SCOPE Work Package 6
Survey Report

Web-portals

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1 Introduction

1.1 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
CMDh	Co-ordination group for Mutual recognition and Decentralised procedures – human
EC	European Commission
DCPs	Decentralised Procedure
DHPC	Dear 'Healthcare professionals' Communications
EMA	European Medicines Agency
HCP	Healthcare professional
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
MS	Member State
NCA	National Competent Authority
PAR	Public Assessment Report
PIL	Patient Information Leaflet
PV	Pharmacovigilance
RMP	Risk Management Plan
RSS	Really Simple Syndication / Rich Site Summary
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SmPC	Summary of Product Characteristics
WP	Work Package

1.2 Attachments

Ref No	Document name	Author(s)
1	Web-portals – pdf version of final survey circulated to member states	WP6.4

1.3 Table of contents

1.4 Executive summary

This report outlines the collection of information about EU National Competent Authority (NCA) use of web-portals to provide pharmacovigilance information through a questionnaire completed by member states. The survey forms the initial activity of the SCOPE Joint Action Work Package 6 Topic 4 which focuses on web-portals. Results and findings from the survey are intended to inform the recommendations for delivery of guidance for member states.

A web-based questionnaire was developed by the SCOPE WP6 team. Following a period of review and pilot, it was launched in July 2014 and finally closed in October 2014. 25 Member States completed the survey.

The results point to a wide variety of approaches regarding content, target groups, presentation, and future plans for NCA web-portals. Responses suggest that the majority of NCA web-portals host Summary of Product Characteristics (SmPCs), Patient Information Leaflet (PILs), information on how to report ADRs, urgent safety announcement, and press releases. However, less than half of respondents indicated that their web-portal provides Risk Management Plan (RMP) summaries, information which the new PV legislation states must be provided by web-portals. Some respondents noted that more types of information, including RMP summaries, will be published on the web-portal in the near future.

Responses throughout the questionnaire suggest that many member states do not target their web-portals to the general public, but remain primarily aimed at specialists such as Healthcare professional (HCPs) and members of the pharmaceutical industry. Over two-thirds of respondents stated that research has been carried out on website target audience groups in recent years. Many respondents further mentioned that this research has focused on identifying the needs of the public or patients.

Member States may require guidance on how best to ensure that web-portals fulfil the needs of patients and the public, as well as more specialist target groups.

Responses show a significant diversity of the situations and practice in different member states. The lack of clarity and understanding of the definition of a web-portal is considered to illustrate the value of providing guidance and example of practice and experience between member states. Recommendations illustrate with examples of best practice will focus on structuring information, making information accessible and targeting audiences, making use of monitoring and user feedback.

Following the information collected from the survey a number of additional steps will be used to collect some specific additional information from member states to help identify good practice and specific examples to illustrate them.

Specific topics of interest identified that will be taken forward for development of recommendations for best practices on web-portals includes structuring information, accessibility and users feedback/evaluation.

1.5 Background

The new European pharmacovigilance legislation, which came into force in July 2012, defines that Member States are required to have a web portal for provision of safety information. NCAs are advised in Directive 2010/84/EU amending Directive 2001/83/EC:

> *In order to increase the level of transparency of the pharmacovigilance processes, the Member States should create and maintain medicines web-portals*

Specific articles in the Directive also further specify requirements of National Competent Authorities:

> *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 publicly 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 publicly 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;*
> *(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.*

Across the EU, Member States have a variety of web-portals in place to provide safety information, such as SmPCs and PILs, PARs and risk communications. However, it is recognised that there are currently no clear recommendations as to how the information should be provided and what minimum level of information is recommended to be made available. In addition, information may be made available on different web-portals depending on the method by which a medicine is licensed, for example centralised products versus those licensed nationally. This also means there are many various approaches between different Member States regarding what and how information is provided.

Work Package 6, Topic 4 focusses on web-portals and aims to examine web-portals that Member States maintain across Europe to provide safety information and risk communications about medicines. The aim of the topic is to provide practical guidance on meeting the requirements for complying with the legislative requirements, and illustrate this using examples of good practice from member states. Using information collected on the methods and systems used, and building upon that previously collected by the EU pharmacovigilance network, guidance on best practice will be collated and written to suggest how this should best be approached through recommendations and examples.

Recommendations in the best practice guidance will consider recommended minimum features and recommendations for features which are considered best practice for the following:

- Technology (for example including website/content management platforms, specific features within the site, such as search tools)
- Content, including design and presentation
- Managing the website – processes for maintenance and updating content
- Monitoring effectiveness through evaluation and feedback from users

1.6 Context and scope of report:

The report of the results of the audit of safety communication practices in the participating MS is aimed to provide a basis for the further work within WP 6 and for information to the entire project. It may be of interest to produce a shorter version at a later stage for publication.

Responses are not attributed directly to member states who responded to the survey to preserve confidentiality of member states who responded to the SCOPE WP6.4 survey. However it should also be noted that much of the information may be derived from the public websites/webportals of member states directly.

1.6.1 Main goal

This report aims to summarise results of the SCOPE survey answered by member states about web-portals for medicine safety information and direct next steps and recommendations.

1.6.2 Objectives

Results from the survey have been used to identify the range of practice across EU member states, and to direct next steps and recommendations for delivery of guidance on national provision of web-portals. This is to support member states to meet the requirements set out in the EU pharmacovigilance legislation, plus providing suggestions for member states who wish to further improve their web-portals.

1.6.3 Challenges

There are challenges posed from the potential interpretations of questions and terminology e.g. the definition of 'web-portal'. The generalisability of results and comparison of responses between member states could be impacted by differences in interpretation. For recommendations themselves, there will always be the potential for challenges in national applicability with the significant range of contexts, stakeholders and factors relevant in different member states.

2 Methodology

2.1 Tool and survey method:

A questionnaire of 29 questions was developed and hosted online via Survey Monkey. The questions were drafted then reviewed by SCOPE WP6 active partners. The final survey was agreed following a pilot. A printable version of the electronic survey is included in Annex 1.

A link to the questionnaire was sent via email to a selected contact list of respondents representing different European member states. Reminders were sent, via email, to ensure that as many respondents as possible completed the questionnaire.

The survey was launched on 3 July 2014. Two reminder emails were issued in August and September. The original deadline of 12 September 2014 was extended to allow collection of responses from some additional member states, following a further set of personalised reminder emails to those who had not yet submitted a response. The surveys were closed on 3 October 2014.

2.2 Setting and participants:

Officially there were 27 respondents however, only 25 were counted in this report as two respondents completed the survey only up to Q2. Further, some official figures from the Survey Monkey's 'Survey Summary' Excel document provide incorrect response rates: at times respondents who did not select an option but *did* answer the question in the free-text section are not included in the response count.

As the way that questions are presented and phrased impacts how respondents answer, all survey questions have been excerpted below exactly as they appeared.

2.3 Data analysis (quantitative and qualitative)

The questionnaire used a combination of multiple choice questions (both single and multiple questions allowed), drop-down menus, textboxes, and rating questions.

Free text comments have been reviewed to identify key words or topics and grouped together in order to identify themes and trends to inform the conclusions and recommendations.

3 Findings/Results

Limitations

The key problem, which must be highlighted from the outset, is that despite the definition provided in the introduction there remained confusion over the definition of a 'web-portal'. This variety of interpretation of the definition of a web-portal can be seen in some responses given by respondents, as well as in the responses which specifically describe this confusion,

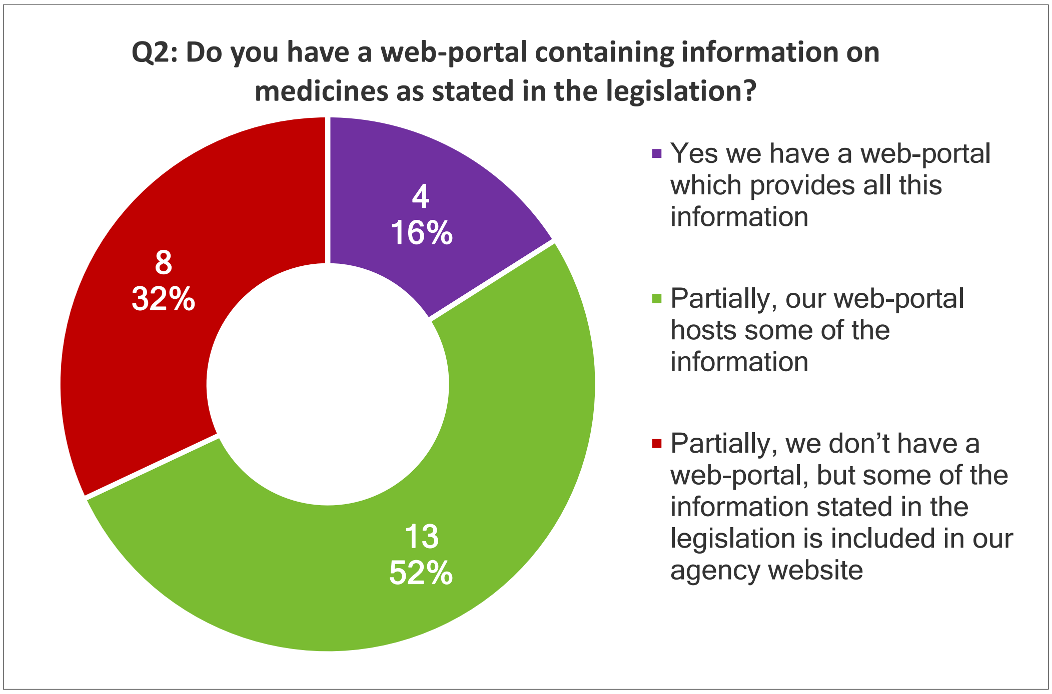
Q1-Q6: Introductory questions on NCA web-portals

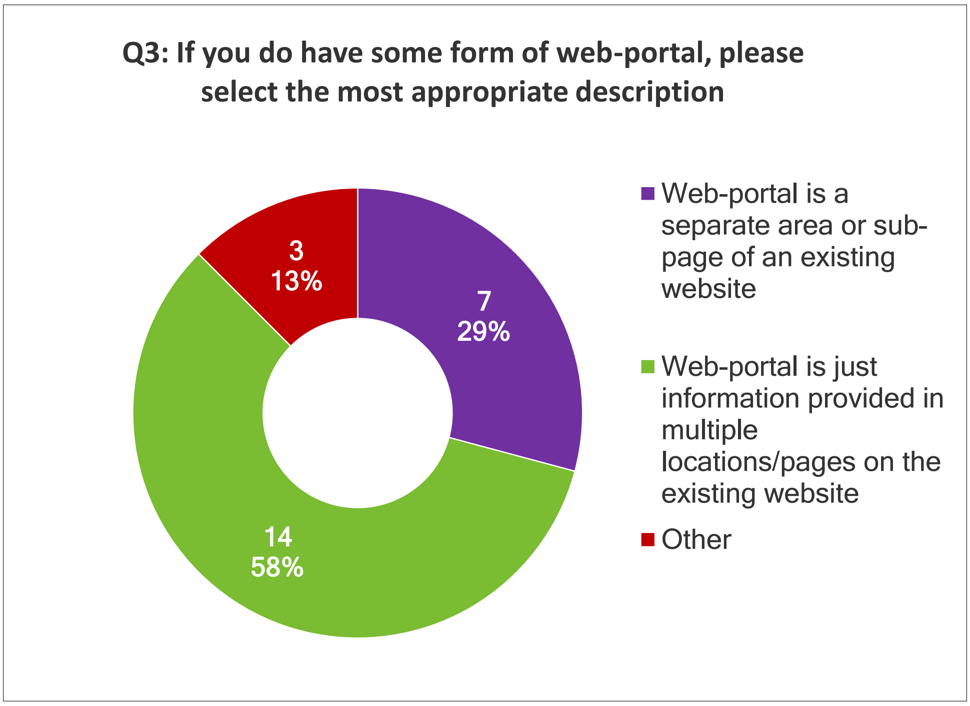
Summary points

- All member states provide information on a website, but there is a lack of clarity over the definition of a web-portal
- For some member states information relating to pharmacovigilance is spread across more than one web-portal
- The approach to organising information varies including using **audience** or **theme-based structures**
- Some MSs are **in the process of introducing changes**, or was planning to do so in the near future.

For **Question 1, Does your agency have a website?**, all 25 respondents answered Yes and provided the website URL.

Question 2 received a response from all 25 respondents. Roughly one-sixth of respondents (4) indicated that their web-portal contains **all** the information. Over half of the respondents (13) stated that **some** of the information outlined in the legislation appears on their web-portal, and the remainder indicated that some of the information **appears on the NCA website**.





Responses to Q3 illustrated the confusion regarding the definition and use of the term 'web-portal' in the survey. For example, one out of the seven respondents who selected option 1, that the web-portal is a separate area or sub-page of an existing website, had indicated in Q2 that they do *not* have a web-portal. Of the 14 respondents who selected option 2 (web-portal is multiple pages on existing website), eight had indicated in Q2 that they do have a web-portal, and five had indicated that they do not have a web-portal. It should be noted that these inconsistencies may also be due to the phrasing of the question, which may be interpreted to as asking for respondents' views on what a web-portal *in* *general* should consist of, or if it asking respondents to indicate what the web-portal for *their specific* NCA consists of.

