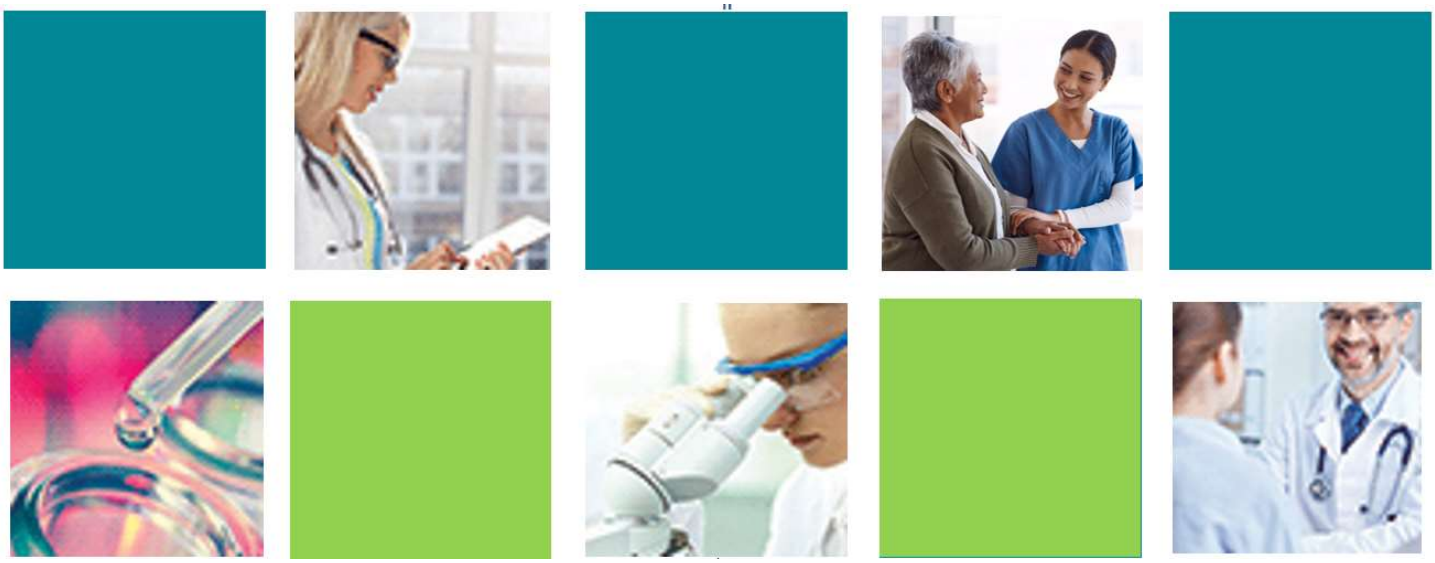
efpia
European Federation of Pharmaceutical Industries and Associations

Enhancing Understanding: The Importance of Effective Communication Materials in the Pharmaceutical Industry

A practical guide



This best practice guidance has been authored by 8 professionals with around a century of collective experience in patient-centric communication and/or working with members of the patient community to develop and deliver health and medicine-related content that is both meaningful and impactful.

Acknowledgments

We extend our sincere thanks to:

- ***Simo Goddijn**, Director of BureauTaal and Plain Language Europe, for your invaluable guidance in promoting clarity in communication.*
- ***Karel van der Waarde**, member of the International Institute for Information Design and board member of the International Plain Language Federation, for your advocacy of plain language principles and effective information design.*
- ***The EFPIA Patient Think Tank**, for your collaborative efforts in enhancing patient-centered communication.*

Your input and support is greatly appreciated.

efpia
European Federation of Pharmaceutical Industries and Associations

Table of contents

Executive summary

This paper provides an in-depth look at health literacy and patient-friendly language as important tools that enhance patient understanding, safety, and engagement, which improve health outcomes and reduce the burden on healthcare systems. It offers guidance on how the pharmaceutical sector can develop easy-to-understand materials that provide patients[i] and their caregivers with the information they need to make treatment decisions and play an active role in their care.

The paper further emphasizes the importance of involving patients in the development of patient-facing content to ensure that materials meet patients' needs effectively. In doing so, it outlines the core principles of health literacy, such as accuracy, accessibility, inclusivity, and actionability of medical information, and introduces the concept of plain language as a key tool for achieving clear and comprehensible patient communication.

Furthermore, the paper presents the general principles of patient-centric communication, highlighting the importance of language clarity, structural and format considerations, use of numbers and visuals, and the significance of accessibility and consistency.

Strategies to stimulate patient-centric communication in the pharmaceutical industry are discussed, covering available tools, training, and services to support the use of plain language, the development of templates, patient involvement, appropriate use of electronic or digital materials, and the need to ensure plain language consistency across all EU languages. Legal considerations are also addressed, acknowledging the potential challenges in developing patient-friendly content and offering solutions to mitigate risks without compromising the integrity and clarity of patient communication.

In conclusion, the paper calls (1) to engage in constructive dialogue with all stakeholders involved to agree on the general principles of patient-centric communication, (2) to create the necessary flexibility to implement these principles and (3) to engage in harmonisation efforts to ensure consistency. Through these aligned efforts, the pharmaceutical industry can provide patients with clearer, more accessible, and more empowering information, ultimately leading to improved health literacy, better adherence, increased patient safety, and better healthcare outcomes.

[i] A patient is a person who uses medical services or services of other people who provide medical treatment. This may involve the prevention, diagnosis or medical treatment of illnesses or the consequences of an accident. There are also healthy patients. These include for example those who have recovered, living organ, blood or stem cell donors, newborns, vaccinated people, recipients of preventive services and screening examinations, pregnant women, or women using contraceptives. In our context, we also include relatives and carers as recipients of our materials in this term.

1. Introduction

Effective communication materials from the pharmaceutical industry are essential for ensuring that patients fully understand their medications and treatments. Materials should be tailored to the needs of the patients, using plain language, visuals, and accessible formats (like videos or digital tools) to make complex medical information more digestible. Additionally, culturally sensitive materials are important to ensure diverse populations can also understand the information and follow their treatment properly. This paper will examine the use of health literacy principles and patient-friendly language, along with digital tools and formats, to create accessible and actionable content that empowers patients and enables them to be engaged in their healthcare.

