

The Council of Europe and its European Directorate for the Quality of Medicines and HealthCare at a Glance

and

The Council of Europe Exploratory Survey on Electronic Leaflets

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*Meeting on Electronic Patient Information Leaflets in Medicines
(E-PIL) and Patient Safety*

Reykjavík, 17 October 2019



Presentation outline

✓ Part I

Council of Europe

European Directorate for the Quality of Medicines and HealthCare (EDQM)

European Committee on Pharmaceuticals And Pharmaceutical Care (CD-P-PH)

✓ Part II

Background and aim of exploratory survey on electronic leaflets

Results

Conclusions and next steps

Council of Europe (1)

Founded in 1949

The oldest pan-European organisation

47 member countries > 820 million Europeans

Headquarters in Strasbourg (France)

Core values: Protects human rights
Promotes democracy
Protects the rule of law

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE



Council of Europe (2)



Council of Europe

International intergovernmental organisation

47 countries

Initiatives often take the form of conventions, resolutions and recommendations addressed to member states

is NOT



European Union (EU)

Unique economic and political partnership

28 countries

Member states have delegated some of their sovereignty so that decisions on specific matters can be made democratically at European level

Council of Europe (3)

Council of Europe
Conseil de l'Europe

47 Member States
États membres

www.coe.int

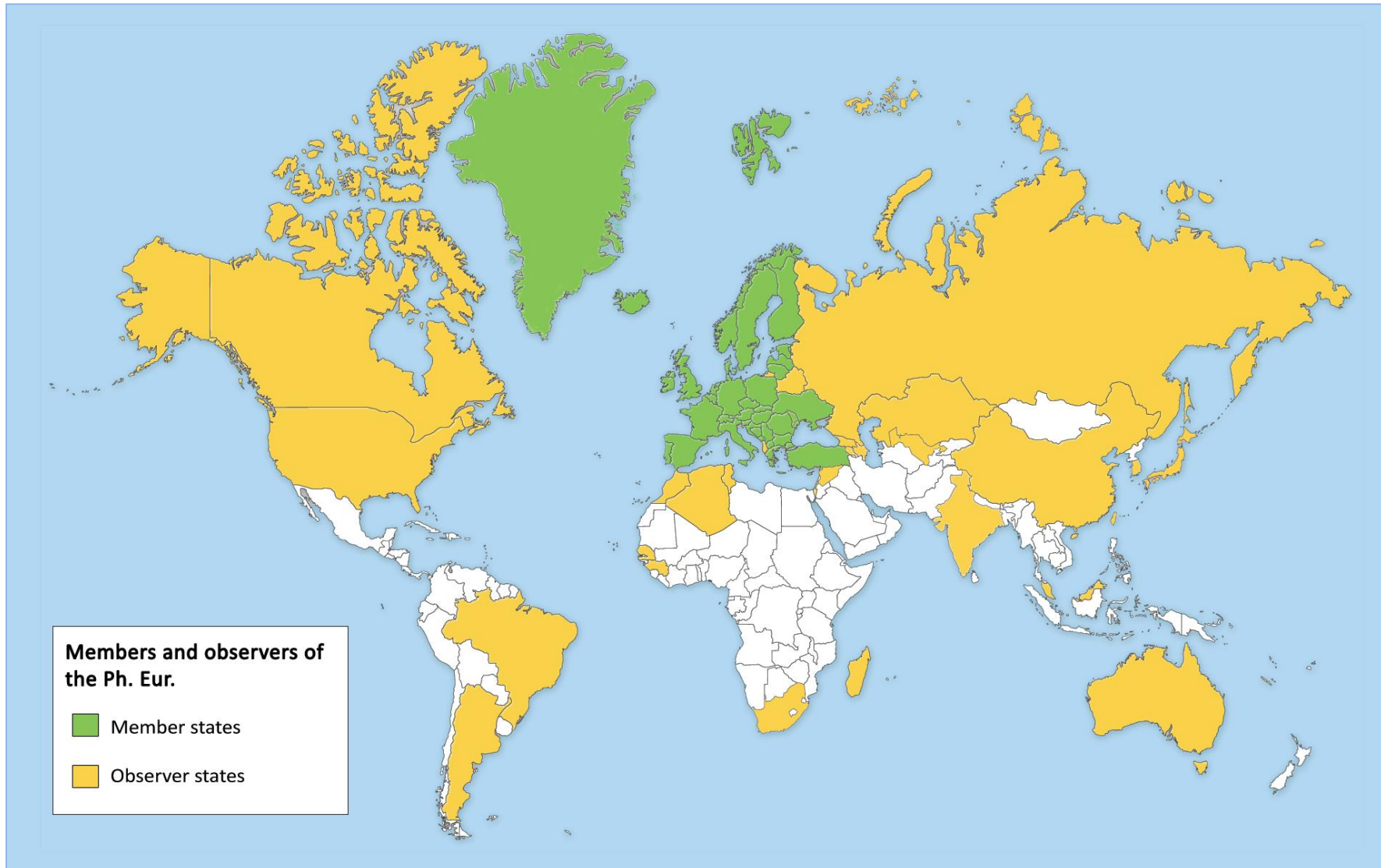
European Directorate for the Quality of Medicines and HealthCare (EDQM) (1)

- ✓ A Council of Europe's Directorate
- ✓ Activities based on the Convention on the Elaboration of a European Pharmacopoeia (1964)



- ✓ Leader in protecting public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use
- ✓ Mission: contribute to the **basic human right of access to good quality medicines and healthcare** and to promote and protect human and animal health

EDQM (2)



