

From: The National Adult Literacy Agency (NALA), Ireland

Response to:

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/E

Focusing on:

Chapter VI Product information and labelling –
Outstanding issues and how to address them

November 2023

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Introduction

The **National Adult Literacy Agency (NALA)** in Ireland is a registered charity with close to 2,000 members. We believe literacy is a human right.

We are committed to making sure people with unmet literacy, numeracy and digital literacy needs can fully take part in society and have access to quality learning opportunities that meet their needs.

We do this through:

- Advocacy and policy
- Literacy awareness training and outreach
- Learner information, provision and support
- Plain English editing and training
- Professional development events, resources and support
- Research

Our main message

When reading medicinal labels and leaflets people with literacy, numeracy and digital needs are at risk of making mistakes in terms of:

- dosage
- frequency
- timing
- other instructions

Medicinal packaging and labelling should always be literacy friendly.

Literacy, language, numeracy and digital literacy skills

These skills involve listening, speaking, reading, writing, using numbers and everyday technology to communicate, to build relationships, to understand information and make informed choices.

Literacy, numeracy and digital literacy skills enable people to reach their full potential, be active and critical participants in society. These skills also help address poverty and social exclusion. These life skills allow us to participate in, and make sense of, the world.



Literacy, language, numeracy and digital literacy skills vary by context so these skills must be tested in different settings. Patients' skills can be strong in one area, for example reading, but low in another area such as numbers.

Unmet literacy, language, numeracy and digital literacy needs arise because of educational and wider structural inequalities. Sadly, these inequalities feature across Europe and the world. We provide statistics on literacy difficulties on pages 7-8.

Literacy and equality

Literacy is a barometer of equality and is the gateway to creating a society that is better and equal for all. Equality is not about treating everyone in the same way, but it recognises that individuals' needs are sometimes best met in different ways.

Like you, we too adhere to the 'no patient is left behind' principle.

About our submission

We are pleased to have the opportunity to contribute to this important consultation. Our focus is on Chapter VI Product information and labelling.

If you put our recommendations in place, it will greatly benefit patients' understanding of medicinal package leaflets and product labels in real-life settings such as home, hospital, and elsewhere. This will particularly benefit the significant numbers of patients and carers in Europe with literacy, numeracy and digital needs. It will lead to improved health outcomes for patients and care-givers and reduced health costs for governments.

To achieve this, you need to keep patients involved when designing, creating, testing and approving medicinal packaging and labels.

We ask you to consider and apply our recommendations.

We invite you now to read our submission. It has two parts:

Part 1: Outstanding issues and how to address them

Part 2: About us and our work to promote awareness and share solutions around literacy, numeracy and digital issues focusing on our work in the health sector.

Part 1: Outstanding issues and how to address them

We commend your draft directive's good intent regarding medicinal package leaflets and labels. That is why we spotlight four outstanding issues with Chapter VI and how to address them.

Outstanding issues in Chapter VI

Issue 1: Patients with general literacy, numeracy and digital needs are not explicitly referenced or outlined – page 7

Issue 2: What appropriate action means – page 11

Issue 3: Concern around how legible, clearly comprehensible and indelible information will be agreed and checked from a literacy-awareness perspective – page 12

Issue 4: Overly limited view of information design in aiding patients' understanding – page 14

In the following pages, we look at each issue and how to address it.

Issue 1: Patients with literacy, numeracy and digital needs are not explicitly referenced or outlined

The directive needs to focus on patients with literacy, numeracy and digital needs and their specific needs.

You refer to digital literacy needs. You also refer to the needs of:

- older people,
- people with language needs,
- people with health literacy needs, and
- people with disabilities.

These are all helpful. However, there are wider adult literacy and numeracy issues for people in Europe, particularly those aged 25-64. This is a very important issue when considering access to medical packages and labels.

Literacy – European figures

Statistics for adults aged 25-64 year in Europe show that:

- Just over 1 in 4 (25.5%) have low basic digital skills
- Just over 1 in 5 (21.8%) have low problem-solving skills
- Just over 1 in 5 (20.2%) have low numeracy levels
- Almost 1 in 5 (18%) have low literacy skills. (CEDEFOP, 2020).