This lack of clarity can also be seen in the free-text responses for those who selected 'Other'.

Question 3 was skipped by one respondent. This respondent had indicated in Q2 that their organisation *does* have a web-portal and that it provides all information as stated in the legislation.

Further elaboration was provided in responses to **Question 4** which asked respondents to describe in free-text their web-portal. Three respondents skipped this question, and two respondents wrote 'N/A'. The remaining 20 respondents described their web-portals in varying detail. *Note also that features of the web-portals are the focus of Q9 and Q10.*

Most of the 20 respondents mentioned the following features:

- Database or register of authorised drugs
- List of drugs under additional monitoring, or a link to the EMA website
- ADR form for patient and/or HCP reporting
- Administrative information on drugs, such as active substance, MAH, authorisation date
- PILs/SmPCs
- PARs
- DHPCs

Some of the 20 respondents mentioned that the web-portal also contained the following:

- A search engine for the drugs database or web-portal in general
- The availability of RMPs or RMP summaries
- Information on the importance of ADR reporting, and how to report an ADR
- ADR statistics and data
- Information on MRPs and DCPs
- Warnings and other drug safety updates, including press releases
- Pharmacovigilance legislation

That the same key words repeatedly came up in many of the responses suggests that there is general consensus on what information their web-portal should contain, i.e. the content. How this information is presented, and to whom, appears to be a more complex question. Responses suggest that approaches as to how to present the information are varied. Four respondents explicitly mentioned that information relating to pharmacovigilance is spread across more than one web-portal. These respondents mentioned that different websites are used either to present different types of information (legislation on one website, SmPCs on another, and PILs on another, as one example); or to present information to different target groups (one website aimed at HCPs, MAHs, and distributors, another website aimed at the public as another example).

Within singular web-portals, approaches of presenting the information also appear to be varied. One new website switched from an **audience- to theme-based structure** for navigation. Conversely, two respondents wrote that information is presented **primarily according to audience** (HCP, Industry, Patient, etc).

From free text comments received MSs may benefit from guidance about how to present the information most effectively. How member states present information on their web-portals is closely tied to whom the primary target audience is, and whether or not the member state thinks that information aimed at one type of audience should be adjusted for another type of audience. These themes are addressed more fully in later survey questions.

Three respondents also indicated that their web-portal was either **in the process of introducing changes**, or was planning to do so in the near future. Planned changes mentioned by these respondents include:

- Inclusion of RMP summaries
- Inclusion, or increased visibility, of DHPCs
- Inclusion of, or additional, educational material
- Inclusion of PARs

Question 5 received 23 responses; two respondents skipped

Twenty respondents said that their web-portal is part of the NCA website. No other option was selected by a respondent, but the remaining three respondents each added comments in 'Other'. Two of these respondents stated that they do not have a web-portal. The other reiterated that a separate web-portal does not exist, and that information appears on the NCA website. If one includes this free-text response in the data for the first option ('Part of NCA'), the results can be shown in the below table as bracketed figures.

Q5: Is your web-portal…

Answer Options	Response %	Response Count
1. Part of NCA website	87 (91)	20 (21)
2. Part of Ministry website	0	0
3. A completely separate website	0	0
4. Other (describe)	13 (9)	3 (2)
Answered question		***23***
Skipped question		***2***

Question 6 asking for the web-portal URL received 22 responses; three respondents skipped it. A further three out of the 22 respondents did not provide a URL, but instead added comments denoting that they do not have a web-portal:

The provision of respondents' web-portal URLs may be useful for the potential next step of analysis, which could be to manually look at the web-portals to record anything noteworthy.

Q7-Q8: Languages

Summary

- Member States present information in their national language(s), with many also providing information in English

Question 7 and **Question 8** each received 24 responses out of a possible 25. The 24 responses for both questions, i.e. showing primary and secondary/alternative languages offered by each MS, are presented in the below table.

Key:

🟪 = Primary language
🟩 = Secondary/alternative language(s)

MS / Language	BE	BG	CZ	DK	EE	ES	FI	FR	GR	HR	HU	IE	IS	IT	LT	LV	MT	NL	NO	PT	RO	SE	SI	SK	UK	MS / Language	Count: Q7	Count: Q8
Bulgarian		🟪																								Bulgarian	1	-
Croatian			🟩							🟪																Croatian	1	-
Czech			🟪																							Czech	1	-
Danish				🟪																						Danish	1	-
Dutch	🟪																	🟪								Dutch	2	-
English	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟪	🟩	🟩	🟩	🟩	🟪	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟪	English	3	21 (22)
Estonian					🟪																					Estonian	1	-
Finnish							🟪																			Finnish	1	-
French	🟩							🟪																		French	1	1
German																										German	-	-
Greek									🟪																	Greek	1	-
Hungarian											🟪															Hungarian	1	-
Irish												🟩														Irish	-	1
Italian														🟪												Italian	1	-
Latvian																🟪										Latvian	1	-
Lithuanian															🟪											Lithuanian	1	-
Maltese																	🟩									Maltese	-	1
Norwegian																			🟪							Norwegian	1	-
Polish																										Polish	-	-
Portuguese																				🟪						Portuguese	1	-
Romanian																					🟪					Romanian	1	-
Slovak																								🟪		Slovak	1	-
Slovene																							🟪			Slovene	1	-
Spanish						🟪																				Spanish	1	-
Swedish							🟩															🟪				Swedish	1	1

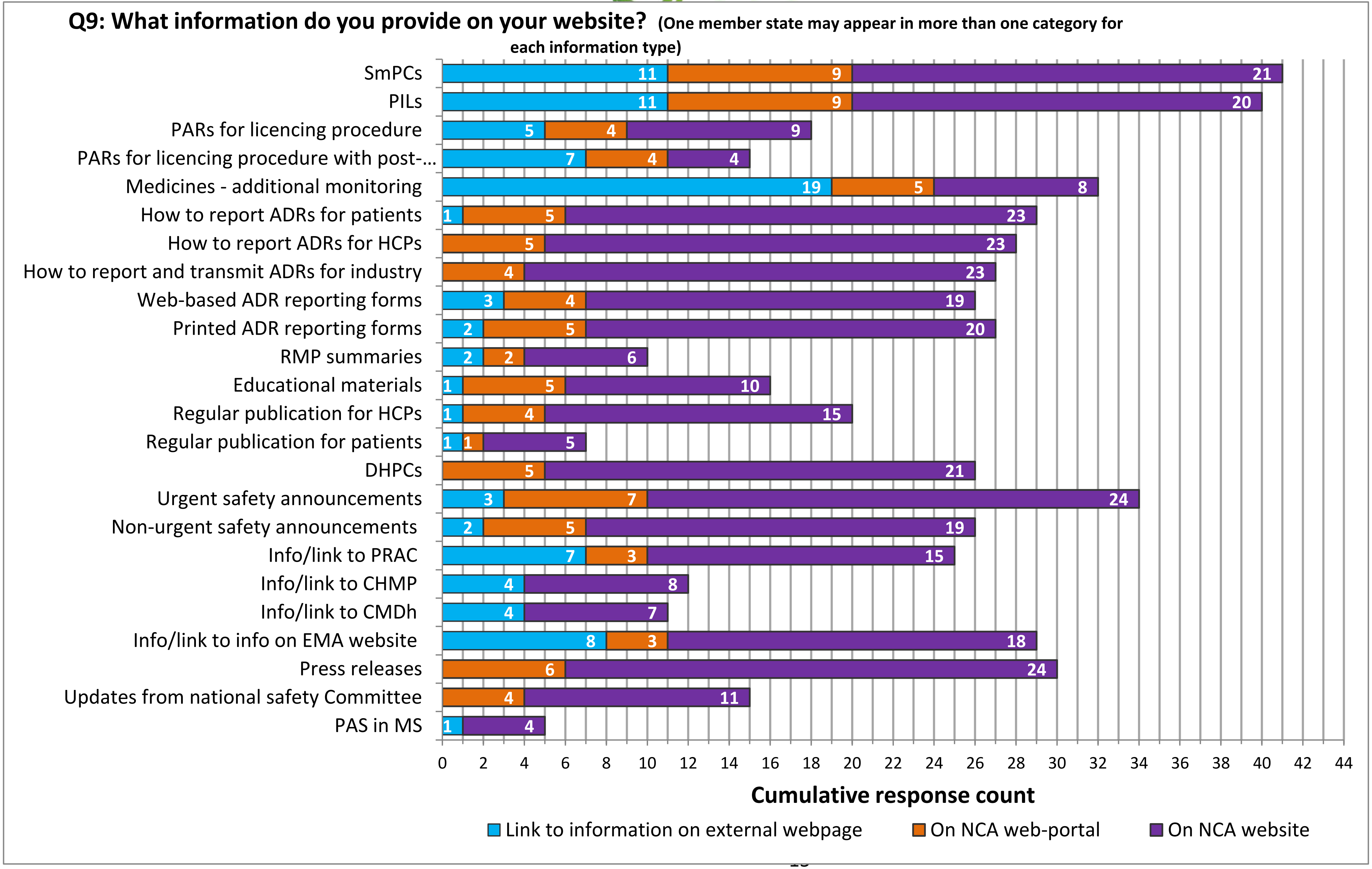
Q9-Q11: Information – Content

Summary

- There a significant diversity in the pharmacovigilance information provided on websites/web-portals, the majority of which is hosted directly on NCA websites/portals
- Access to SmPCs, PILs, Urgent safety announcements and Press releases/media announcements were provided by all member states
- The types of information that respondents indicated were least likely to be provided, either on the NCA's website, web-portal, and/or external website were Post-authorisation studies, publication/bulletin for patients and RMP summaries
- Only a proportion of Member States have any links to information on the EMA website
- Member States most frequently update safety information (e.g. SmPC, PIL. PAR, urgent safety announcements), but the majority of responses showed that most information is updated at a frequency less than monthly, or was not applicable.
- Information is most frequently provided as html/webpage and pdf documents

Question 9 received responses from all 25 respondents. The question asked both for what information is included, and where it is published. Respondents were instructed to select as many options as applicable, so one member state may appear in more than one category for each information type. The large amount of resulting data can be presented in the below table, which shows response counts per type of information and per location.

Due to the length of the original options, answer options in the table have been abbreviated.


Q9: What information do you provide on your website? (One member state may appear in more than one category for each information type)
SmPCs 11 9 21
PILs 11 9 20
PARs for licencing procedure 5 4 9
PARs for licencing procedure with post-… 7 4 4
Medicines - additional monitoring 19 5 8
How to report ADRs for patients 1 5 23
How to report ADRs for HCPs 5 23
How to report and transmit ADRs for industry 4 23
Web-based ADR reporting forms 3 4 19
Printed ADR reporting forms 2 5 20
RMP summaries 2 2 6
Educational materials 1 5 10
Regular publication for HCPs 1 4 15
Regular publication for patients 1 1 5
DHPCs 5 21
Urgent safety announcements 3 7 24
Non-urgent safety announcements 2 5 19
Info/link to PRAC 7 3 15
Info/link to CHMP 4 8
Info/link to CMDh 4 7
Info/link to info on EMA website 8 3 18
Press releases 6 24
Updates from national safety Committee 4 11
PAS in MS 1 4
0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36 38 40 42 44
Cumulative response count
Link to information on external webpage
On NCA web-portal
On NCA website

As the above chart shows data spread across answer options rather than across MS/respondent, it may be useful to further describe the data according to MS. More in-depth analysis and comparison of responses across MSs may be required at a later stage.

All 25 respondents indicated that they provide the following, either on the NCA website, web-portal or via an external webpage:

- SmPCs;
- PILs;
- Urgent safety announcements;
- and Press releases/media announcements

On the provision of **SmPCs**, 24 out of 25 respondents stated that the information is **provided on the NCA website and/or web-portal**, and ten of these respondents stated that SmPCs are also provided via an **external website**. One respondent stated that SmPCs are provided only via a link on an external website (i.e. not on the NCA website and/or web-portal).

On the provision of **PILs**, 2 out of 25 respondents indicated that PILs are provided only via a link on an external website. All respondents stated that **urgent safety announcements** are provided on the NCA website and/or web-portal, and all respondents indicated the same for media announcements/**press releases**.

