SCOPE Work Package 6
Good Practice Guide

Web-based Safety Information

Shortened version

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SCOPE

SCOPE Work Package 6 Good Practice Guide – Web-based Safety Information

(Shortened version)

Contents

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Acknowledgments

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Authors

Jane Ahlqvist-Rastad, Adriana Andric, Ilaria Baldelli, Anna Marie Coleman, Amelia Cupelli, Yvette Escudero, Jess Hearn, Yngvil Knudsen, Miguel Ángel Maciá, Line Michan, Dolores Montero, Alfonso Rodriguez, Maria Root, Hilde Samdal, Ivana Sipic, Annika Wennberg

1. Introduction

1.1 Purpose of the document

The purpose of this document is to guide NCAs who do not have a fully established web system, into developing a useful and accessible platform for presenting safety information. The important considerations in developing a web platform are discussed, and case studies are reported for NCAs to reference. For MSs with more established systems, this document also provides some guidance on how these systems might be optimised going forward.

1.2 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
DCP	Decentralised Procedure
DHPC	Direct Healthcare Professional communication
EU	European Union
EPAR	European Public Assessment Report
GVP	Good Vigilance Practice
HCP	Healthcare Professional
HMA	Heads of Medicines Agencies (EU NCA Network)
MA	Market Authorisation
MAH	Market Authorisation Holder
MOP	Member of the Public
MRP	Mutual Recognition Procedure
MS	Member State(s)
NCA	National Competent Authority
PhV	Pharmacovigilance
PIL	Patient Information Leaflet
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SmPC	Summary Product Characteristics
SOP	Standard Operating Procedure
WP	Work Package

1.3 Attachments

Ref No	Document name
Annex 1	NCA Survey on web portals
Annex 2	Sources of advice
Annex 3	Examples of user testing cases
Annex 4	Examples of communication strategies

1.4 The role of the internet

The internet is an integral part of everyday life, and has changed the way patients and doctors obtain health information (1). A study in 2013 reported that 72% of internet users claimed they search online for health information and 24% of internet users look for information about drug safety or recalls (2, 3). The methods of presenting data to either healthcare professionals (HCPs), patients or industry are vital in relaying accurate and reliable information. Good Vigilance Practice (GVP) Module XV highlights the importance of websites in Pharmacovigilance (PhV) risk communication, stressing the need for information to be accessible to all stakeholders (4). Module XV also emphasises the importance of utilising emerging communication avenues, and of maintaining consistency across all channels of communication, for example, when using multiple web tools.

This document presents case studies of *how* NCAs present their national PhV information; providing both examples of good practice and examples where NCAs have gone 'above and beyond' in their methods. Concepts like 'awareness' and 'user testing' are discussed to provide basic building blocks on which NCAs might optimise and develop their web communication, considering future platforms.

There are a plethora of factors that regulators need to consider when creating web content, from knowing their audience, to understanding how technology is evolving. A few considerations are highlighted below, and discussed in more strategic detail in Section 4.

1.5 Knowing your audience

Knowing the target audience and users of NCA websites allows content to be tailored to meet their needs. Main audiences can be further explored by carrying out surveys and interviews (online, on the phone or face-to-face, where possible).

As per the survey on this topic (WP6 – Web-portals) (Annex 7.1), most MSs feel their website is more relevant to industry stakeholders, less to HCPs and least to patients. However, when NCAs are prioritising the presentation of information, it is primarily information related to HCPs and patients that is of most importance. Regulators must think about their audience, and how patients, HCPs and industry typically access safety data through their websites – for example, do they exclusively use search functions to find information or are they happy to navigate through each subpage? If Summary of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) are the most commonly accessed safety information, are these most readily available to users? If patients are more likely to use a neighbouring site, consider why this is and whether data can be shared or adapted.

To make a website clear, helpful and easy-to-use, it should be structured around the needs of the website users. User testing is a way of finding out the needs of your main audiences. User testing can be done by conducting surveys and interviews, and by monitoring user behaviour (e.g. using Google Analytics).

1.6 Technical considerations

The presentation of safety information on websites needs to take into account users accessing safety data through tablets, social media and apps, which is becoming more common. With this in mind, NCAs should consider incorporating Responsive Web Design (RWD) into their digital strategies, possibly having multiple digital strategies for multiple digital platforms, ideally within a single overarching strategy document. A website using RWD automatically adapts the layout to match the users' viewing environment, allowing the same content to be viewed across multiple platforms. For example, there are many factors that need to be considered when accessing NCA websites through tablet devices, namely: resolution differences and the ability to navigate through touch.

The use of social media can be a powerful tool in dissemination of information, however, there are many considerations that regulators encounter when creating a profile. In fact over half of MSs do not currently have a strategy in place for the use of social media. Providing enough resources to maintain a good reputation and operation of a high-level Twitter feed can be burdensome. However, the benefits of using social media are significant, namely allowing the dissemination of information widely and rapidly, through multiple channels. Using social media can also increase NCA web traffic by directing readers to agency webpages.

The development of media apps is an even greater task for NCAs. An example of the complexity involved is demonstrated by the WEB-RADR project, which created an app for adverse drug reaction (ADR) reporting (8). This app not only allows reporting of ADRs to an agency, but also allows users to view statistics on ADR reports and to keep up-to-date with the latest medicines news articles.

A final consideration for regulators is their national requirements: some have to integrate into government or parent organisation web systems, which may limit their freedom to decide how to present safety information.

From WP6 – Web-portals, Q18, only 42% of NCAs have a dedicated 'digital strategy', and most cover the development of mobile browsing and involvement in social media. 72% of MSs have future plans to optimise their websites by use of mobile versions, use of a mobile app/social media, and improving the website layout.

1.7 Resource considerations

A significant consideration for web development within NCAs is the available resources, in terms of both finance and staffing. Generally, good maintenance of complex platforms would require a dedicated web team, together with input from communications and PhV teams.

The more technical NCAs wish to be with their web-based communications, the bigger the human resource and financial impact. For example, sending out email alerts to inform users of updates to the website requires frequent input over a sustained period of time (i.e. maintaining a mailing list and preparing the email alerts). As such, regulators have to balance what is useful versus what is achievable, prioritising and in some cases creating long-term targets, which could mean utilising available resources over a longer time frame.

In addition to identifying resources to create and maintain web communications, NCAs should also consider developing quality control steps and creating auditable measures. This could be as simple as monitoring the number of web views, all the way through to user surveys and monitoring of incoming queries. This can feed into a 'lessons learnt' type strategy.

1.8 Legal requirements

Not only do NCAs have to make their safety information highly useable and accessible, they also have to comply with EU and national legal requirements. The development of NCA communications weighs up these legal requirements versus what users access through NCA websites, and prioritises accordingly. Regulators also have to consider the legal regulations of their users, for example industry and HCPs have their own rules to follow, which can rely heavily on the information available to them through the regulators.

Below are the legal requirements for MSs to present PhV information in a web-based format as defined in Directive 2010/84/EU, amending Directive 2001/83/EC (9). Attention should be given to Article 102 and Article 106 within this Directive, both of which are discussed in more detail in Section 2.

Article 102 specifies that MSs shall:

> *'ensure that the public is given important information on PhV concerns relating to the use of a medicinal product in a timely manner' […]*

Article 106 sets out minimum requirements for information that:

> *'the Member States shall make publically available' […]*

GVP Modules also provide some background information into web-based risk communication:

> ***XV.B.5.4.*** *A website is a key tool for members of the public (including patients and healthcare professionals) actively searching the internet for specific information on medicinal products. Competent authorities as well as marketing authorisation holders should ensure that important safety information published on websites under their control is easily accessible and understandable by the public. Information on websites should be kept up-to-date, with any information that is out-of-date marked as such or removed. The legislation on pharmacovigilance foresees the creation of an EU medicines web portal which will contain information on all medicines authorised in the EU [Article 26 of Regulation (EU) No 1235/2010]. This web portal will become a key tool for communicating up-to-date safety information to EU citizens and will contain information in all EU official languages. Each Member State shall set up and maintain a national medicines web-portal which shall be linked to the EU medicines web-portal. [DIR Art 106a]. Until the web portal is fully established and into operation, the Agency's website will be acting as an interim platform to convey this important up-to-date safety information.*

The mention of 'web-portals' in this GVP module has been a source of confusion to MSs, specifically debating the differences between a web-portal and a website. The idea is for each agency to have its own website, which 'portals' to a European Medicines Agency (EMA) central website. This encourages the EMA to act as a regulatory hub, where the 'EU medicines portal' is planned to house safety information on all EU-regulated medicines, central and national. A link to each NCA website currently exists in a contact list on the EMA website, but the EMA will develop a more functional and directed linkage to specific areas on agency websites (10). For now, the focus for NCAs is on making their own website as user-friendly and informative as possible.

There is more clarification needed on what exactly this means for NCAs, however, the overarching statements in the GVP modules is that web-based safety information is vital, and should be maintained well by all NCAs and the EMA.

2 Compliance with minimum requirements

The 2010 PhV legislation states that all MSs should present a minimum amount of PhV information on their website to maintain transparency, accessibility and to make the reporting of ADRs as efficient as possible.

2.1 EU Directive 2010/84/EU

Article 102(b)

> *Facilitate patient reporting through the provision of alternative reporting formats in **addition to web-based formats***

Article 102(d)

> *Ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through **publication on the web-portal** and through other means of publically available information as necessary.*

Article 106

> *Each Member State **shall set-up and maintain a national medicines web-portal** which shall be linked to the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004. By means of the national medicines web-portals, the Member States shall **make publically available** at least the following:*
>
> ***(a)*** *Public assessment reports, together with a summary thereof;*
>
> ***(b)*** *Summaries of product characteristics and package leaflets;*
>
> ***(c)*** *Summaries of risk management plans for medicinal products authorised in accordance with this Directive;*
>
> ***(d)*** *The list of medicinal products referred to in Article 23 of Regulation (EC) No 726/2004;*
>
> *a. The Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring.*
>
> *b. The list referred to in paragraph 1 shall include an electronic link to the product information and to the summary of the risk management plan.*
>
> *c. the Agency shall remove a medicinal product from the list five years after the Union reference date referred to in Article 107c(5) of Directive 2001/83/EC.*
>
> ***(e)*** *Information on the different ways of reporting suspected adverse reactions to medicinal products to national competent authorities by healthcare professionals and patients, including the web-based structured forms referred to in Article 25 of Regulation (EC) No 726/2004*

These Articles highlight the legal requirements for communicating PhV information: patients need to be able to report through web-based methods, users need to have access to PhV-related information in a timely manner, and each website should present the information listed in Articles 106(a) – (e) for each medicinal product, as required.

2.2 Good practice case studies

The SCOPE survey on web portals was created to gain insight into the current mechanisms used by 25 EU NCAs to communicate safety information through their websites (Annex 7.1). This survey presented NCAs with a mixture of multiple choice and free-text questions covering a broad spectrum of topics including: web content, audience, design and digital strategies.

In addition to this survey, NCAs were asked to review each other's websites and provide comments on the methods of communicating safety information. From these reviews, case studies for good practice were drawn out and developed for presentation in this guidance document. Some work from SCOPE on ADR reporting (WP4) is also referenced here, particularly surrounding the use of reporting forms and of raising awareness to NCA activities. Collecting this data provided examples of good practice in PhV across Europe. The survey to HCPs (WP6 – Healthcare Professional Survey: Medicines safety communications and their effectiveness) also offered insights into the communication of risk from a HCP point of view, and therefore provides useful insights for this document.

Below are some key points drawn from both the SCOPE survey results and the feedback received upon asking NCAs to review each other's websites. Each recommendation is discussed in further detail below, with snapshot examples taken from each NCA website (11).

Suggested recommendations

- Publishing RMP summaries together with other medicines information (e.g. SmPCs, PILs, PARs) in an NCA's medicines database may be the most accessible method of communicating PhV information
- Regarding the publication of PILs and SmPCs, it is recommended that this information is available to users through NCA websites irrespective of the authorisation process (national/central)
- Regarding ADR reporting information, it is important to consider the audience, e.g. educating members of the public and HCPs about reporting can be two different things, particularly if the NCA has separate reporting forms for each type of reporter
- Providing users with instructions on how to populate web forms can also be useful, as well as making the web form as accessible as possible from the NCA webpage; consider a link on the main page and a link within any PhV section

- Regarding the timely publication of safety data, NCAs could consider publishing their data in line with the responses of HCPs from the HCP survey conducted in their MS, and NCAs which did not participate in the survey should continue to apply a prioritisation process, where audience testing could help inform which safety communications should be updated more regularly
- On the basis of legal requirements and the importance of new safety information, and not on user preferences, SmPCs, PILs and safety announcements are the most important safety communications to publish regularly when updates are made

2.2.1 Article 106: web content

From the survey data, most of the content required of the EU Directive is presented by MSs on their websites; some MSs present this in one location, whilst others use external links. More detailed discussion below explores each type of PhV communication and the methods by which NCAs present this information on their websites.

Article 106 (a): Public Assessment Reports

A Public Assessment Report (PAR) is created for all medicines that have been granted or refused market authorisation (MA). This provides public information on a medicine, including how it was assessed. PARs are prepared during the application phase and subsequently updated to publicise ongoing safety decisions made about authorised medicinal products. The EMA keeps an up-to-date list of information relating to centrally authorised medicinal products, including PARs, and also publish a public-friendly summary of PARs.

The target audience for safety PARs is primarily HCPs and others with a scientific interest and background. This could be an important consideration when deciding whether PARs should be published by all NCAs, as per the EU Directive. For example, if a MS has performed user testing and determined that their PAR target audience do not visit the site to view PARs, then publishing them may not be useful and may result in a negative impact on resources for NCAs.

Likewise, the content of the PAR may be deemed too detailed, even for HCPs. Structuring the document in such a way as to allow readers to decide on the depth of research they would like to do in relation to a medicinal product is most useful. Ultimately it will be the decision of each NCA as to the publication of PARs to address this article of the Directive.

PARs are currently presented by 12 MSs (WP6 – Web-portals, Q9, Annex 7.1). As an example of PAR publications, the Medicines and Healthcare Products Regulatory Agency (MHRA, UK) has a link on their homepage which directs users to information surrounding the publication of PARs for nationally authorised medicines, stating that the EMA/Heads of Medicines Agencies (HMA) publish those coordinated by the EU regulatory network (**Figure 1** below).

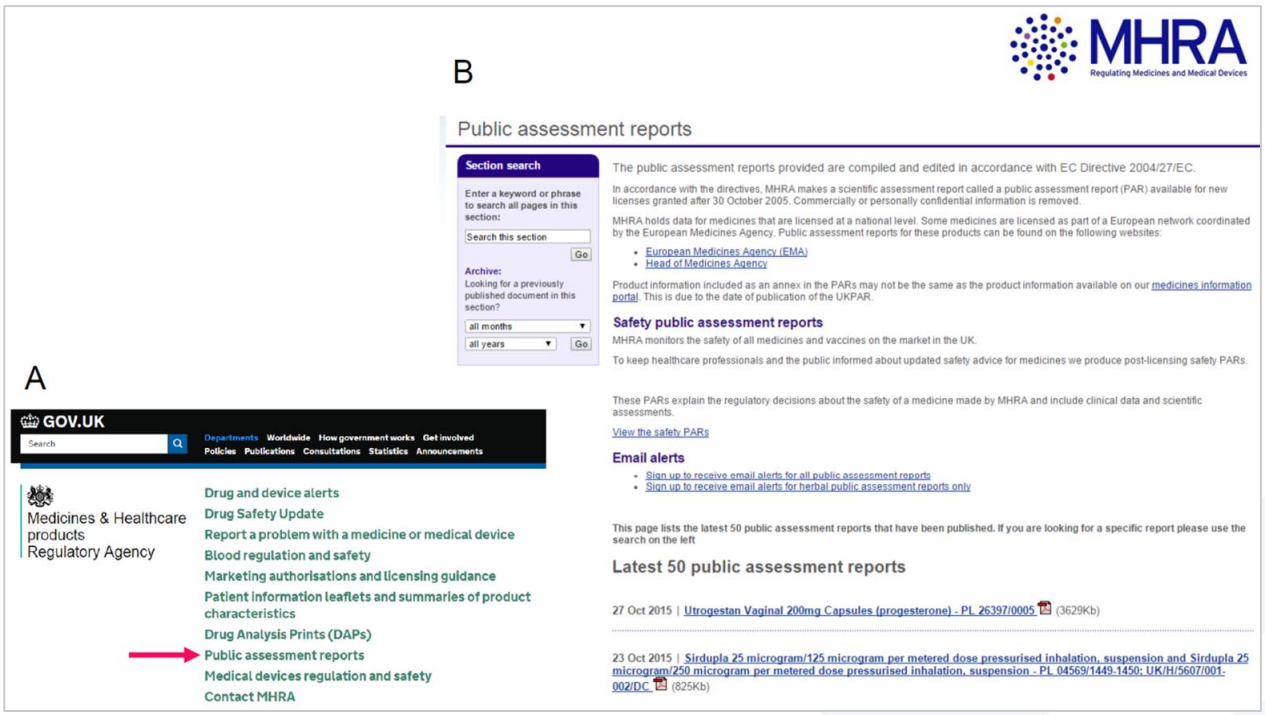


Figure 1. Screenshot from the Medicines and Healthcare Products Regulatory Agency (MHRA, UK) website showing (A) The main MHRA webpage with links to specific safety information and (B) the webpage dedicated to PARs. Medicines and Healthcare Products Regulatory Agency – PARs

Article 106 (b): Summaries of Product Characteristics and Patient Information Leaflets

SmPCs are the basis of information for HCPs, describing the medicinal product's properties and how the medicine should be used to be safe and efficacious. This information is updated throughout the lifecycle of the medicine. The main target audience for SmPCs are HCPs, and therefore the format of this information should be considered to make it as accessible for HCPs as possible. The primary time for HCPs to access this information is during prescribing; therefore integrating SmPCs into prescribing systems could increase the usefulness of this document.