CEDEFOP IS the European Centre for the Development of Vocational Training.

Let's focus for a moment on low numeracy levels. Low numeracy levels mean you struggle with:

- percentages,
- dosages,
- estimating risks, and
- probability.

Literacy – European figures from the international adult literacy survey (PIAAC)

The latest international adult literacy survey (PIAAC 2012) showed that many European countries had **more than 15%** of citizens at the lowest level of literacy (5 levels in all) on the prose literacy test. They include:

- Belgium (Flanders),
- Czech Republic,
- Hungary,
- Ireland,
- Poland,
- Portugal,
- Slovenia, and
- Switzerland.

This survey also showed that Sweden had the lowest level of citizens with literacy skills at 8%. We are expecting findings from the latest International Adult Literacy Survey (IALS) in 2024.

Literacy – health literacy

Research shows limited (inadequate or problematic) health literacy for many countries. The prevalence ranged from about over 1 in 4 respondents (28.7%) in the Netherlands to about 6 in 10 (62.1%) in Bulgaria. (The European Journal of Public Health, 2015).

A later European health literacy survey (2019-2021) of 17 countries has been done. Taking Ireland as an example, this survey found that over a quarter (28.4%) of citizens had limited health literacy. (NALA Webinar, 2021)

Low literacy levels means people may not understand medicinal information

Research shows the worrying consequences of low literacy and health literacy levels when it comes to reading, using, and correctly following instructions on medical labels and similar. Findings are concerning. Here is why:

- “Take one tablet three times per day” was correctly understood by 79% of people.
“Take one tablet at breakfast, one lunch and one at dinner” was correctly understood by

97% of people. (Sahm, et al, 2011)

Another study of five common prescription bottle labels tested showed:

- nearly half of all participants (46%) misunderstood at least 1 label, and
- just over half (51.8%) made a mistake on the dosage, and
- just over a quarter (28.2%) misunderstood the dose frequency. (Davis, et. al., 2006).

Collins et al. (2014) gave warfarin (blood thinner anticoagulation product) material to patients to read. One group had to read it on their own. The other group read it with the help of a counsellor. The findings were as follows:

- Adequate literacy: Half (50%) passed the Anticoagulation Knowledge Test after just reading vs. 84.6% after pharmacist counselling down to 34.6% two weeks later
- Low health literacy: Almost a quarter of people (23.5%) passed after just reading, about 60% (58.8%) after counselling, 35.5% two weeks later. (Collins et al, 2014)

If all involved in package leaflets and labels make themselves aware of the issues around health literacy and take action to address them, then they can increase patients' understanding and health outcomes.

If you use patient-centred labels and package, you can help people with limited literacy, numeracy and digital needs information.

Patient Centred Labels tested against standard labels showed that the former had 91% correct interpretation rate relative to 66% correct interpretation of standard labels (66%). (Sahm et al. 2012)

How to address issue 1

1.1 Explicit reference: Make an explicit reference to the **general and specific** needs of people with literacy, numeracy and digital needs of patients in the final directive, ideally as a distinct article (as you did for people with disabilities in Article 71).

1.2 Define literacy: Include a broad definition of literacy, like ours, in the directive and

proposed guidance.

1.3 Require literacy awareness training: Require literacy awareness training and supports for all developers and testers of medicinal materials in a range of real-life situations.

1.4 Continue to promote plain language and universal design principles.

1.5 Make the following change: Change this proposal:

“If the package leaflet is only made available electronically, the patient’s right to a printed copy of the package leaflet should be guaranteed upon request and free of charge...”

to read:

“Patients should always be offered paper versions of package leaflets free of charge.”

Why? The suggested revised text would remove the need for patients with literacy needs to have to ask for paper leaflets, which some may be reluctant to request. Most patients will likely still opt to go online, so environmental measures will be intact.

Issue 2: What ‘appropriate action’ means

The consultation paper states that:

“The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals.”