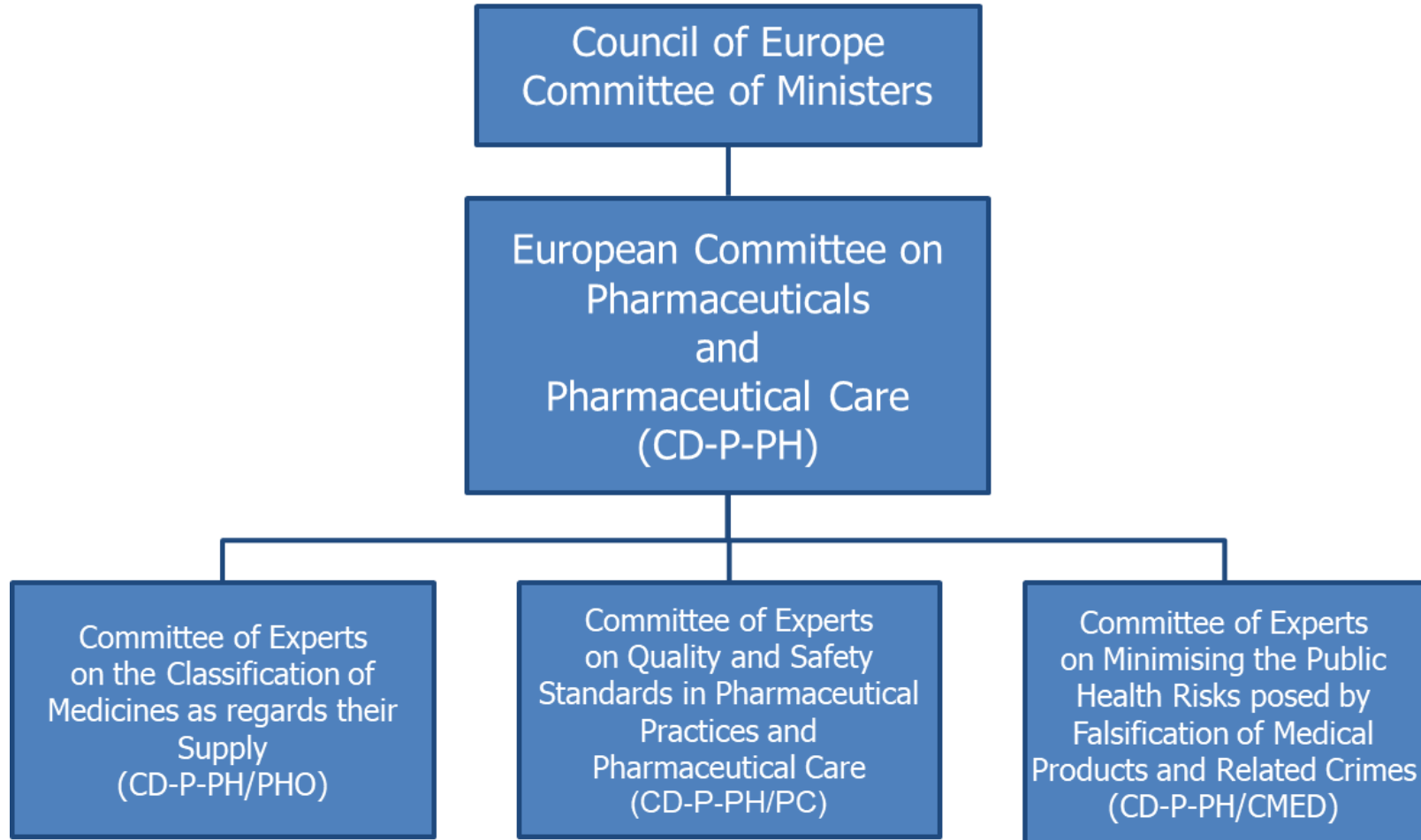
Members: 38 countries and European Union

Observers: 28 countries, Taiwan Food and Drug Administration, and World Health Organization

European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) (1)

- ✓ It reports directly to the **Council of Europe Committee of Ministers**
- ✓ It supports authorities in times of increasing social gaps and resource constraints to make the **medication process safer**, more **responsible** and **accessible** to all who need it
- ✓ It oversees the drafting process of **legal instruments** (e.g. resolutions), **policies** and **guidance documents**
- ✓ It consists of **senior officials** in ministries and medicines agencies responsible for health policies
- ✓ It meets in Strasbourg (EDQM premises) once a year
- ✓ EDQM is responsible for the Secretariat of the CD-P-PH

CD-P-PH (2)



CD-P-PH (3)

Areas of work

Classification of medicines

Recommendations on classification of medicines and their supply conditions

Melclass database

Focus on public health promotion, patient safety and accessibility of medicines

Longstanding experience and expertise available to European and national authorities

Pharmaceutical care

Harmonised provisions and practices for rational use of medicines (community and hospital pharmacy level)

Promotion of pharmaceutical care approach (patient-centred care)

Support to development of pharmaceutical professionals and their expertise, and enhancement of collaborative partnership between key-players in medication use process

Combating falsified medical products

Development of multi-sectorial approaches for public health protection

Platform for exchange of information, experience and knowledge for professionals

Networking and cooperation among member states (e.g. Single Points of Contact network (SPOC))

Promotion and support to implementation/monitoring of MEDICRIME convention

Exploratory survey on electronic leaflets - Background

- ✓ **Project title:** Medicinal information to patients who do not understand the language of medicine packages and patient information leaflets (PILs)
- ✓ **Project coordinator:** Mr Einar Magnússon (former Icelandic delegate to the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH))
- ✓ **Committee of Experts:** Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)
- ✓ **Secretariat and project management:** EDQM (Council of Europe)

Aim

- ✓ **Problem statement:** Increasingly, interactions take place between healthcare professionals (HCPs) and patients who do not share a first language

Language discrepancies may create barriers to healthcare, compromise quality of care and worsen health outcomes

Language barriers can have a negative impact on understanding of PILs and hamper safe and appropriate use of medicines
- ✓ **Aim:** map out what different countries currently do to ensure that foreign patients receive sufficient information about their medications in case they do not understand the national language of the country where medical care is provided to them
- ✓ **Methods:** questionnaire developed by Mr Magnússon with support of Georgia (Ministry of Health), Ireland (The Pharmacy Regulator) and Italy (Italian Medicines Agency)

Results (1)

✓ **Target respondents:** delegates of member States parties to the Ph. Eur. Convention (committees: CD-P-PH and CD-P-PH/PC)

✓ **Response rate:** 17 out of 39 delegates completed the questionnaire (response rate: 43.6%)