The importance of creating understandable, patient-friendly communication materials with consistent strategies cannot be overstated. Pharmaceutical companies produce a wide variety of communication materials to help patients understand their medications and treatments. Some common examples include Patient Information Leaflets (PILs), Informed Consent Forms (ICFs), Risk Minimisation Materials, Plain Language Summaries (PLSs), and clinical study recruitment materials, among many others. Often, industry struggles with finding a balance between high complexity and understandability, especially when preparing materials for audiences without a medical or regulatory background. Clear, easy-to-understand information can help patients make informed decisions, follow their treatment plans correctly, and feel more confident in managing their health[1]. Additionally, a lack of understanding of the materials patients receive can be a significant contributor to non-adherence. Non-adherence to medications for chronic diseases, which stands at a staggering 50%, results in up to 50% of treatment failures. This issue is further magnified when considering the 200,000 lives lost annually in the EU due to non-adherence[2] and the significant economic burden of €80–125 billion every year[3]. These figures underscore the importance of the topic, not only to enhance patient understanding and safety but also to support patient engagement and thus potentially reduce healthcare costs and improve overall health outcomes.

To make sure communication materials meet patients' needs, they should be involved in all stages of a medicine's life cycle and in developing patient-facing materials[4]. In the context of this paper, we define a patient as a person who uses medical services. This may involve the prevention, diagnosis

or medical treatment of illnesses or the consequences of an accident. There are also healthy users of medical services. These include for example those who have recovered, living organ, blood or stem cell donors, newborns, vaccinated people, recipients of preventive services and screening examinations, pregnant women, or women using contraceptives. In this paper, we also include these healthy users of medical services and also relatives and carers as recipients of our materials in the term 'patient'.

This paper provides a holistic industry view on what is needed to create clear, concise patient-friendly communication materials, highlighting the benefits these bring to both patients and the healthcare industry. It includes tools, techniques, and strategies to be used in the creation of these materials and discusses the importance of collaboration with impacted stakeholders to promote and implement these approaches. By prioritising patient-friendly communication materials, the pharmaceutical industry intends to foster better patient understanding, patient safety, adherence, and overall health outcomes, while building stronger relationships with the patient community and healthcare providers.

2. The starting point of patient-friendly communication materials: health literacy and patient-friendly language

a) What is Health Literacy?

According to the Centers for Disease Control and Prevention (United States), health literacy involves both personal health literacy and organisational health literacy[5,6]:

- Personal health literacy is the degree to which individuals can find, understand, and use medical information (i.e., scientific terms and concepts), as well as services, to make health-related decisions and take actions for themselves and others[7].
- Organisational health literacy is the degree to which organisations enable individuals to find, understand, and use information, as well as services, to make health-related decisions and take actions for themselves and others.

Health literacy is important because each of us, at some point, has or will need to seek, understand, and act on information related to our health and our treatment. Being able to understand information about diseases or conditions and the ways to prevent them helps people stay healthy. In the same way, being able to understand information about available therapies for a disease or condition, helps patients play a more active role in their care and treatments.

As the degree of health literacy is a strong predictor of health outcomes[8,9,10], it is needed to invest in improving health literacy. To support this, organisations in the health sector, including the pharmaceutical industry, should comply with the core principles of health literacy (see section 2b) and patient-friendly (plain) language (see section 2c) when developing patient-friendly communication materials.

b) What are the core principles of health literacy?

To support and improve health literacy, communication materials should be:

- **Accurate**: The information presented should be in line with the science behind it, accurate, and delivered in a way that people can understand[11].
- **Accessible and inclusive**: Medical information should reach the people it is intended for. Where and how information is presented affects how accessible it is (i.e., how easy it is to obtain and use). Some things to consider include[3]:
  - Is the information shared where people can see it?
  - How does the information reach those not actively seeking it?
  - What is the key message of your document?
  - Does your choice of medium (audio, video, text), format, font, color, background, layout, and visuals make the information easy to listen to or watch?
  - Do the images or video match the text and are they supported by useful captions?
  - Can your information be used by individuals from different backgrounds? Does it respect for example cultural differences, and does it provide medical information in a way that is not intimidating or offensive to people?
- **Actionable**: Medical information is only helpful if people can use it to make well-informed decisions and/or change their choices and behaviors to improve their health. To achieve this goal, content creators should limit the amount of background that is included in their communication materials so they can focus on the information that helps people make informed decisions and take action.[3.]

c) What is patient-friendly language?

As mentioned in section 2a, the use of patient-friendly language is key when creating patient- facing documents. Patient-friendly language (also more broadly known as, and hereafter referred to as plain language) means to adapt the language of any communication or information to the needs of the patient.

Plain language is a concept that focuses on clear and simple communication on a language level that is directed to the majority of the population. It is a tool to achieve content that is clear and easy to understand for a patient, caregiver, or the general public. Plain language starts with drafting the

communication not from the point of view of the sender but from the point of view of the receiver – thus, the concept is consistent with health literacy principles. According to the ISO Standard for Plain Language[12], these are the governing principles:

- The audience gets what they need (relevant).
- The audience can easily find what they need (findable).
- The audience can easily understand what they find (understandable).
- The audience can easily use the information (usable).

Almost anything − including patient information about medicines − can be written in plain language without oversimplifying or compromising scientific accuracy. When using plain language, one reaches a larger audience and gets the message across more easily, and in a friendlier way.

3. General principles of patient-centric communication

In this section, we will describe the fundamental aspects that contribute to effective, patient-centric communication in the pharmaceutical industry. It serves as a guide to the principles that underpin consistent patient-centric communication.

a) Goal of the communication

As discussed in Section 2a, the goal of using plain language in communication is to ensure that the key message is understandable to the audience the first time they see, read, or hear it. To achieve this, two steps should be followed: 1) identify the target audience and 2) clarify the intended action for the audience.

Determine the audience

The audience for materials written in plain language usually is people with little or no formal education in healthcare or medicine.

For materials prepared by the pharmaceutical industry, this includes:

- People who participate(d) in a clinical study.
- People from patient organisations.
- People who receive or seek treatment.
- Caregivers, including family members or other close relatives.
- Children and teenagers.
- Investors, funders, or payees.

In addition, materials in plain language can also support healthcare professionals, for example for topics outside their therapeutic area.

It is important to use a level of communication that can be understood by the majority of the population.

