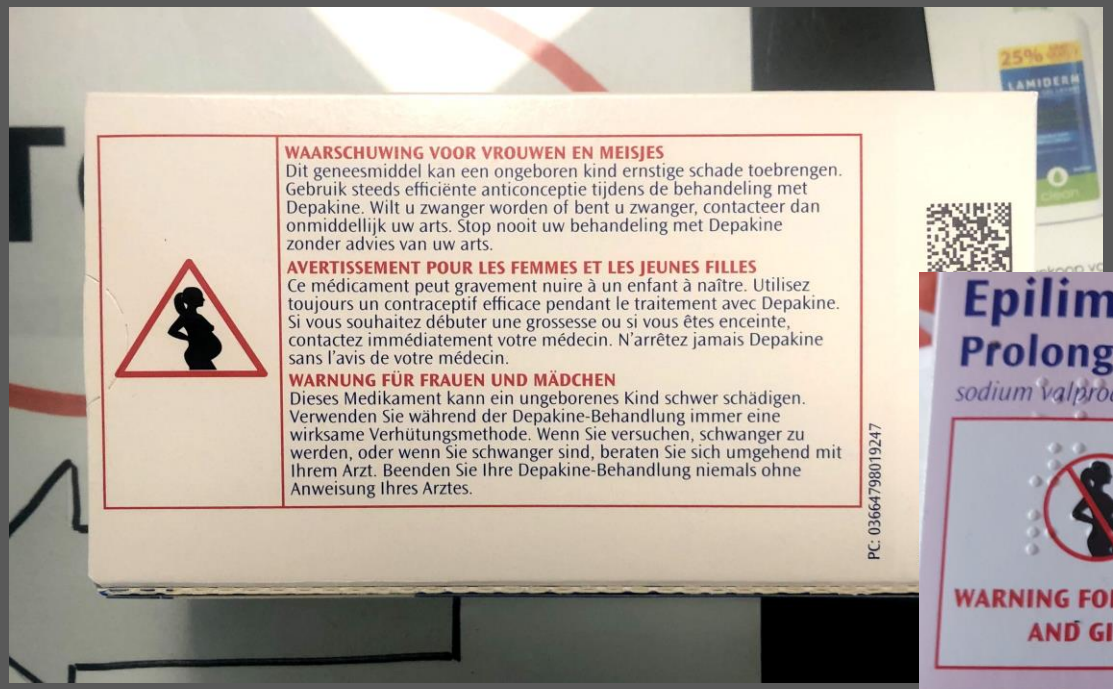
Adults:

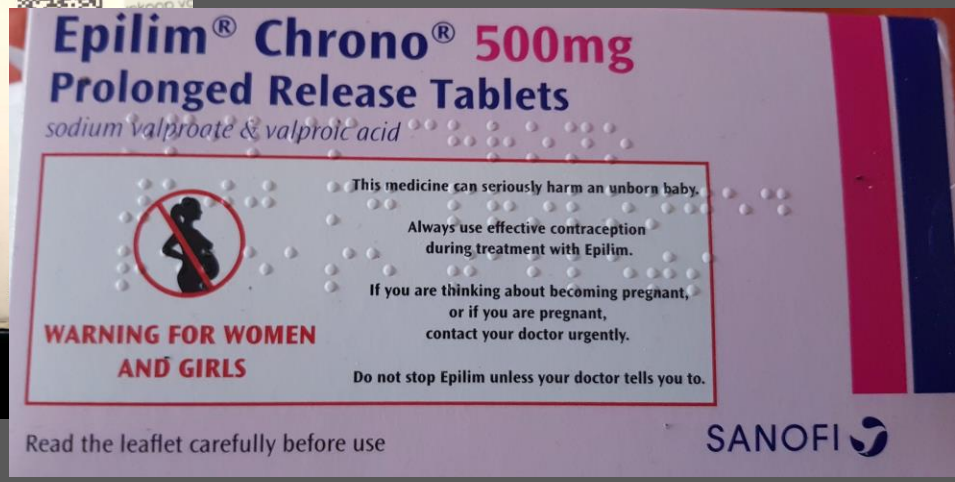
The recommended dose is 1200 mg-1800 mg daily in divided doses. Lower doses may be prescribed by your doctor. Due to the nature and severity of your condition, the doctor may increase your medication to a maximum of 2400 mg daily, taken in 3 or 4 divided doses.