We find this unclear. Firstly, what do you mean ‘appropriate action’ and who makes the final decision on what ‘appropriate action’ is and in what settings? How does your understanding of appropriate action align with the latest definition of health literacy and its focus on finding, understanding and using information and services?

Secondly, there is an issue with the wording of the original text. It presumes most of us understand punctuation correctly. Many people will read this as if there is another comma, which changes the meaning:

...enabling users to act appropriately, when necessary, with the help of...

With the second comma, this means that there is **always** help of a healthcare professional. We suggest you change this to:

... enabling users to act appropriately. In some cases, this may be decided with the help of healthcare professionals.

How to address issue 2:

2.1 Clarify appropriate action: Clarify what ‘appropriate action’ means in this context. We suggest that this means that a patient can consistently read, understand and safely use the medicines in different settings (hospital, home, so on), ideally on their own.

2.2 Involve patients: Involve a representative sample of patients with literacy needs in deciding what ‘appropriate action’ means when they are trying to follow a package leaflet and or label. Make sure these patients are involved from the early design of leaflets (and labels) and right through to testing use in different settings, and ideally approving final resources.

Issue 3: Concern around how legible, clearly comprehensible and indelible information on packages and labels will be agreed and checked from a literacy-friendly perspective

The consultation paper also states that:

“The package leaflet and labelling particulars referred to in this Chapter shall be

easily legible, clearly comprehensible and indelible.”

We are pleased to note that you plan, in consultation with the Member States and the parties concerned, to ‘draw up and publish detailed guidance’ on: “

- a) the wording of certain special warnings for certain categories of medicinal products;
- b) the particular information needs relating to non-prescription medicinal products;
- c) the legibility of particulars on the labelling and package leaflet.”

and so on. This is welcome. We also think that the package leaflets and labels should ‘reflect’ patients’ group feedback (see Article 64) – and more.

However, we are concerned about:

- who will agree on legibility and how this will be done,
- what ‘clearly comprehensible’ means,
- what ‘indelible’ means here, and
- what and how **desired achievements for patients with literacy, numeracy and digital needs** will be described in guidance and tested in real-life settings.

How to address issue 3:

3.1 Consult effectively with patients and users with literacy, numeracy and digital needs. (See earlier recommendation 2.2)

Consider too these ‘audience insights’ from CDC (2023):

- do background research on the patients’ literacy and numeracy skills,
- recruit readers with low literacy skills,
- create tasks for patients to achieve based on package leaflets and labels and assess how well the leaflets and labels work to correctly use and recall medicinal instructions in different settings,
- separate patients with literacy needs from average readers into different testing groups for more effective feedback.

Again, tests should be done in real-life settings.

3.2 Consult with other experts, including health literacy researchers. These tests should be performance based and include experts from:

- information design,

- behavioural science,
- plain language,
- literacy and health-literacy areas.

Experts in literacy and health-literacy should ideally be research experts whose work shows useful findings and solutions based on collaboration with patients with low literacy, numeracy and digital skills on a range of areas.

3.3 Use the latest and best communication resources: Base the proposed guidance on:

- the first ISO standard on Plain Language published this year; and
- [Communications Toolkit for Services to the Public: A universal design approach 2023](#). This toolkit advocates for accessibility specifications that designers must follow at the procurement bid stage. This is an invaluable resource for marketing professionals to know about and use. They could refer to it in procurement documents when seeking health literacy researchers to do performance-based assessments of patients' use of leaflets and labels, or when developing videos or other digital resources about health information.
- **Avoid relying on readability checkers:** Do not rely on readability checkers or use them prudently if checking legibility. They are not reliable enough. (Schriver, K, 2017).

Issue 4: Overly limited use of modern information design techniques

We note too:

“Article 73 Symbols and pictogram: The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information [...] and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.”

The above options of symbols and pictogram are valuable but too limited. How are testers supposed to know what is clear for specific patient groups without the value of proven tests using user-friendly (includes information design such as visuals) design and patient input? User-friendly design and patient input is particularly important for patients with literacy, numeracy or digital needs.