Clarify the intended action

Analyse and determine the key message of the communication material. Consider what the audience needs to do according to the key message and make this clear in the communication. Try to

anticipate and answer the questions the target audience is likely to ask. Leave out any unnecessary details.

Can the audience:

- Find the information they need?
- Understand the information they find?
- Use the information?

Using clear wording, structure, and information design will help communicate the key message easily to the audience. The audience should be able to easily identify the purpose of the communication, whether they have actions as a result of the communication, and what their actions are.

b) Language

Writing in plain language means much more than using familiar words or keeping sentences short[13]. It is also about the writing style and how the content is organized for the target audience.

The key principles for plain language writing are as follows:

- Write for the target audience.
- Use inclusive language.
- Use clear and concise language.
- Keep the language factual, neutral, non-promotional, unbiased, and non-misleading.
- Write in an active voice. Avoid nominalization of verbs, instead use verbs (e.g., use the word 'intend' instead of 'intention', 'decide' instead of 'decision', and 'fail' instead of 'failure').
- Limit each paragraph to one idea and keep it short.
- State the major point(s) first before going into detail.
- Keep the sentences short as much as possible.
- Use everyday words. If the technical terms are mentioned, explain them on the first reference or in a glossary of terms.
- Use consistent terminology (e.g., avoid speaking about “doctor” in one paragraph and “physician” in another).
- Do not describe patients as victims or with terms that imply helplessness (e.g., do not use "afflicted with", and "suffering from").
- Do not use euphemisms and figurative language (e.g., do not use words like “differently abled”, “special needs” or “challenged” to redefine or minimize a disability’s real impact.

- Do not use double negatives (e.g., do not use sentences like ‘The drug is not for patients with no history of allergies’).
- Avoid using colloquial language or idioms specific to a region or country (e.g., "sick to the stomach", "feeling under the weather").
- Avoid the use of words or phrases that could be interpreted multiple ways (e.g., "stool")
- Leave out unnecessary words. (e.g., instead of ‘Doctor made a decision’ write ‘Doctor decided’; instead of ‘The study has a requirement for’ write ‘The study requires’).

Revise and check:

Remember to reread the text and check the following:

- Is the goal of the document clearly indicated?
- Is the vocabulary appropriate to the audience and the goal of the document?
- Are the ideas expressed logically?
- Does it flow?
- Have the audience’s potential questions been answered?
- Have additions from other authors introduced any duplication, contradictions, or addition of new technical terms?
- Consider asking a second person to review the content with a fresh look.

How to achieve the desired readability

Readability is a measure of how easy it is to read a piece of text. The readability of text depends on its content, style, format, and its organisation[14]. Although readability level of text can also be measured with readability formulae and writing support tools, e.g., the "Editor" function in Word or ProWritingAid, Grammarly, and others (see Section 5a), readability testing and readability scores are useful but not in themselves enough to ensure that the text is easy to understand[15,16].

To ensure sufficient readability in the target audience, it is strongly recommended to conduct patient engagement activities and co-creation, when relevant. Participants may include patients, parents of paediatric patients, or the public. Various methods exist to obtain study participants, patient communities, and general-public feedback on plain language materials, including interactions within the pharmaceutical company, partnering with patient organisations, or specialists an independent third party, or using online services to host virtual panels.

c) Structure and format of written documents

In the pharmaceutical industry, we are often required to work according to regulations or within pre-defined templates. For example, Article 37 of the EU CTR 536/2014 highlights regulatory requirements for 'Summaries of Clinical Trial Results for Laypersons' (further referred to as lay summaries/plain language summaries), and product-information templates have been developed by the European Medicines Agency's Working Group on Quality Review of Documents, among others. More information on templates can be found in Section 4b.

However, it is still possible to further structure the communication within these templates to help the audience to better understand. It is good practice to define the key message first to provide a summary and give context before introducing any supportive details. This ensures the audience receives necessary information while reducing unnecessary specifics. When updating or adding text to an existing document, consider the existing structure of the communication to ensure clarity.

It is also important to structure your communication using design features that are easy to follow, such as headings, lists, tables, and graphical elements. To improve comprehension, consider following the below principles:

- Use a consistent approach with a defined layout.
- Use headlines and descriptive subheadings to organise information. For example, using a question as a subheading leads people to read the paragraph below the subheading[17,18].
- Keep enough "white space". Separate topics by one or two lines.
- Consider the use of bullet points instead of long sentences with lists of items.
- Consider the use of bold type to highlight important words.
- Use clear and easy to read font types and sizes[19,20].
- If the use of a medical term is necessary, use it in brackets after the plain language explanation.
- Use clear and simple infographics with explanatory text to present complex information.
- Limit use of unnecessary imagery (icons, logos, etc.).
- Avoid text in ALL-CAPS and underlining.
- Where appropriate, use links to additional information and resources for online summaries and background information. Give the link a clear name, so the reader knows where the link will

take them[21]. Please note that such links need to be minimal since hyperlinks may become out of date.

d) Use of Numbers

When using numbers to convey a message, the numbers should be clear and easy to understand, adhering to the following recommendations[22]:

- Numbers are recorded using numerals rather than text (e.g., 1, 2, 3 instead of one, two, three)
- When possible, use whole numbers rather than factions or decimals
- Frequencies are easier to understand than percentages (e.g., 4 out of 5 instead of 80%)
- Express the numbers in a clear way. Do not make the audience do the math.

e) Use of visuals

To reduce the risk of miscommunication regarding medicinal products, the pharmaceutical industry provides patient-focused written materials that are created in collaboration with regulators to ensure that scientifically accurate information is communicated to patients and healthcare providers about the medicinal product. The level of scientific and medical literacy among patients differs, and different linguistic and cultural backgrounds also present challenges for communication. Additionally, a patient's condition may impair their literacy level and their ability to access information. Well-developed and commonly used visual elements like symbols, images, pictograms, and "comic" style visuals for children and young adults may help to alleviate some of these discrepancies, leading to more effective communication about a medicinal product to the patients. Benefits of using images and pictograms include[23]:

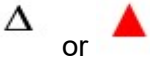
- Enhanced comprehension and recall of medical information, especially for patients with lower literacy levels, language barriers, or cognitive difficulties[24,25].
- Increased prominence of important information.
- Ability to show concepts that are hard to describe in text alone, such as illustrating how to use a home test, medical device, or medicine correctly[26].