Focus on: 'Enable users to act appropriately'

Recommendation 2: Focus on performance

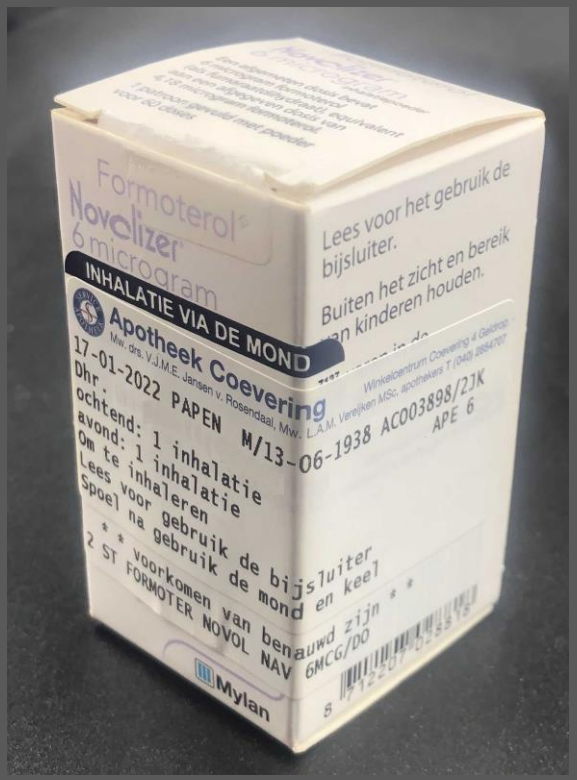
Not: obligatory and detailed contents





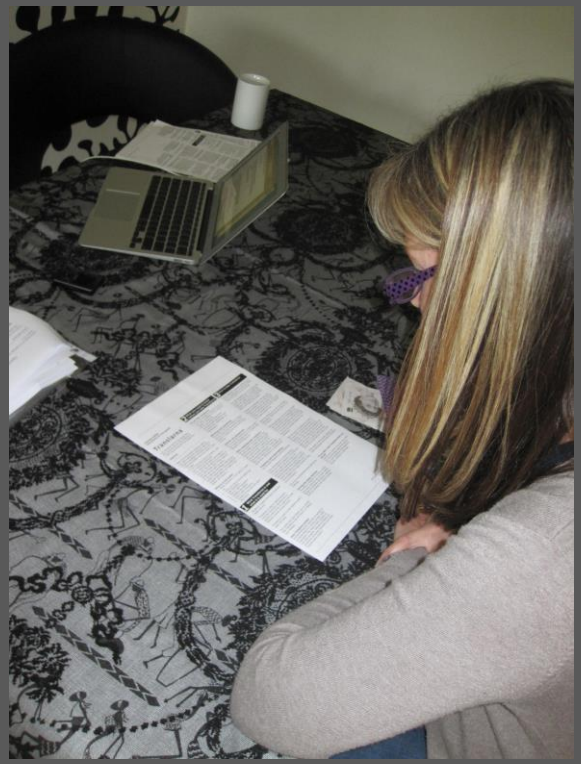
Needs to be: 'effective dialogues'

Not: pictograms, symbols, type size, …



Needs to be: ‘optimize visual design’