The Norwegian Medicines Agency (NOMA) implemented this by converting the SmPCs into xml format to allow integration into prescribing systems. Producing SmPCs/PILs in such a format also allows easier searchability using tools like eMC (electronic Medicines Compendium), which allows users to search by document 'section' and 'drug name' (12). Unfortunately NOMA found this working process (converting from word to xml format) to be resource-intensive and it could not be maintained.

In order to make this information more accessible, it may be useful to start requesting initial submissions of SmPCs in a structured data format that can easily be presented in different information channels specifically tailored to the different needs and preferences of HCPs (and patients). NCAs could perform user testing (Section 4) to identify whether integration into prescribing systems could be a better way to present this type of information, or indeed whether presenting SmPCs on both their national website and through prescribing systems would optimise usefulness, taking into consideration the resources required. If SmPCs remain in pdf format, they need to be indexed with a table of contents, with embedded links to document sections, in order to be user-friendly.

The Patient Information Leaflet (PIL) is created based on the SmPC, primarily focuses on the safe use of the medicine and is most often discussed with patients during medicinal prescription or dispensing. The PIL is found in a hard copy format, as part of the medicinal packaging, which is useful as a reference when starting new medication or for review of the section on adverse reactions.

To access this information outside of a prescription context patients can use NCA websites, where the format is primarily a pdf version of the hard copy leaflet. As with SmPCs, NOMA have proposed having PILs in a different, more structured data format, labelling them as patient information (PI), and not specifically presenting them as a leaflet. This could allow the inclusion of links to other relevant sources of information, for example, safety information from RMPs. However, this would be dependent on user testing in MSs, and whether the PIL is already fit-for-purpose, or whether there are other avenues besides the NCA website where patients might wish to access this information, requiring a different format.

Regarding publication of SmPCs and PILs on NCA websites, all 25 MSs surveyed stated that information on both are currently presented on their agency website and/or as links to the EMA website (WP6 – Web-portals, Q9, Annex 7.1). Post-survey evaluation of NCA websites showed that some NCAs present this information on their own website for nationally authorised medicines (**Figure 2** below), and provide links to this information on the EMA website for centralised medicines. When linking to the EMA website, it is most efficient for NCAs to route users straight to the medicine in question, whether this is a direct link to a pdf on the EMA website, or linking to the medicines page on the EMA site and manually navigating to SmPCs/PILs from there. The latter is less demanding on IT systems, as the link provided will always stay the same, even if SmPCs/PILs for a medicine are themselves updated. Some NCAs route users to the EMA search function and not directly to the medicines information on the EMA website, and some do not include centrally authorised medicines in their databases at all. Collectively this is hindered by the IT limitations of MSs and the EMA.

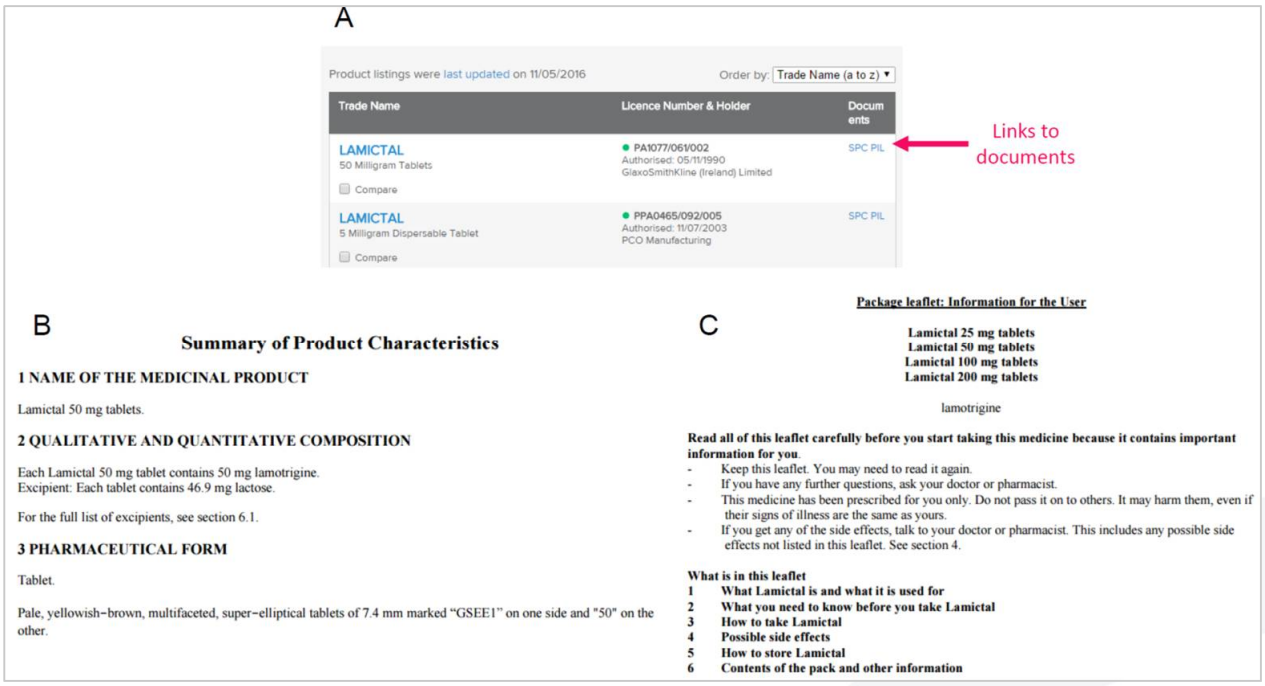


Figure 2. Screenshot from the Health Products Regulatory Authority (HPRA, Ireland) webpage showing links via embedded pdf documents (A) to the SmPC (B) and PIL (C) information for the nationally authorised drug Lamictal. Health Products Regulatory Authority – find a medicine

As an example of a different approach, the UK has a stand-alone subpage dedicated to SmPCs and PILs, and therefore does not require an initial search to access this type of medicines information (**Figure 3** below).

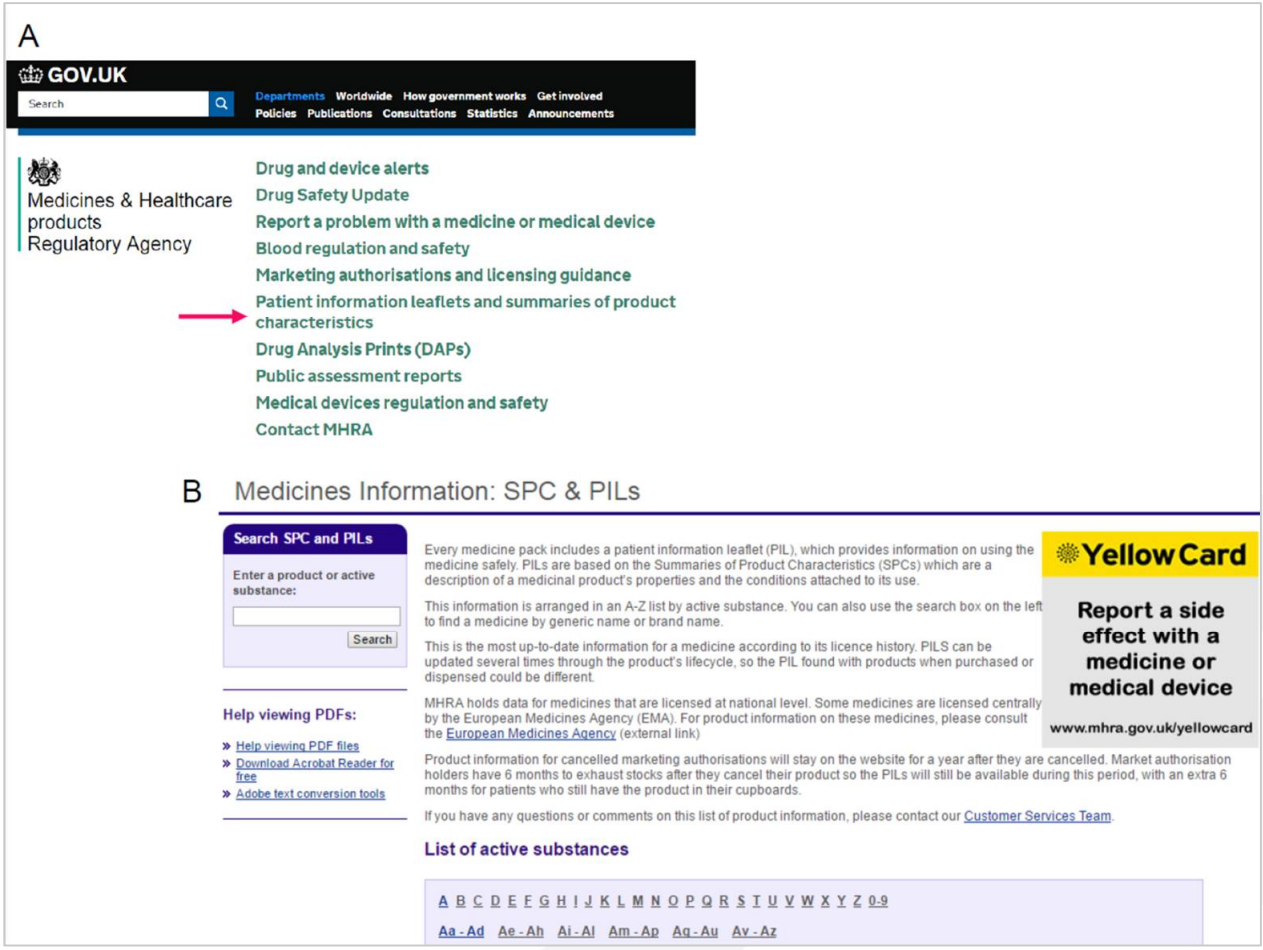


Figure 3. Screenshot from the Medicines and Healthcare Products Regulatory Agency (MHRA, UK) homepage showing the link to SmPCs and PILs (A), and the dedicated subpage for this information (B). Medicines and Health Products Regulatory Agency – SmPCs and PILs

These examples from the MHRA and from the HPRA show two different ways of presenting SmPCs and PILs on NCA websites. The first accesses SmPCs and PILs through the NCA drug database, first searching for a medicine then opening links to the information of interest. The latter has a separate section on the website dedicated to SmPCs and PILs only, where the medicine search is performed after users have decided on the information they wish to access. The former method has the benefit of not requiring any pre-knowledge about the type of information required by the user, with the latter assuming that HCPs know to access SmPCs for their information, and patients to access PILs for theirs.

Article 106 (c): Risk Management Plan summaries

Risk Management Plan (RMP) summaries are found in part VI of the RMP and are split into 2 main sections: the first uses tables to summarise the safety concerns, risk minimisation and PhV measures for a medicine; the second summarises this information in more lay-friendly terms. The PhV Directive states that RMP summaries, not RMPs, should be published on NCA websites. However, the RMP summary does not currently exist as a separate document in most MSs, which complicates the publication of this information due to IT limitations and because it can be resource-intensive.

There is not currently a template in place for creating national RMP summaries as separate documents, although the EMA already creates RMP summaries after centralised procedures are complete, meaning that a standard is in place to allow consistency. The template used by the EMA is planned to be updated based on pilot testing. Allocating resources to allow extraction of the RMP summary from the RMP, or creating a new RMP summary based on the RMP, is a consideration for NCAs.

An additional consideration is where best to publish RMP summaries. The primary target audience for these summaries would be HCPs and members of the public (MOPs), although industry and researchers may access this information as a wider interest. Publishing RMP summaries together with other medicines information (e.g. SmPCs, PILs, PARs) in a drug database appears to be the most accessible way to access PhV information. Ideally this database is part of the NCA website, however, some NCAs may choose to publish this information on external databases, if user testing has identified this as the most useful method.

9 MSs stated that RMP summaries are currently presented on their website (either directly on the website, or through links to an external site) (WP6 – Web-portals, Q9, Annex 7.1). Some present the entire RMP (or links to the entire RMP), where the summary is a section within the RMP document.

Hungary (OGYÉI) specifically request RMP summaries from Market Authorisation Holders (MAHs), providing instructions for submission on their website:

> *"Marketing authorization holders are reminded that a summary of the RMP will be published on the national or the European medicines web-portal. This requirement also applies to existing medicinal products with an RMP. After the RMP gained acceptance during the evaluation procedure, applicants shall submit the Hungarian summary of the RMP. The time of submission must be before the end of the evaluation procedure. As for already existing RMPs authorized via the national or MR/DC procedures where Hungary acted as RMS, MAHs are requested to submit a Hungarian summary thereof to the Institute by 31 December 2012 at latest. Regarding procedures where Hungary acted as a CMS, the schedule of submission and content of the summary shall be agreed upon by the RMS, and a Hungarian summary should be submitted thereafter. As for the summary of the RMP for centrally authorized medicinal products, the guidance of the EMA shall be followed.*
>
> *The summary of the RMP will follow the new format and content as set out in the Commission Implementing Regulation and as detailed in the relevant GVP module."*

The French National Agency for the Safety of Medicines and Health Products (ANSM) provides RMP summaries through a separate section presenting life cycle information for products. ANSM provides a list of nationally and centrally authorised medicines subject to RMPs, with the RMP summary for each medicine available on the website (National Agency for Medicines and Health Products Safety – Cervarix RMP).

The publication of RMP summaries is still very much under discussion across the EU. However, NCAs could consider publishing this information either directly on their websites or through links to national or central databases.

An overall consideration regarding the content required for compliance with the Directive should decide whether all information is presented in a central location, i.e. through the NCA database on medicinal products, alongside SmPCs, PILs, PARs etc. According to the Directive requirements (Article 106) the RMP summaries should be included in the NCAs' websites, although the EMA publishes the RMP summaries of centralised products. It would be easier for users if all of the product information available is nationally located in the same place, and for centrally authorised medicinal products the NCA could use a link to the safety information on the EMA database.

Article 106 (d): Additional monitoring

Additional monitoring lists refer to medicines that are being monitored more closely by regulators, and have a black triangle in their PIL and SmPC. This list presents medicines that contain a new active substance not authorised pre-2011, all biological medicines authorised after January 2011, medicines undergoing post-authorisation safety studies (PASS), and medicines given conditional approval or authorised under specific circumstances.

For additional monitoring lists, 19 MSs have links to an external website and 13 MSs provide this list on their NCA web-portal/website (WP6 – Web-portals, Q9, Annex 7.1). All 25 MSs present this information in some form.

As a good example, France has a section on its website titled 'Drug Surveillance' that publishes the list of medicines under additional monitoring in a table, describing whether the medicine is marketed in France or not, the reason for it being on the list, and the MAH. Each medicine links to the EMA to provide appropriate documentation.

Romania also have a clear section for additionally monitored medicines (**Figure 4** below), presenting an informative EMA video on what the black triangle means, as well as links to the EMA list of black triangle medicines and links to associated GVP modules.