It is important that visuals created for patient-facing materials are developed with accessibility to all patients in mind, including those with impaired vision or hearing as outlined in the Accessibility section (3G). In this regard it is good practice to also include descriptions of the visuals in captions

or alternative text (also known as alt text). This will allow people who use screen audiences and other assistive technology to know what the images contain.

Unfortunately, current regulations in the EU allow for the definition of symbols, images, and pictograms to occur at a national level (as opposed to an EU or global standard), which results in two challenging scenarios for patients: either the same or similar symbols have multiple meanings across the EU, or there are a variety of symbols, images, or pictograms in the EU with a shared meaning. One example of this can be seen when comparing the various symbols used across the EU for products that may affect the ability to drive or use motor vehicles, see Figure 1.

Figure 1: Various Symbols used to signify if a substance affects the ability to drive

			
France[1]/Spain	Denmark/Finland/Norway/	Austria/Romania	Slovenia[2]

1 In addition to the symbol shown France has an additional three images to represent levels of impaired driving.

2 Slovenia uses two symbols to capture the level of driving impairment.

Development of easy to comprehend pictograms and images presents its own challenges though as these tools must be carefully designed and tested, especially for images that are not well known nor standardised. For this reason, it would benefit both the pharmaceutical industry and patients to have an EU standardised approach and catalogue of unambiguous symbols, images, and pictograms that can be used in patient-friendly materials.

f) Use of other media

Digital communication tools, including video and audio content, mobile health apps, telemedicine, and online medical information resources have emerged as powerful tools for promoting and improving health literacy to improve health outcomes[27]. Having a range of information available in different formats enables patients to choose the media that helps them to best understand. Moreover, these tools provide content creators with the opportunity to add impactful and interactive features to make medical information more accessible. More specifically:

- **Video and audio content** can make it easier for the audience to understand complex medical topics. Videos complement, and even strengthen, content provided in print and increase patient knowledge, as well as understanding by as much as 38%[28]. It is important to make sure that the video and audio content provided is always using plain language.
- **Mobile health apps or platforms** provide convenient access to medical information, self-monitoring tools, and personalised interventions that may be helpful to some people, empowering them to play a more active role in their health. These solutions could also entail integration of gamification elements to enhance user engagement. By doing so, patients can acquire knowledge about their healthcare needs through interactive tools such as quizzes, simulations, and challenges, ultimately resulting in enhanced health literacy.
- **Online health resources** such as Medscape and WebMD provide a helpful platform to offer more in-depth information that supports patient education, decision-making, and self-management. When referring to online health resources the trustworthiness of these sources should be carefully assessed according to predefined criteria[29].
- **Telephone and online assistance** provide answers to information requests by patients.

g) Accessibility

It is crucial to ensure that everyone has access to essential information about their medicines and health. For people with reduced vision or hearing, blindness, deafness, or cognitive impairment, accessing information can be a challenging task. However, by following specific principles and guidelines, we can make the information more accessible and useful for these individuals. For example, the Guideline on the Readability of the Labelling and the Package Leaflet of Medicinal Products[30] provides information on the packaging information on how the requirements for Braille can be met, as well as how to make the patient information leaflet available in formats suitable for the blind and partially sighted patients.

The foundation for creating accessible information is adopting an inclusive design approach from the beginning. Inclusive design involves considering the diverse needs of all potential users during the development process. By including individuals with reduced vision or hearing in the design and testing phases, you can identify barriers and implement solutions to ensure accessibility[31].

The following principles and best practices should be followed to increase accessibility.

- **Plain language, structure, format, layout, and clarity** (also see 3a, 3b, 3d, 4a and 4e)
- **Multimodal presentation**, such as text, audio, and visuals (also see 3c, 3e, 3f). This ensures that users can choose the mode that suits their needs best.
- **Screen reader compatibility**: Ensure that your information on medicines is compatible with common screen reader software, like JAWS or NVDA. This includes providing proper HTML tags, alt text for images, and applying plain language principles such as logical heading structures.
- **Closed Captioning and Transcripts**: When creating videos or multimedia content, include closed captions for individuals with hearing impairments. Provide transcripts of audio content to ensure that all information is accessible to those who cannot hear it.
- **Adjustable Text Size, Fonts, and Colour:** This flexibility allows individuals with visual impairments to customise the content to their specific needs.
- **Consistent Navigation**: Implement clear menus, headings, and links to help users with screen readers or other assistive technologies navigate through the content seamlessly. Consistency reduces confusion and enhances usability.
- **Interactive Accessibility**: If your information includes interactive elements, such as forms, ensure that these features are accessible. Use proper labels, ARIA (Accessibility Rich Internet Applications) roles, and keyboard navigation support. Conduct usability testing with individuals who have disabilities to identify and address any accessibility issues.
- **Accessibility Guidelines Compliance:** Adhere to established accessibility guidelines, such as the Web Content Accessibility Guidelines (WCAG) or local accessibility standards.
- **User Feedback and Continuous Improvement:** Encourage user feedback and actively seek input from individuals with visual or hearing impairments. An iterative approach ensures that your information remains inclusive and up to date.

Keep in mind that many tools are already built-in to existing apps and devices, such as VoiceOver for iOS and Narrator on Windows devices.

Please note that many of the principles and best practices to ensure accessibility can only be applied when the information is available in an electronic format. As such, the electronic availability of patient-facing materials is crucial.

h) Consistency

Plain language concepts should be incorporated throughout all the patient-facing materials.
Since various plain language documents are created for the patient community at different stages of clinical trials and the product life cycle and local regulatory requirements for these documents may differ, there may be a considerable variation in the way information is presented in these materials.
Consistency of study descriptions and terminology between various plain language-based documents is important for easing patient communities' comprehension. Some examples include:

- Informed Consent Form
- Plain Language Protocol Synopsis
- Lay Summary of trial results
- Plain Language Summary of Publication
- Patient Information Leaflet

Besides the benefit for the patient community, the reuse of text from one document in another increases authoring efficiency.
The usage of specific templates with standard statements in plain language provides a consistent and comprehensive way of capturing and presenting information in patient-facing documents. For better terminology management, we need to use standard plain language terms including publicly available glossaries, e.g., the European Medical Agency (EMA) Medical Terms Simplifier[32], Dutch Medicines Evaluation Board (MEB) Patient-Friendly Terms list[33] and the Multi-Regional Clinical Trials Center Clinical Research Glossary[34]. Pharmaceutical companies are also advised to develop their own plain language terms glossary and use that consistently for all relevant plain language documents.