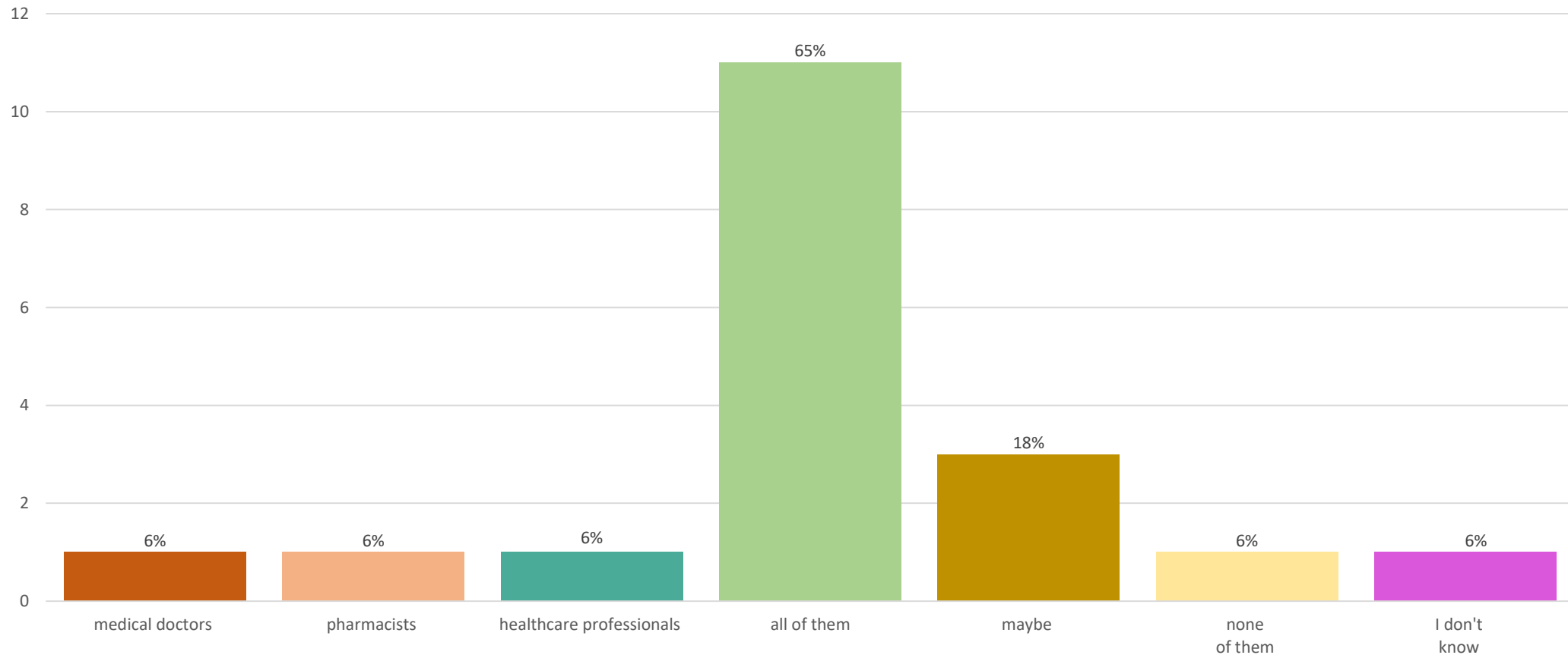
✓ **Respondents:**



Bulgarian Drug Agency
Czech Republic - State Institute for Drug Control
Danish Medicines Agency
Estonian State Agency of Medicines
Finnish Medicines Agency
Georgia - Drug Agency of the Ministry of Health
Iceland - University of Iceland
Ireland - Pharmaceutical Society of Ireland
Italian Agency of Medicine
Latvia - Medicines Agency of Latvia
Netherlands - Medicines Evaluation Board
Norwegian Medicines Agency
Poland - Chief Pharmaceutical Inspectorate
Portugal - National Authority of Medicines and Health Products
Slovenia - Agency for Medicinal Products and Medical Devices
Spanish Agency of Medicines and Medical Devices
Swiss Federal Office of Public Health and Swissmedic

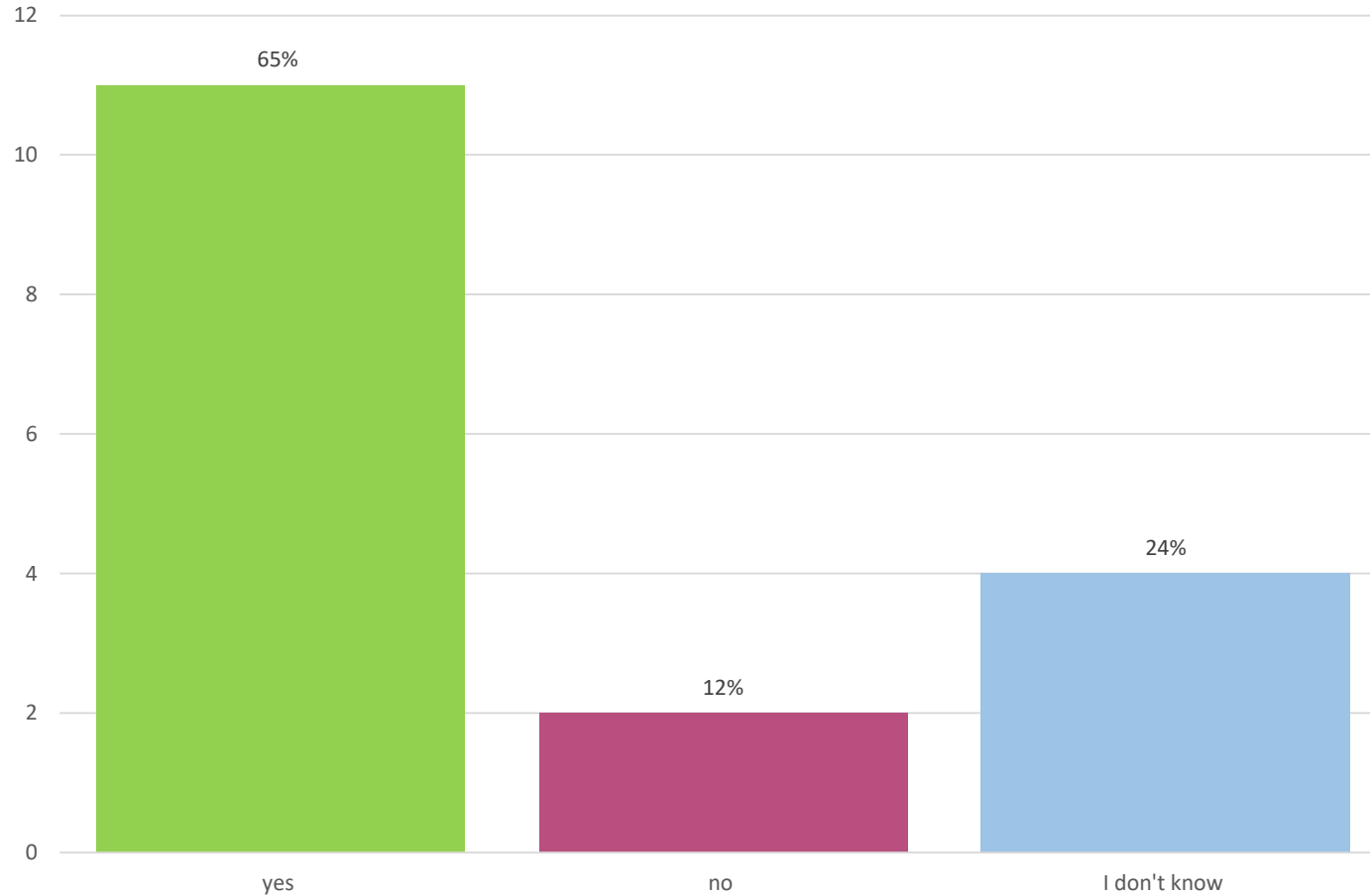
Results (2)