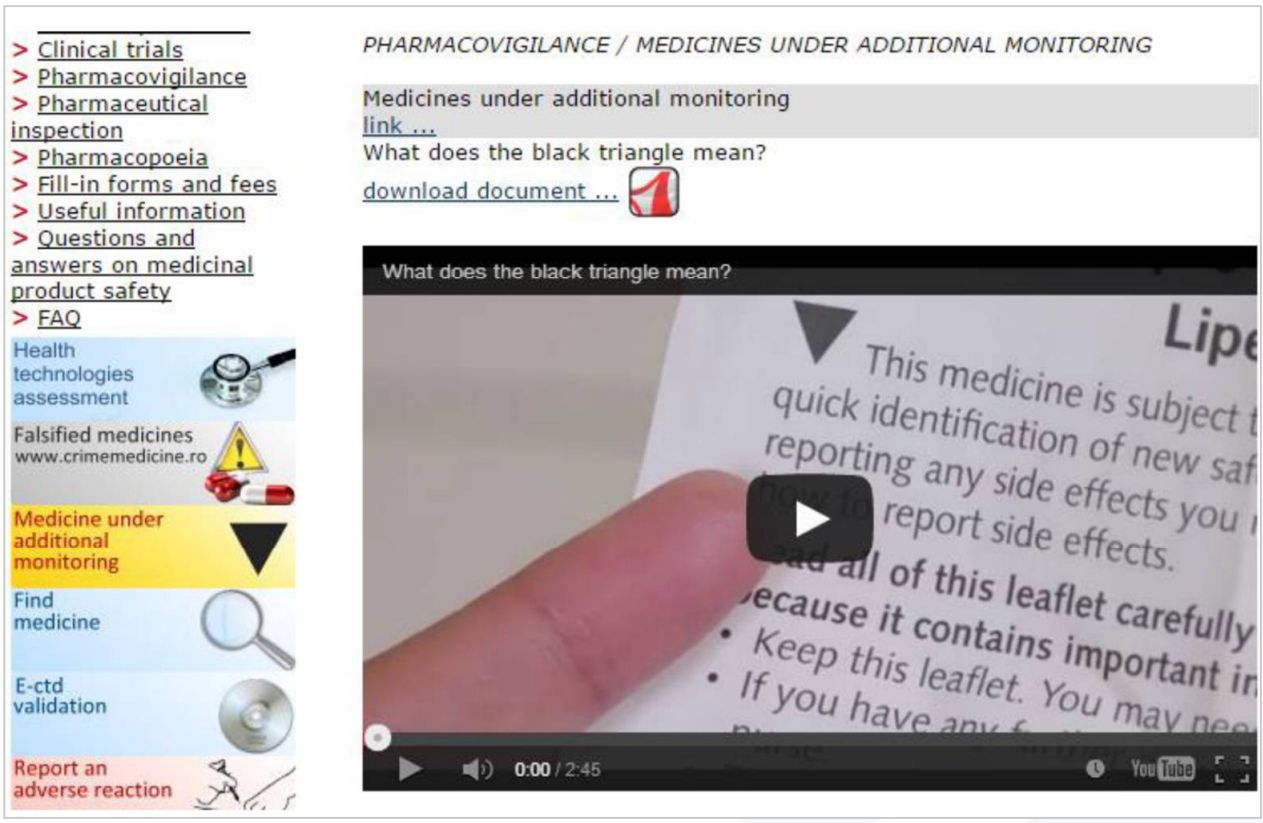


Figure 4. Screenshot from the National Agency for Medicines and Medical Devices (ANM, Romania) webpage showing the subsection provided for additionally monitored medicines, as well as the link to the EMA website and an educational video. National Agency for Medicines and Medical Devices – Additional monitoring

Article 106 (e): Information on reporting ADRs

Increasing the information published about ADR reporting can both increase the number of reports and increase the quality of reports. This information could cover how to populate an ADR form, as well as inform reporters what happens once a report is submitted. There are various different methods by which information can be presented; one of the most interactive is to produce a video. This could be a useful resource for giving an overview of what ADRs are and how an ADR report can help improve public health. For example, the Irish Academy of Continuing Medical Education (iaSME), has created a YouTube video summarising the process of occurrence and reporting of ADRs to the Health Products Regulatory Authority (HPRA) of Ireland (at the time called the Irish Medicines Board (IMB), and highlights the outcomes when that ADR is, and is not, reported (13). This type of video can be very useful in encouraging HCPs to report all ADRs to their national agency, particularly if published on the NCA's website, and overlaps with the work being performed as part of SCOPE WP4 (ADR collection).

In addition to this type of information, a step-by-step guide is also very useful when educating reporters on how to populate reporting forms. Such presentation of information is discussed in Section 2.2.2.

NCAs should not only make the material itself as understandable as possible, but also make access to those materials as easy as possible with respect to navigating websites. A homepage section highlighting ADR reporting would be an effective option, with educational information presented once the user has routed to the ADR reporting subpage. It is important to consider the audience, e.g. informing MOPs and HCPs about ADR reporting can be two very different things, particularly if the NCA has separate reporting forms for each type of reporter.

All 25 of the surveyed MSs present this type of information on their websites, with 23 of these presenting this information to industry, patients and to HCPs (WP6 – Web-portals, Q9, Annex 7.1). Having ADR reporting advice available through the NCA's main webpage and through the PhV-dedicated subpage may make reporting more accessible.

There are two main methods by which NCAs tailor reporting information for patients, HCPs and industry. The first asks users to select their function on the website (i.e. report an ADR), and then on following pages asks a user to identify themselves with a user group. From here, information is tailored to that user group.

An example of this is taken from the Spanish Agency for Medicines and Medical Devices (AEMPS) webpage, which directs from the homepage to ADR reporting forms and information (**Figure 5A**). After clicking the homepage button for ADR reporting, the user is routed to an intermediary page (**Figure 5B**) before routing to a page asking whether they are a HCP or a citizen, from which information is tailored (**Figure 6**, page 22).

Figure 5. **(A)** Screenshot from the Spanish Agency of Medicines and Medical Devices (AEMPS) homepage highlighting the icon for reporting ADRs. Agency of Medicines and Medical Devices – homepage **(B)** Intermediary website where users select their region, before going to a separate page to identify their user type.

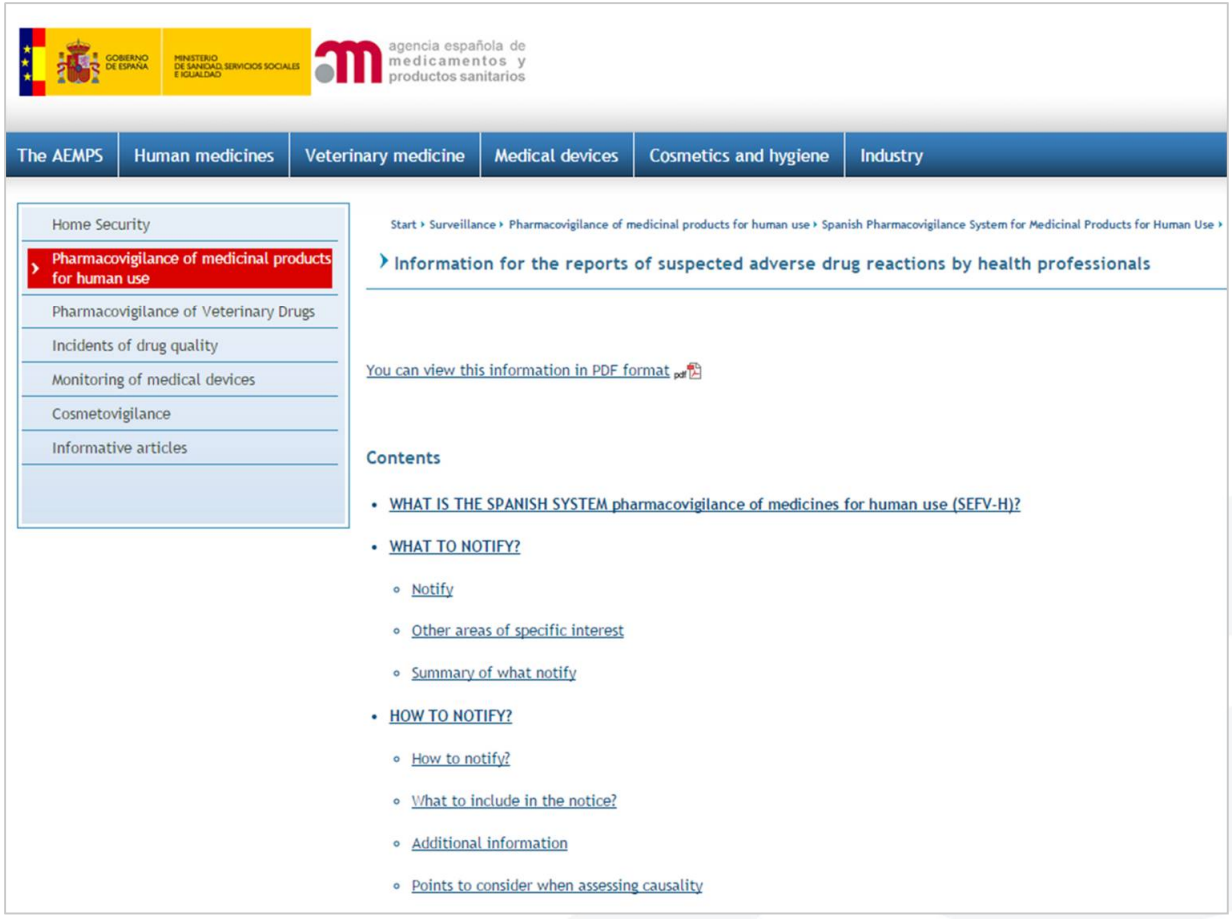


Figure 6. Screenshot from the Spanish Agency of Medicines and Medical Devices (AEMPS) webpage highlighting the information provided to HCPs for ADR reporting. Agency of Medicines and Medical Devices – ADR reporting

The information presented by Spain is in an easy-to-follow Q&A format, with subheadings routing users to more information on each topic and the full page downloadable as a pdf document.

The second method to allow information tailoring is for NCAs to ask users to first identify themselves at the homepage, and then for all the information that follows to be user-specific. An example of this second method of directing users to ADR information is shown by the Malta Medicines Authority in **Figure 7**, below. Here users are asked to identify themselves as patients, industry or HCPs before browsing begins.

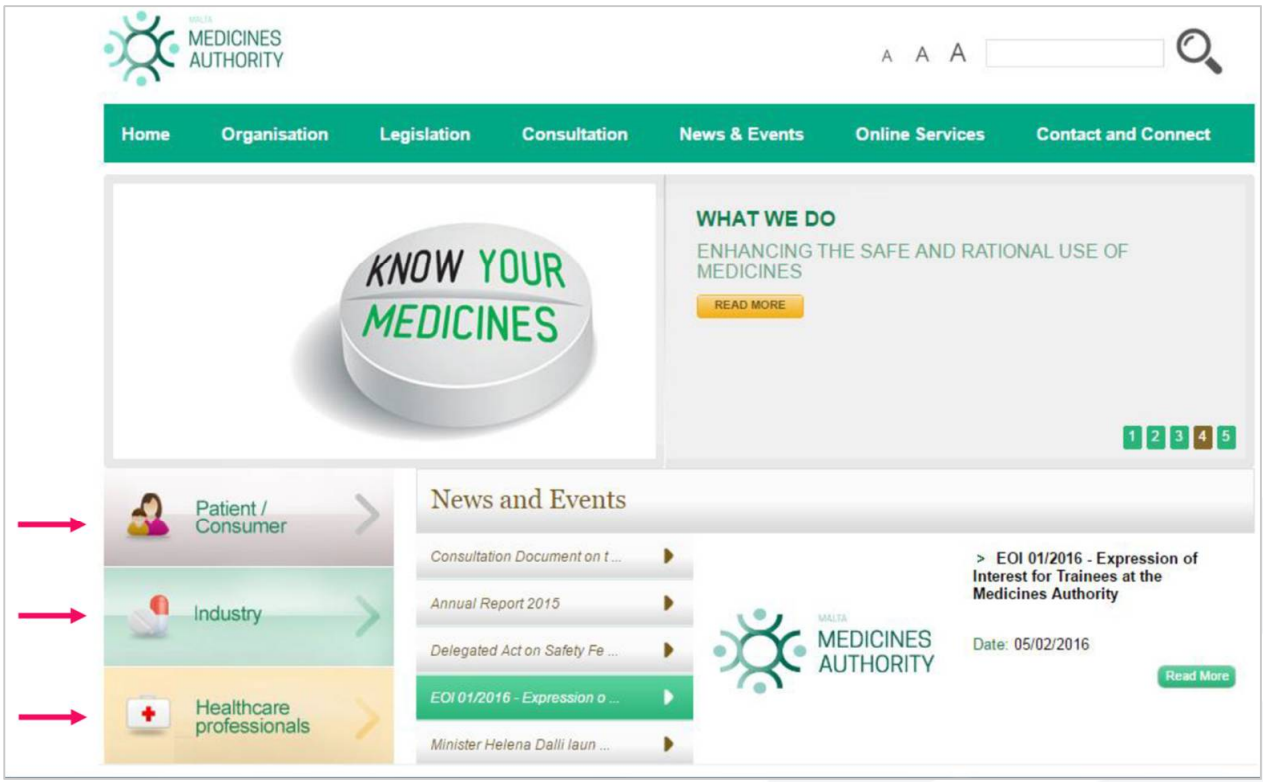
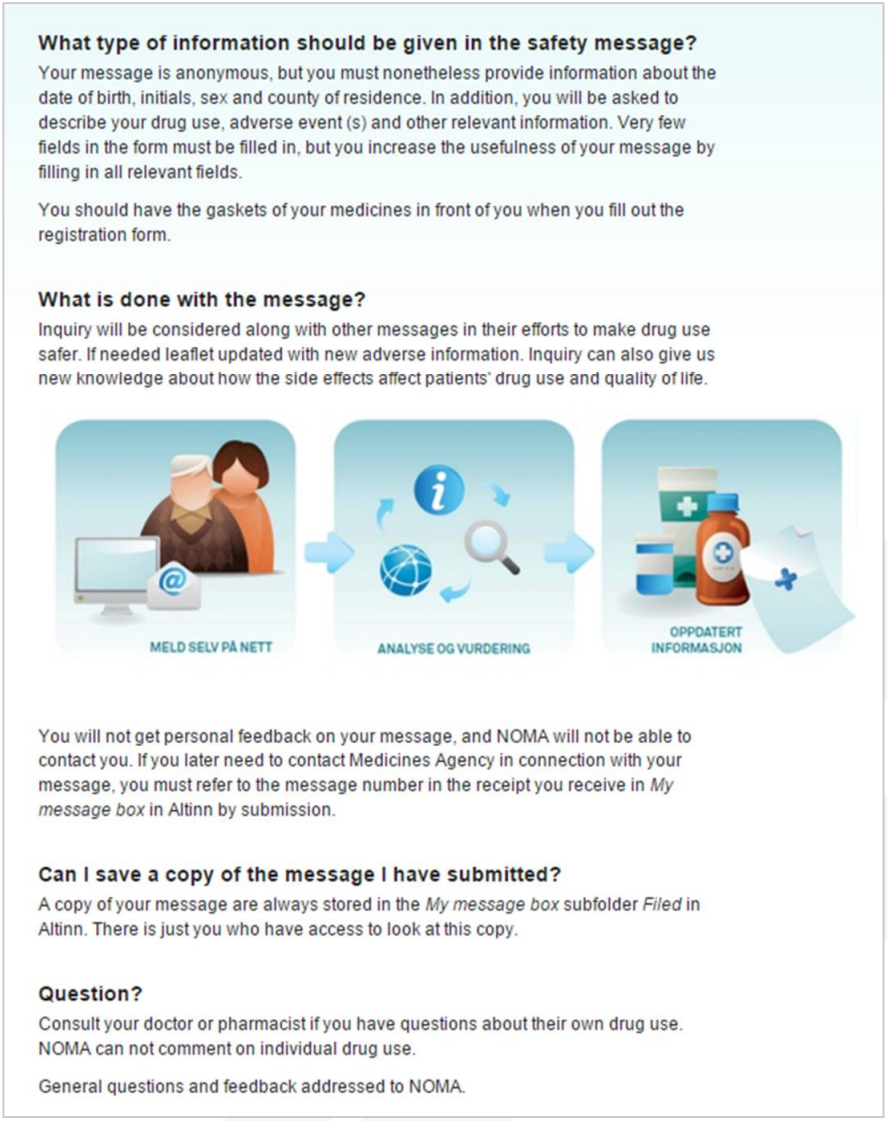


Figure 7. Screenshot from the Malta Medicines Authority webpage highlighting the ability to select user type. Medicines Authority – homepage

Regarding the content and presentation of ADR reporting information, the Norwegian Medicines Agency (NOMA) is a good example of using a Q&A type format to break up the information, particularly for patients. Importantly, NOMA provides infographics describing what happens once a safety report is submitted by a patient (**Figure 8** below). Details of user-specific safety information are covered further in Section 3.



What type of information should be given in the safety message?

Your message is anonymous, but you must nonetheless provide information about the date of birth, initials, sex and county of residence. In addition, you will be asked to describe your drug use, adverse event (s) and other relevant information. Very few fields in the form must be filled in, but you increase the usefulness of your message by filling in all relevant fields.

You should have the gaskets of your medicines in front of you when you fill out the registration form.

What is done with the message?

Inquiry will be considered along with other messages in their efforts to make drug use safer. If needed leaflet updated with new adverse information. Inquiry can also give us new knowledge about how the side effects affect patients' drug use and quality of life.

You will not get personal feedback on your message, and NOMA will not be able to contact you. If you later need to contact Medicines Agency in connection with your message, you must refer to the message number in the receipt you receive in *My message box* in Altinn by submission.

Can I save a copy of the message I have submitted?

A copy of your message are always stored in the *My message box* subfolder *Filed* in Altinn. There is just you who have access to look at this copy.

Question?

Consult your doctor or pharmacist if you have questions about their own drug use. NOMA can not comment on individual drug use.