4. Stimulating patient-centric communication in the pharmaceutical industry

In this section, we discuss the multifaceted strategies and tools that can be employed to enhance patient-centric communication across all patient-facing materials. It looks to enable organisations to actively implement patient-friendly language.

a) What tools, training, and services are available to support the use of plain language

Writing in plain language is a skill that requires training and resource investment. Various medical writing and plain language agencies provide services to (re-)write texts in plain language. However, many also provide training courses that can be useful in building knowledge of, and experience with, writing plain language documents. As a first step in their patient-friendly language journey, organisations should ensure their staff is trained by plain language experts. Alternatively, plain language experts can be consulted to prepare or review patient-facing documents.

Digital tools can also support writing plain language by providing wording suggestions, checking the readability, and promoting the consistent use of plain language terms. For example:

- A **term base** can support the consistent use of plain language in your organisation by providing plain language alternatives for medical and scientific terms.
- **Writing assistant tools** can support the use of correct and easy language, assess the language level of the text, and improve readability. Some of these tools also include term base functionality.
- **Large language model-based AI**, such as ChatGPT, may be helpful in translating a medical text to plain language if provided with the correct prompt. However, it comes with significant challenges and risks. Accuracy is a primary concern, as current AI models often produce errors, hallucinations, and misinterpretations. Medical texts often contain terms that AI struggles to handle, leading to potential inaccuracies. Consistent translation is also crucial, but AI may provide varied outputs for the same terms. To mitigate risks, expert review is essential.

Medical experts and plain language specialists should validate AI-generated content. Continuous training, incorporating new medical literature and guidelines, as well as user feedback, are vital for improving accuracy and accessibility. Generative AI holds promise but must be used cautiously. Human reviews are indispensable.

While these tools can aid the creation of plain language texts, it is important to note that human review is essential to make sure that the meaning and emphasis remain in line with the intended message. In addition, most current digital tools are not yet able to apply the plain language principles for the formatting of texts. Therefore, investing in training as well as digital tools for the development of patient-facing materials is advisable.

b) Development of templates

Templates are an important element in the development of plain language material. Standardisation of data presented in text, tables, and graphics using formatting that follows the principles of plain design helps improve readability and ease of understanding of the information and may reduce reader frustration.

Templates also help authors to organise and present information in a clear and straightforward way. Additionally, templates can be used to ensure that all required and essential elements are included in the material. This standardising of the templated information can ease concerns from a legal perspective (where needed) and reduce the time to review and approve the materials. Within templates, instructional text can be added to guide the author on what information should be included or excluded in each section, while still allowing the author flexibility to include information that is important for the audience to know. This is especially relevant as information and expectations about plain language can evolve over time. Flexibility is also critical so that content can be tailored to a specific audience when necessary and to ensure that templates are helpful tools rather than prescriptive outlines. Testing templates with individuals who represent the target audience is an important step. Feedback from this testing can provide insight into how individuals without expert knowledge read and understand the material and can identify formatting or data presentation issues that interfere with readability and understanding. In addition, user testing feedback may reduce the time to review these materials by addressing formatting issues during template development instead of at the time of the final review of the material.

Regular review and testing of templates allow for updates based on evolving audience needs and capabilities, helping to ensure these tools are supporting the author in the development of relevant and meaningful information for patients and the public.

Industry sharing of user testing feedback for both templates and materials via publications, working groups, and forums, etc. can help to build plain language expertise among other sponsors, academia, and regulators.

c) How to involve patients & how to take into account the patient population's specific needs

The involvement of patients in the development of patient-facing materials is already formalised for patient information leaflets. Patient information leaflets are subject to articles 59(3) and 61(1) of Directive 2001/83, requiring that the leaflet reflects the results of consultations with target patient groups. Details about these consultations are provided in the "Guideline on the Readability of the Labelling and the Package Leaflet of Medicinal Products for Human Use"[35]. The guideline focuses on the user testing method to test the readability of a leaflet with a group of selected test persons. It is a development tool that is flexible and aims to identify whether the information is understood as presented, and whether it conveys the correct message to those who access it. However, it does not necessarily improve the text as such, as it does not always consider specific patient needs e.g. regarding the benefit-risk balance.

Plain language also emphasises the need to create any communication with the target group in mind, i.e. putting oneself in the shoes of the patient, so the alignment and exchange with patients fit perfectly with this concept.

The benefits of working with patients are tangible in this field. Authorities and regulators acknowledge these advantages as well. In principle, patients should be involved in all stages of a medicine's life cycle. Patient engagement from the beginning of the product development is important to understand its benefits and risks. Collaboration, removing barriers, and cultural shifts are ways to facilitate patient engagement. Diverse patient views, training, and involvement in research and regulation are

encouraged. Patient involvement in data collection and privacy protection is crucial. Thus, patients should contribute to patient-facing materials used throughout the life cycle. Additional measures for high-risk medicines are important[36].

For example, the EMA "is committed to ensuring that the patient voice is included in the different regulatory activities of a medicine's lifecycle, which improves the quality of and trust in the regulatory decisions and in new medicines placed onto the EU market." This cooperation with patients and consumers has been established via the Engagement Framework[37] and complements interactions with professionals.
Qualitative focus group discussions during the development and revision of all patient-facing material could supplement this method. The German Working Group "AG Beipackzettel" is an example of such cooperation on equal terms. Another example is the IATF (Interassociation Task Force of the major EU Pharma Associations) group's work with the involvement of stakeholders.

Discussions with patient representatives are often very revealing and an eye-opening experience. Patients are usually very willing to take part in these discussions and to support the development of plain language material as they, and the other patients that they represent, will ultimately benefit from these efforts. Just making sure that the text is understood does not guarantee that it provides all necessary and relevant information. Patients can e.g. provide insights about the daily life and challenges of a patient and identify information that is valuable for support.

Depending on the product, inclusion of lived experiences in the materials can enhance their relatability and effectiveness. Patient representatives recommend establishing a communication loop where patients receive feedback on how their input was considered[38]. In this way, the patient involvement becomes more active, fostering a sense of involvement and validation. Engaging patients actively at every stage of the process, from development to dissemination, can ensure their needs and preferences are addressed.
Depending on the material being reviewed it may require different inputs - individual patients as well as patient community representatives or caregivers including family members.
Of course, there are legal limitations and practical considerations for the involvement of patients regarding remuneration, intellectual property, ethical approvals, and selection processes.