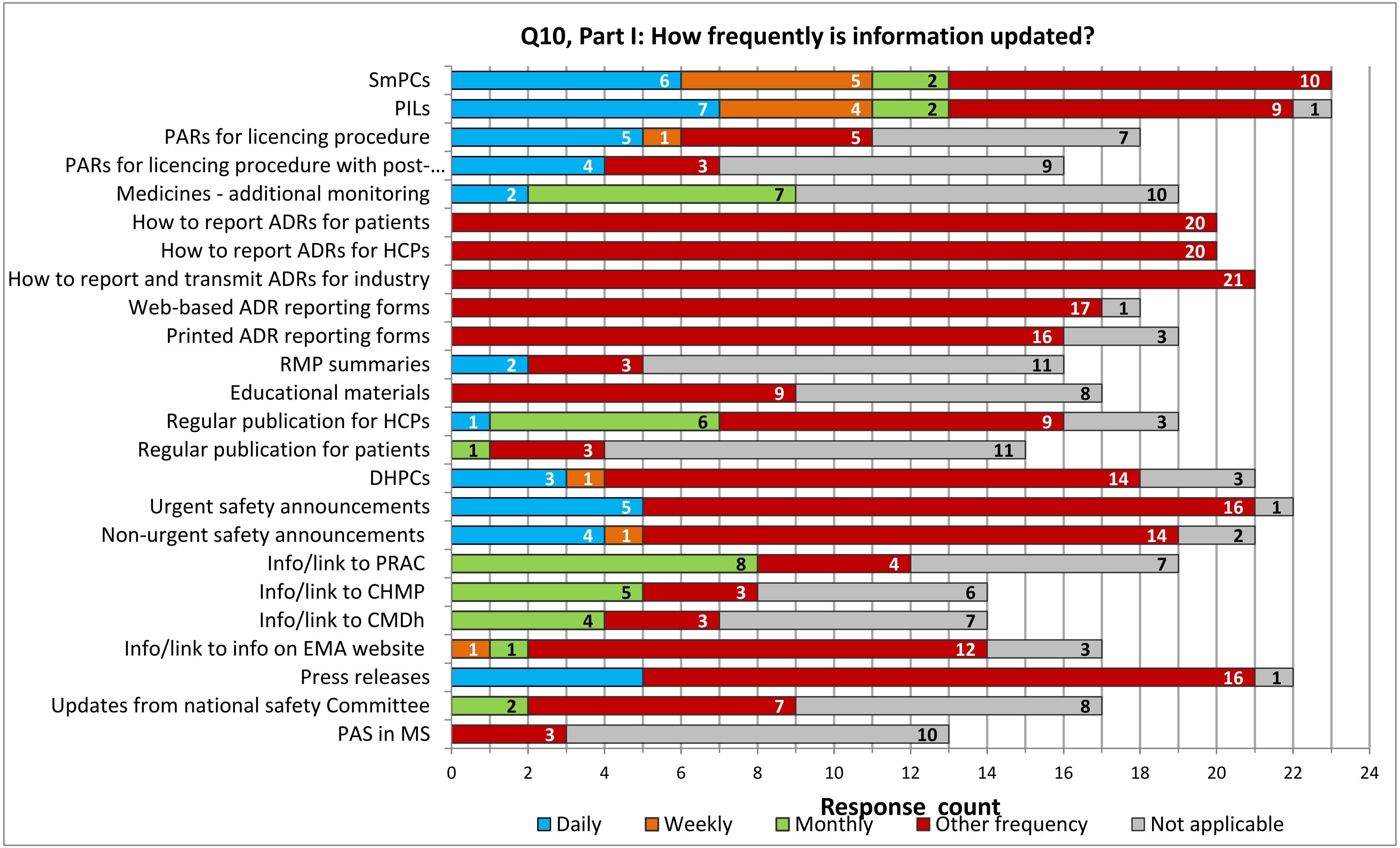
Information on **how to report ADRs** for patients, HCPs, and industry (three separate options) was the second modal response, with 24 respondents selecting each of these options. None of the 25 respondents indicated that they did not provide this information for *any* of the stakeholder groups – i.e. all 25 respondents indicated that they provided this information for at least one out of the three stakeholder groups. **Twenty-three out of 25 respondents selected all three options**, indicating that they provided information on how to report ADRs for patients, and HCPs, and industry. Further, all respondents who stated that they provided information to a particular stakeholder group indicated that it did so **via either the website or the web-portal**. A few respondents indicated that the information was *also* provided via an external website, but none of the respondents indicated this without also selecting the website and/or web-portal options.

The types of information that respondents indicated were *least* likely to be provided, either on the NCA website, web-portal, and/or external website, are as follows:

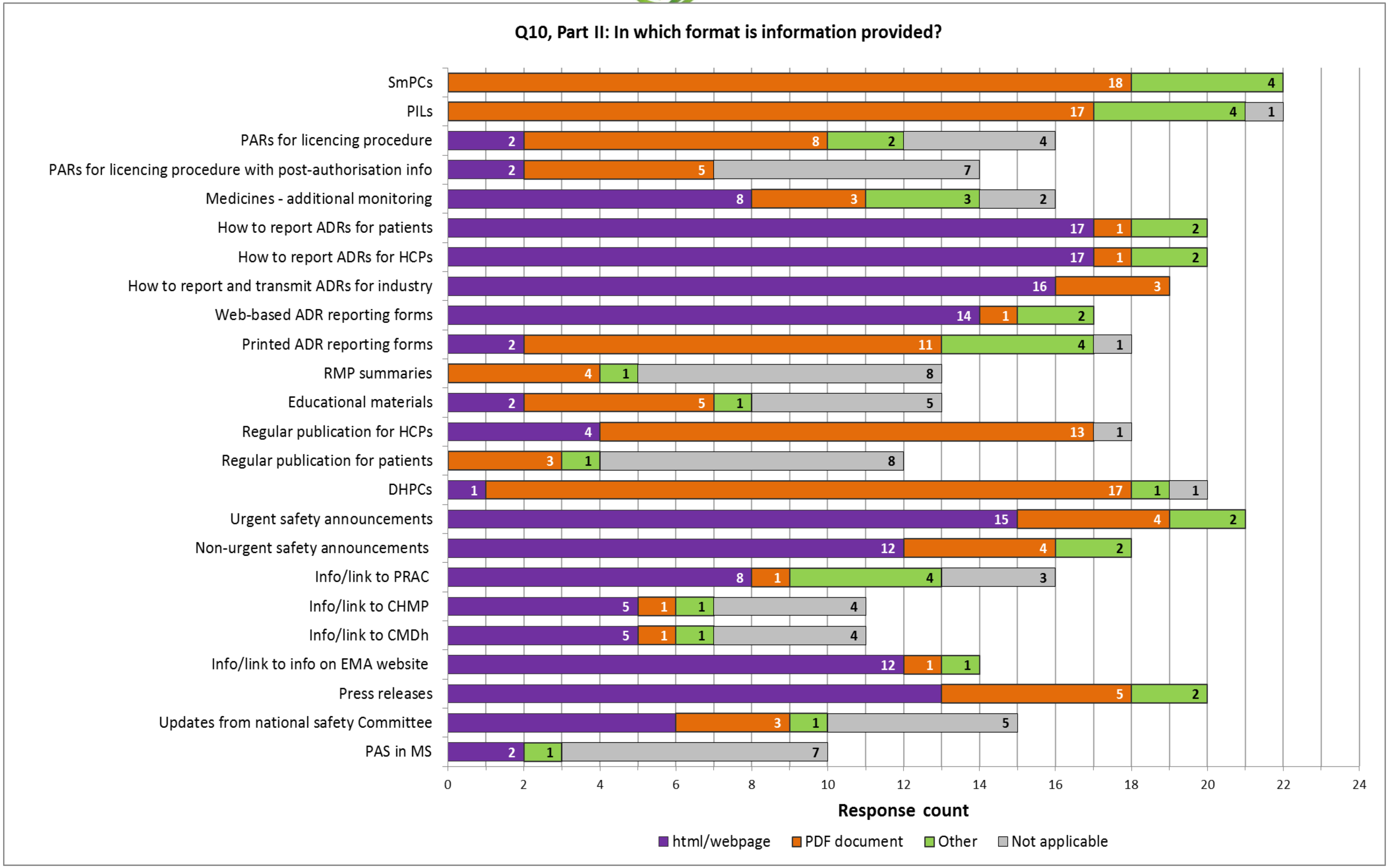
- Post-authorisation studies in the respective MS (5 responses)
- Regular publication/bulletin for patients (6 responses)
- RMP summaries (9 responses)
- Information/link to CMDh agendas/minutes/recommendations/conclusions/communications (9 responses)

Twenty-four respondents answered **Question 10** about format of information and frequency of update. As the response count for the two parts of the question differs for some options, the results have to be displayed separately. Note that 'Not Applicable' counts have been included in the graphs, in light grey, to ensure that total response count per option is displayed. As can be seen from the graphs, while Q10 had responses from 24 respondents, many respondents skipped (i.e. did not select 'Not Applicable') some parts of the question. For example, only 13 respondents selected an option (including 'Not Applicable') when asked how frequently 'Post-Authorisation Studies in your Member State' are updated.

As a large number of responses for both parts of Q10 was **'Other'**, and no free-text option was offered for respondents, it **may be useful to further investigate** these responses. It may also be useful in the future to look at how MSs responded across the different options.



Q10, Part I: How frequently is information updated?

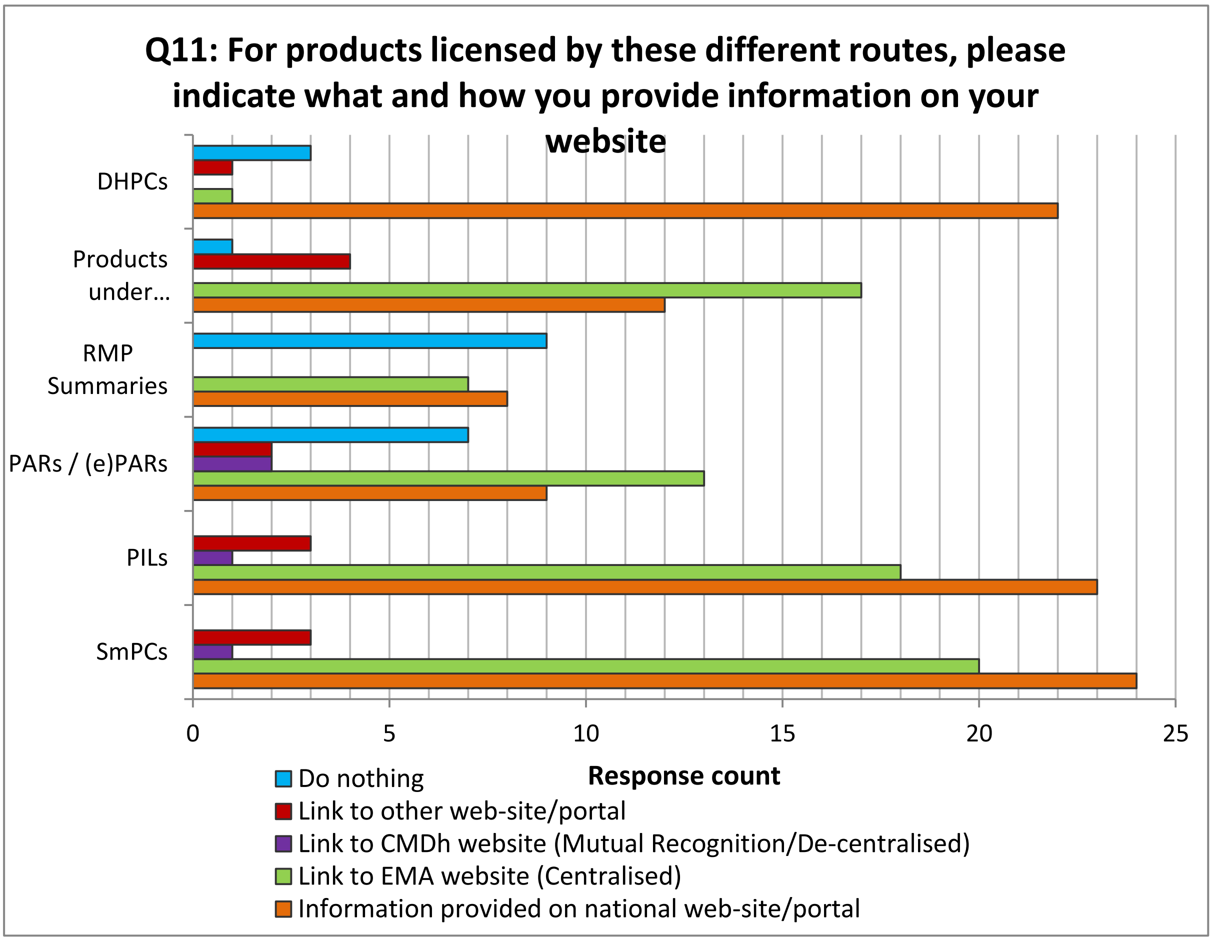


Q10, Part II: In which format is information provided?

For the **first part of Q10**, **'Other' was the most frequent response**. Such a high count for 'Other' suggests that either the options offered were inadequate for the question (MSs might update items of information on a fortnightly or annual basis, for example); or that few MSs have a set schedule/routine for updating website information (MSs might instead update information on an ad-hoc or as-needed basis). **Without further clarification,** it is not possible to ascertain from the question alone.