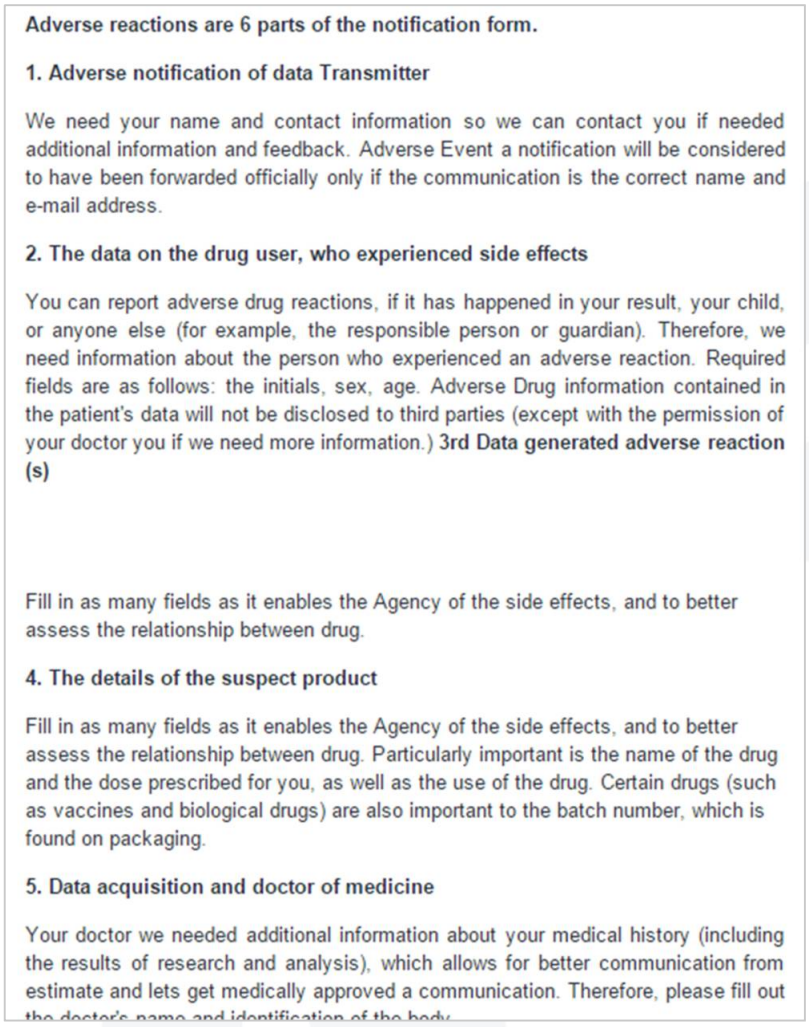
General questions and feedback addressed to NOMA.

Figure 8. Screenshot from the Norwegian Medicines Agency (NOMA) webpage showing the information provided to patients on ADR reporting. Norwegian Medicines Agency – ADR information for patients

2.2.2 Article 102(b): web-based patient reporting forms

Patient reporting of ADRs is important in monitoring the safety of marketed medicines, in addition to spontaneous reporting by HCPs. Patient reporting can increase the speed with which a signal is detected and should be considered as a complementary source for signal detection and not an alternative to HCP reporting. Nevertheless, under-reporting is well documented throughout Europe, and patient reporting helps to alleviate this.

Regarding access to reporting forms, NCAs may have a separate website for reporting (e.g. the Yellow Card website for UK reporting) or may have the reporting form integrated into their NCA website (14). Patient reporting forms need to be highly accessible and intuitive to complete; drop-down boxes and automatically populating fields are several methods that can be used to make it easier for patients to provide accurate reports. Providing information in helping patients to populate web-forms can also be useful. A good example of providing such information is demonstrated by the Estonian State Agency of Medicines (**Figure 9**). Here Estonia describes the different sections of the reporting form and provides helpful guidance on how to populate information.



Adverse reactions are 6 parts of the notification form.

1. Adverse notification of data Transmitter

We need your name and contact information so we can contact you if needed additional information and feedback. Adverse Event a notification will be considered to have been forwarded officially only if the communication is the correct name and e-mail address.

2. The data on the drug user, who experienced side effects

You can report adverse drug reactions, if it has happened in your result, your child, or anyone else (for example, the responsible person or guardian). Therefore, we need information about the person who experienced an adverse reaction. Required fields are as follows: the initials, sex, age. Adverse Drug information contained in the patient's data will not be disclosed to third parties (except with the permission of your doctor you if we need more information.) **3rd Data generated adverse reaction (s)**

Fill in as many fields as it enables the Agency of the side effects, and to better assess the relationship between drug.

4. The details of the suspect product

Fill in as many fields as it enables the Agency of the side effects, and to better assess the relationship between drug. Particularly important is the name of the drug and the dose prescribed for you, as well as the use of the drug. Certain drugs (such as vaccines and biological drugs) are also important to the batch number, which is found on packaging.

5. Data acquisition and doctor of medicine

Your doctor we needed additional information about your medical history (including the results of research and analysis), which allows for better communication from estimate and lets get medically approved a communication. Therefore, please fill out

Figure 9. Screenshot from the State Agency of Medicines (Ravimiamet, Estonia) displaying the information provided to patients to aid in ADR reporting. State Agency of Medicines – ADR reporting information

Of the 25 surveyed, 23 MSs have an electronic system in place for patients to report ADRs through their website, with 15 using downloadable forms that can be printed and sent to the NCA (WP4 – Review of reporting forms, Q7). Also from this WP4 survey, 70% of NCAs design their reporting forms in house, whilst 30% use professional web designers. Some of the recommendations to come out of the survey highlighted the need to perform user testing studies for all electronic reporting forms, not just patient forms.

Looking at the structure of the reporting forms, **Figure 10**, below, highlights the progress functionality provided by the Icelandic Medicines Agency (IMA) and the Malta Medicines Authority in their patient web-form, allowing ADR reporters to track the advancement of their submission.

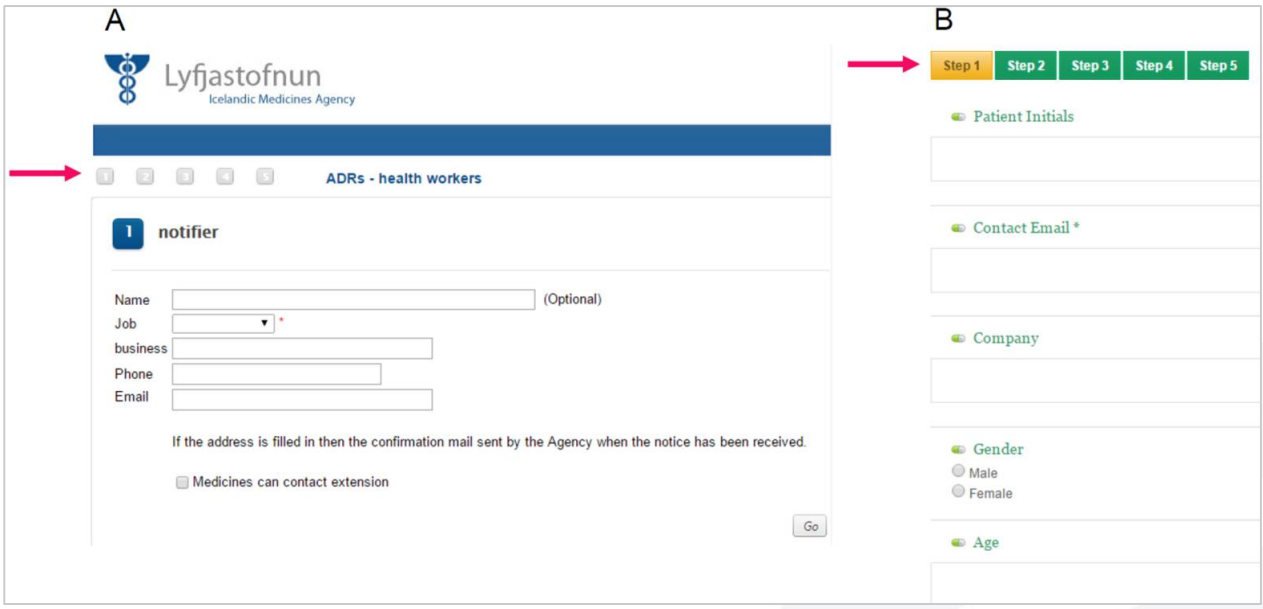


Figure 10. Screenshots of Icelandic Medicines Agency (**A**) and Malta Medicines Authority (**B**) patient e-forms, highlighting the step-by-step description so that patients can measure their progress. (A) Icelandic Medicines Agency – ADR reporting web form (B) Medicines authority – ADR reporting web form

Regarding the fields used in electronic reporting forms, mandatory fields used by NCAs include patient and reporter demographics, the medicinal product(s) and adverse reaction details. Some additional fields used included clinician details, medication errors and pregnancy information. The validation of reporting fields is another aspect of electronic reporting. The HCP survey (WP6 – Healthcare professional survey: medicines safety communication and their effectiveness) collected feedback from patients and consumers with respect to risk communication and safety information, and explores this further.

SCOPE (WP4 – ADR collection) will be developing a generic form that MSs may utilise. The aim is to initially develop the form in an E2B R2 format, with the functionality to develop it into an R3 format when required. Given that some NCAs do not yet have the background database to support electronic reporting, this will also be a consideration during the development of this core reporting form, and NCAs may be able to utilise the Content Management System itself to extract and compile the incoming data.

2.2.3 Article 102(d): updating safety information

As per the EU Directive, information should be presented in a timely manner. Survey data showed that there were significant variations in the frequency with which PhV information is updated across European NCAs (WP6 - Web-portals, Q10, Annex 7.1). Some update key information, like PILs, SmPCs and safety announcements, on a daily basis, others weekly or monthly.

From the survey conducted to HCPs (WP6 – Healthcare professional survey: medicines safety communication and their effectiveness, Q19) information on how often they would like to receive risk communications, and whether they would be open to receiving communications more than once was collected. Therefore NCAs may consider publishing their data in line with the responses of HCPs in their MS, and others continue to apply a prioritisation process, where audience testing (Section 4) could help inform which safety information should be updated more regularly. On the basis of importance, and not on user preferences, SmPCs, PILs and safety announcements are the most important communications to publish regularly, where updates are required. It should be left to the NCA to assess their national preferences and identify how often PhV information should be updated.

2.3 Additional considerations

2.3.1 Translating safety information

Although not part of the EU Directive, presenting national safety information in a common language in addition to the MS's national language(s) could facilitate European coordination, particularly for industry users. Many of the NCA websites have an English-translated version that users can display, and for those that do not, online translators work well enough to allow website navigation.

However, for some NCAs, the English-translated webpage has a tailored structure, different to that of the national website. Some agencies have direct links to PARs on their native site, but lose this functionality for the English-translated site. This may be because the NCA site does not publish centrally authorised medicines, and it is less likely that a non-national user would wish to access PARs for a nationally licensed medicine. However, should the medicine be going through a wider authorisation process, it may be beneficial for users to access English translations of such documents. Whether documents are translated should be decided at a national level according to user surveys and the usefulness of having English versions.

2.3.2 Risk communications

Although not mentioned in the EU Directive, some NCAs present direct healthcare professional communications (DHPCs) on their website, and in some MSs, like Croatia, the national legislation requires the publication of this communication. These can be helpful to healthcare and pharmaceutical industry professionals. For example, publishing these on the NCA website can act as a 'back-up' for HCPs in case they do not receive the DHPCs sent to them in the post, or as a repository in case the HCPs would like to consult them further. **Figure 11** below shows Belgium's Federal Agency page for DHPCs.

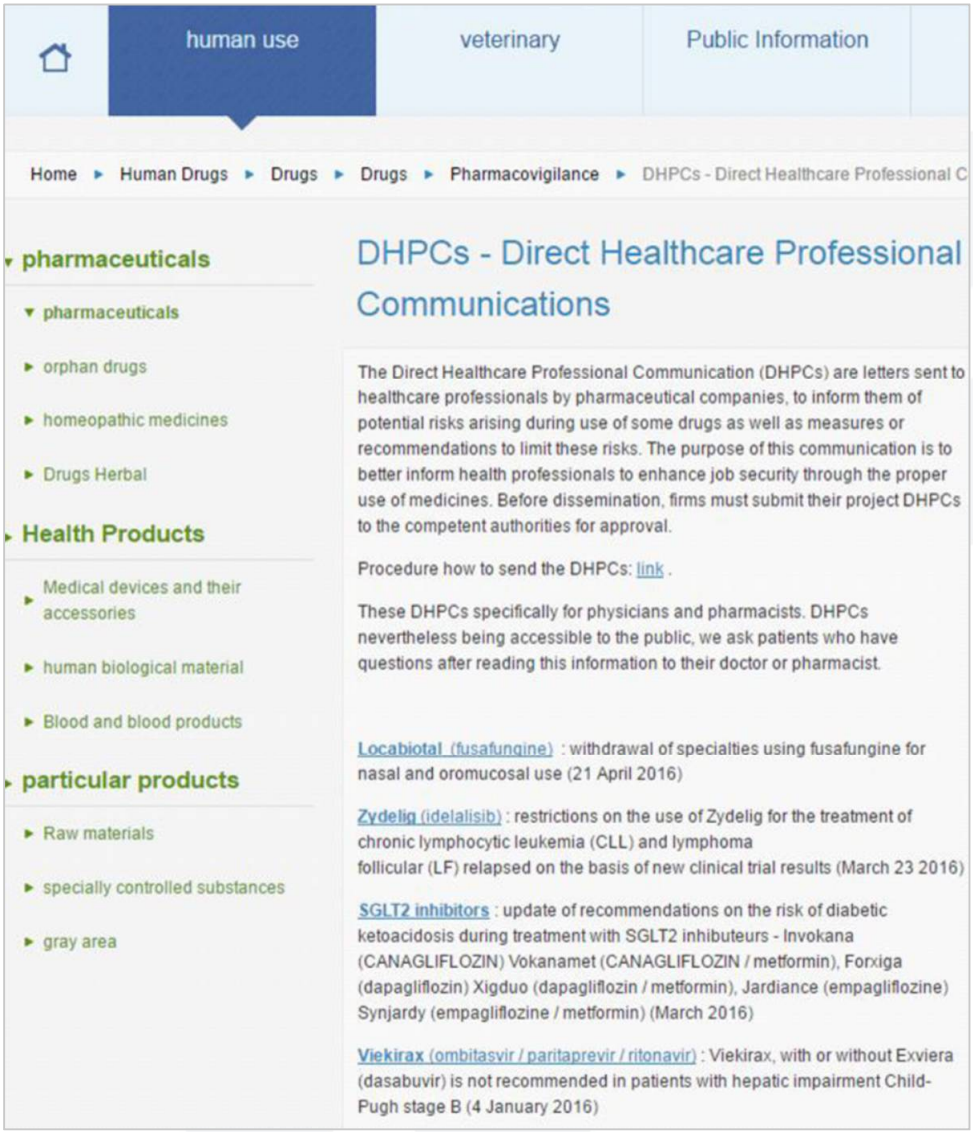


Figure 11. Screenshot of a list of DHPCs published on the French website of Belgium's Federal Agency for medicines and healthcare products (translated using Google translate). Federal Agency for medicines and healthcare products – DHPCs

As another example, the Spanish agency presents risk communications together with safety information for medicinal products through CIMA, their medicines information centre. Below**, Figure 12A** shows a database search for CELLCEPT, with **Figure 12B** highlighting some of the risk information presented alongside the SmPC, PIL and EPAR for this medicinal product.

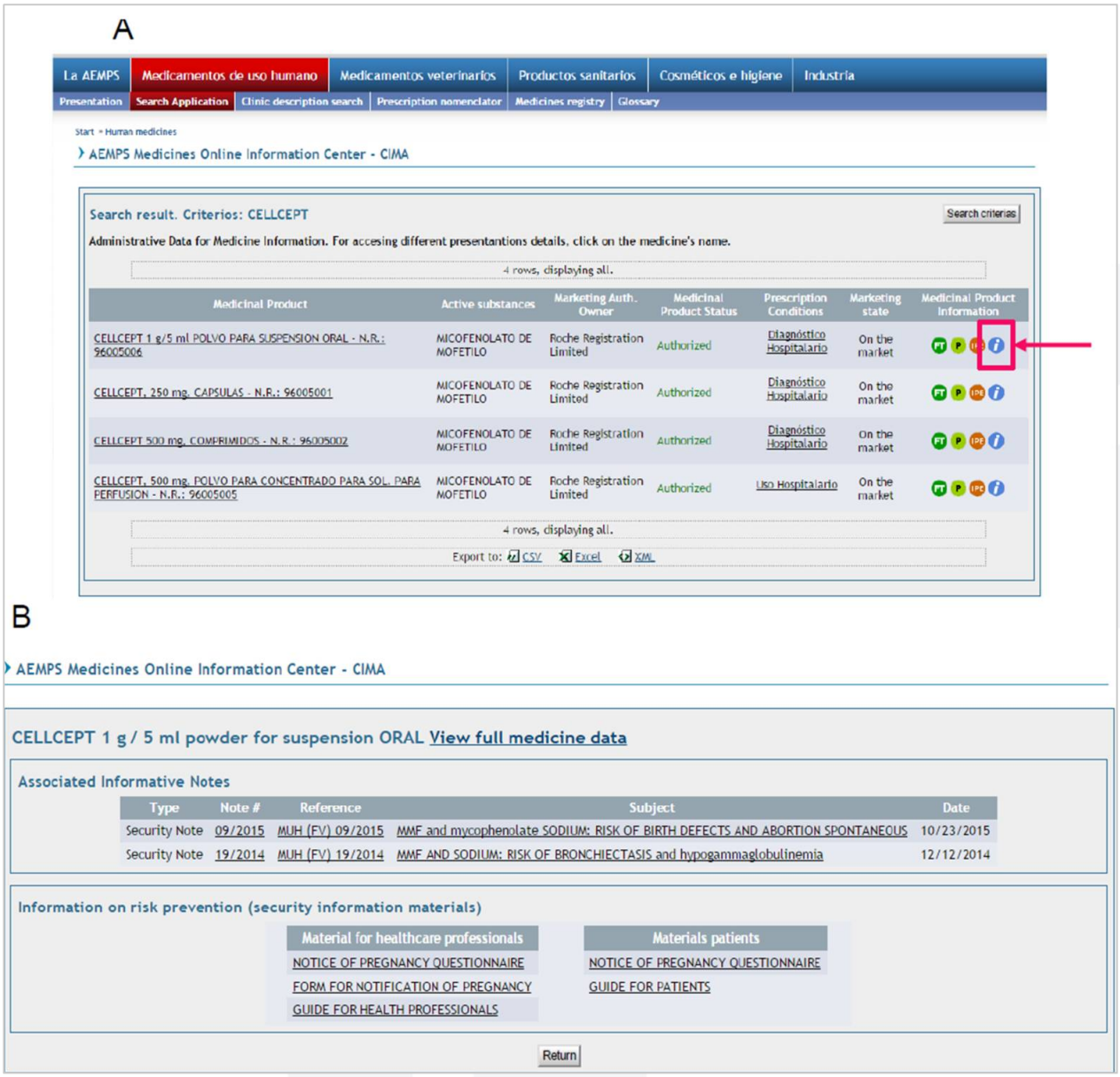


Figure 12. Screenshots of a database search for CELLCEPT on the Spanish agency website. The top image (**A**) shows the results of the search, with the SmPC, PIL and EPAR all available for the medicinal product (CIMA database search); the second image (**B**) shows the additional information (i) presented for this medicine.