Therefore, the approach to this kind of cooperation should be guided by 'Patient Engagement/Advocacy' teams within different companies - who can help facilitate these activities with the patient community while respecting any regulations about the interactions with patients.

d) How to leverage electronic versions of patient-facing materials to increase readability and accessibility

Section 3g describes how inclusive design of information can help increase accessibility for patients with visual, hearing, or other impairments. In this section, a more detailed description will be given on how electronic information can increase accessibility, readability, and impact for all. Several tools are explained below:

- **Interactive Features and Multimedia Integration.** Electronic platforms offer opportunities to incorporate interactive features and multimedia elements that can significantly enhance the accessibility of medical information. Videos, diagrams, and images can also be included or linked in to visually explain medical concepts (refer to sections 3e, 3f, and 4e), making the information more engaging and easier to understand.
- **Flexibility of electronic content.** Electronic content can be accessed on various devices such as computers, phones, or tablets at any time, improving the accessibility of important medical information for patients.
- **Personalisation and Tailored Content.** Electronic formats provide the flexibility to tailor information according to individual audience needs compared to traditional paper formats where the information is static. By incorporating patient-specific data (in a General Data Protection Regulation (GDPR) compliant way), such as their health condition, treatment plan, and medication history, electronic platforms can generate personalised content. This customisation helps patients receive information that directly relates to their specific circumstances, increasing their understanding and engagement with their healthcare.
- **Multilingual Support.** By providing translations of electronic documents into various languages, healthcare providers and pharmaceutical companies can ensure that patients from different linguistic backgrounds have access to accurate and comprehensible information. This inclusive approach promotes health equity and empowers patients to actively participate in their own care.

- **Real-Time Updates and notifications.** Electronic platforms enable faster updates of medical information and allow for real-time notifications to the audience when the information changes, which can significantly benefit and empower patients. Electronic platforms may also allow for patient-reported adverse events or outcomes to be directly reported to regulators and manufacturers. This would allow for potentially faster communication of safety signals between all parties and with validated communication channels, it's also possible that reliable Real World Data could be generated through these resources.
- **Artificial Intelligence:** As generative AI transformers and Large Language Models evolve and mature, it will become possible in the near future for patients to interact with their product information documents in the form of written or verbal question and answer chats. This will enable the patient to more directly inquire about items of interest to them. AI-supported tools should be sufficiently validated by experts and patients, the role AI plays in the generation of information should be clarified. They should be in compliance with the EU AI Act[39] and other applicable legislation.

Making electronic information available also includes making sure that this information can be easily found and accessed by all patients. Strategies that can facilitate this include for example linking the physical medicine pack with online resources through the use of codes such as QR codes or 2D Matrix codes or accessing the electronic information via the online patient health record or medicine list. Over time other solutions may be explored to make trustworthy electronic information easy to find.

Currently the pharmaceutical industry is involved in several projects to drive the implementation of electronic versions of patient-facing materials. Examples of these projects are the open innovation project IMI Gravitate Health (www.gravitatehealth.eu) and the not-for-profit initiative Pharmaledger (www.pharmaledger.org). Both projects benefited from the cooperation with patient representatives as they explore ways to deliver electronic information by making this information easy to find and convenient to access. Examples from these projects include the use of smart phone applications that specialize in linking the physical medicine pack with online resources, like electronic patient information, using scannable codes (i.e. QR codes, 2D Data Matrix, GTIN) or enabling access to personalised electronic patient information, highlighting relevant information based on the user's medical history and profile. Over time other solutions may also be developed that help to find trustworthy electronic information easily in addition to these methods.

e) How to ensure that plain language is plain in all EU languages

In order to enable patients to understand the benefits and risks of the medication they are taking, European regulations as well as local legislation and regulations in the EU countries require that pharmaceutical companies provide translations of the information about their products.
As English is the primary language used to develop the core documentation in most pharmaceutical companies, the texts are translated from English into the local language(s). To preserve the language level and patient-friendly wording of a document while translating, the following must be considered:

- **Provide the translator with general advice for translating text in plain language**[40], for example:
  - Keep the following features: short sentences, active sentences, easy language (plain terms, easy structure of sentences, easy words, verbs, same word for same concept).
  - Keep formatting, for example: bullet points, bold font, and numbers as they are written in the source document.
- **Keep in mind that what is considered patient-friendly in one language may not be in other languages:** This is important to keep in mind when developing core documents that will be translated. In addition, what is acceptable in style and tone of voice may differ due to cultural and societal nuances and the language spoken in a country. Therefore, it is important to allow translators some flexibility as long as the meaning and emphasis of a text remain the same. Consider involving local patient organizations in the review. Even if not required in the language a core document is written in, an additional (optional) explanation in plain language could be added for medical terminology to support translation and to maintain consistency across translations. Furthermore, translating a plain language glossary of medical terms to the target language(s) can also support consistent translation.

f) Legal considerations

Plain language material often raises questions about legal implications. In the end, the most important goal is that patients receive the information they need and can understand it.
Legal counsel or legal reviewers may raise questions when the material is specifically created for patients and the public. In some cases, legal counsel may assess that these materials could be perceived as promotional or possibly coercive by the public. Patient-facing documents such as

informed consents, enrolment materials, patient information leaflets, and plain language summaries often require a review by legal to review for non-promotional tone and messaging and to ensure accuracy and consistency with other public information such as the Summary of Product Characteristics (SmPC) and scientific publications.

In some European countries, the Patient Information Leaflet (PIL) is as legally binding as the Summary of Product Characteristics. This means that the content of the PIL should cover all the topics in the SmPC to mitigate legal risks for the marketing authorisation holder, even if this impacts the readability of the PIL.

Promotional risk has been a consideration in the presentation of trial results written and shared publicly in plain language. Historically, there have been concerns that voluntarily producing and sharing this material could be considered promotional particularly when there is no regulation in place requiring these. For example, lay summaries of clinical trial results are required by regulation in the EU, whereas there is no regulatory requirement for these summaries in the US. There is often a perception that using simple or plain language may make the medical terminology less precise and that there is a risk that plain language wording could be seen as coercive or misleading[41]. In contrast, the risk of using medical jargon is that the terminology will not be understood at all. Plain language is usually more clear and less abstract and therefore makes it easier for public to understand the information.