When 'Other' and 'Not Applicable', the two most commonly selected responses for Q10 Part I, are discounted, **the most commonly selected option was 'Daily'**. The option with the fewest counts was 'Weekly'. For the **second part of Q10**, **'html/web-page' was the modal response**, closely followed by 'PDF document'.

All 25 respondents answered **Question 11**. Respondents were able to select more than one option per type of information. Across all six types of information asked about in the question, the most commonly selected option was **'Information provided on national web-portal'**. **RMP summaries** and **PARs** had the highest count for **'Do Nothing'**.



As is suggested by the above graph, most respondents selected 'Link to EMA website' as well as 'Information provided on national web-portal' for **SmPCs** and **PILs**. Nineteen respondents indicated that SmPCs appear **both on the NCA web-portal and as links to the EMA** website.

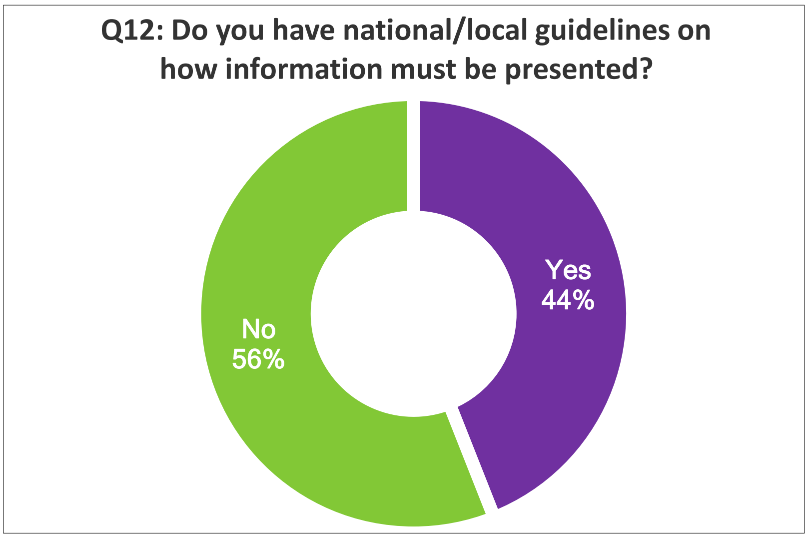
The respondent selected ‘**Do Nothing**’ for every category apart from SmPCs and PILs, the highest count for ‘Do Nothing’ from a single MS. As a category, ‘**RMP summaries**’ had the highest number of ‘Do Nothing’ counts (9 respondents), and the fewest counts for ‘Information provided on national web-portal’.

Q12-Q15: Information: Presentation

Summary

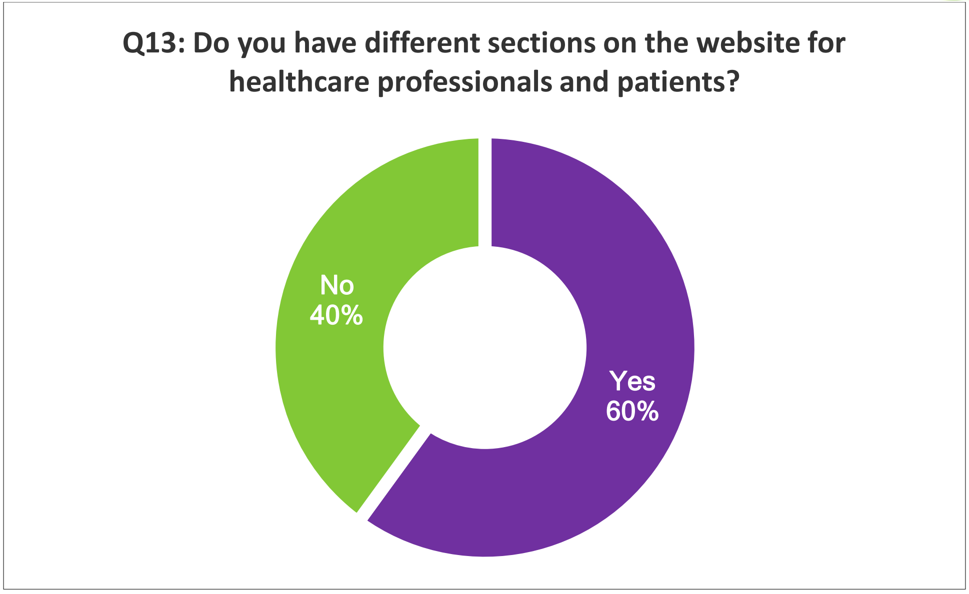
- About a third of member states have national guidelines on presentation of information
- Nearly two thirds of member states have a separate section for healthcare professionals and patients
- The majority of member states provide information for patients with some adaption such as simpler language, layout, use of national languages or provision of questions and answers, three member states aim to use simple language regardless of audience, and some do nothing
- There is some correlation between answers suggesting that there is a link between having national/local guidelines on how website information should be presented, and adapting information provided to patients compared with that provided to HCPs.
- Most respondents indicated that they group information by topic/theme

All 25 respondents answered **Question 12**, with 11 selecting Yes and 14 selecting No.



Of the 11 who responded **Yes**, all 11 provided further details in the free-text section of the question. Most free-text responses mentioned or alluded to the existence and use of **agency-wide SOPs**.

The two questions following Q12 attempted to gauge to what extent, and how, information is tailored to patients and HCPs. **Question 13** received responses from all 25 respondents. Fifteen indicated that they have different sections for HCPs and patients, while 10 respondents indicated that they do not.



Question 14 invited respondents to provide descriptive free-text answers on how they present information differently to two key stakeholders, patients and HCPs. Twenty-four respondents provided an answer to this question, some of whom wrote detailed descriptions. One respondent skipped the question.

For the purposes of presenting the information more concisely, the free-text answers can be roughly categorised as follows:

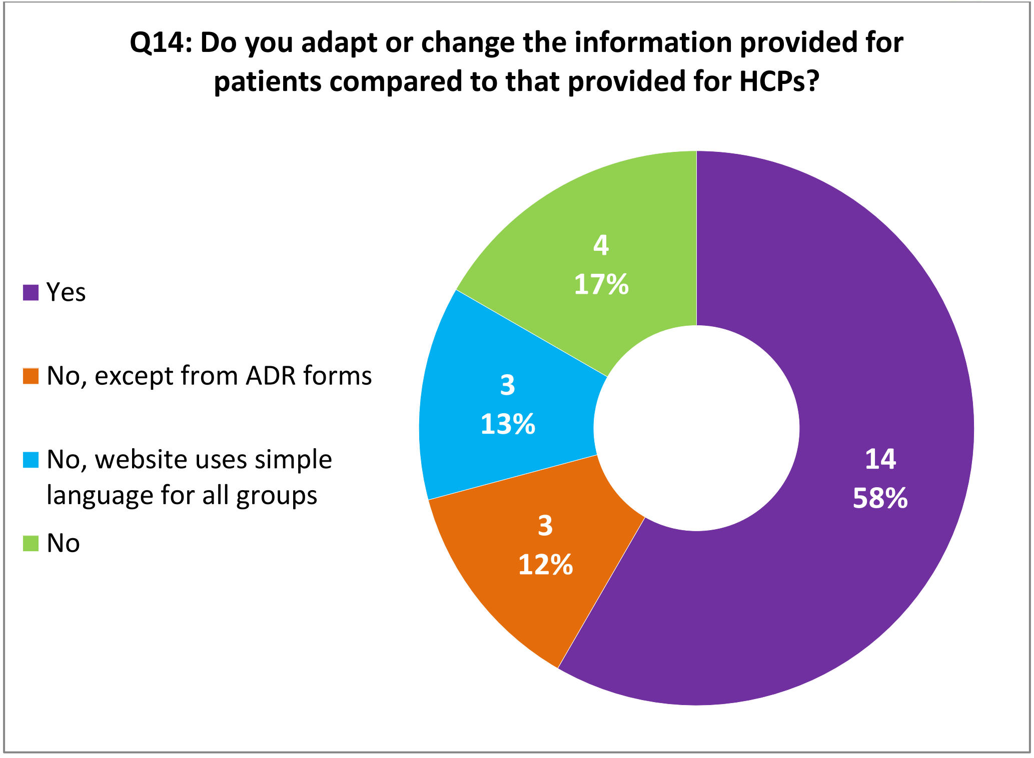
1. **Yes (14 MSs)** - Respondents mentioned one or a combination of the following:

    - clearer, simpler language for information targeted to patients; specialist terms explained
    - clearer layout for patients
    - separate news pieces are written for each target group;
    - inclusion of more PV information HCPs, such as marketing authorisation status
    - addition of Q&A pieces to help patients understand topic/piece;
    - use of native language for patients, as opposed to English for HCPs

2. **No, but ADR reporting forms** for patients use simpler language: (3 MSs)

3. **No, but website aims to use simple language regardless** of target group: (3 MSs)

4. **No**: (4 MSs)

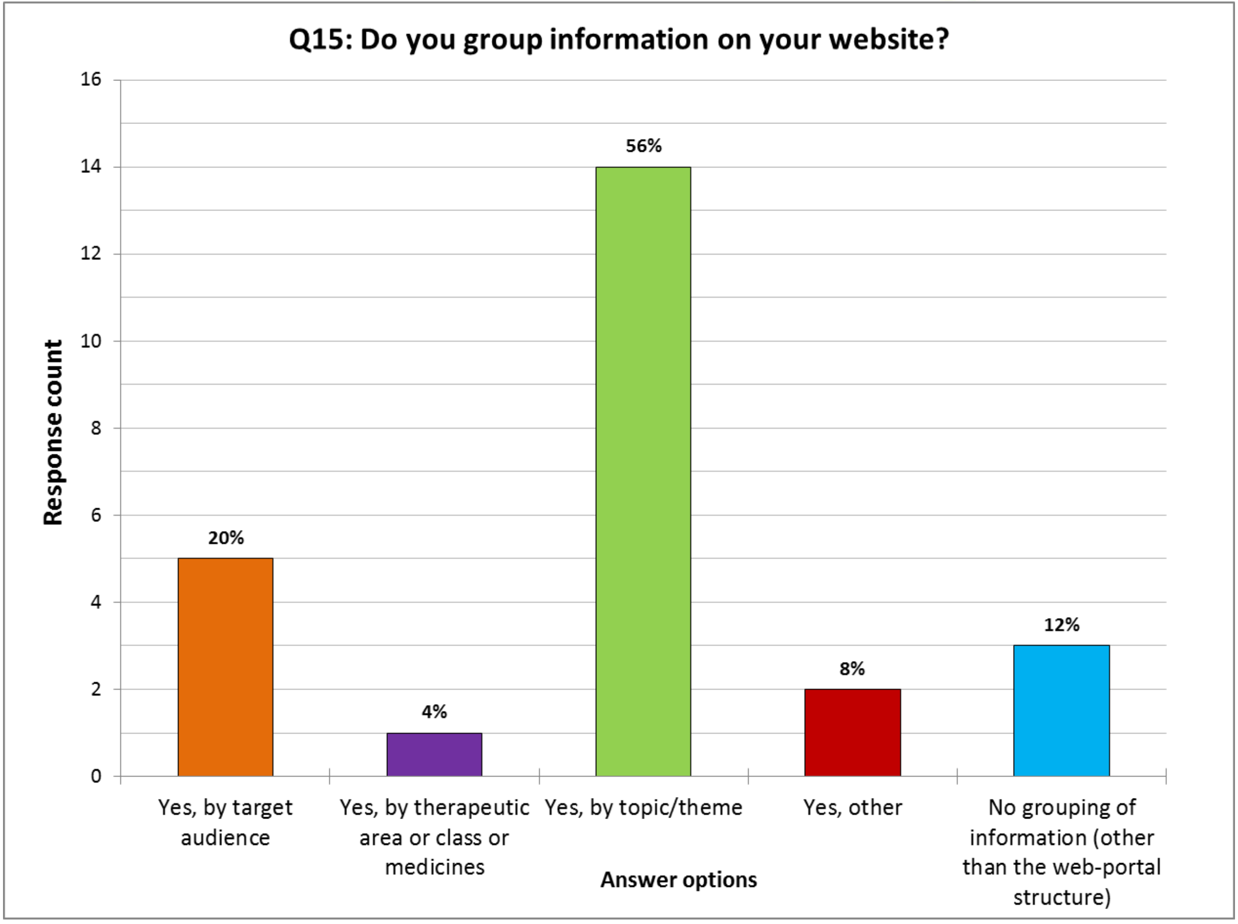


There appears to be **little correlation** between answers for **Q13 and Q14**, suggesting that having separate sections for patients and HCPs does not make an NCA more or less likely to tailor information on its website to patients and HCPs. For example, one respondent noted that while there are separate website sections for patients and HCPs, information is not adapted for these target groups. This suggests that some websites that have separate sections for patients and HCPs do so for **ease of user navigation**, rather than for clarity of information provided.