In your opinion, do physicians and/or pharmacists in pharmacies, and/or healthcare professionals, encounter difficulties in providing patients who do not understand the language of the PIL with the necessary information?



Results (3)

In general, do you think there is an issue in your country with foreign patients receiving sufficient information about their medication in case they do not understand the national language?



Results (4)

What methods are used in your country to present the necessary information about taking or using a medicine to patients who do not have a full understanding of the language of the PIL?

Different methods mentioned - Examples (not exhaustive list)

Denmark: Information will most likely be available from doctors and at the pharmacy in English, although not necessarily written information

Finland: An interpreter can be used to translate the main points of the PIL

Iceland: Mostly through a close relative/friend that interprets or in some cases contact a professional interpreter

Ireland: Possible options: counselling by pharmacists, interpreter, instant translator, asking if a friend or family member might have better knowledge and understanding of the language, drawings

Netherlands: Kijksluiter/Watchyourmeds, i.e. a 'library' of approximately 6000 videos, in which the most important information from the official PIL is explained in easy to understand language

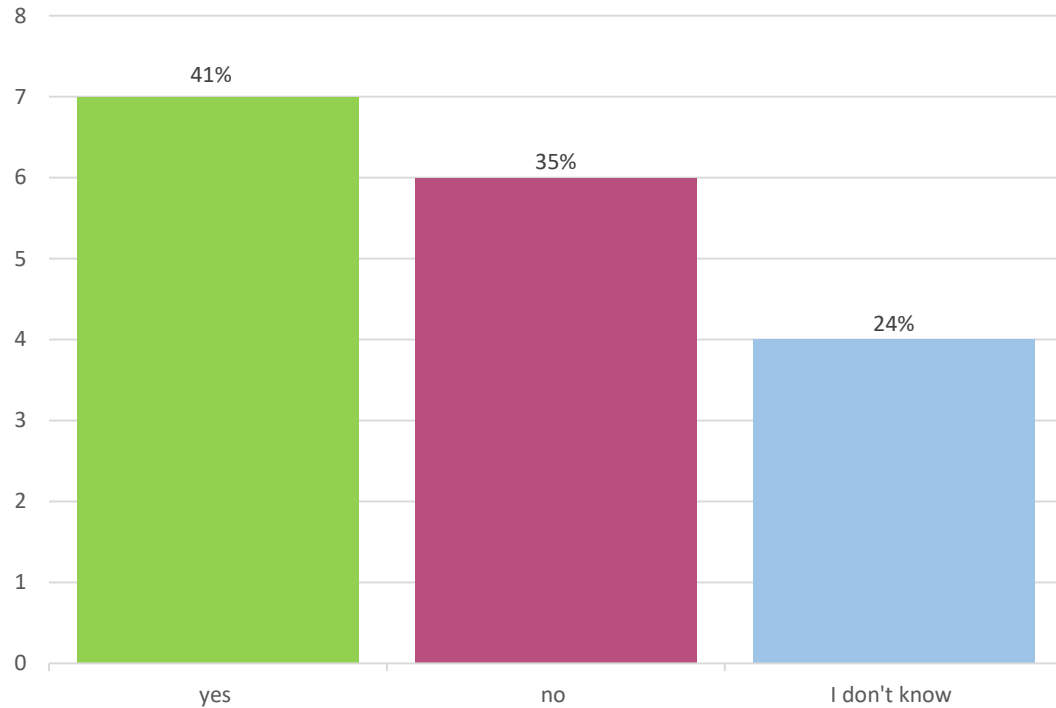
Portugal: No standard methodology - when possible, relevant information about taking/using a medicine is transmitted orally to patients

Switzerland: Translation with electronic devices

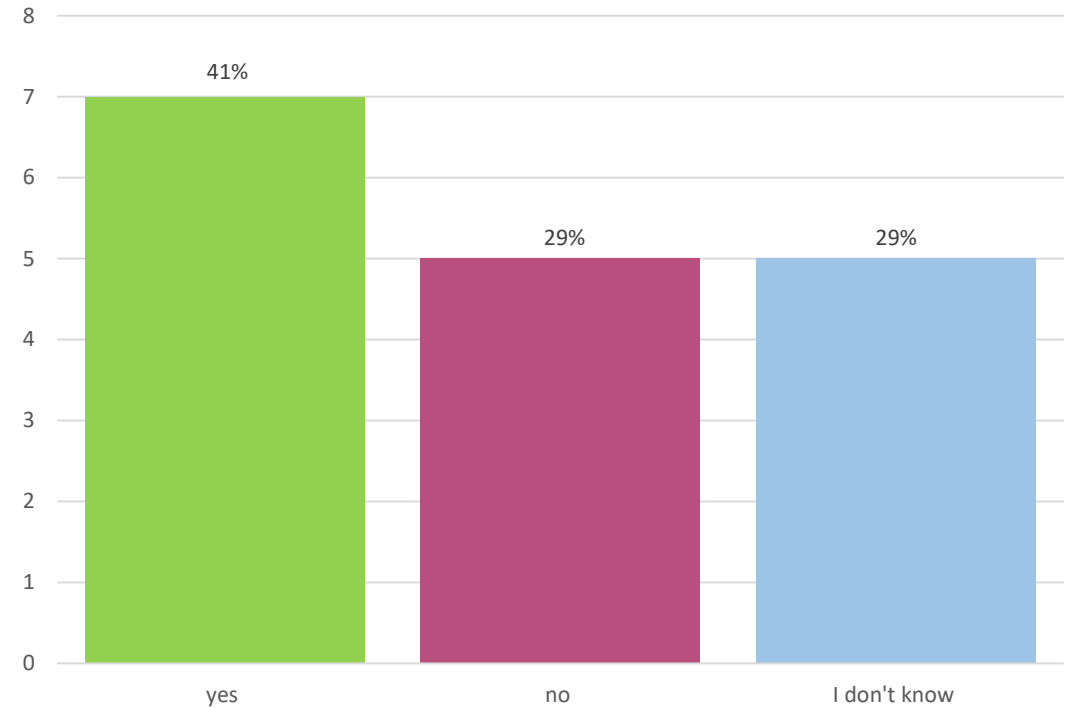
Results (5)

Are PILs in different languages:

Available in your country?