This chapter has summarised the key requirements of the new PhV Directive, and has tried to present the current European perspective with regards to presenting safety information. Case studies allow those NCAs with less-developed web systems to see how they might improve the dissemination of the required documents in the most accessible way. However, this section also discussed current difficulties in publishing certain types of documents, and highlights the ongoing EU-wide discussions on how best to fulfil the requirements of the Directive.

3 Presenting safety information

This section showcases a selection of NCA websites that use a variety of methods to present their PhV information. Examples include basic structuring of information, user-specific tailoring of language and content, and increasing accessibility of information. At the beginning of each section, there are listed some 'hints and tips' that NCAs may wish to adopt to optimise their presentation of safety information.

3.1 Language style

Hints and tips

- Using plain language that can be easily understood by anyone, and defining technical terms (e.g. using 'hover-over' definitions)
- Maximising impact by clearly stating any actions that need to be taken (or not taken) and addressing the reader in the second person

All website content should be written in plain language so that it can be easily understood by everyone. Using plain language means using short sentences and clear, simple words that most people (including non-specialists) will understand. It means avoiding technical terms if possible and, if unavoidable, making sure that they are defined on first mention or with 'hover-over' definitions (see below). The Plain English Campaign website is a useful source for guidance (Annex 7.2.3), with specific guidance on plain English in relation to medicine (15).

3.1.1 Communicating to persuade

When the purpose of a communication is to persuade someone to do (or not do) something, ensure that the recommendations are stated clearly at the start (e.g. in a 'key messages' list).

It can be helpful to write information in the second person – e.g. 'if **you** are taking this medicine **you** should…', instead of '**patients** taking this medicine should….'; or 'do not prescribe this medicine to…', instead of 'health professionals should not prescribe this medicine to…'. Text written in the second person can have more impact than text written in the third person, as it involves the reader by addressing them directly.

3.1.2 User-specific language

60% of MSs have separate sections on their websites targeting patients and HCPs (WP6 – Web-portals, Q13, Annex 7.1). However, for those who do not have separate locations, some use simpler or more complex language for targeted ADR reporting, and others use simpler language universally, to increase patient understanding. Of the 10 MSs that do have separate sections for HCPs and patients, the patient information is made simpler, clearer, less bulky and can include Q&As. For HCPs, more complex language is used and more information is presented.

Language for patients and non-specialist audiences

When writing about medicines safety information, NCAs should consider how someone taking that medicine might react, and how NCAs may want them to react. Is the information likely to cause concern? Is there a risk that someone might stop taking their medicine after reading this information? What actions do NCAs want (or not want) the reader to take as a result of reading this information? It can be helpful to inform the reader of what the new information is, and what they should do as a result, for example:

> *"…We have received 56 reports of this side effect in people taking medicine X to date. If you take medicine X, there is no need to stop taking it. If you have any questions or concerns, speak to your doctor or pharmacist during your next visit."*

When writing for patients, using the word 'patients' may not always be the best way forward, for the following reasons:

- The information may be relevant to other people, besides patients (e.g. carers who buy medicines for others, HCPs looking for information to pass on to their patients, people who are not taking the medicine but have an interest in it for other reasons)
- Not all patients may consider themselves patients (e.g. women taking contraceptive pills), therefore they might not read information that's labelled as 'information for patients'

For example, instead of 'information for patients', consider writing 'information for people who take drug X' or 'what to do if you take drug X'.

Language for healthcare professionals and specialist audiences

When writing for specialist audiences (e.g. healthcare or pharmaceutical industry professionals), using plain language is just as important as writing for non-specialist audiences. For example, although not PhV-focused, research into the use of specialist language in legal documents found that the more educated the person and the more specialist their knowledge, the greater their preference for plain language (16). If this principle is applied, there may be no need to group information based on user-type; instead all content should be made universally understandable. However, the type of information presented could still differ in applicability for different user-types. More on grouping is discussed in Section 3.2.

Using certain techniques it is possible to allow the user to choose the complexity of the information that they can access. This can be achieved by having keywords, with links to more specialist explanations, or more easily with 'hover-over' statements as discussed below. In this way, a user can decide whether they want surface information or would like to go into more detailed layers of content. This is supported in the survey performed with HCPs, exploring their preferences for risk communication across European MSs (WP6 – Healthcare professional survey: medicines safety communication and their effectiveness).

3.1.3 'Hover-over' definitions of technical terms and acronyms

Avoid using technical language and jargon if possible (see the note on plain language at the start of this section). However, if a technical term is unavoidable, it can be helpful to code for a definition to appear when the reader hovers their cursor over or clicks on each mention of the word. This can also be done for acronyms and abbreviations (**Figure 13**).

Figure 13. Screenshots from the European Medicines Agency website (**A**) and the Agency for Medicinal Products and Medical Devices of Croatia (HALMED) website (**B**), showing examples of 'hover-over' definitions. (A) European Medicines Agency – PhV (B) Agency for Medicinal Products and Medical Devices of Croatia – Medicines

3.2 Grouping of information

Hints and tips

- Grouping information allows users to be directed to areas of interest
- NCAs use a variety of methods for grouping, including by audience, therapeutic area and topic
- However, grouping can mean that NCAs are repeating information in different areas of their website if applicable to multiple groups

14 NCAs group their information by topic or theme, with 1 MS grouping by therapeutic area or medicinal class (WP6 – Web-portals, Q15, Annex 7.1). Some NCAs also provide subsections on their homepage for 'centralised', 'mutual recognition procedure (MRP) and decentralised procedure (DCP)' and 'national procedures' medicines, to assist users in searching for medicine-specific information. MSs must be careful not to make assumptions about the users' levels of prior knowledge; if themes or topics are not known, it should still be possible for users to access information – for example, by using a search function. Discussed below are some examples of information grouping, including the benefits and risks of different approaches.

3.2.1 Grouping by target audience

A common way to group information is by type of website user, also known as target audience. Common target audiences of an NCA's website are people who buy or take medicines, HCPs and pharmaceutical industry professionals. An important aspect of communicating safety information is identifying who your main target audiences are; this is discussed further in Section 4. **Figure 14**, below, is an example of user-specific grouping by the Bulgarian Drug Agency and the Icelandic Medicines Agency.

One of the pros of grouping by target audience is that users can quickly be directed to the areas of the website relevant to them. However, there can be significant duplication of information on NCA webpages if information is relevant to more than one user group. For example, information on the safety of medicines sold over the counter may be relevant to both pharmacists and people who buy those medicines. In addition, information that MSs think is relevant to a particular target audience may be more relevant to a different target audience in practice.

Figure 14. Screenshot from the Bulgarian Drug Agency (**A**) and the Icelandic Medicines Agency (**B**) websites to show the segregation of information by audience on each homepage. (A) Bulgarian Drug Agency – homepage (B) Icelandic Medicines Agency – homepage

3.2.2 Grouping by therapeutic area or medicinal class

The benefits of grouping by medicinal area is that if the user is looking for specific information on only one therapeutic area, they are quickly and easily directed to it, instead of having to filter out irrelevant search results, for example (**Figure 15** below). However, not all website content will fit into these categories: some may fit into more than one category, while other content may not fit into any of these categories.

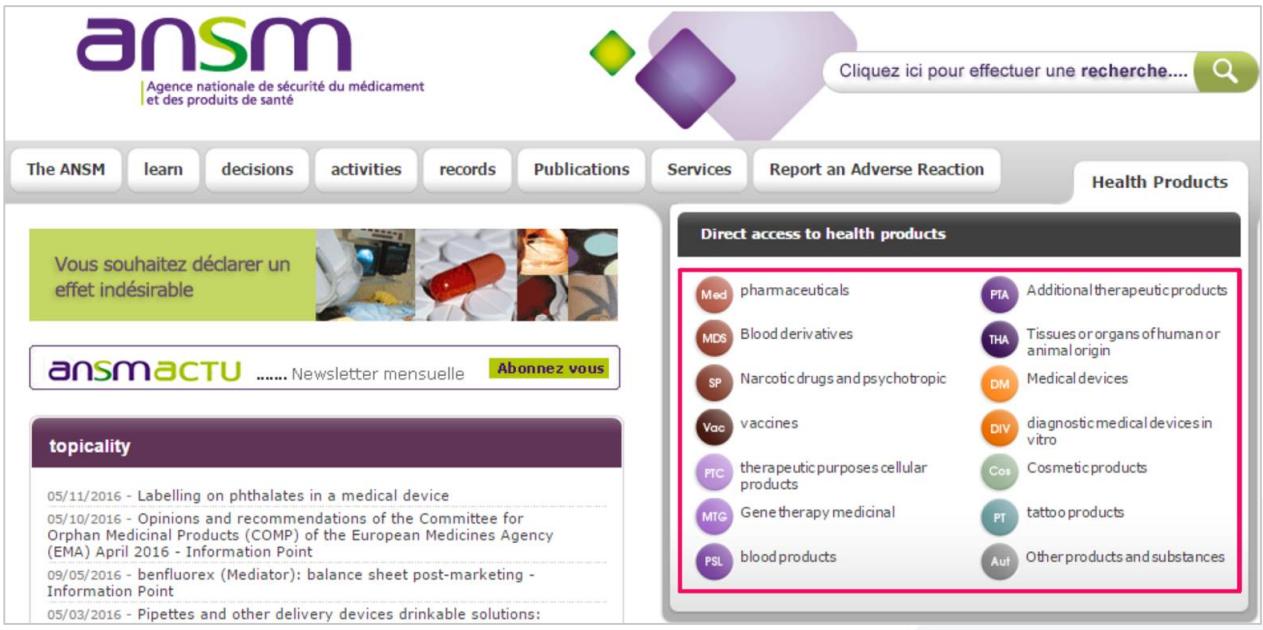


Figure 15. Screenshot of the homepage of the French National Agency for the Safety of Medicines and Health Products (ANSM) to show the grouping of content by therapeutic area. National Agency for the Safety of Medicines and Health Products – homepage

3.2.3 Grouping by information topic or theme

Regarding grouping by topic or theme, information is not duplicated; users can find what they're looking for regardless of which target audience group they belong to. However, it's not possible to list every website page in these site maps, so it may not be obvious which section a particular page is in. In these cases, the user may need to use a search box. **Figure 16**, below, shows examples of grouping information by theme on the websites of the Finnish Medicines Agency, the Hungarian National Institute of Pharmacy and the Danish Health and Medicines Authority.

Interestingly, each of the examples in **Figure 16** group information using different techniques. For example, in **Figure 16A**, clicking on one of the grouping options takes users to a separate dedicated page on that topic; from this page users can select subgroups. In **Figure 16B**, the subtopics under the four key groups are already displayed; users can then route straight to a specific topic. In Figure 16C, once users click on one of the key groups, e.g. 'Health and treatment', selectable subtopics appear.

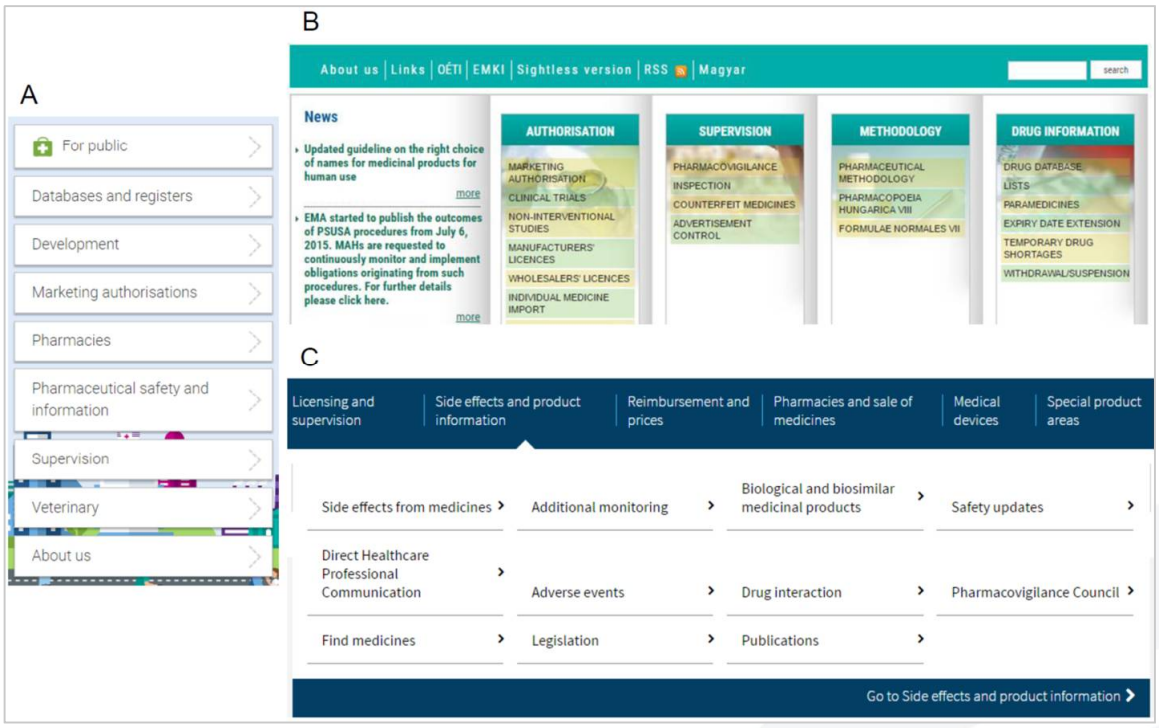


Figure 16. Screenshots of the Finnish Medicines Agency (**A**), the Hungarian National Institute of Pharmacy (OGYEI) (**B**) and the Danish Health and Medicines Authority (**C**) homepages, showing grouping by theme. (A) Finnish Medicines Agency – homepage (B) National Institute of Pharmacy and Nutrition – homepage (C) Danish Medicines Agency – homepage.

Although the benefits of grouping information have been discussed, it should be noted that careful thought should be given in order to reduce introducing limitations to such navigation – i.e. vital information should still be available to all users, it may just be best to present said information in a different manner for different user types. This is most applicable to grouping by target audience. Other forms of grouping can result in duplication of information on websites, which can introduce issues when keeping documents up to date. Ultimately it will be for the NCA to decide whether grouping is relevant in their MS, and which type of grouping would be most appropriate for their target audience.

3.3 Search functions

Hints and tips

- Having search functionality is important, particularly for users who are not familiar with PhV information
- An example is to have a medicinal products database, which holds all information for each searchable product
- Using autofill can greatly increase the ease and speed with which users can find what they are searching for

From the survey on web-portals (Q24, Annex 7.1), 24 MSs have a search functionality built into their website, with 11 MSs having automatic keyword indexing, and 10 MSs having manual indexing capabilities.

3.3.1 Document databases

One way of presenting safety information is through a searchable documents database. This allows the website user to enter a particular product/substance name, click 'search' and be presented with all the available documents relating to the medicinal product/substance (SmPCs, PILs, PARs, etc.). An example of presenting all information for a medicinal product, including both risk communications and general safety information, was highlighted in Section 2.3.2, which showed pages from the Spanish website, CIMA.

Ideally, the document database should be able to retrieve results for both centrally authorised and nationally authorised medicines. However, this is not currently always possible due to technical limitations on some sites. **Figure 17** and **Figure 18**, below, present good examples of such search functions.