Patient experts can provide a significant benefit to the development of patient-facing communication materials contributing their patient perspective, for example when advising on content and the readability of material. Clear standards and guardrails on the proper conduct of these important interactions vs. non-permitted promotional activities towards general public, are necessary and would benefit all.

Another legal concern exists that plain language materials may be viewed by patients as a replacement for advice from their healthcare professionals. For example, concerns have been raised that plain language trial results could lead people to make health care decisions based solely on the information in one summary. For this reason, Plain Language Guidance (GLSP)[42] recommends that organisations clearly state that Plain Language Results summaries are the results from one study and may not reflect the results from other studies. In addition, many organisations also indicate that people should not make any changes to their healthcare without consulting their healthcare provider. Organisations should clearly convey the message that they are not advising about patient care in plain language trial results summaries. They also want to be clear that any recommendations and

guidance in other patient facing materials are aligned with product labels approved by regulators. This can be a challenge when a material is based on one study and may not be closely aligned with a product label, which represents an analysis of data from many studies.

Benchmarking assessment of how other organisations are preparing and sharing their plain language materials can provide an overview of how other stakeholders interpret and translate the current legal framework into action. Clearly defining the purpose and the limitations of the material in plain language helps to guide readers and may also help mitigate the risk of the material being perceived as promotional from a legal perspective. Care should be taken to make any legal disclaimers clear and understandable. Providing medical information in plain language shows respect and appreciation to patients and their caregivers. It also may help to build trust in research. As such, the benefits and value of using plain language should be discussed by legal counsel.

5. Discussion & Conclusions

This paper began by describing the concept of health literacy and the importance of patient-friendly language in healthcare, setting the stage for our subsequent discussions. In the section "General Principles of Patient-Friendly Language," we introduced the core principles that underpin effective patient communication across all document types, including formatting and structure. We then moved on to discuss strategies for stimulating the use of patient-friendly language in the pharmaceutical industry, highlighting the tools and techniques that can be used, and laying out the considerations involved.

In conclusion, the pharmaceutical industry recognises the pivotal role of moving towards patient-friendly communication materials in enhancing understanding and promoting health literacy. The principles and tools outlined in this paper represent a collective effort to establish a framework that places patients at the centre of our communication efforts.

The goals are clear:

- **Engage in Constructive Dialogue:** We invite all stakeholders, including regulatory bodies, healthcare professionals, patient organisations, and fellow industry members, to engage in constructive dialogue. All stakeholders should work together to bring the principles in this paper into action, to address the diverse needs and expectations of patients
- **Create Necessary Flexibility:** We acknowledge that the pharmaceutical environment is highly regulated, and many processes and documents are governed by legislation and guidelines. However, in the interest of all parties involved, we need to create the necessary flexibility within these constraints. By doing so, we can unlock the potential to implement these patient-centric principles without compromising safety or regulatory compliance.
- **Harmonise Implementation:** We understand that implementation can be challenging when different countries and regions manage patient communication in varying ways. Therefore, we call for harmonization efforts across the European Union and beyond. Let us collaborate to establish a common ground and best practices, ensuring consistency in the use of tools such as pictograms and terminology while respecting cultural and linguistic diversity. As such we also encourage further efforts in global regulatory harmonization initiatives such as the

International Council on Harmonisation, International Coalition of Medicines Regulatory Authorities, and the International Pharmaceutical Regulators Program.

In this journey towards patient-centric excellence, we recognize that no single entity can achieve these goals alone. It requires a collective commitment from all stakeholders to transform the approach to patient communication. By aligning our efforts, we can provide patients with clearer, more accessible, and more empowering information, ultimately trying to contribute to improved health literacy, better adherence, increased patient safety, and better healthcare outcomes.

We invite all stakeholders to join us in this transformative journey.

[1] Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association. *Health literacy: report of the Council on Scientific Affairs*. JAMA 1999;281(6):552-7. PMID: 10022112.
[2] European Commission. *Adherence to medical plans for older people.* Available online at https://futurium.ec.europa.eu/sites/default/files/2021-10/A1%20infographic.pdf. Last accessed on March 25, 2024.
[3] Agh, T., Van Boven, J.F.M., Kards, P.. *Europe's cost of living crisis jeopardises medication adherence*. BMJ 2023;380:p747. DOI: 10.1136/bmj.p747.
[4] Council for International Organizations of Medical Sciences (CIOMS). *Patient involvement in the development, regulation and safe use of medicines. Report of the CIOMS Working Group XI*. 2022. DOI: 10.56759/iiew8982
[5] Centers for Disease Control and Prevention. *What is Health Literacy?* Available online at https://www.cdc.gov/healthliteracy/learn/index.html. Last accessed on December 1, 2023.
[6] What is Health Literacy?, Centers for Disease Control and Prevention. Available online at https://www.cdc.gov/healthliteracy/learn/index.html. Last accessed on December 1, 2023.
[7] TransCelerate BioPharma, Inc. *Consent: Health Literacy*. 2017.
[8] Kickbusch, Ilona, Pelikan, Jürgen M, Apfel, Franklin & Tsouros, Agis D. (2013). *Health literacy: the solid facts.* World Health Organization. Regional Office for Europe. https://iris.who.int/handle/10665/326432. Last accessed on October 7, 2024.
[9] Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association. *Health literacy: report of the Council on Scientific Affairs*. JAMA 1999;281(6):552-7. PMID: 10022112.
[10] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2010). *National Action Plan to Improve Health Literacy.* Available at: https://health.gov/communication/HLActionPlan/pdf/Health_Literacy_Action_Plan.pdf. Last accessed on October 7, 2024.
[11] Centers for Disease Control and Prevention. *What is Health Literacy?* Available online at https://www.cdc.gov/healthliteracy/learn/index.html. Last accessed on December 1, 2023.
[12] ISO 24495-1:2023(E)
[13] Please also refer to ISO Standard 24495-1:2023(E) on plain language.
[14] W.H. Dubay. *The Principles of Readability*. January 2004, 92627949:631-3309
[15] Council for International Organizations of Medical Sciences (CIOMS). *Patient involvement in the development, regulation and safe use of medicines. Report of the CIOMS Working Group XI*. 2022. doi: 10.56759/iiew8982
[16] Beime B, Menges K. *Does the requirement of readability testing improve package leaflets? Evaluation of the 100 most frequently prescribed drugs in Germany marketed before 2005 and first time in 2007 or after.* Pharmaceutical Regulatory Affairs 2012; 1(2). DOI: 10.4172/2167-7689.1000102.
[17] Plainlanguage.gov. *Add useful headings.* https://www.plainlanguage.gov/guidelines/organize/add-useful-headings/. Last accessed October 7, 2024.
[18] Van Horen, F., Goddijn, S (2024). *Schrijf begrijpelijk! Aan de slag met schrijven op B-1 niveau*.
[19] Plainlanguage.gov. *Design for reading*. https://www.plainlanguage.gov/guidelines/design/. Last accessed October 7, 2024.
[20] Leserlich.info. L*eserlich & lesbar*. https://www.leserlich.info/kapitel/leserlich-und-lesbar-en.php. Last accessed October 7, 2024.
[21] Plainlanguage.gov. *Write effective links*. https://www.plainlanguage.gov/guidelines/web/write-effective-links/. Last accessed October 7, 2024.
[22] Harvard Catalyst. *Plain Language Materials Development Checklist*. https://catalyst.harvard.edu/wp-content/uploads/2023/01/Plain-language-checklist-FINAL.pdf. Last accessed October 7, 2024.
[23] Kheir, N., Awaisu, A., Radoui, A., El Badawi, A., Jean, L, Dowse R. *Development and evaluation of pictograms on medication labels for patients with limited literacy skills in a culturally diverse multiethnic*