There is, however, **some correlation** between answers for **Q12 and Q14**, suggesting that there is a link between having national/local guidelines on how website information should be presented, and adapting information provided to patients compared with that provided to HCPs.

- 11 respondents answered **Yes to Q12**, indicating that the have guidelines on how to present website information. Roughly **73%** (8 respondents) of these 11 stated in **Q14** that their website **actively tailors information** for patients and HCPs.
- **All 3 respondents** who indicated in Q14 that information on the website is written to be **suitable for *all* groups** (i.e no active tailoring; blue option in Q14 pie chart) indicated in Q12 that they **do *not* have guidelines** on how to present website information.
- Of the 10 respondents who, in **Q14**, indicated in any way that they **do not tailor information** (green, blue, orange options of Q14 pie chart), **70%** (7 respondents) had stated in Q12 that they **do not have presentation guidelines**.

Question 15 asked respondents if information is grouped on their website, offering four options. All 25 respondents answered this question.



Most respondents (14) indicated that they **group information by topic/theme**. One respondent selected ‘By therapeutic area of class of medicines’.

There appears to be **little link** between how NCAs group information on their website, and whether or not they have guidelines regarding how to present website information. They key pattern that does emerge, however, is that there **may be a link** between NCAs **not grouping information**, and NCAs **not having presentation guidelines**: all three respondents who indicated in Q15 that information is not grouped had also indicated in Q12 that they do not have presentation guidelines. However, with such little data, it is not possible to infer with a degree of confidence.

Q16-Q19: Target audience

Summary

- Overall, respondents voted their websites as most relevant for industry, followed by healthcare professional, less relevant for patients and least for media/press
- The prioritisation of audience depends on the issue/topic or the specific target groups
- Respondents referred to processes that are involved in prioritising , including reference to strategies, audience research, site traffic, and the methods of communications
- Others references considered when prioritising included urgency, therapeutic area and social impact
- Themes around respondents digital strategies were generally focused on plans to design or adapting webpages for mobile phones, for active participation in social media, use of agency-wide communications strategies
- Most respondents to the survey have undertaken some sort of research into website target groups in the form of questionnaires. The most commonly stating purpose of research was to identify user needs and habits and assess how effective/trusted the agency was in communicating and identify unmet needs.

All 25 respondents answered **Question 16**. The option which received the most counts for ‘5’ (extremely relevant) was **Industry**; Media/**Press** received the fewest counts for ‘5’. The results are displayed below in descending order of ‘5’ counts.

Q16: How relevant do you think the website content is for the following audiences? (On a scale of 1 not relevant to 5 extremely relevant)

Answer Options	1	2	3	4	5
Industry	1	0	1	7	15
Healthcare professionals	1	1	4	6	12
Patients/public	1	4	6	5	8
Media/press	0	1	9	6	7

Four respondents rated the relevance of information offered on their website as ‘5’ (extremely relevant) for all four options.

It is likely that one respondent representing misread the question and thought the scale was from 5 (lowest) to 1 (highest) having selected 1 for HCPs, 2 for patients, 1 for industry, and N/A for media. This was the only respondent who selected 1 for more than one audience group, and the mean of its selections is by far the lowest of all responses (see below table). Further, in the next question (Q17), it states that the priority target group is HCPs, which again suggests that the ‘1’ given to HCPs in Q16 should have been a 5. However, as this can only be speculated without further validation, the data for Q16 for the purposes of this analysis has been left as it originally was.

What the figures from Q16 can tell us about websites **depends on how the question is interpreted**. As the question effectively asked respondents to rate the information on their own website, the figures could be seen as a measure of the confidence of each respondent in the information provided on their own website. Alternatively, Q16 data may hint at which target groups are seen as the priority for websites (Q17 deals more explicitly with this). Responses for Q16 could also point at which target groups respondents feel are less adequately provided for on their website, either intentionally (not seen as a priority target group) or inadvertently.

If one looks at some basic descriptive statistics for responses given **per target group**, across all respondents, it is possible to deduce which target groups respondents overall feel are most or least adequately provided for on their website. This can be shown in the below table. Overall, respondents voted their websites as **most relevant for industry**, and **least relevant for patients**.

Target audience group	Mean	Median
Industry	4.46	5.0
Healthcare professionals	4.13	4.5
Media/press	3.83	4.0
Patients/public	3.63	4.0

Question 17 asked respondents to describe in free-text how they prioritise the target audience. The phrasing of the question may be considered rather ambiguous: it is unclear if respondents were being asked to describe the process that leads to prioritisation, the factors that are considered, or simply to name which target groups are prioritised. The ambiguity is reflected in the responses.

Twenty-two respondents answered this question; three skipped it; and three respondents wrote ‘No prioritisation’ or ‘No’. Of the remaining 19 respondents who provided a descriptive answer, their responses can be summarised as follows. Note that some responses have been included in more than one category due to the nature of the response:

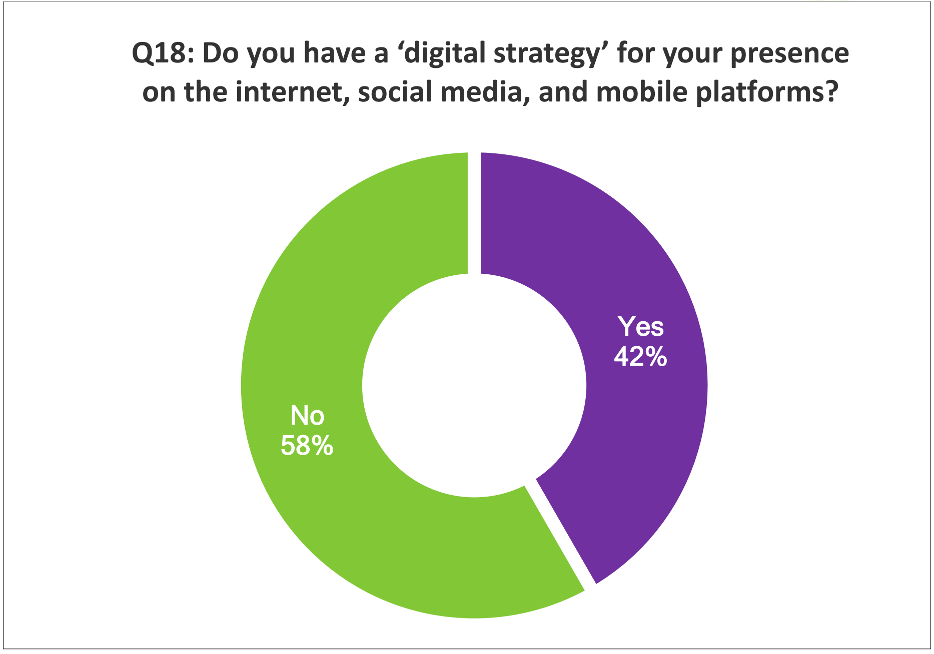
- Two respondents stated only that prioritisation **depends on the issue**/topic
- Ten respondents referred to **specific target groups** in their responses (e.g. HCPs, industry):
    - Seven of these respondents explicitly indicated that they prioritise some target groups for its website over others, with **HCPs named as the first priority** by six respondents, one stated that industry is the first priority.
    - One respondent stated that the three main target groups – HCPs, patients, and industry – are **prioritised *equally***, apart from when specific information needs to be prioritised according to target group
    - One stated only that information is categorised **according to target group**
    - One stated that they **have three different websites**, with one each for HCPs, industry, and patients.

- Six respondents referred to the ***processes* that are involved**, either in finding out which target groups to prioritise, or in communicating to those prioritised groups.
    - Three respondents stated that agency-wide stakeholder **reviews**, audience **research**, and corporate communications **strategies** inform who is prioritised for website information.
    - Three respondents focused on **how important information is communicated**, either by providing certain target groups with additional information (e.g. a daily bulletin for HCPs) or by ensuring that key information reaches the right audience (e.g. by placing it on the landing page of the website)
- Finally, two respondents referred to ***factors* that are considered** when deciding to whom information should be targeted, such as **urgency**, therapeutic area, and **social impact**.

Some further points of interest can be taken from the responses. One respondent noted that **site traffic** also informs their prioritisation process, stating that part of the reason why industry and pharmacies are the top two priority target groups is because “they are the ones that account for most of the traffic on the site”. It was pointed out that the reason why doctors, dentists, and nurses are low down on the priority list is because they are virtually absent as users of the website, and that these groups have other sources of information to use. Another respondent echoed this, explaining that its priority group of HCP’s is focused on pharmacists, as they visit the website most often.

Importantly, one respondent states that, before it can include patients and the public as a key target group for its website, it needs to “perform a big campaign, otherwise patients would not be informed on the possibility to visit NCA website”. This may suggest that some member states **could be hesitant to make patients a key target group** of their website due to concern or doubts over whether patients will know that the resource exists. This then leads to questions over **how websites are promoted** and branded. However, more research is needed before inference can be made based on just one response.

The first half **Question 18** received 24 responses, 10 of which were Yes, and 14 were No. The one respondent who skipped the first half of the question explained in the free-text section that it was not clear what was meant by ‘digital strategy’.



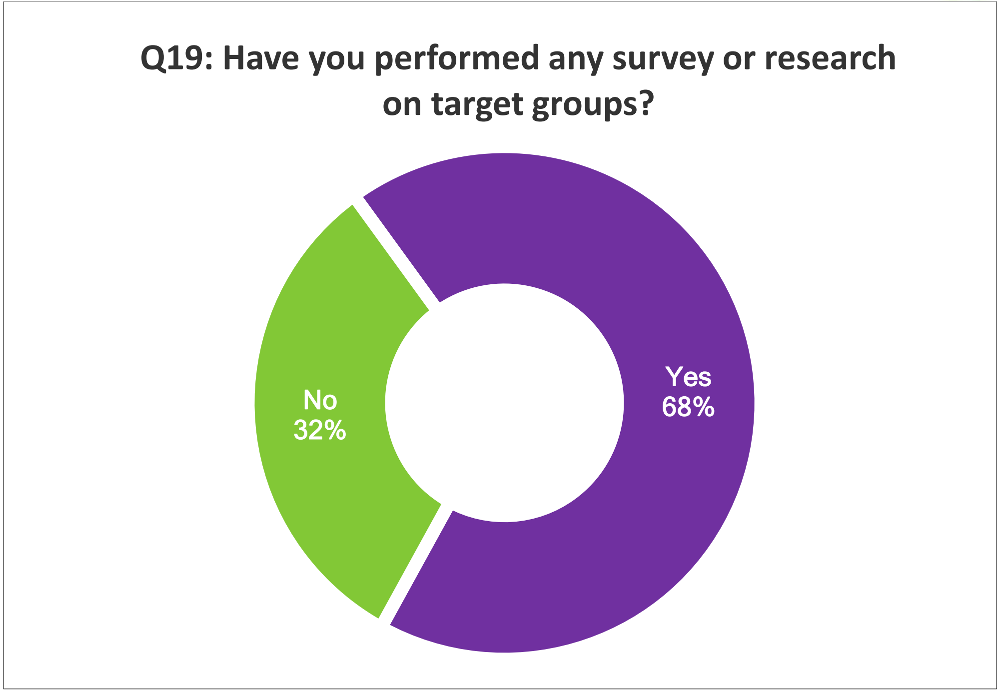
Twelve free-text responses were received. All ten respondents who answered Yes in the first half of the question went on to further elaborate, and two respondents who answered No in the first half went on to provide comments in the free-text section. Generally, some key themes which emerge from the responses include:

- Designing or adapting webpages for **mobile phones** (responsive web design)
- Active participation in at least one **social media forum**, the most commonly identified being **Twitter**. Facebook and YouTube were also identified. Use of agency-wide **communications strategies**
- Several respondents stated that **digital strategies were being developed**, either for social media presence or **for mobile phone use**

One response was particularly detailed, and its key points can be summarised:

- Strategy is based on **user surveys**
- **New website**, key changes of which include:
    - Improved **search** function; change from target-group navigation to **theme-based navigation** (based on requests from users); simple language
- Mobile platforms: **under discussion** and development, including a **mobile app** of the pharmaceuticals database and a **mobile version** of the website
- Social media: User surveys had not provided any new knowledge on specific need or expectations from users on social media

Question 19 was answered by all 25 respondents, and responses indicate that most represented in the survey have undertaken some sort of research into website target groups. Seventeen respondents (68%) answered Yes, and eight (32%) answered No.



Sixteen of the Yes respondents then went on to describe, in widely varying detail, the research in the free-text section of the question. Fifteen out of the 16 respondents made direct reference to the use of **questionnaires or polls**. Some respondents provided further detail on the **methods** used and the **application** of the research.

Summary of the free-text responses to Q19

The free-text responses offer a rich insight into the often extensive research so far conducted into target groups. **Research is often in the form of questionnaires,** but a few respondents mentioned **other types of qualitative research**, such as interviews, focus groups, and workshops. Most respondents stated that their research was **aimed at patients and the public**, with many also including **HCPs** and sectors of the pharmaceutical **industry**. From the responses which provided details, the **most commonly stated purpose of research was to identify user needs** and habits and **assess how effective/trusted the agency was** in communicating to stated target groups. Research has generally been **used by agencies to identify unmet needs**, and to **develop communication strategies** and/or changes.