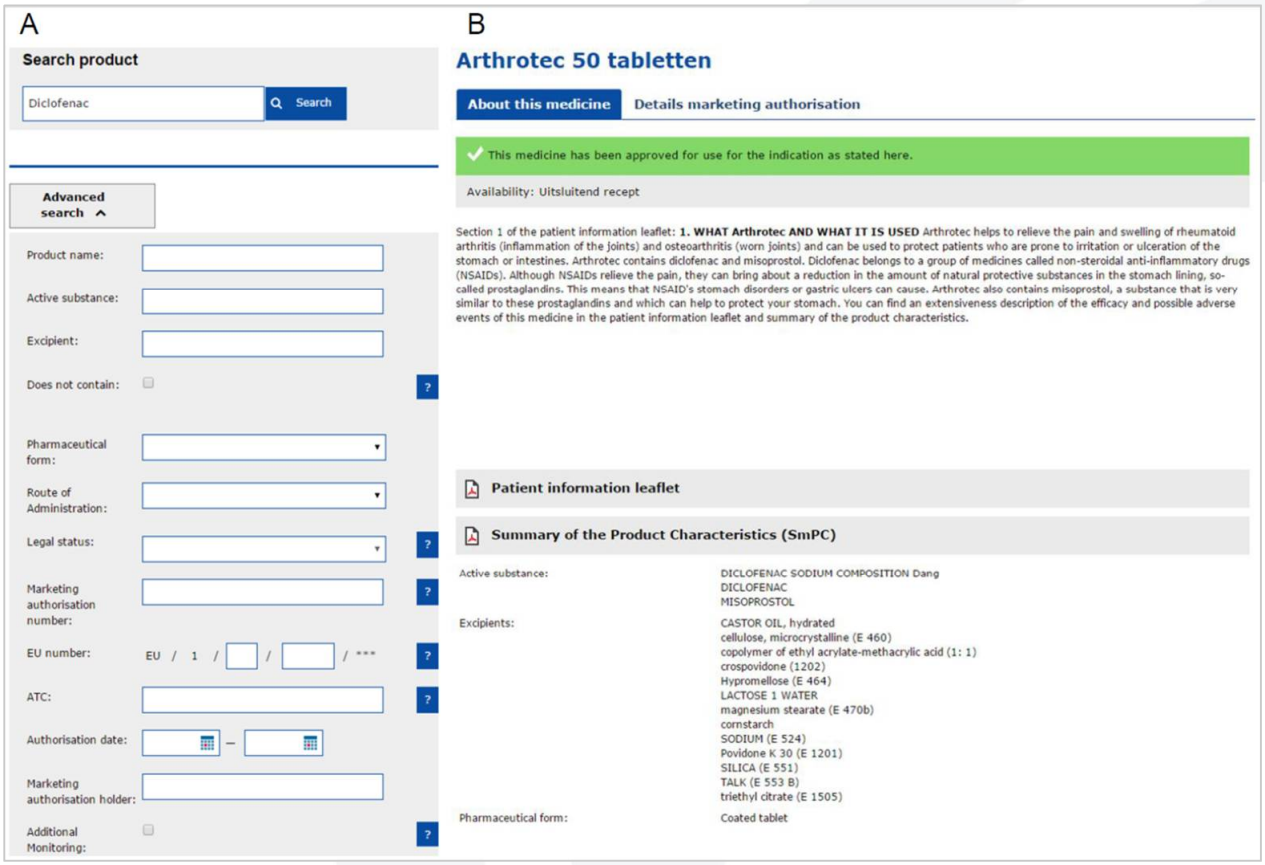


Figure 17. Screenshot from the Dutch Medicines Evaluation Board showing the Medicines Data Bank advanced search functions (**A**) and one of the search results for the search term 'diclofenac' (**B**). Medicines Evaluation Board – drug search

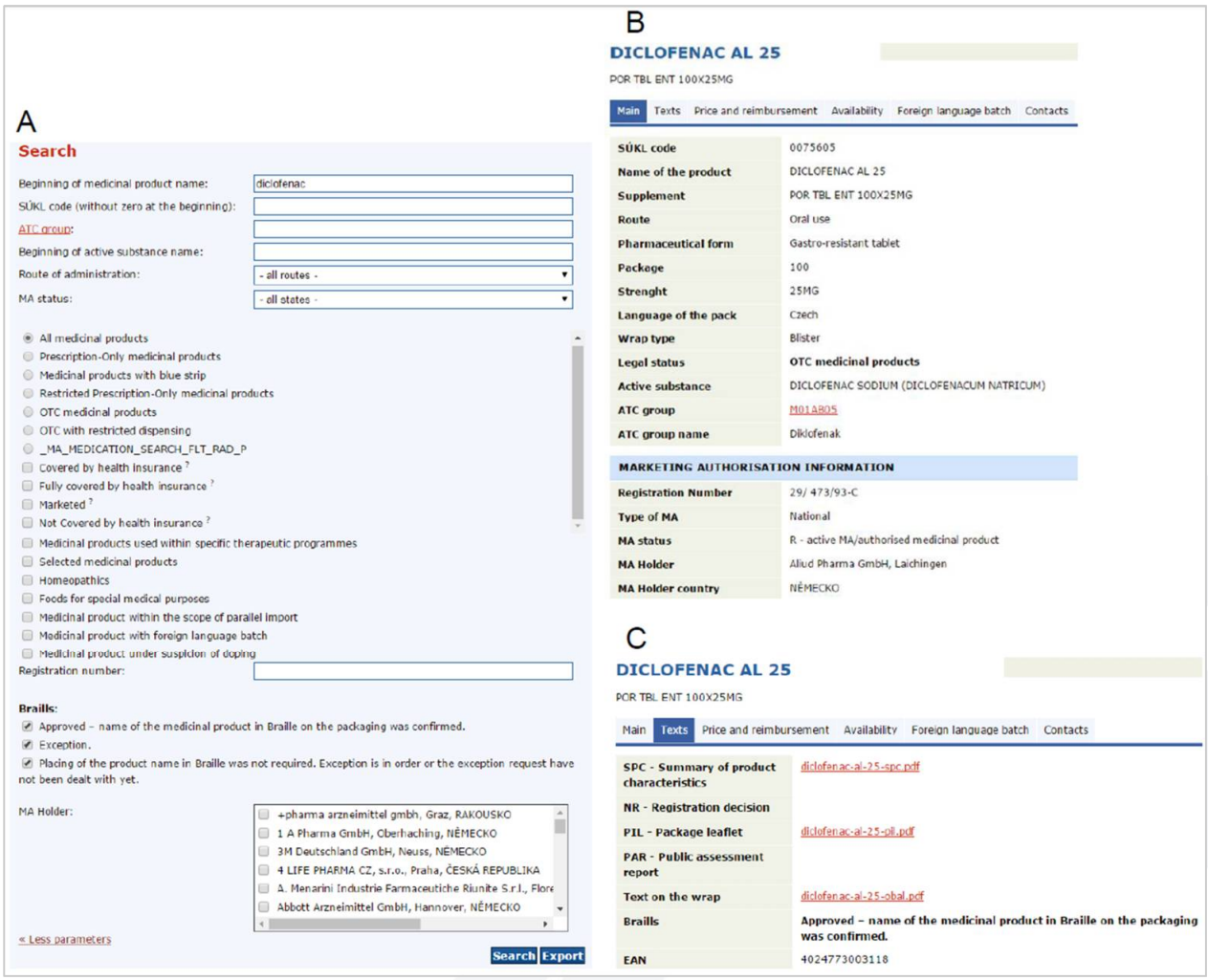


Figure 18. Screenshot from the Czech State Institute for Drug Control, showing the Medicines Data Bank advanced search functions (**A**) and the 'basic' information (**B**) and available texts (**C**) for one of the search results for the search term 'diclofenac'. State Institute for Drug Control – drug search

3.3.2 Autofill and other search functions

If technical resources allow, a 'medicinal products dictionary' can be added to a website's metadata to enable 'autofill' functions, so that, for example, when a user starts typing a drug name into the search box, a list of all drugs starting with those letters appears automatically (**Figure 19** below). It can also be helpful to allow searching by parts of the product names to account for misspelling.

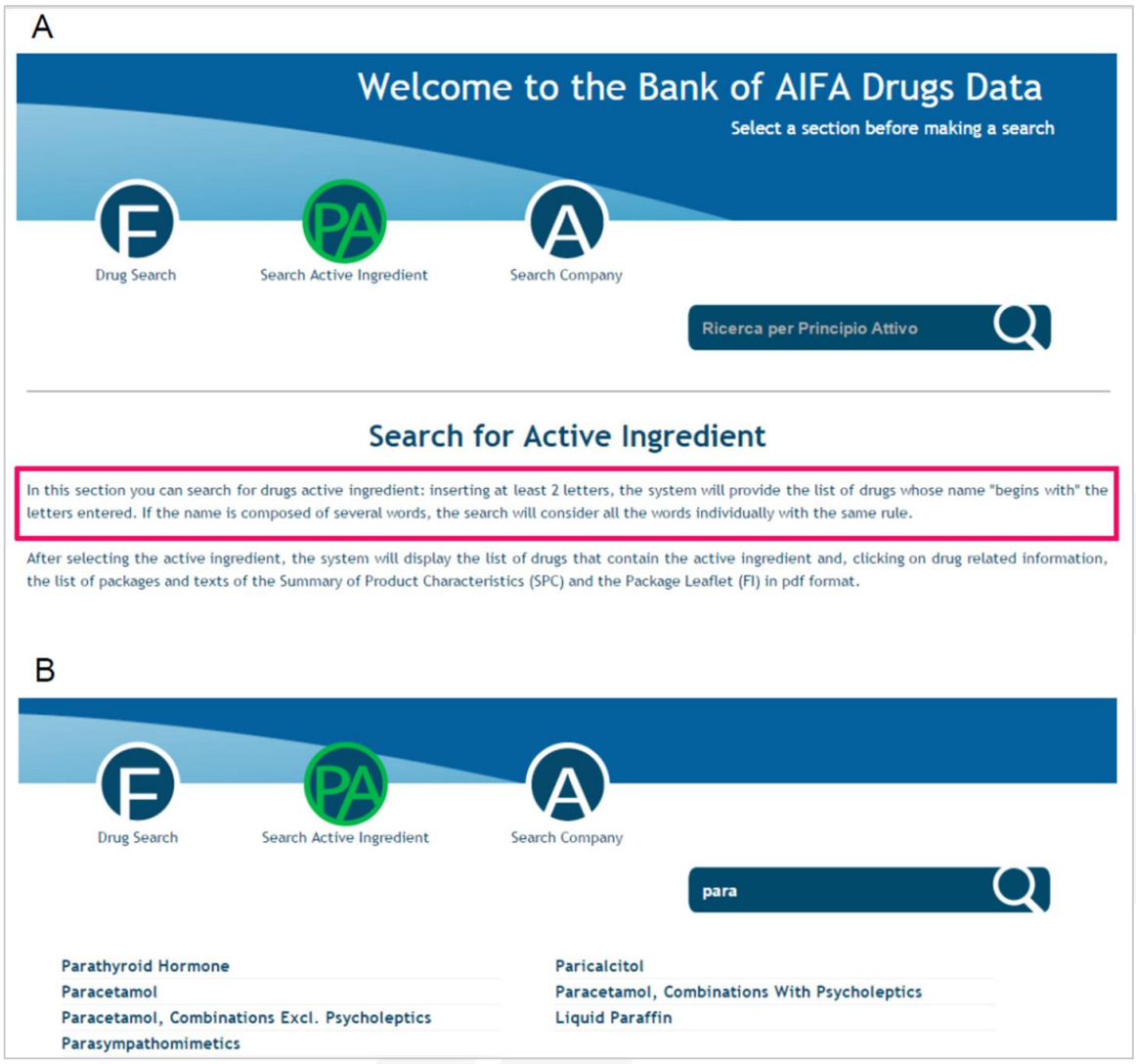


Figure 19. Screenshots from the Italian Medicines Agency showing the Drugs database (**A**). Drugs can be searched for by entering at least two letters; the system will provide a list of drugs with names beginning with the letters entered. If the name is composed of several words, the search will consider all the words individually using the same rule. As an example, searching for the letters 'para' retrieved 7 hits beginning with those letters (**B**). Italian Medicines Agency – drug search

3.4 Layout of individual webpages

Hints and tips

- 'Front-loading' content by putting the most important words at the start allows content to be read quickly and optimises search engine results
- Summarise the content and key messages at the top of the page
- Use subheadings in pages that contain a lot of text

3.4.1 'Front-loading'

'Front-loading' means putting the most important words at the start of titles, subheadings, paragraphs and sentences. It allows readers to quickly understand what the text is about and optimises search engine results.

The way people read webpages is different to the way they read paper documents. They don't necessarily read top to bottom or even from word to word. Instead, they only read about 20 to 28% of a webpage (17). Eye-tracking studies show that people tend to read a webpage in an 'F' shape pattern (**Figure 20**) (18). They look across the top, then down the side, reading further across when they find what they need. This means that putting the most important information first (unlike this paragraph) is crucial.

Figure 20. 'Heat maps' from user eye-tracking studies of three websites (18). The areas where users looked the most are coloured red; the yellow areas indicate fewer views, followed by the blue areas, which were the least viewed.

Figure 21, below, gives an example of providing safety information using front-loading principles. Here, the page starts with a bold title followed by a brief summary of the information to be discussed. Following this are a series of left-aligned headings and short paragraphs of decreasing impact – i.e., the first paragraph identifies the key feature of the webpage, with subsequent paragraphs providing supporting information.

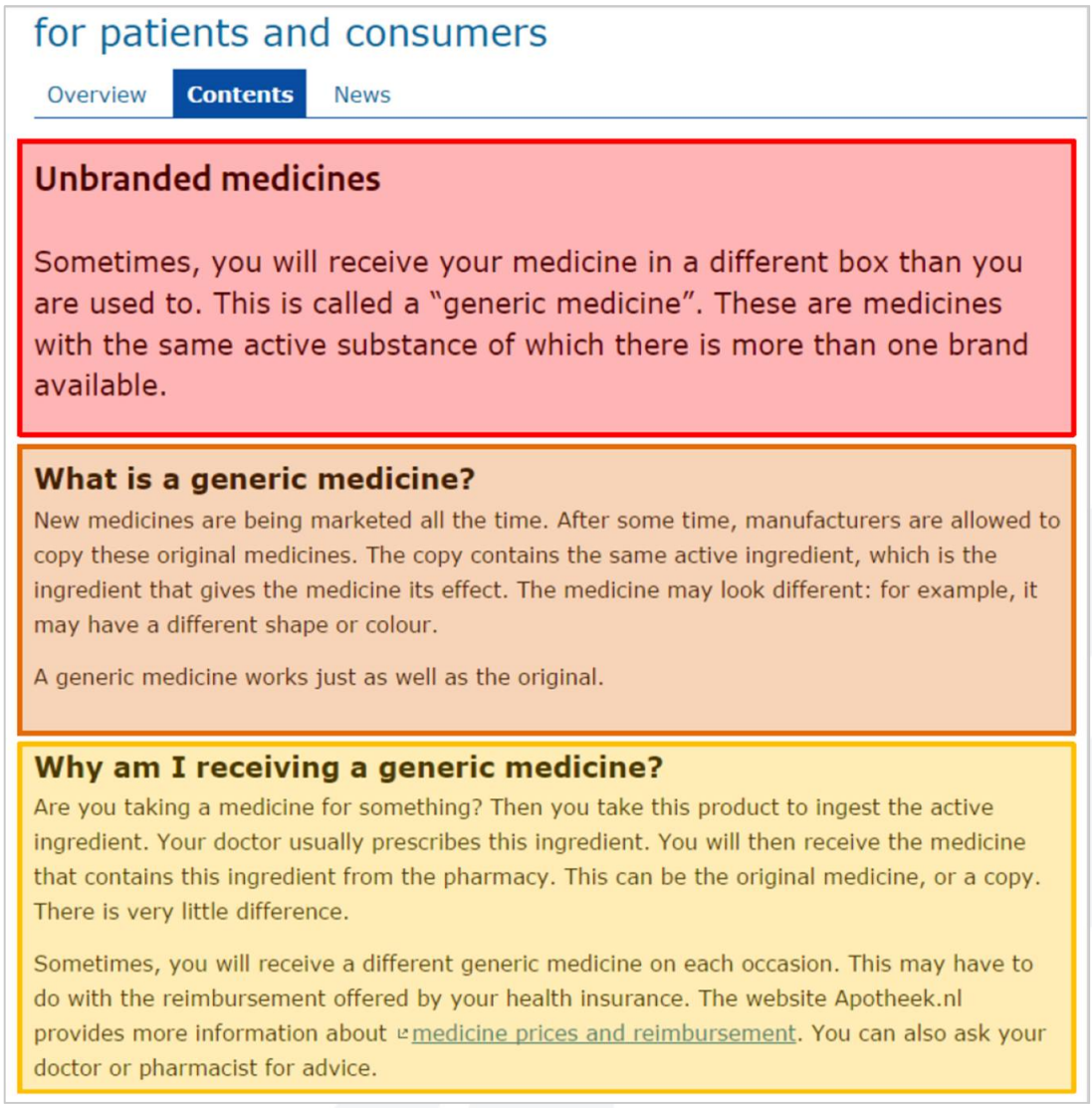


Figure 21. Screenshot from the Netherlands Medicines Evaluation Board (MEB) website, demonstrating the ranking of information by impact. Medicines Evaluation Board – unbranded medicines

3.4.2 Summary boxes

If a webpage contains a lot of text, it can be helpful to include a summary and/or key messages at the top of the page. That way, the person reading the page can understand what it is about as soon as they open it. It also means they will not miss important information if they don't scroll to the bottom of the page. **Figure 22**, below, taken from the Medicines and Healthcare Products Regulatory Agency (MHRA, UK) website, shows the use of both a short summary and of highlighting key points.