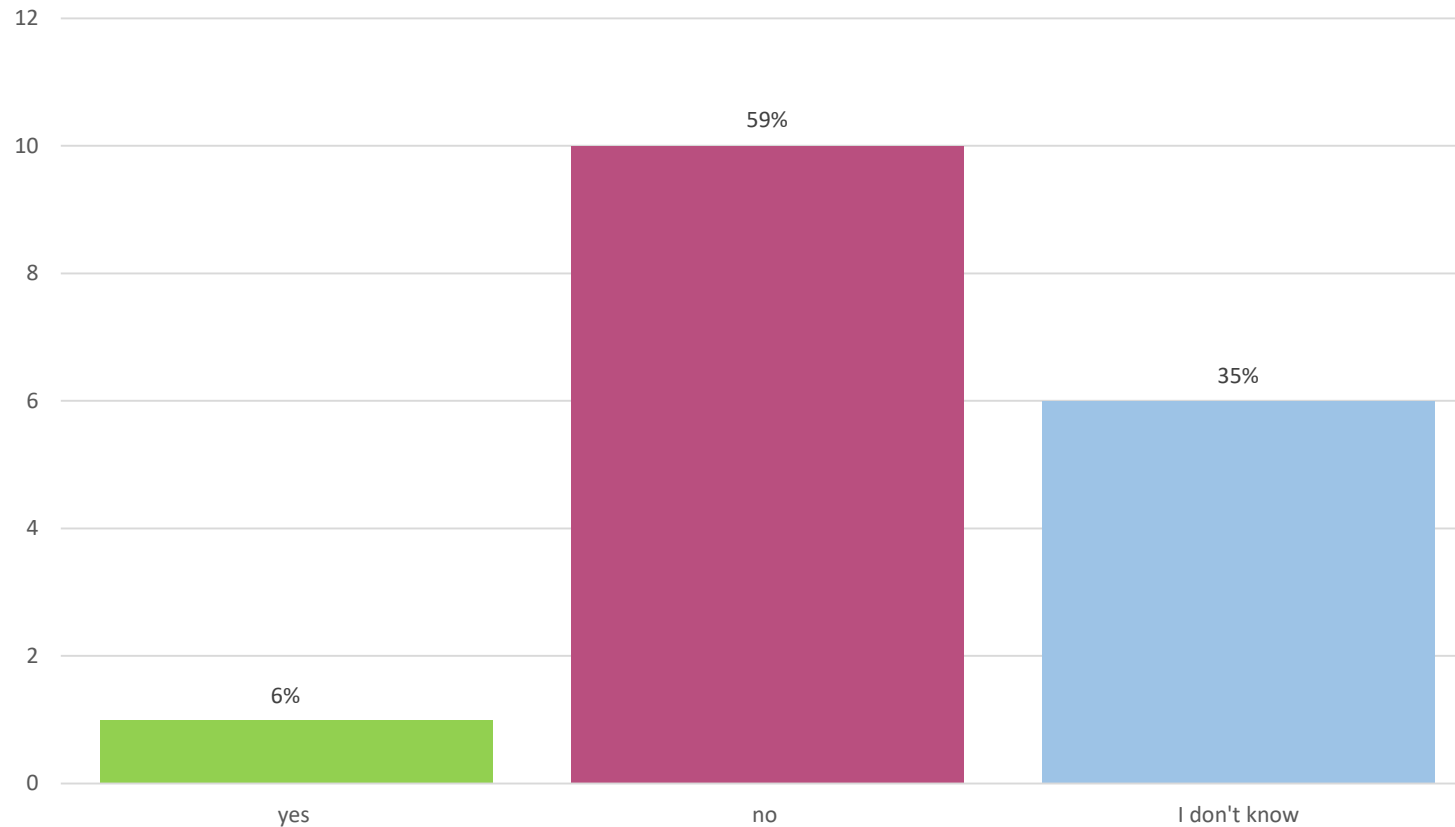


Used in your country?



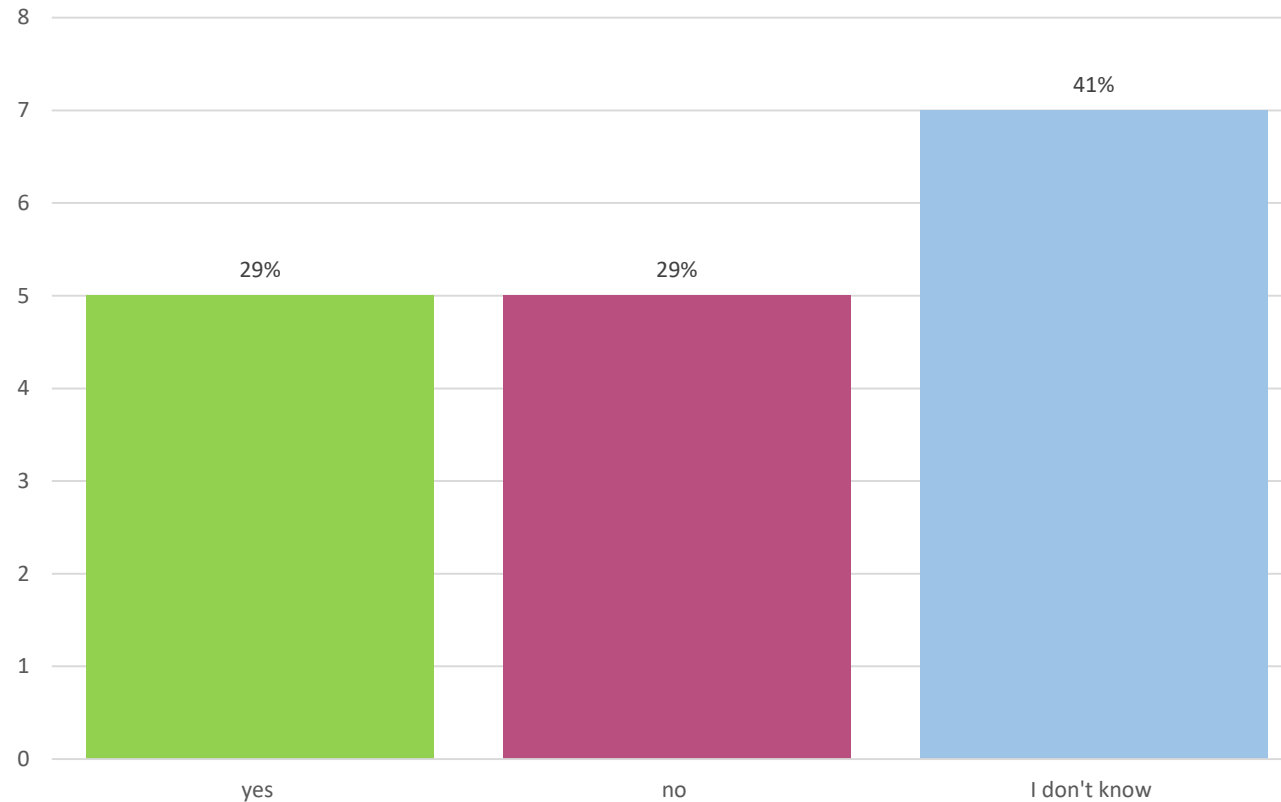
Results (6)