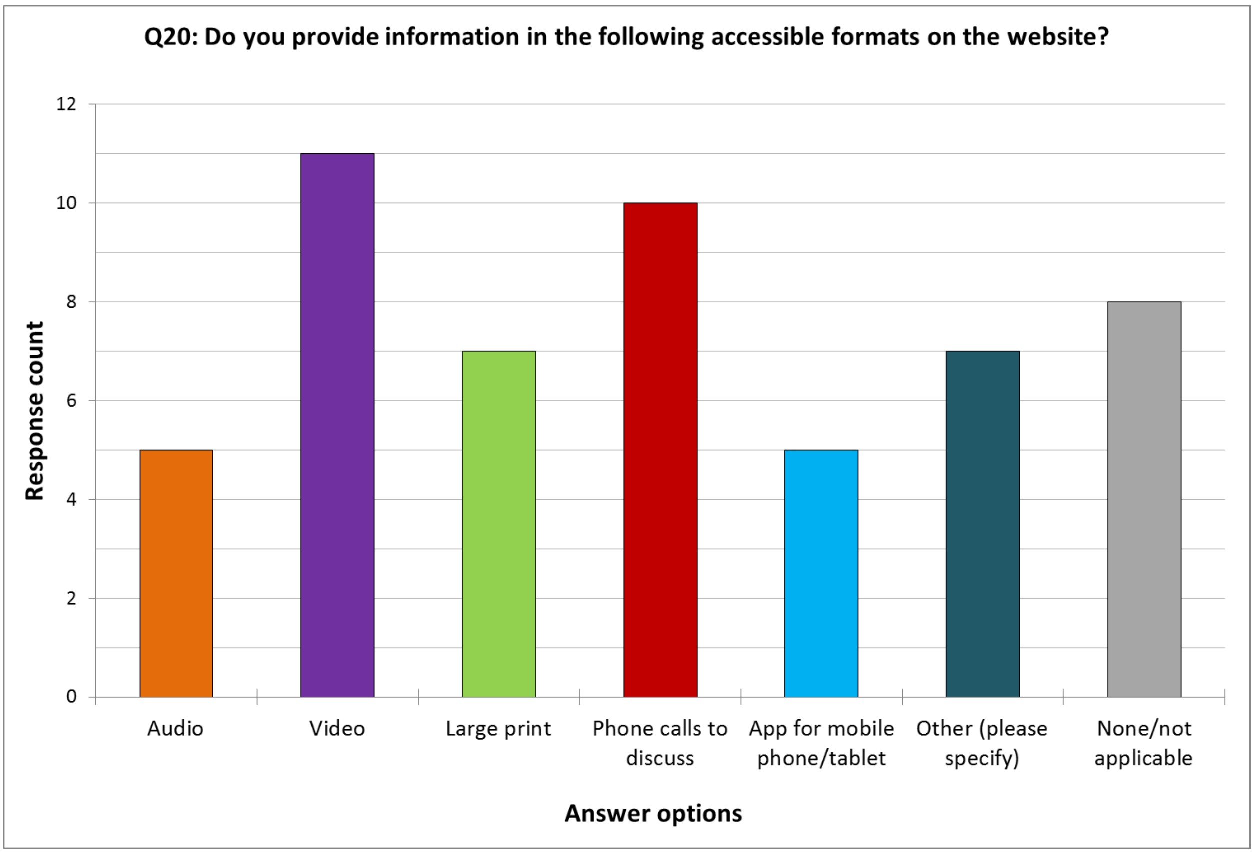
Considering that many member states have already undertaken extensive research into users of their web-portals, it may be useful to the aims of WP6.4 to ask respondents for summaries and key findings of their research.

Q20: Accessible formats

Summary

- The most common alternative methods used by member states to provide information was video media and telephone calls
- Audio and mobile phone/tablet app were least often used.

All 25 respondents answered **Question 20**. Respondents were able to choose more than one option. **'Video' was the modal response** (11 counts), with 'Phone calls to discuss' a close second (10 counts). Audio and mobile phone/tablet app were selected the fewest times (5 counts each). **One third** (8 respondents) stated that their website does not provide information in any accessible format. **Seventeen respondents selected at least one of the positive options.**



Of the 17 respondents who selected a positive option, most (11) selected more than one option. The responses, per respondent, can be presented in the below table. The median number of positive options selected is 2.

BG				Phone calls to discuss	
CZ	Audio	Video		Phone calls to discuss	App for mobile phone/tablet
DK		Video		Phone calls to discuss	
EE		Video	Large print	Phone calls to discuss	
ES	Audio	Video	Large print		App for mobile phone/tablet
FI			Large print		
FR		Video		Phone calls to discuss	
GR				Phone calls to discuss	
HR		Video			
IE		Video		Phone calls to discuss	
IS				Phone calls to discuss	
IT	Audio	Video	Large print		App for mobile phone/tablet
LV	Audio	Video	Large print		
MT		Video			
NL		Video	Large print		
PT			Large print	Phone calls to discuss	App for mobile phone/tablet
SE	Audio			Phone calls to discuss	App for mobile phone/tablet

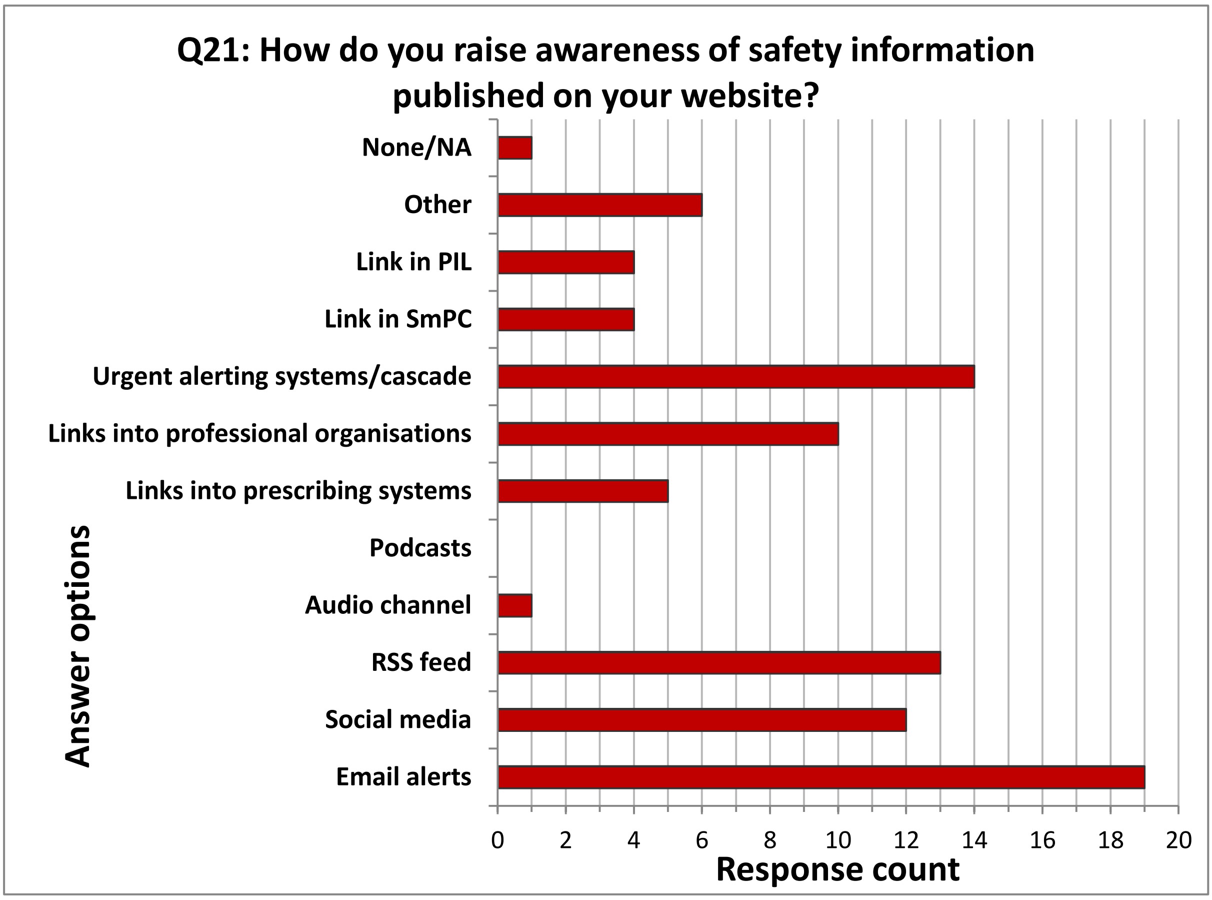
Free-text responses in the ‘Other’ section of Q20 mainly offered clarification on answers given.

Q21-Q23: Raising awareness of safety information

Summary

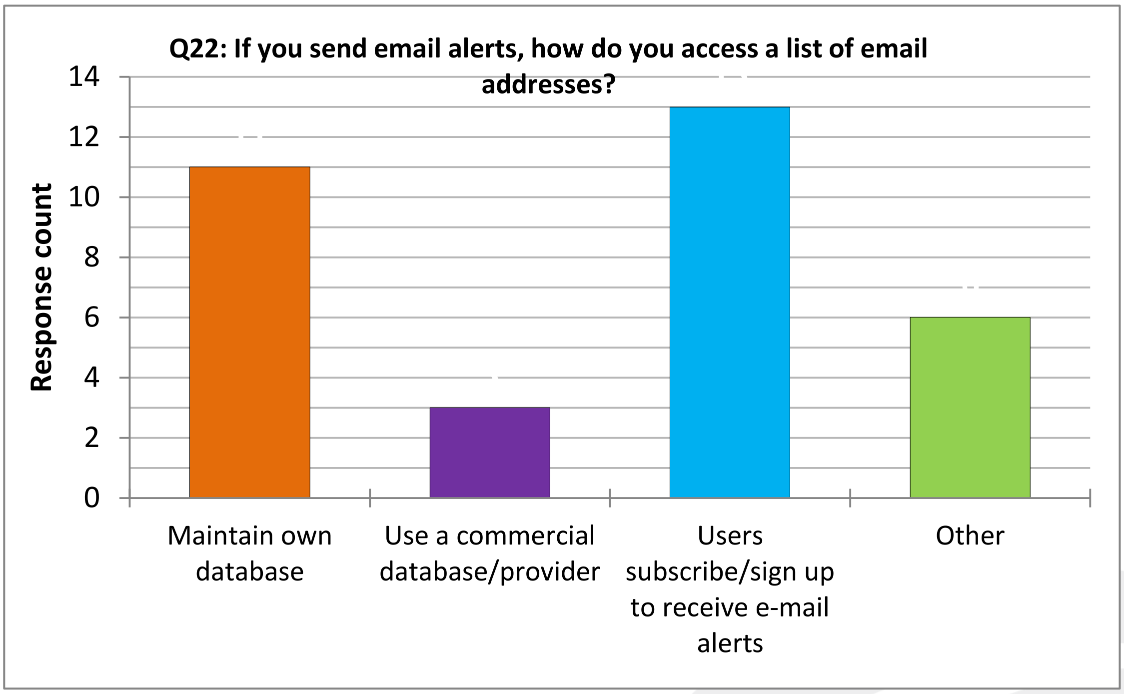
- Email was the most commonly used method for raising awareness of safety information, often used in conjunction with social media and RSS feeds
- Most respondents have a national mailing list of users who have subscribed to receive email alerts, with very limited use of commercial databases alongside these national lists.

Question 21 was answered by all 25 respondents, although one respondent did not select an option, instead writing in the free-text 'Other' section. (Note that this is why summary data for this question gives a response count of 24.) .



‘**Emails**’ was selected the most number of times (19). **No respondent selected ‘Podcasts’**. Responses suggest that **email alerts are often used in conjunction with social media and RSS feeds**: only four respondents who chose ‘Emails’ did not also choose ‘Social media’ and/or ‘RSS feeds’; and ten respondents selected all three. The ‘Other’ responses mentioned some methods and tools not offered in the question.

Twenty respondents answered **Question 22**, with most respondents (13, or 65%) indicating that their mailing list is made up of users who subscribe to receive email alerts. Over half of the respondents who answered this question indicated that they maintains their own database for email alerts. Only three respondents indicated that they use a commercial database, but no respondent indicated that they use *only* a commercial database (i.e. another option was also selected).



