EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update of the QRD template
Package Leaflet improvement

Joint PCWP-HCPWP plenary meeting – 2 July 2024

Presented by Monica Buch
EMA Labelling Office (H-Q-LAB)

Project update

- September 2023 – April 2024
  - ✓ QRD subgroup meetings and exchanges with industry
- Surveys with patients/consumers/HCPs
  - ✓ Survey on general aspects (December ‘23)
  - ✓ Survey on **‘key information section’** and benefits/risks balance (March ‘24)
- Major changes agreed within QRD subgroup and with industry
- Thorough discussions on **‘key information section’**
- QRD subgroup proposal endorsed by QRD Group

‘Key information section’ - *Considerations by QRD subgroup*


EUROPEAN COMMISSION

Brussels, 22.3.2017
COM(2017) 135 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

in accordance with Article 59(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use


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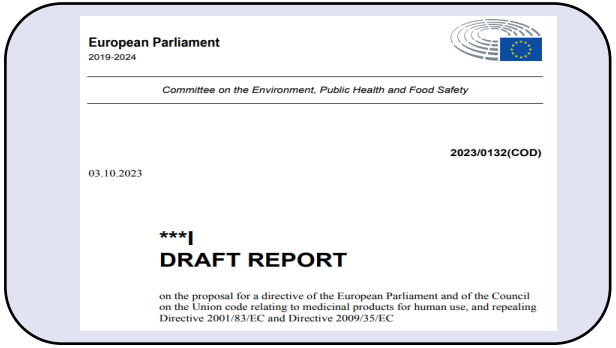
14 November 2017
EMA/680018/2017
Stakeholders and Communication Division

EMA action plan related to the European Commission’s recommendations on product information[1]

The European Medicines Agency (EMA) recognises the importance of the European Commission report[2] and its recommendations to improve the EU product information. This represents a unique opportunity to improve the information EU patients receive on their medicines, within the boundaries of the current legislation.

In order to meet high public expectations that the report has generated, it is important that any action is properly planned and executed, relevant stakeholders are involved and due consideration is given to the required expertise, timing and resources.


European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2023/0132(COD)

03.10.2023

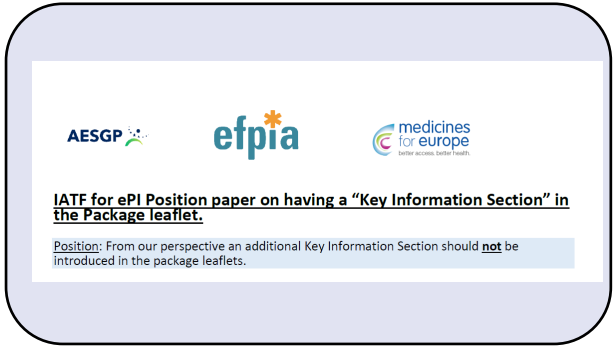
***I
DRAFT REPORT

on the 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


MHRA
Regulating Medicines and Medical Devices

tga .gov.au

FDA


AESGP

efpia

medicines for europe
better access better health

IATF for ePI Position paper on having a “Key Information Section” in the Package leaflet.

Position: From our perspective an additional Key Information Section should **not** be introduced in the package leaflets.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Results of stakeholder survey: key information section & information on medicine benefits

19 April 2024

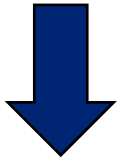
Presented by Kaisa Immonen, EMA Patient Liaison

QRD subgroup decision and proposal

Concerns raised against the '**key information section**' are acknowledged and mostly shared

however

the considerations previously mentioned cannot be disregarded



QRD subgroup decides to work on the inclusion of a **'key information section'** in the PL

Four proposed models discussed with Industry and the QRD Group

Models discussed

Australian model

- Too long
- Summary concept
- Extensive information
- No benefits/risks information

UK model

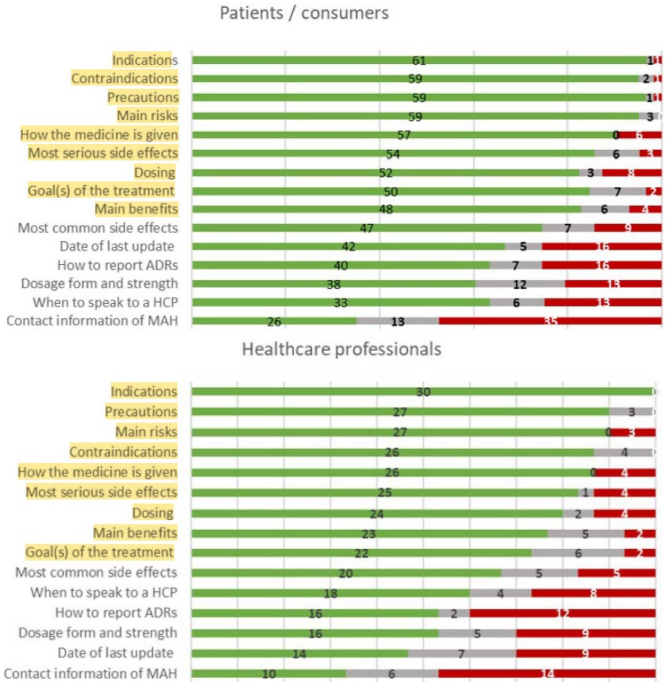
- Less impact on length
- Can be tailored to product class
- Information on benefit can be included

Academia model

- Excellent concept, very visual
- May not work for all types of products
- Might be better suited for section 1 or Medicines Overview

QRD subgroup model – Endorsed by the QRD Group

'Key information' - based on results of survey with patients/consumers/HCPs



INFORMATION REQUIRED

- ✓ Indication
- ✓ Goal of treatment
- ✓ Main benefits
- ✓ Contraindications
- ✓ Important precautions
- ✓ Serious side effects
- ✓ Main risks
- ~~✓ Dose & how to take~~

QRD subgroup model

Package leaflet: Information for the <patient> <user>

{(Invented) name strength pharmaceutical form}
{active substance(s)}

KEY INFORMATION

[Indication and goal of treatment/main benefits]
[The therapeutic indications should be briefly stated here together with the goal of treatment (i.e. main benefits expected) and a cross-reference to section 1.]

[Contraindications <and important precautions>]
[All contraindications should be briefly mentioned here together with a cross-reference to section 2.]
[If there is a very important precaution on which the patient's action is essential, include it here with a cross-reference to relevant section.]

[Most serious side effects/main risks]
[Include a summary of the potential serious side effects together with a cross-reference to section 4.]

For full detailed information about this medicine, please read the rest of this leaflet.

- Concise section at the beginning of the PL
- Only key safety messages
- Factual and non-promotional information
- Should not be a summary of the PL
- Cross-references to relevant sections
- Instruction to read the rest of the PL
- Format and need for heading to be discussed
- Guidance to be further elaborated
- Results of user testing to be considered

Next steps

- Finalise guidance and changes in QRD template
- Circulate QRD template for endorsement by the QRD Group
- Release proposed QRD template for public consultation
- Assess comments received during public consultation
- Final discussion at multistakeholders workshop
- User testing (by EMA and Industry)
- Final adoption by the QRD Group
- Translation process and publication

THANK YOU

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