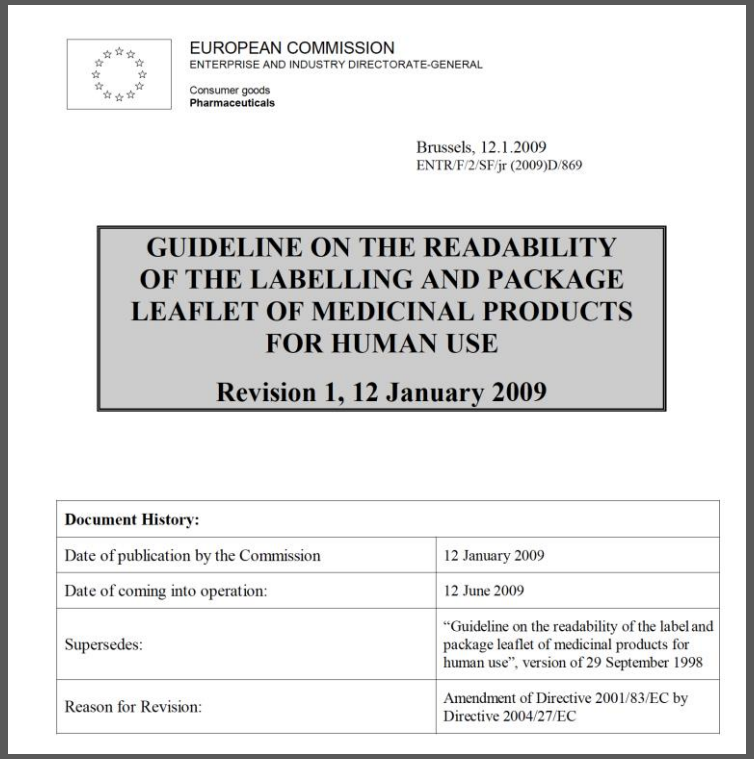
Not: a single obligatory readability test



Needs to be: ‘listen to patients’

Recommendation 5: Provide appropriate guidelines

Not: ‘a list of optional considerations’



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, 12.1.2009
ENTR/F/2/SF/jr (2009)D/869

GUIDELINE ON THE READABILITY OF THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE

Revision 1, 12 January 2009

Document History:	
Date of publication by the Commission	12 January 2009
Date of coming into operation:	12 June 2009
Supersedes:	“Guideline on the readability of the label and package leaflet of medicinal products for human use”, version of 29 September 1998
Reason for Revision:	Amendment of Directive 2001/83/EC by Directive 2004/27/EC

‘Line spaces should be kept clear.’

‘Long sentences should not be used.’

Needs to be: ‘process-, performance-, evidence based’

Recommendation 6: Apply the legislation

Not: ‘lack of funding, people, tools, and training’

Needs to be: ‘support regulatory authorities’

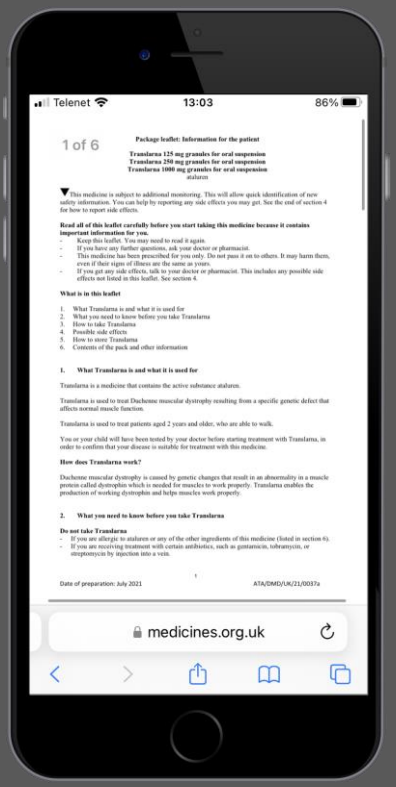
Recommendation 7: Give it a telling name