Two respondents who added information in the ‘Other’ section provided useful information for the purposes of this survey: information sent out ***to Health Journalists****. or to pharmacists and GPs* ***via professional organisations****.*

Question 23 received responses by 22 respondents. All three respondents who skipped Q23 had also skipped or written ‘N/A’ for Q22. Respondents could select more than one option. **Eight respondents** indicated that they aim to contact **all five target groups** in email alerts. A further two respondents indicated that they aims to contact **all target groups apart from patients/public.**

Answer Options	**Response Count**
Pharmacists	16

Patients/public	10
Other (please specify)	14
Nurses	11
General Practitioners	14
Doctors	14

Many respondents wrote in the ‘Other’ free-text section, either clarifying their selections or providing information not offered in the question options. One, for example, stated that while it does not usually send emails, it does so in exceptional circumstances:

None of the respondents who had selected all five target groups in this question, added that its **also sends email alerts to health agencies** and the **Ministry of Health.**

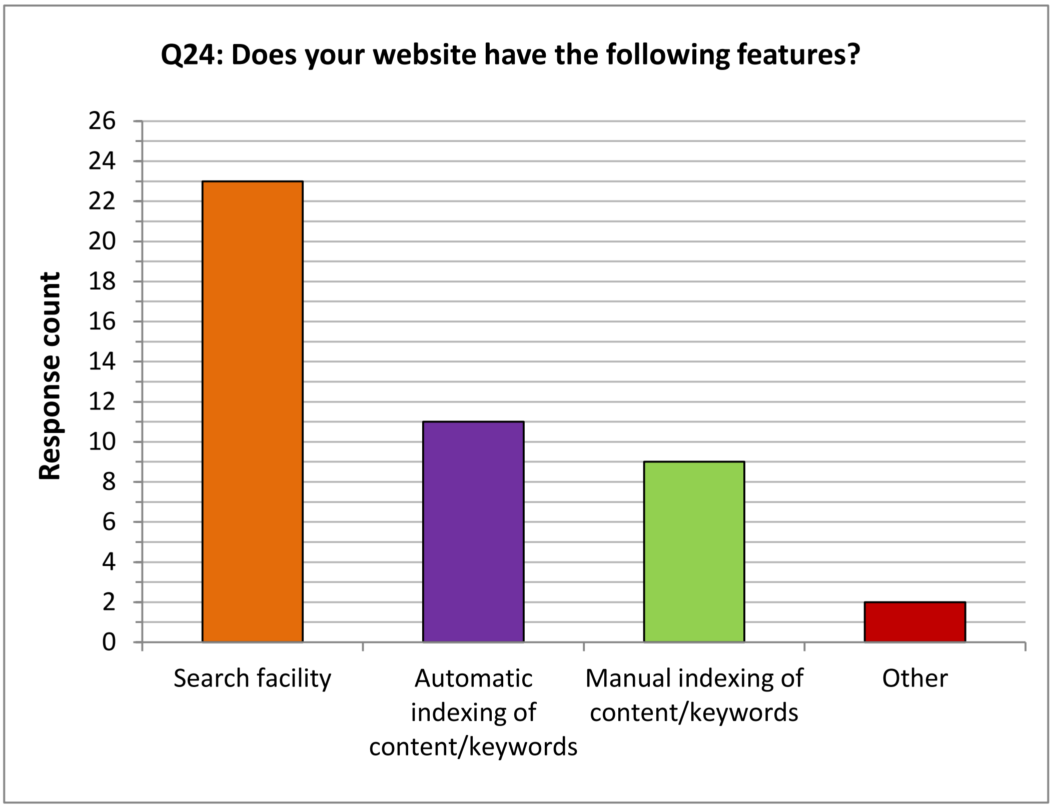
Another wrote that its online alerting system **allows subscribers to tailor their own email alerts** by selecting the stakeholder group they belong to, as well as their areas of interest and was the only respondent to state that it offered this option to subscribers.

Q24-Q28: Administration and management of website/website content

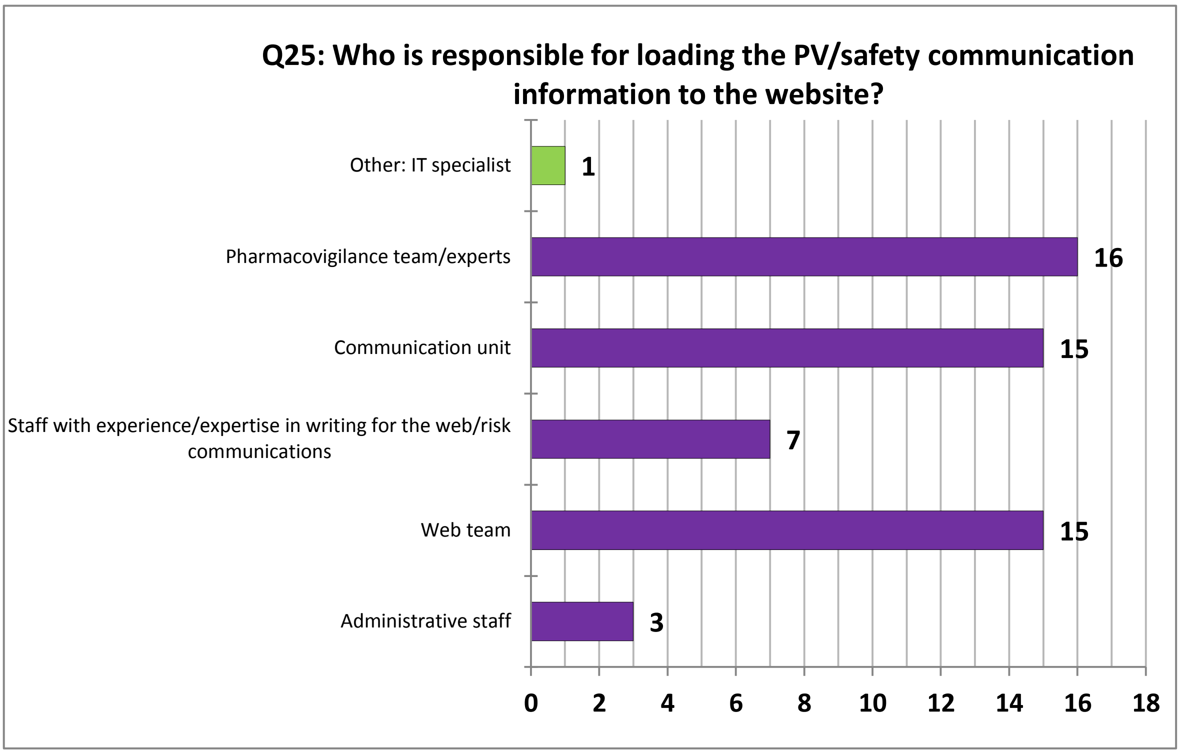
Summary

- Search facilities are widely provided on websites/portals, with many respondents also having manual and automatic indexing of content
- Responsibilities for loading information varies between respondents but appears to be a joint or shared operation between the PV team and the communication team
- 80% of respondents indicated that they have a quality control/approval process
- The majority of respondents indicated that they monitor website visits alongside more active forms of usage and feedback monitoring
- Nearly three quarters of respondents indicated future development plans in the next 12/24 months.

Question 24 was answered by 24 respondents. One respondent skipped the question, and one respondent did not select an option but wrote in the free-text 'Other' section that a keyword search is "possible only on the individual page". Every one of the remaining 23 respondents who did answer and select an option selected '**Search facility**'. Sixteen respondents chose 'Search facility' *as well as* at least one option out of 'Automatic indexing' and 'Manual indexing'.



Question 25 was answered by all 25 respondents. Respondents could select more than one answer. The modal response, with 16 counts, was '**PV team/experts**', but 'Web team' and 'Communication team' both came close second with 15 counts each. One respondent selected **all five options**, while one respondent selected none of the options but wrote in the 'Other' free-text section "**IT Specialist**".

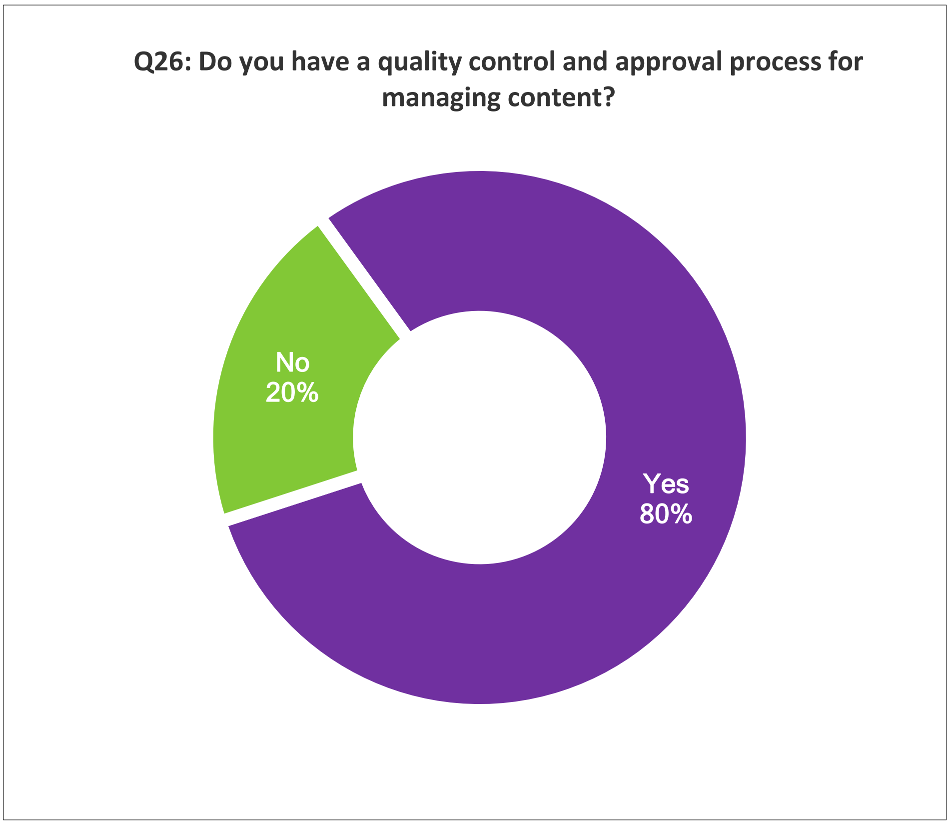


All three respondents who selected '**Administrative staff'**, the option with the lowest count, **also selected 'Communication unit'**, suggesting that the administrative staff responsible for uploading PV information are part of the communication unit.

Eleven out of the fifteen respondents (73%) who selected '**Communication unit' also selected 'Pharmacovigilance team/experts'**. This suggests that, for many represented in this questionnaire, uploading PV information to the web-portal/website is a joint or shared operation between the PV team and the communication team.

Twelve of the 16 respondents (three quarters) who selected '**Pharmacovigilance team/experts' also selected at least one other option**, suggesting again that the uploading of PV information is often supported by staff who specialise in communicative, web, or administrative aspects of the agency. One respondent who selected 'PV team/experts' clarified in the free-text section that the uploading of PV information was carried out by the **Head of Post-Authorisation Safety**.

All 25 respondents answered **Question 26**, with one respondent selecting neither Yes or No, but adding a descriptive response in the free-text section. The free-text response suggests that they *do* have a quality control process in place, and has therefore been included in the Yes count for the purposes of data analysis.



Twenty respondents (80%) indicated that they do have a quality control/approval process for managing web content.

In the free-text section, sixteen respondents described the processes involved in varying detail. Many respondents mentioned SOPs/guidelines and/or the involvement of the communications team.

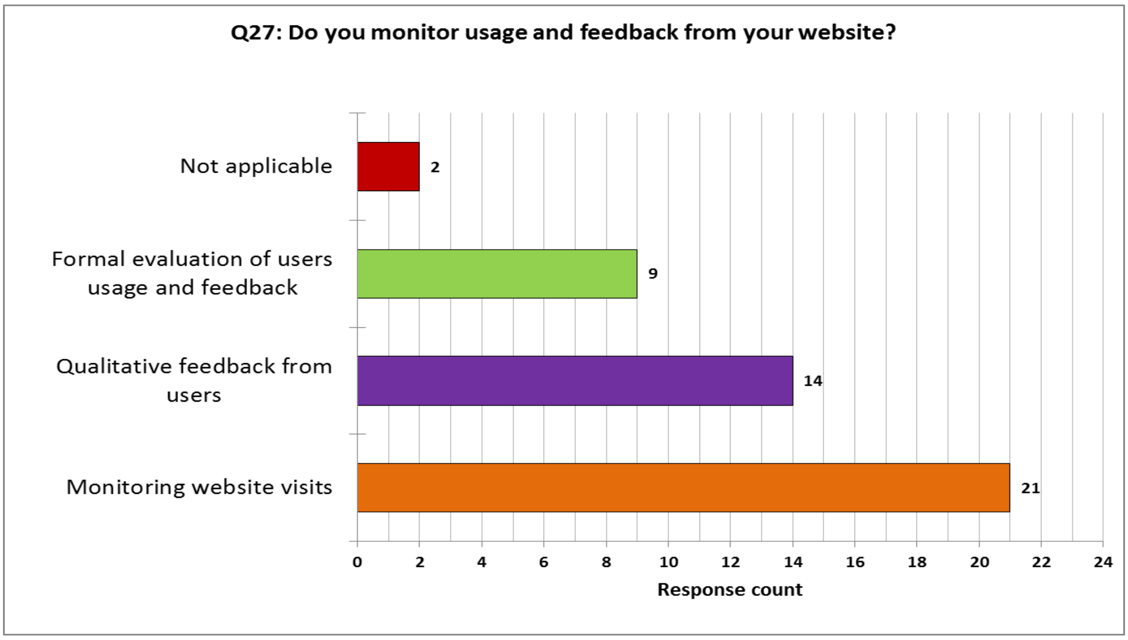
There appears to be **some correlation** between **having a web team upload information** (Q25) and **not having an approval process** (Q26). **All five respondents** who answered No in Q26 had also indicated in Q25 that the **web team** is responsible for uploading PV safety, and three of these five respondents had indicated in Q25 that **only the web team** is responsible for uploading information. Conversely, only two respondents who had selected '**Pharmacovigilance team/experts'** in Q25 went on to select No in Q26 (these two respondents had also selected 'web team' in Q25), and only one respondent who selected '**Communication team'** in Q25 went on to select No in Q26 (this respondent had also selected 'web team' in Q25).