Figure 22. Screenshot from the UK's MHRA website showing a brief summary and list of key points at the top of the page. Drug Safety Update – Latanoprost

3.4.3 Subheadings

If a webpage contains a lot of text, breaking it up with subheadings can make it more digestible. This helps the reader quickly skim-read the page to understand what it's about and find the information that is most relevant to them. It can also be helpful to include the subheadings in a hyperlinked table of contents sidebar, so the reader can see all the subheadings as soon as they land on the page and click on the subheading that is most relevant to them. **Figure 23**, below, highlights an example of using such a table of contents sidebar.

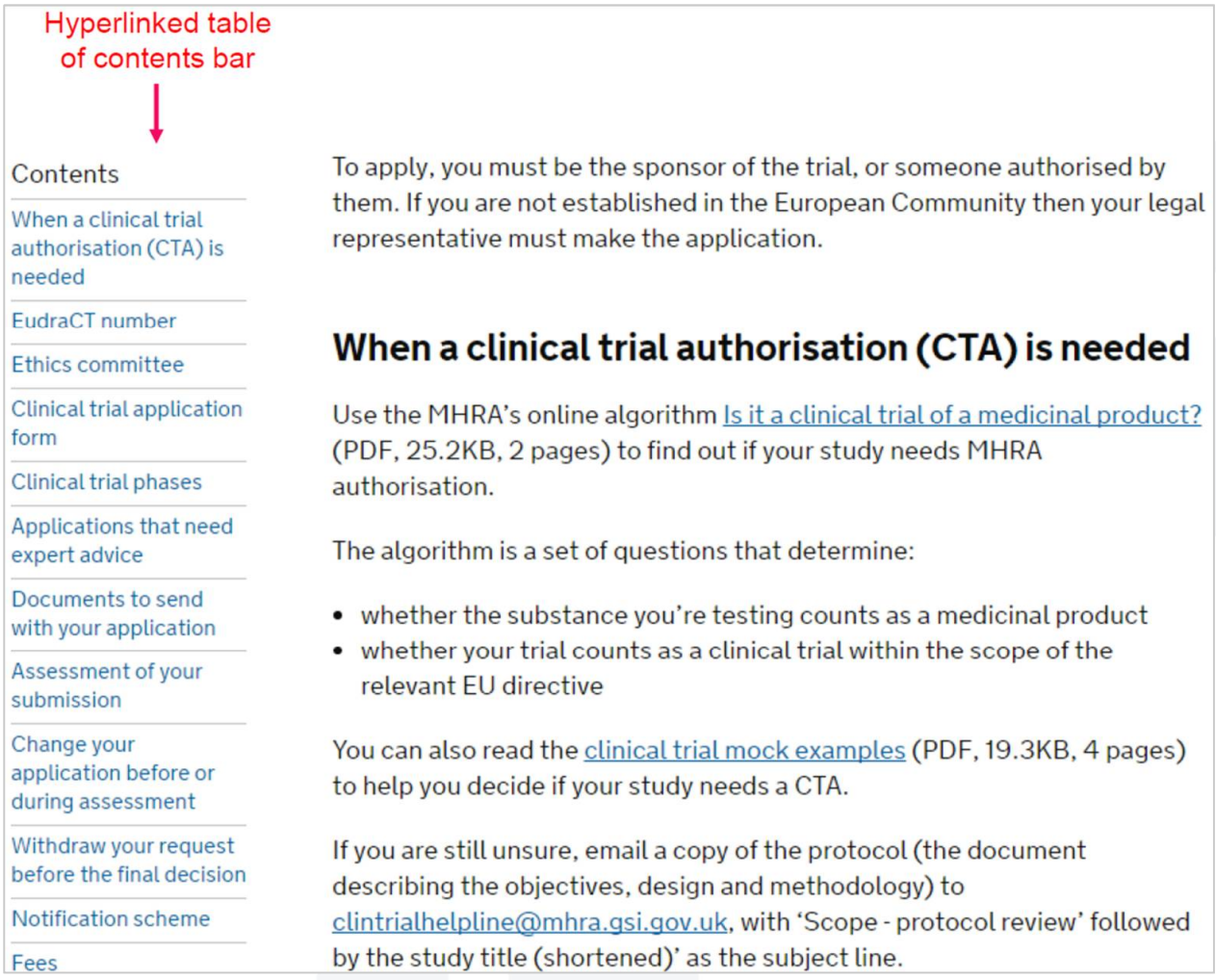


Figure 23. Screenshot from the UK's MHRA website showing subheadings listed in a hyperlinked table of contents sidebar. Medicines and Healthcare Products Regulatory Agency – table of contents

Another way to make a webpage containing a lot of text more reader-friendly is to present it in an 'accordion' style, by hiding the paragraphs under subheadings. The reader first sees only the subheadings, and can then click on the subheadings they are interested in to 'expand' that section and reveal the hidden text. This is shown in **Figure 24**, below.

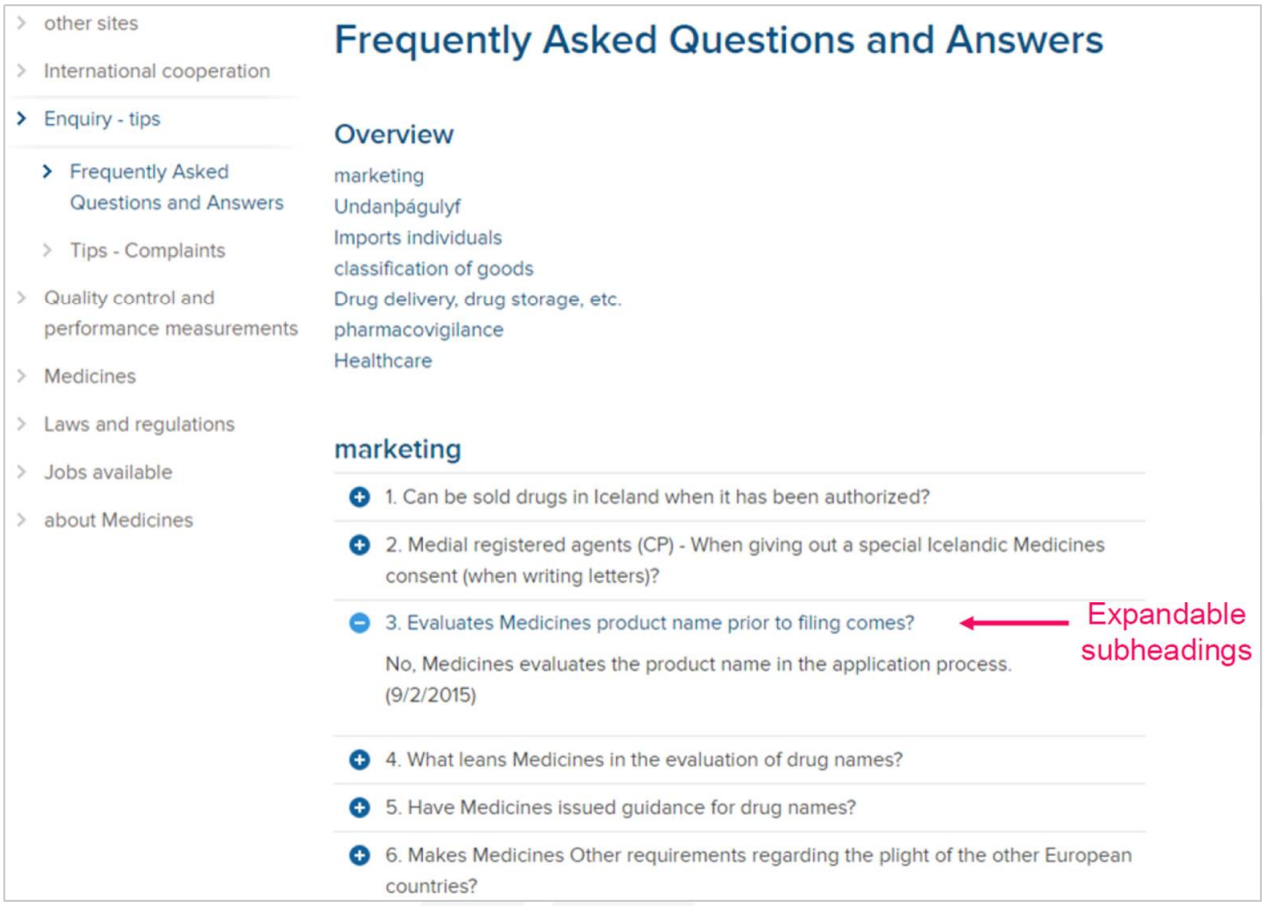


Figure 24. Screenshot from the Icelandic Medicines Agency website showing expandable accordion-style subheadings. Icelandic Medicines Agency – frequently asked questions

This technique can also be used to present information in 'onion layers'. This means presenting a high-level overview of information at the start of the article and going into more detail towards the end. This way, readers who only want brief information can choose how much detail they want to read (**Figure 25** below).

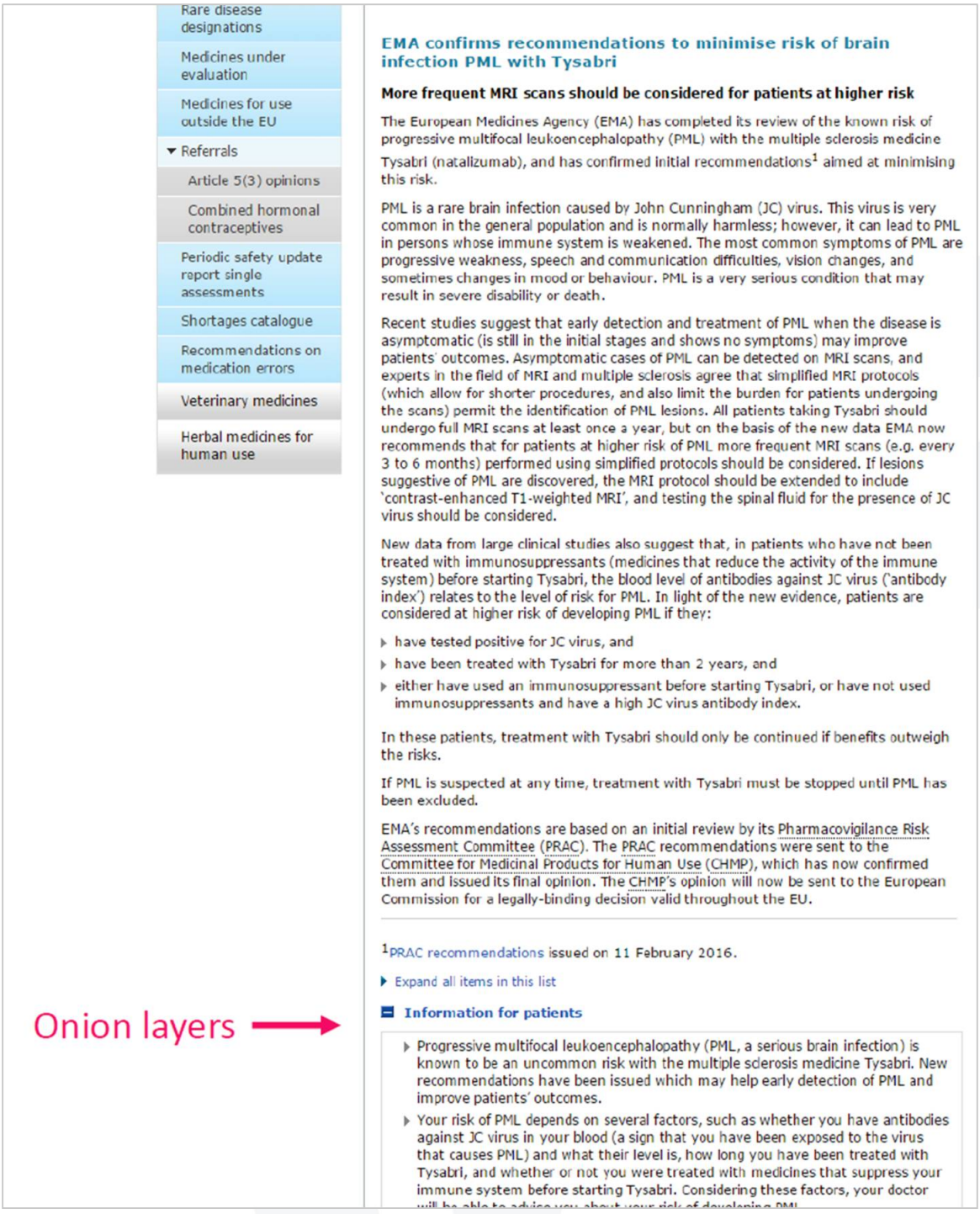


Figure 25. Screenshot from the European Medicines Agency (EMA) website showing information presented in 'onion layers' of detail. European Medicines Agency – Tysabri

3.5 Information format

Hints and tips

- News updates are a good way to navigate users to the most recent safety information
- More active forms of communication, like safety bulletins, can prompt HCPs into taking action
- Using visual and interactive tools can help convey important information

Providing information in a variety of formats is vital in optimising the accessibility of safety information. For example, the WP6 report for patients and consumers highlighted the importance of presenting information in a video format, particularly for complex concepts. Information that will be useful to reference in the future may be best presented in a downloadable format and information directed at patients may often be most easily understood when presented in a Q&A format. Below are some examples of presenting communication in the most accessible way.

3.5.1 News updates

All surveyed NCAs present news articles on their webpages (WP6 – Web-portals, Annex 7.1). Some NCAs present this information in ways that make the communication more accessible to users.

Both the Latvian State Agency of Medicines and the Norwegian Medicines Agency use icons in their news feeds. Latvia highlights news items that require action from users with an information icon and Norway highlights a 'News about drugs' monthly edition, which is published under the general news section (**Figure 26**).