Do you think the methods used in this regard are sufficient to ensure the safe and appropriate use of medicines in your country by those who do not understand the national language?



Results (7)

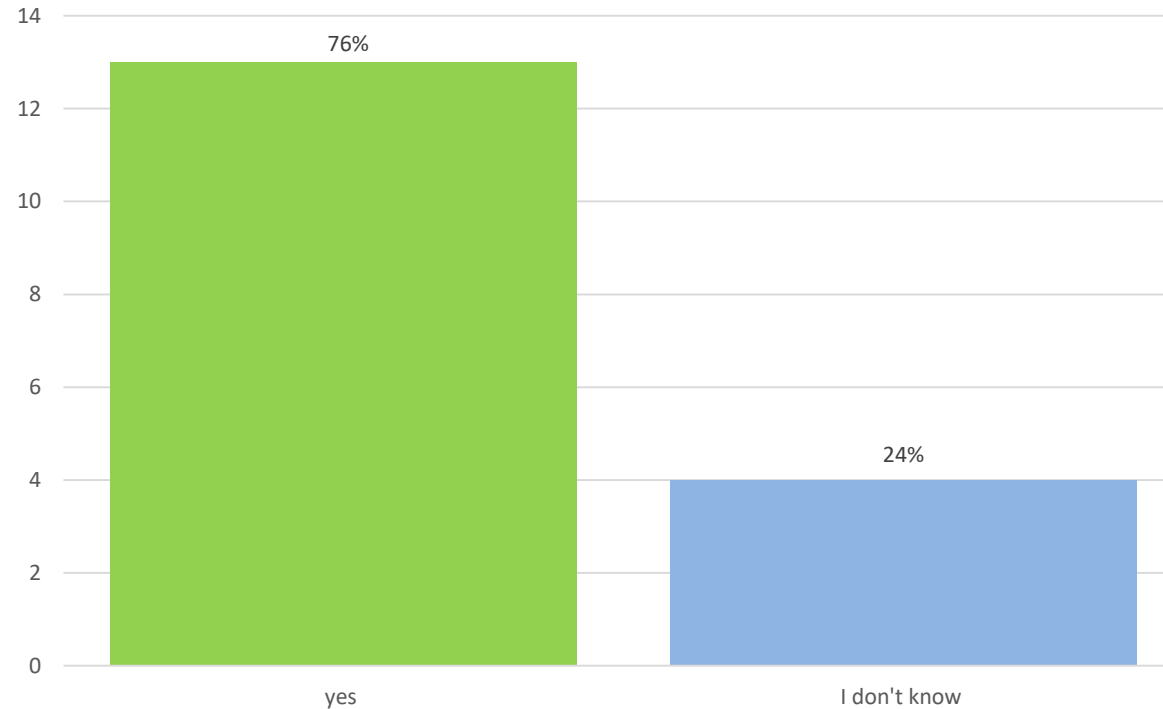
Do you expect that new methods and/or instruments will be available in the near future (e.g. the next 5 years)?



In case of positive answer, which ones? Most answers refer to the availability of e-leaflets with official translation in several languages

Results (8)

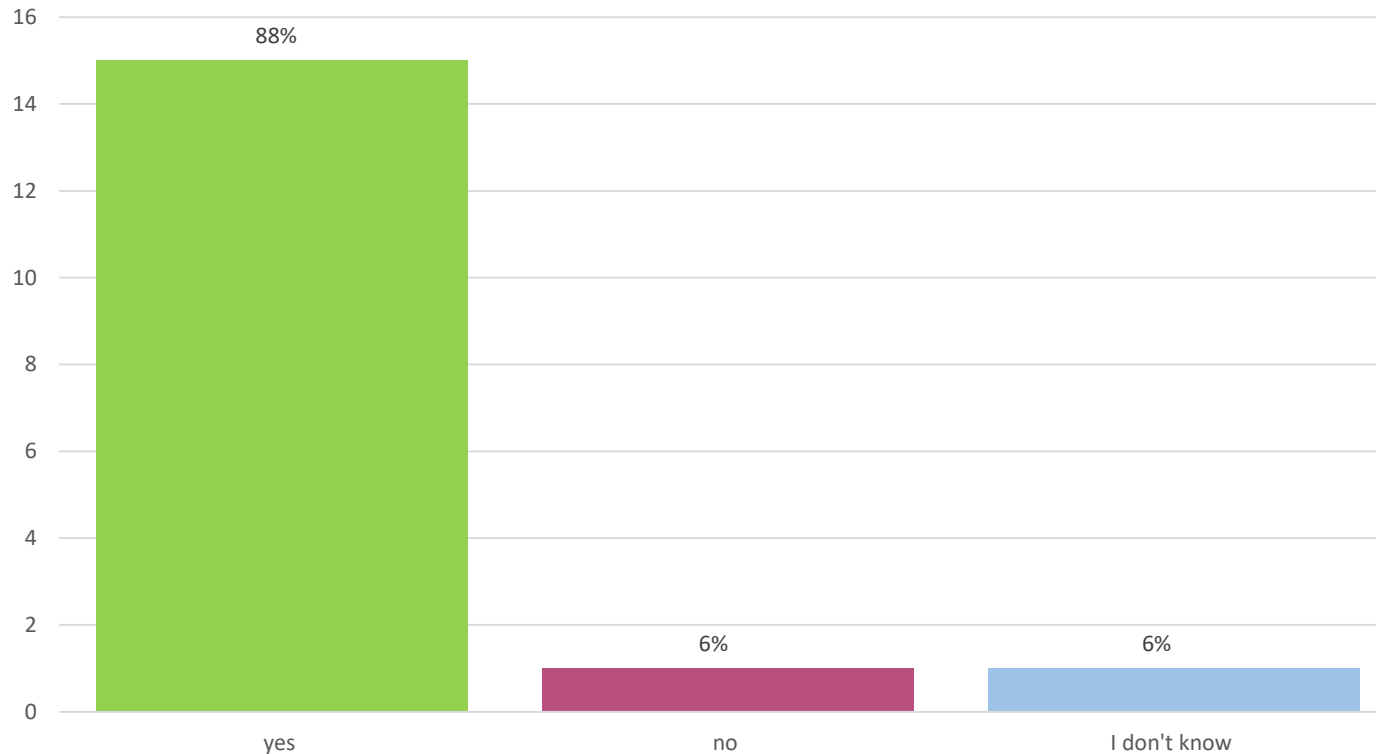
Do you think that understanding of PILs would improve if electronic leaflets written in different languages were available for printing in pharmacies/ hospitals/ sanitary outposts (e.g. immigration centres) and supplied with the medicine to patients who cannot access their PIL electronically?