Interestingly **some correlation can be found across other questions**, too, although without a larger sample or further investigation, patterns found in this questionnaire cannot be highlighted with certainty and no causal relationships can be deduced. Some interesting observations, however, can be seen. For example:

- All five respondents who said in Q26 that there was **no quality control or approval process** for managing web content **had said in Q12 that they do not have national/local guidelines** on how information must be presented.
- Four out of the five No respondents in Q26 had said in Q13 that their website **does not have different sections** for HCPs and patients.
- Four out of the five respondents in Q26 had stated in Q18 that they **do not have a digital strategy**.
- Four out of the five No respondents in Q26 had stated in Q20 that their website **does not provide information in any accessible formats**.
- **All eleven respondents** who answered in Q12 that they **have national/local guidelines** on how web information should be presented also stated in Q26 that they **have a quality control** and approval process for managing content.

All 25 respondents answered **Question 27**. Respondents were able to select more than one option. The majority of respondents (84%) indicated that they **monitor website visits**. Monitoring website visits appears to be the **most basic type of monitoring**: not only is this option the modal response, but only two respondents out of the 23 who selected a positive response (i.e not 'N/A') had not selected 'Monitoring website visits'. Five respondents who selected 'Monitoring website visits' did not select at least one other option. Thus it seems that most member states monitor website visits **alongside** more active forms of usage and feedback monitoring.

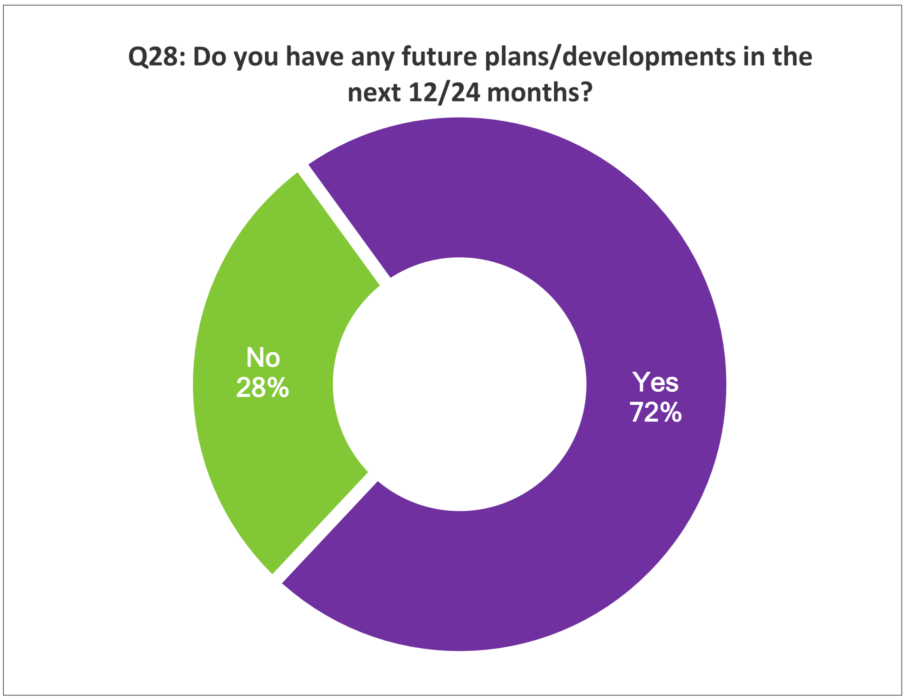
Twelve respondents indicated that, **as well as monitoring website visits**, they **also use qualitative feedback** from users. Seven respondents selected **all three options**.



Nine respondents provided more detail in the free-text section of the question. Many of the responses mentioned themes and tools similar to those mentioned in

Q19 ('Have you performed and survey or research on target groups?'), such as annual formal reviews, user questionnaires, and Google Analytics.

All 25 respondents answered **Question 28**. Almost three quarters (18 respondents) selected yes.



All 18 Yes respondents provided further details in the free-text section. Many of the details provided had already been either alluded to or described in previous answers, such as work on mobile versions of websites using responsive design, investigating the use of a mobile app and/or social media, adding material (such as educational material), and improving the layout of the website.

Q29: Any further information

Question 29, the final question of this questionnaire, invited respondents to provide any further information that they wished to. Of the nine respondents who wrote something in response, five wrote ‘No’ or ‘N/A’. A further respondent highlighted the inherent weakness of this questionnaire, echoing concerns at the start of the questionnaire.

4 Summary and discussion of the results

A response rate of 25 responses from a possible 27 active SCOPE partner member states is considered to be excellent and may be considered to show that they are keen to obtain more information and guidance about provision of information through web-portals. The diversity in information provided, maturity of systems and strategies indicates that recommendations and guidance could be a useful and welcome output for use nationally.

Introductory questions on web-portals

It is understood from these results that all member states who responded provide pharmacovigilance information on a website of some sort. However, it is clear there is a lack of clarity over the definition of a web-portal and how/if this differs from a website, and it may be considered that they would benefit from a clear definition.

Member states consider they have a specific web-portal for pharmacovigilance information, or that his information is included in the wider agency website. For some member states information relating to pharmacovigilance is spread across more than one web-portal, the example provided being the sites are for different audiences.

The approaches used by member states to organise information on webportals/website varies. Some use the audience as the basis to provide this, with others using theme-based structures such as therapeutic area.

Many member states are in the process of introducing changes, or are planning to do so in the near future. It is recognised that RMP summaries and PARs in particular are not provided by all MSs presently, and that this may be related to the recognition of ongoing establishment of a mature system for the EU.

Languages

As may be expected, information is provided in national language(s), with almost all providing information additionally in English

Information – Content

There is a significant diversity in the pharmacovigilance information provided content on websites/web-portals. The lack of clarity over the definition of a web-portal is likely to have affected the results showing where this information is hosted, but it can be concluded that the majority is directly on websites/portals.

Access to SmPCs, PILs, Urgent safety announcements and Press releases/media announcements were provided by all responding member States on their own website or via external sites.

The types of information that respondents indicated were least likely to be provided, either on the website, web-portal, and/or external website were Post-authorisation studies, publication/bulletin for patient, RMP summaries and links to Information/link to CMDh documentation.

Only a limited proportion of member states have any links to information on the EMA website, although it was not clear if this is an intentional omission or that not all had yet introduced such links. Recommendation and guidance may be of particular value in this area for member states who do wish to add linkages in the future.

Member states most frequently update safety information including SmPCs, PILs, PARs, urgent safety announcements, but the majority of responses showed that most information is updated at on an ‘other frequency’, suggesting that this was less than monthly, or was not applicable.

Information is most frequently provided as html/webpage and pdf documents – SmPC, PILs, PARs and DHPCs most commonly being provided as pdfs as may be expected, with guidance on ADR reporting and other content commonly provided as html.

Information: Presentation

About a third of member states have national guidelines on presentation of information, with free text responses indicating that they are usually Standard Operating Procedures.

Nearly two thirds of member states have separate sections for healthcare professionals and patients. The majority of member states provide information for patients with some adaptions applied such as use of simpler language, layout, use of native languages or provision of questions and answers. A small number of member states explained that they aim to use simple language regardless of audience, some do nothing.

There may be considered to be some correlation between answers suggesting that there is a link between having national/local guidelines on how website information should be presented, and whether they actively adapt information provided to patients compared with that provided to HCPs.

Most member states responding indicated that information content on their website was grouped by topic/theme, although there was also mention of therapeutic area or class of medicines, and target audience.

Target audience

Overall, most respondents considered their websites as relevant or extremely relevant for industry. Healthcare professionals also featured highly on the relevance scale, although less extreme.

Responses for patients and the public are spread more evenly across the range of relevance scores and may be considered the lowest relevance overall, although a peak is still seen at ‘extremely relevant’.

The content was also considered relevant for the media/press although most frequently reported to be around the middle of the scale, with fewest responses for ‘extremely relevant’ out of all the categories.

Prioritisation of the target audience appears to depend on the issue/topic or the specific target groups considered. Member State referred to processes that are involved in prioritising, including reference to strategies, audience research, site traffic, and the methods of communications

Themes around member state digital strategies were generally focused on plans to design or adapting webpages for mobile phones, for active participation in social media, use of agency-wide communications strategies

Most member states represented in the survey have undertaken some sort of research into website target groups form of questionnaires, most commonly stated purpose of research was to identify user needs and habits and assess how effective/trusted the agency was in communicating and identify unmet needs

Accessible formats

Most member states provided at least one of the accessible format options listed, with video followed by telephone calls being the most common alternative methods member states use to provide information. Audio and mobile phone/tablet app were least often used.

It is not clear from the results how decision are made about which formats to use with the results spread relatively evenly between the different format options provided.

Raising awareness of safety information

Email was the most commonly used method for raising awareness of safety information, often used in conjunction with social media and RSS feeds which also featured highly in the responses.

Most respondents have a national mailing list of users who have subscribed to receive email alerts, with very limited use of commercial databases alongside these national lists.

Most respondents used at least one of the listed methods – with only one response indicating no methods were used to raise awareness of safety information. Some examples of systems used in member states were significantly more complex than others for example allowing users to tailor email alerts to specific topic areas.

Administration and management of website/website content

Questions around the functionality of member state website/portals show that search facilities are widely provided. Many also have manual and automatic indexing of content.

The responses about responsibilities for loading information to webportals shows more varied results but most commonly appears to be a joint or shared operation between the PV team and the communication or administrative team.

In the free-text section, sixteen respondents described the processes involved in varying detail. Many respondents mentioned SOPs/guidelines and/or the involvement of the communications team and overall 80% of respondents indicated that there was a quality control/approval process in place.

There appears to be correlation between responses for member states that have a web-team to upload information and them not having an approval process. This correlation is also seen with the same member states not having different sections for HCPs and patients or a digital strategy which may reflect less mature risk communications systems or web-portals

The majority of respondents indicated that they monitor website visits, as the most basic measure of website use, alongside more active forms of usage and feedback monitoring

As indicated under the first section nearly three quarters of respondents indicated future development plans in the next 12/24 months, which shows there may be value in the recommendations and guidance from this topic.

5 Conclusions and next steps

As previously noted, it is considered that there was a good response rates from surveys sent out. Responses show a significant diversity of the situations and practice in different member states. The lack of clarity and understanding of the definition of a web-portal is considered to illustrate the value of providing guidance and example of practice and experience between member states. This may facilitate developments in member states aiming to update and improve their web-portals for pharmacovigilance.

Following the information collected from the survey a number of additional steps will be used to collect some specific additional information from member states to help identify good practice and specific examples to illustrate these:

1. Manually review of a sample of websites. This will be using a combination of ‘use cases’ to simulate the experience of individuals seeking specific types of information, alongside more qualitative review of a range of aspects of the site such as design, organisations, presentation, and navigation. The websites will be assessed in their primary language where possible rather than relying solely on the English versions.
2. Request and review documentation where member states are willing to share these to identify good practice – focussing mainly on high level documentation rather than Standard Operating Procedures i.e. strategies covering communication, risk communication, digital platforms, quality audit, and any guidelines currently used.
3. Investigate user friendliness and user feedback through obtaining summaries of user research undertaken nationally.

Following identification of recommendation and best practices, guidance will be developed illustrated with examples, which will then also be used to support future training or a workshop delivered by WP6.

6 Recommendations/best practices

The guidance and recommendations will use examples of practice in member states to illustrate the diverse approaches used nationally. The specific topics of interest below have been identified in the survey that will be taken forward for development of recommendations under key headings:

Structuring information
How to tailor information for specific audiences, e.g. public, industry, healthcare professionals, grouping information e.g. by product, disease area, etc. with examples of good practice.

Making information accessible
How to make it easy to find information, linking to other sources of information including the EMA, making information accessible regardless of tools/systems e.g. “open linked data”, use of publicity and feedback to raise awareness, access from mobile devices again all illustrated with examples of good practice

Monitoring usage/feedback

Obtaining user evaluation and feedback and using this to inform and enhance web-portals