population. Research in Social and Administrative Pharmacy 2014; 10(5): 720-730. DOI: 10.1016/j.sapharm.2013.11.003.

[24] Houts, P.S., Bachrach, R., Witmer J.T., Tringali, C.A., Bucher, J.A., Localio, R.A. *Using pictographs to enhance recall of spoken medical instructions*. Patient Education and Counseling 1998; 35(2): 83-88. DOI: 10.1016/S0738-3991(98)00065-2.

[25] Houts, P.S., Doak, C.C., Doak, L.G., Loscalzo, M.J. *The role of pictures in improving health communication: A review of research on attention, comprehension, recall, and adherence*. Patient Education and Counseling 2006; 61(2): 173-190. DOI: 10.1016/j.pec.2005.05.004.

[26] Mateti, U.V., Nagappa, A.N., Attur, R.P., Bairy, M.,Nagaraju, S.P., Mallayasamy, S., Vilakkathala, R., Guddattu, V., Balkrishnan, R. Preparation, validation and user-testing of pictogram-based patient information leaflets for hemodialysis patients. Saudi Pharmaceutical Journal 2015; 23(6): 621-625. DOI: 10.1016/j.jsps.2015.01.022.

[27] Fitzpatrick, P.J. Improving health literacy using the power of digital communications to achieve better health outcomes for patients and practitioners. Frontiers of Digital Health 2023;5. DOI: 10.3389/fdgth.2023.1264780.

[28] WebMD Ignite (2022). *Empower and engage with patient education videos*. Available online at https://webmdignite.com/blog/empower-and-engage-patient-education-videos. Last accessed on October 7, 2024.

[29] Gravitate Health. *A Digital Health Information Journey. Empowering and equipping Europeans with health information for active personal health management and adherence to treatment*. https://www.gravitatehealth.eu/. Last accessed October 7, 2024.

[30] European commission. *Guideline on the readability of the labelling and package leaflet of medicinal products for human use (Revision 1, 2009)*. https://health.ec.europa.eu/document/download/d8612682-ad17-40e3-8130-23395ec80380_en. Last accessed October 7, 2024.

[31] Sabina Sieghart, Björn Rohles, and Ann Bessemans. 2024. Empowering Independence Through Design: Investigating Standard Digital Design Patterns For Easy-to-Read Users. In Proceedings of the CHI Conference on Human Factors in Computing Systems (CHI '24), May 11–16, 2024, Honolulu, HI, USA. ACM, New York, NY, USA, 18 pages.

[32] European Medicines Agency. *EMA Medical Terms Simplifier. Plain-language description of medical terms related to medicines use*. https://www.ema.europa.eu/en/documents/other/ema-medical-terms-simplifier_en.pdf. Last accessed October 7, 2024.

[33] Dutch Medicines Evaluation Board. *List of patient-friendly terms for the package leaflet*. https://english.cbg-meb.nl/documents/policy-documents/2023/01/01/lijst-met-patientvriendelijke-termen-voor-bijsluiters. Last accessed October 7, 2024.

[34] The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. *Clinical Research Glossary*. https://mrctcenter.org/glossary/. Last accessed October 7, 2024.

[35] European commission. *Guideline on the readability of the labelling and package leaflet of medicinal products for human use (Revision 1, 2009)*. https://health.ec.europa.eu/document/download/d8612682-ad17-40e3-8130-23395ec80380_en. Last accessed October 7, 2024.

[36] Council for International Organizations of Medical Sciences (CIOMS). *Patient involvement in the development, regulation and safe use of medicines. Report of the CIOMS Working Group XI*. 2022. DOI: 10.56759/iiew8982

[37] European Medicines Agency (2022). *Engagement Framework: EMA and patients, consumers and their organisations*. EMA/649909/2021.https://www.ema.europa.eu/system/files/documents/other/updated_engagement_framework_-_ema_and_patients_consumers_and_their_organisations_2022-en.pdf. Last accessed October 7, 2024.

[38] EFPIA Patient Think Tank consultation, November 2024.

[39] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU)

2016/797 and (EU) 2020/1828 (Artificial Intelligence Act). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689

[40] ISO 24495-1:2023(E)

[41] Schindler, T. *Lay Summaries of Clinical Study Results*. Regulatory Writing: An Overview, 2nd edition, Regulatory Affairs Professional Society (RAPS), December 2020, ISBN 978-1-947493-55-1, 265-277.

[42] Directorate-General for Health and Food Safety, European Commission (2021). Good Lay Summary Practice. https://health.ec.europa.eu/document/download/8a42b8f5-4ec3-4667-969c-3dd89ea8b270_en?filename=glsp_en.pdf. Last accessed: October 7, 2024.