If not, what obstacles could there be to have PILs available in electronic format? No comments provided

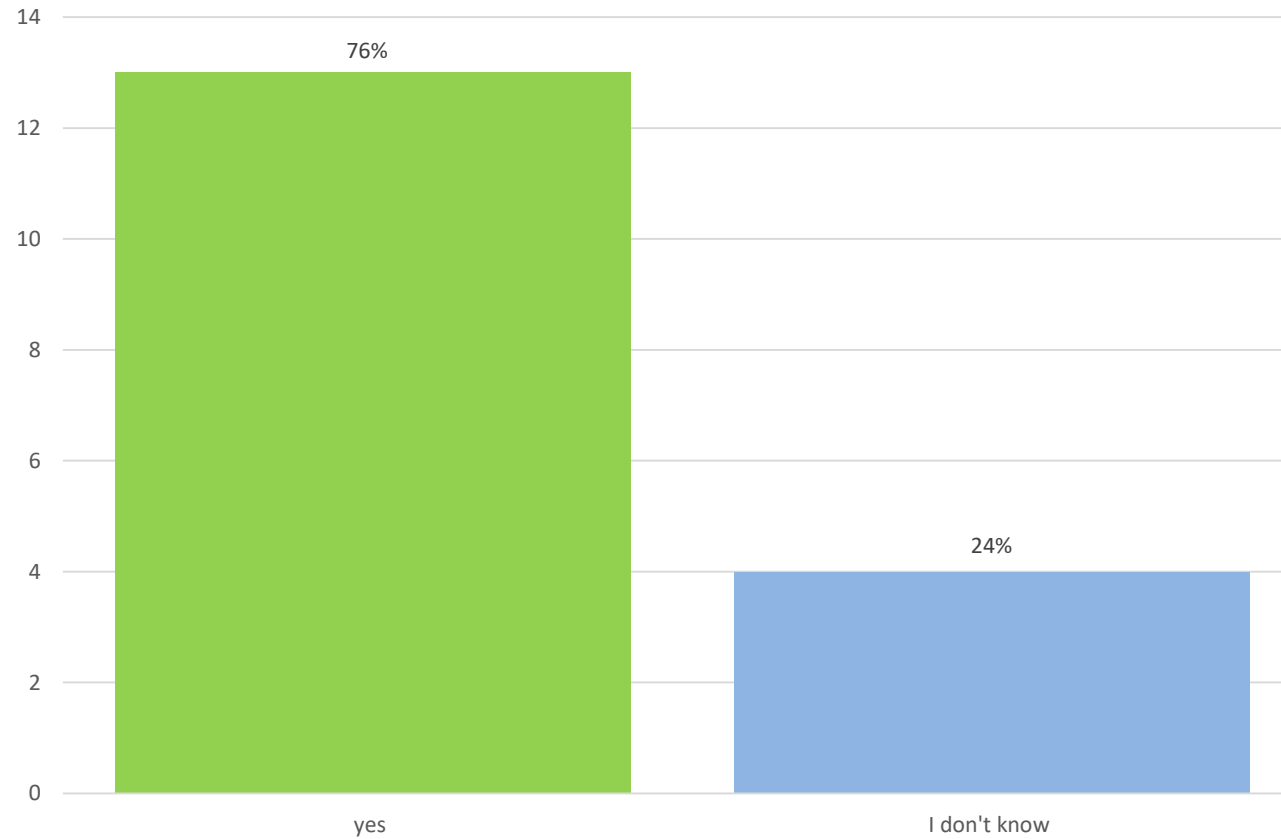
Results (9)

Do you think that understanding of PILs would improve if electronic leaflets written in different languages were available on the websites of the national competent health authorities or accessible on personal computers, smartphones and/or other electronic devices?



Results (10)

In your opinion, would it be feasible to have PILs in electronic format?



Results (11)

What could be the advantages and disadvantages?