There is much research showing how appropriate design (not just text) can contribute to strategic reading, understanding and use. Here is just one example:

Researchers in Northwestern University simplified the text and icons used in nine prescription-medication warning labels and then tested them with 530 patients along with standard warnings. Their findings were as follows:

Almost 92% of patients correctly interpreted the simplified warnings with new icons. This compares to 79% of patients who correctly interpreted the standard warnings. (Wolf et. Al, 2010)

Information design covers four main areas:

- context,
- language and writing,
- visual perception, and
- visualization (example: showing quantities or points of time on a measurement scale).

All areas are important and need to be integrated into the development and testing of clear information for patients.

How to address issue 4:

4.1 Broaden scope, test and continue to learn and apply learning: If you want patients, particularly patients with literacy, numeracy and digital needs, to easily understand text, then you need to use a combination of methods. This combination would include both clear text in legible font along with a wider range of visual formats. Examples of these formats are: icons, drawings, and literacy-friendly videos where appropriate (with captions), and so on.

Finally:

The above issues and recommendations would support greater and wider patient access to literacy-friendly medicinal packages and labels. In fact, some of these actions would also support other areas of work such as helping patients with literacy, numeracy and digital needs report adverse reactions (see Article 64).

We hope that you found our submission helpful. Please continue reading to learn more about us.

Part 2: Why we are worth listening to

We are the National Adult Literacy Agency (NALA), a registered charity in Ireland. We believe literacy is a human right. We are committed to making sure people with unmet literacy, numeracy and digital literacy needs can fully take part in society, and have access to quality learning opportunities that meet their needs.

Here is an overview of our work in this area with a particular focus on efforts and achievements in promoting access to quality and clear information on health matters to adults with literacy, numeracy and digital needs.

Our track record of raising awareness of literacy and health literacy needs

NALA has been at the forefront of work on health literacy awareness and making the link between literacy levels in Ireland and the impact this has on people's health. We work closely with the Health Service Executive (HSE) and other healthcare providers in Ireland and elsewhere to progress this area through research, training and advisory services.

You might like to view our [video on Better Communication – Better Health](#) (9 minutes).

Our work for decades with health sector services

We recognise that people working in the healthcare sector play an important part in improving health literacy and numeracy by communicating more clearly and making information and services more accessible to patients. We provide research, training, health-literacy audits and specialist advice.

You might like to:

- view this video on [Communicating in plain English](#) – a video we co-produced with the Irish Health Information and Quality Authority.
- read [Guidelines for Communicating Clearly with Plain English with our Patients and Services Users](#) – a resource we developed with the Irish Health Service Executive to support its staff.

Health information for the general public

There is more to health literacy than learning. We support adults with literacy, numeracy and digital needs to improve their knowledge of health information.

[You might like to read more about this work on our site.](#)

Crystal Clear Mark

This national programme sponsored by MSD offers pharmacies the opportunity to gain a unique quality mark.

You can read more about the [Crystal Clear Mark](#) on our site.

Health literacy awareness

We have partnered with the Irish Cancer Society (ICS) to produce health literacy awareness videos to support cancer patients and their families.

We developed these short videos to give detailed information around key areas which affect patients' lives on a daily basis. They provide a patient's perspective and include helpful tips.

You might like to view three [health literacy videos](#) on our site about health appointments, test results and supports between appointments.

Cancer health literacy eLearning course for health professionals

We also partnered with the Irish Cancer Society to produce a short eLearning course for healthcare professionals that explores the benefits of good health literacy practice in cancer care. MSD Ireland funded the course.

You might also like to take this [eLearning course](#). (20 minutes)

We look forward to continued communication and collaboration. Please do not hesitate to contact us for any further information or clarification.

More reading and references:

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The National Adult Literacy Agency (NALA) is a charity and membership based organisation. We work to support adults with unmet literacy, numeracy and digital literacy needs to take part fully in society and to have access to learning opportunities that meet their needs. NALA does this by raising awareness of the importance of literacy, doing research and sharing good practice, providing online learning courses, providing a tutoring service and by lobbying for further investment to improve adult literacy, numeracy and digital literacy skills.

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