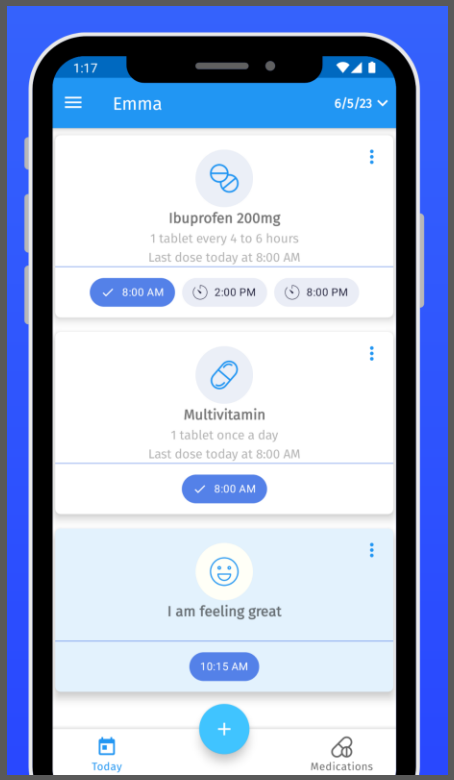
Not: ‘Package leaflet’

Needs to be: ‘medicine guidance’

Recommendation 8: Develop digital information

Not: ‘repeat shortcomings in digital formats’





Needs to be: ‘apply all recommendations’

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3. **Potential consequences**
4. The next steps

If not revised, we will continue:

- to try to achieve undeterminable aims
- to believe in incorrect assumptions
- to underrate visual design
- to ignore patients
- to hinder MAHs through poor guidance
- to hinder authorities through lack of support
- to use an obsolete name
- to repeat shortcomings in digital formats

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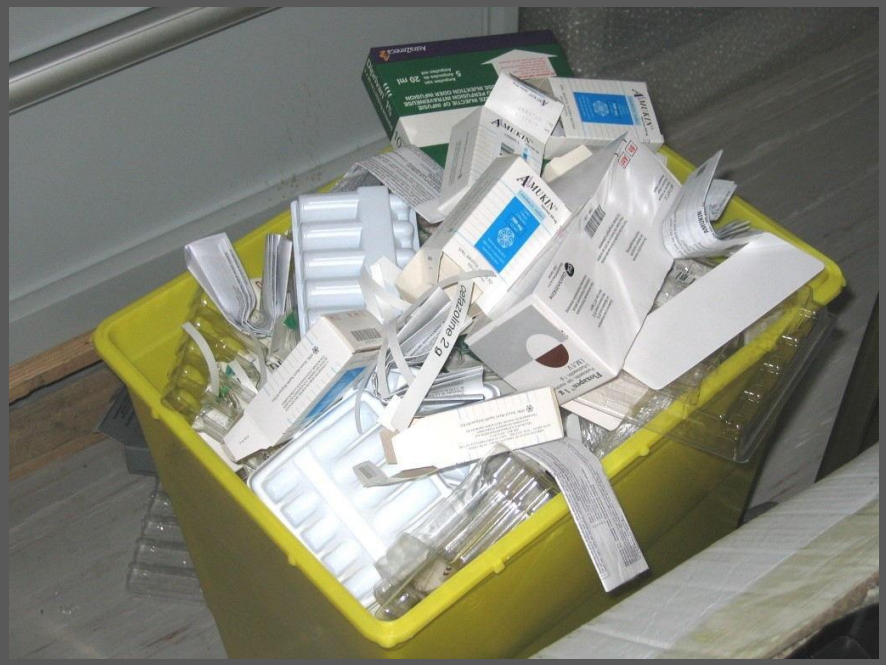
4. **Conclusions: reasons to change**

To conclude: There are four reasons to change:

- **Shortcomings** need to be eradicated
- The revision needs to be based on **evidence**
- Regulations must **benefit patients, authorities, and MAHs**. (= combine healthcare, legal, and financial)

- It might take a very long time before there is another opportunity to change …
  (*Deadline for comments: November 8, 2023*)

Thank you



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