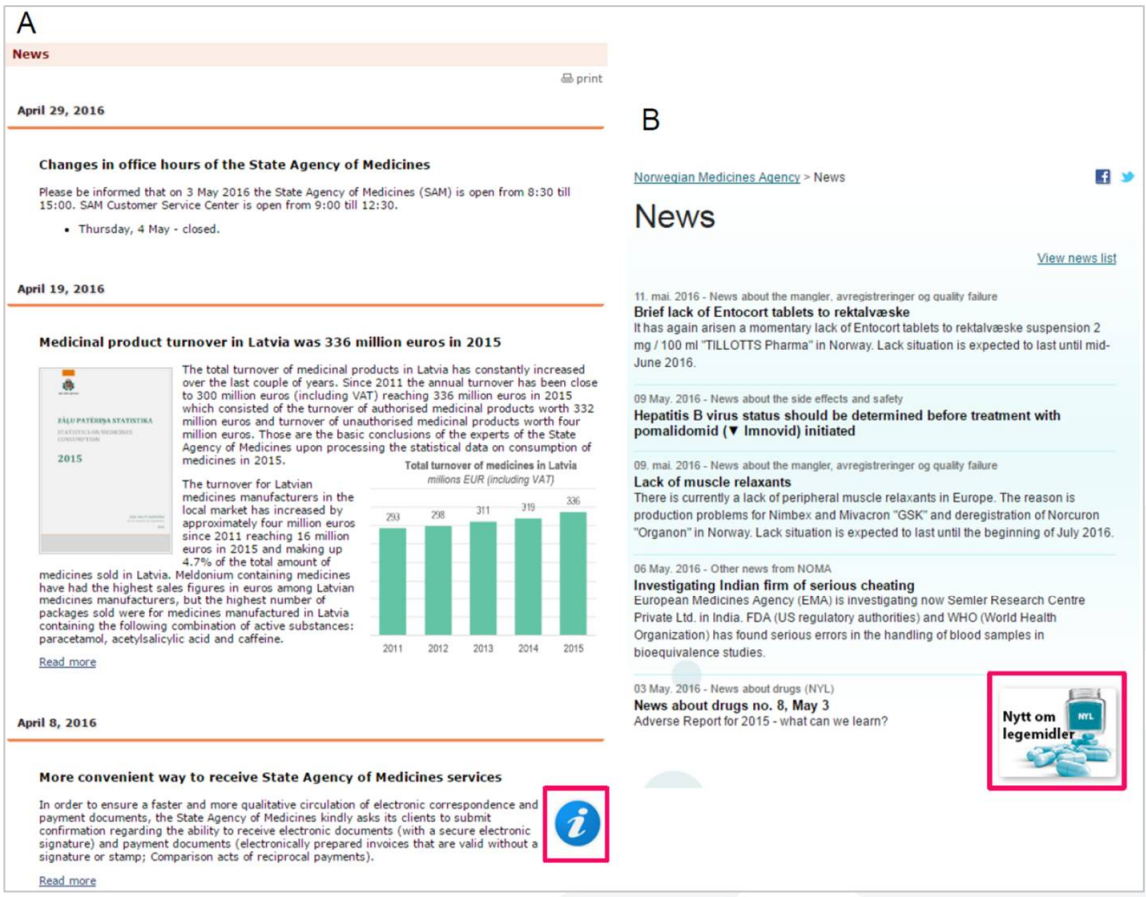
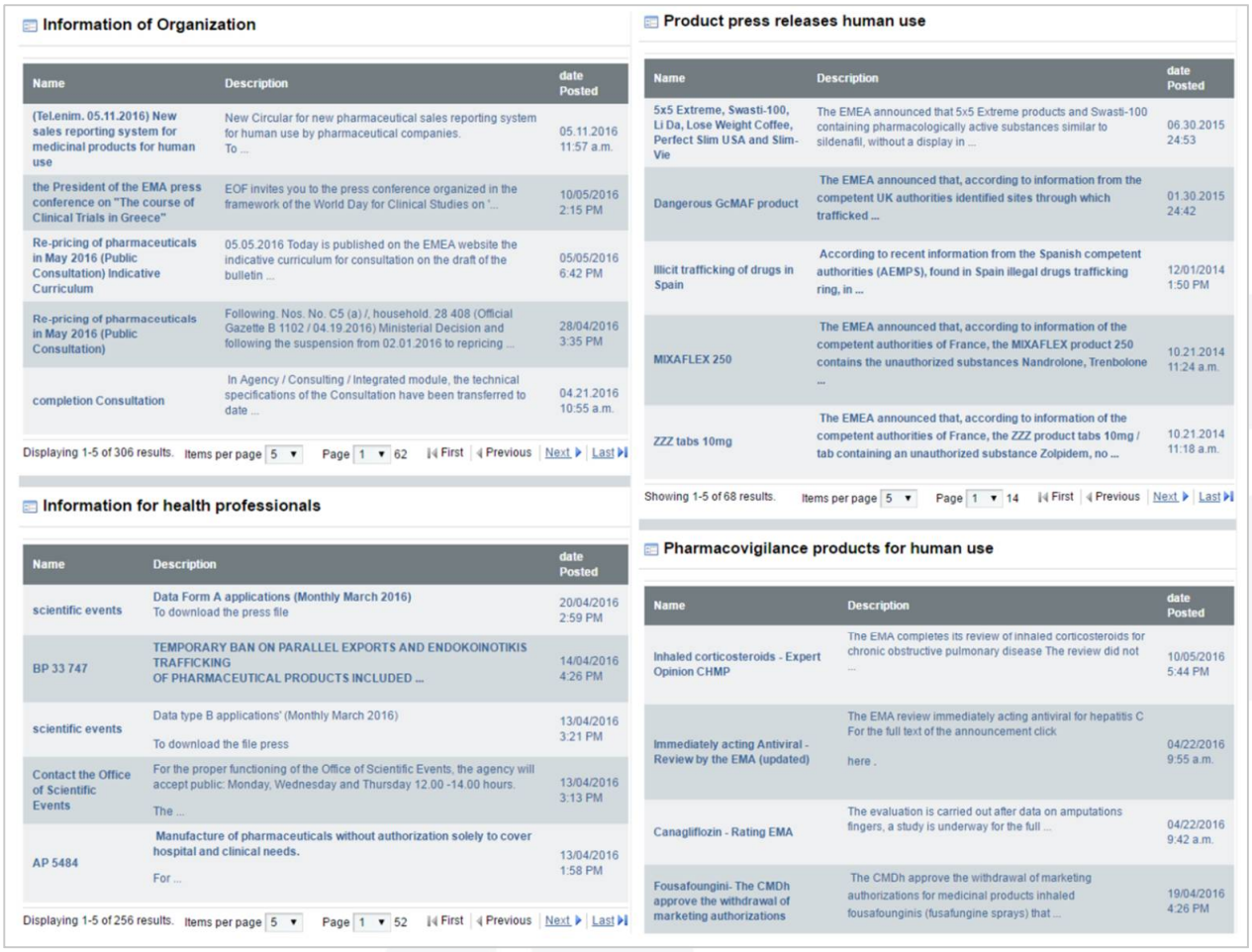


Figure 26. Screenshots of the State Agency of Medicines of the Republic of Latvia (**A**) and the Norwegian Medicines Agency (**B**) news pages, highlighting the use of icons in highlighting news types. (A) State Agency of Medicines of the Republic of Latvia – news (B) Norwegian Medicines Agency – news

On the Greek National Organisation for Medicines homepage, announcements are focused and found in the central part of the webpage, split into subsections for different themes: agency information, announcements and press releases for human products, PhV, cosmetics, laws, medical devices and contests. This format is highlighted in **Figure 27** below.



Information of Organization

Name	Description	date Posted
(TeLenim. 05.11.2016) New sales reporting system for medicinal products for human use	New Circular for new pharmaceutical sales reporting system for human use by pharmaceutical companies. To ...	05.11.2016 11:57 a.m.
the President of the EMA press conference on "The course of Clinical Trials in Greece"	EOF invites you to the press conference organized in the framework of the World Day for Clinical Studies on "...	10/05/2016 2:15 PM
Re-pricing of pharmaceuticals in May 2016 (Public Consultation) Indicative Curriculum	05.05.2016 Today is published on the EMEA website the indicative curriculum for consultation on the draft of the bulletin ...	05/05/2016 6:42 PM
Re-pricing of pharmaceuticals in May 2016 (Public Consultation)	Following. Nos. No. C5 (a) /, household. 28 408 (Official Gazette B 1102 / 04.19.2016) Ministerial Decision and following the suspension from 02.01.2016 to repricing ...	28/04/2016 3:35 PM
completion Consultation	In Agency / Consulting / Integrated module, the technical specifications of the Consultation have been transferred to date ...	04.21.2016 10:55 a.m.

Displaying 1-5 of 306 results. Items per page 5 Page 1 62 First Previous Next Last

Information for health professionals

Name	Description	date Posted
scientific events	Data Form A applications (Monthly March 2016) To download the press file	20/04/2016 2:59 PM
BP 33 747	TEMPORARY BAN ON PARALLEL EXPORTS AND ENDOKOINOTIKIS TRAFFICKING OF PHARMACEUTICAL PRODUCTS INCLUDED ...	14/04/2016 4:26 PM
scientific events	Data type B applications' (Monthly March 2016) To download the file press	13/04/2016 3:21 PM
Contact the Office of Scientific Events	For the proper functioning of the Office of Scientific Events, the agency will accept public: Monday, Wednesday and Thursday 12.00 -14.00 hours. The ...	13/04/2016 3:13 PM
AP 5484	Manufacture of pharmaceuticals without authorization solely to cover hospital and clinical needs. For ...	13/04/2016 1:58 PM

Displaying 1-5 of 256 results. Items per page 5 Page 1 52 First Previous Next Last

Product press releases human use

Name	Description	date Posted
5x5 Extreme, Swasti-100, Li Da, Lose Weight Coffee, Perfect Slim USA and Slim-Vie	The EMEA announced that 5x5 Extreme products and Swasti-100 containing pharmacologically active substances similar to sildenafil, without a display in ...	06.30.2015 24:53
Dangerous GcMAF product	The EMEA announced that, according to information from the competent UK authorities identified sites through which trafficked ...	01.30.2015 24:42
Illicit trafficking of drugs in Spain	According to recent information from the Spanish competent authorities (AEMPS), found in Spain illegal drugs trafficking ring, in ...	12/01/2014 1:50 PM
MIXAFLEX 250	The EMEA announced that, according to information of the competent authorities of France, the MIXAFLEX product 250 contains the unauthorized substances Nandrolone, Trenbolone ...	10.21.2014 11:24 a.m.
ZZZ tabs 10mg	The EMEA announced that, according to information of the competent authorities of France, the ZZZ product tabs 10mg / tab containing an unauthorized substance Zolpidem, no ...	10.21.2014 11:18 a.m.

Showing 1-5 of 68 results. Items per page 5 Page 1 14 First Previous Next Last

Pharmacovigilance products for human use

Name	Description	date Posted
Inhaled corticosteroids - Expert Opinion CHMP	The EMA completes its review of inhaled corticosteroids for chronic obstructive pulmonary disease The review did not ...	10/05/2016 5:44 PM
Immediately acting Antiviral - Review by the EMA (updated)	The EMA review immediately acting antiviral for hepatitis C For the full text of the announcement click here .	04/22/2016 9:55 a.m.
Canagliflozin - Rating EMA	The evaluation is carried out after data on amputations fingers, a study is underway for the full ...	04/22/2016 9:42 a.m.
Fousafoungini- The CMDh approve the withdrawal of marketing authorizations	The CMDh approve the withdrawal of marketing authorizations for medicinal products inhaled fousafounginis (fusafungine sprays) that ...	19/04/2016 4:26 PM

Figure 27. Screenshots of the National Organisation for Medicines (Greece) news feed headings, covering agency information, human medicines and medical devices. National Organization for Medicines – homepage

3.5.2 Safety bulletins

Newsletters or bulletins can be an effective way of providing HCPs with a regular summary of medicinal products safety news. They can be hardcopy or electronic. If electronic, they can be published on the NCA website, and an email alert can be sent when new articles are published to those who have subscribed to receive the alerts.

Some examples of bulletins:

- The UK's Medicines and Healthcare products Regulatory Agency (MHRA) publishes Drug Safety Update, a monthly e-bulletin, on their website to promote the safer use of medicines by HCPs. An email alert is sent to over 330,000 subscribers when each issue is published.
- Ireland's Health Products Regulatory Authority (HPRA) publishes several newsletters, including a monthly Drug Safety Newsletter, in pdf format.
- The Italian Medicines Agency (AIFA) publishes their newsletter 'Pillole dal Mondo' ('Pills from the [regulatory] world'). This covers regulatory news issued by AIFA and other agencies (EMA, US Food and Drug Administration (FDA), Therapeutic Goods Association (TGA), Health Canada). It also summarises new evidence emerging from prominent scientific journals about medicines marketed in Italy. The newsletter is sent every day at 6pm to a mailing list of approximately 180,000 registered users.
- The Norwegian Medicines Agency (NOMA) has their own page in the Journal of the Norwegian Medical Association. The journal has a circulation of approximately 30,000. NOMA's 'News About Medicines' is published fortnightly in pdf format on their website. The information is primarily targeted towards GPs, but also covers issues of interest for doctors in specialist practices. It is also read by industry and HCPs in pharmacies. Key topics include discussions of new medicines, new side effects and new reimbursement decisions.

3.5.3 Question & Answer

Discussed above in Section 2 was an example from the Norwegian (NOMA) agency webpage, which provided ADR reporting information for patients in the form of a Q&A (Figure 8). Q&A sections are a great way to encourage website visitors to start asking logical questions when learning new regulatory principles, with case-answers providing a good base for users to reference for specific queries. For those users that have pre-prepared questions in mind, if these are addressed on the website this can increase the confidence that users have in the source of information. Logistically, creating a Q&A section can be quickly done, and can have a big impact.

3.5.4 Icons

Below is an example taken from the Agency for Medicinal Products and Medical Devices of Croatia (HALMED) homepage, which shows icons directing users through external links to projects for which the agency is involved, e.g. SCOPE and WEB-RADR (**Figure 28** below) (8). These links take users to the respective dedicated project pages.

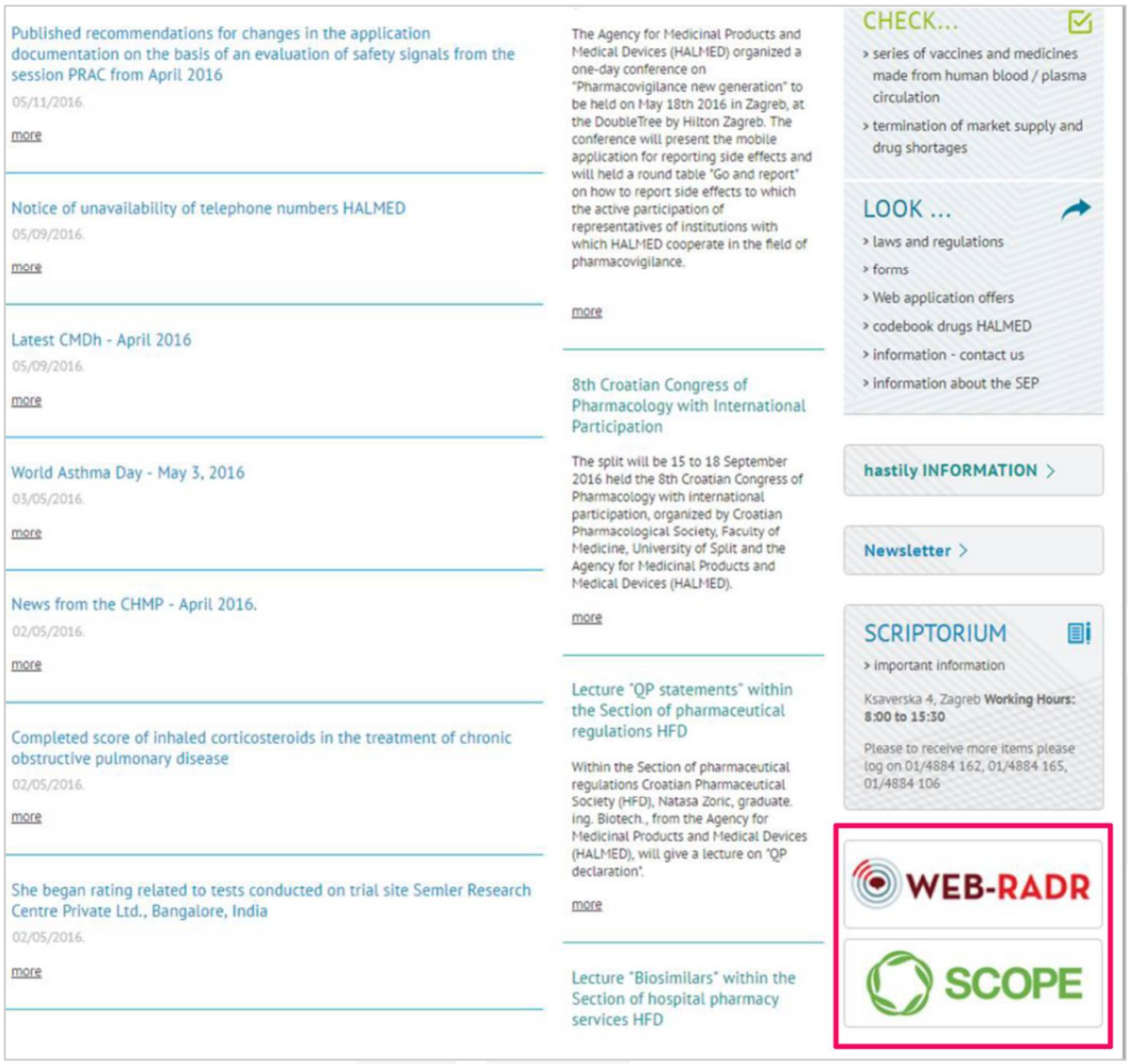


Figure 28. Screenshot from the Agency for Medicinal Products and Medical Devices of Croatia (HALMED) website, showing icon links to projects that the agency is partnered in. Agency for Medicinal Products and Medical Devices of Croatia – homepage

3.5.5 Videos and images

Discussed above, in Section 2, was an example provided by Romania of an EMA educational video regarding black triangle medicines (Figure 4). Using visual aids can be effective in all areas of education, as this is often more memorable than information presented in text, and therefore may be retained for longer. It is also easier to explain a complex subject to someone if speech, body language and/or clear colourful images are used. Although useful, videos should be kept as short as possible, and images kept as simple as possible, in order to be applicable to the widest possible audience.

Unlike using a Q&A format, or using links, the creation of a more interactive platform is far more time-consuming, resource-intensive and costly for NCAs. Identifying the awareness that users have for material would be a good way to identify whether investment in a video is worth the resources or not. As part of SCOPE (WP4 – ADR collection), a video will be developed to assist ADR reporting and raise awareness of regulatory activity. This video could be adapted by any interested European NCA, as appropriate.

A good compromise is to create an infographic. NOMA provide a good example of a useful infographic describing what happens to a safety message once submitted (**Figure 29** below). In this example, the infographic highlights sending the report, followed by analysis and assessment, and finally updating of medicines information. This is a useful way of simplifying and presenting the process of patient/carer reporting.

Figure 29. Screenshot from the Norwegian Medicines Agency (NOMA) webpage showing the information provided to patients on ADR reporting. Norwegian Medicines Agency – ADR information for patients

This chapter has highlighted some interesting aspects of the ways in which NCA websites present their safety communications. This includes both the physical look and feel of the website and its content, as well as possible back-end additions, like autofill capabilities using drug dictionaries. The case studies presented can be used by NCAs to identify areas of most importance, and to adopt the presented methods as appropriate.