Advantages - Examples

Bulgaria: Better understanding of PILs

Czech Republic: Less waste of paper, less burden on staff

Estonia: E-PILs will be structured (easy to compare information of different products, including side effects, etc.) and can be used in different apps/ IT software

Finland: Easier to check the text whenever wished

Iceland: E-PILs give a person important information about their medication: having access to this information is crucial for adherence and safety issues

Ireland: People would be better informed and also, if they have a query about their treatment, they could easily inform a HCP and discuss their concerns

Italy and Switzerland: Improved safe use of medicines

Latvia: Better accessibility

Norway: Easy access on demand

Disadvantages - Examples

Czech Republic: Technical problems

Denmark: Incorrect translation, additional work for MAHs and insufficient expertise at national competent authorities to check translations

Estonia: Extra investments needed

Georgia: It could be opposed by industry

Iceland and Latvia: No particular disadvantages

Ireland: Misunderstandings and fear of not taking the medication due to side effects, not being able to understand the information provided by PILs

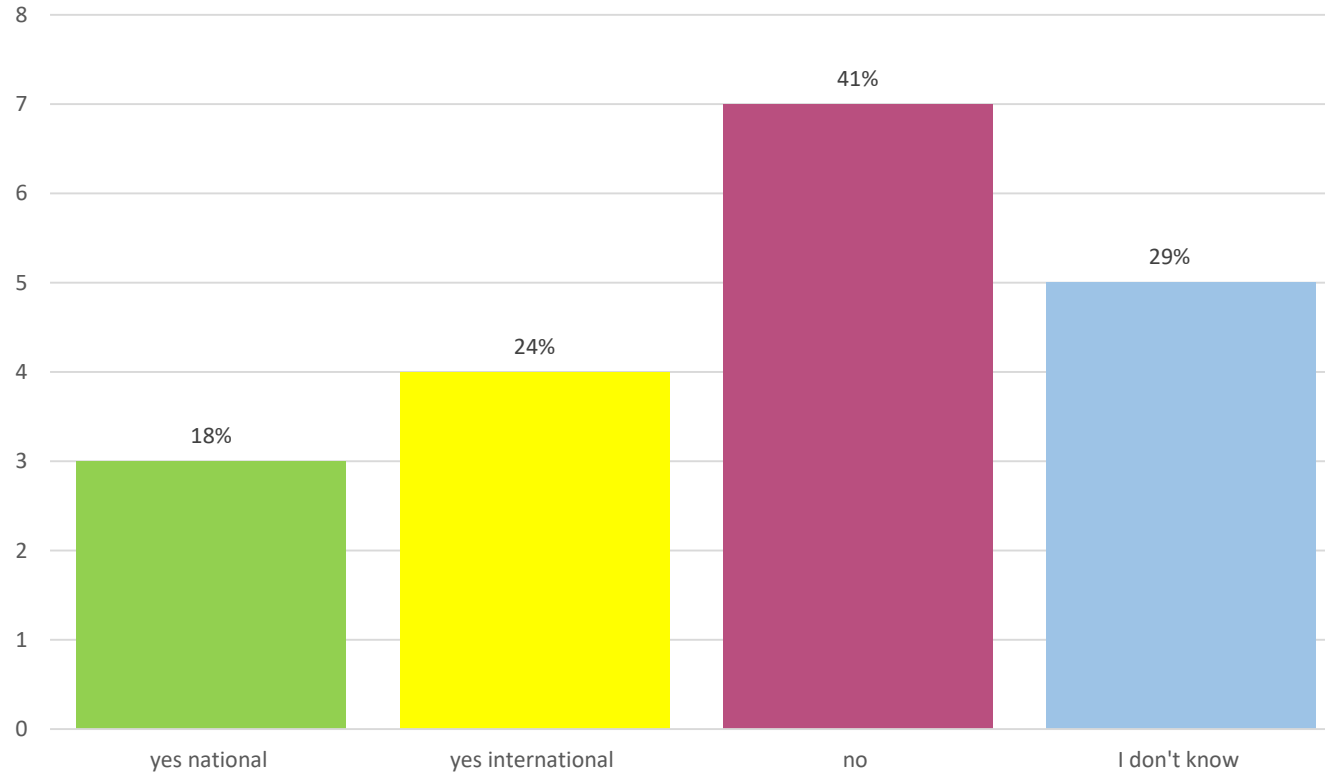
Norway: None, as far as no additional national approval is needed

Poland: Liability issues related to errors in the text of the translated leaflets. No access to e-PILs for patients with no internet access

Switzerland: Failure of translation

Results (12)

Are you aware of ongoing initiatives at national or international level to improve access to medicine information for those who do not understand the national language?



Nationally: Ireland, Netherlands, Norway

Internationally: European Medicines Agency and Heads of Medicines Agencies

Results (13)

What other ways would you suggest to ensure that all patients have access to the necessary information they need to take or use their medicines in a safe and appropriate manner?

Different options mentioned - Examples (not exhaustive list)

Bulgaria: Communication between medical doctor/pharmacist and patients is the most important part of the process: it would be important for patients to have access to both information and HCPs who speak their own language

Denmark: Maybe apps

Estonia: Standardized and structured e-PILs, which can be easily used in different languages using standard terms

Finland: Pharmacies could develop their internet programs (e.g. how to take medicines) (already in some scale in use but to be further developed)

Georgia: Drug searching apps for smartphones would be the best options, even (or especially) for low income countries

Ireland: Educating HCPs to ensure they have the necessary tools to effectively communicate with non-nationals. Having an interactive portal open while having the consultation, so they can access the information needed in the patient's language

Latvia: Competent advice by the pharmacist with a personal approach to the particular needs of the patient

Netherlands: At the CBG-MEB, work is ongoing on the information in PILs (in our national language) to make it easy to understand, including for those who have low (health) literacy. This is also meant to support healthcare professionals and patients in their communication about the appropriate use of medicines

Norway: Provide structured information from the product information that can then be delivered in parts suitable for different situations throughout apps, etc.

Conclusions

- ✓ HCPs seem to encounter difficulties in providing patients who do not understand the language of PILs with necessary information
- ✓ Different methods used to present necessary information to patients but most likely not sufficient to ensure safe and appropriate use of medicines
- ✓ Understanding of PILs could improve:
 - if e-PILs in different languages were available for printing in pharmacies, hospitals, etc. (76% (N=13))
 - if e-PILS were available on web-sites of authorities or smartphones, tablets, etc. (88% (N=15))
- ✓ A number of advantages and disadvantages of e-leaflets could also be identified
 - Advantages: better understanding of PILs, easy access to leaflets, safer use of medicines, less waist of paper
 - Disadvantages: technical problems, additional work for MAHs, fear of not taking medications due to side effects, incorrect translations, responsibility and accountability issues

Next steps

- ✓ Study to be made available on EDQM web-site
- ✓ Study results to be potentially shared with EMA
- ✓ Monitoring of ongoing initiatives in Europe
- ✓ Potential preparation of scientific article
- ✓ Suggestions from the audience welcome

Thank you for your attention!

For more information:

- ✓ Council of Europe: www.coe.int
- ✓ EDQM: www.edqm.eu
- ✓ European Committee on Pharmaceuticals and Pharmaceutical Care
<https://go.edqm.eu/CDPPH>
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