SCOPE Work Package 7
Quality Management Systems

Survey Report: Resource Management

2016

SCOPE

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Contents

Acknowledgments

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The authors acknowledge all Member States who took part in this survey.

1. Introduction

1.1 Purpose of the document

The purpose of this report is to summarise the outcomes of the Work Package 7 (WP7), survey addressing the pharmacovigilance (PV) resources currently available to National Competent Authorities (NCAs). Upon analysis of this survey, this report will present suggestions for achieving good practice on managing resources and delegating PV tasks. Information gathered from the questionnaire will only be referred to in general and will be anonymised in this report.

1.2 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
BEMA	Benchmarking of European Medicines Agencies
CAPs	Centrally Authorised Products
EC	European Commission
EMA	European Medicines Agency
EU	European Union
EURD	European Union Reference Date
EVDAS	EudraVigilance Data Analysis System
FTE	Full Time Equivalent
GVP	Good Pharmacovigilance Practices
HMA	Heads of Medicines Agencies
IT	Information Technology
KPI	Key Performance Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MS	Member State
NAP	Nationally Authorised Product
NCA	National Competent Authority
PASS	Post-Authorisation Safety Study
PDF	Portable Display Format

Terminology	Description
PV	Pharmacovigilance
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
QMS	Quality Management System
RMP	Risk Management Plan
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SD	Standard deviation
SOP	Standard Operating Procedure
WP	Work Package
WGQM	Working Group of Quality Managers

1.3 Executive summary

This report outlines the collection of information from European National Competent Authorities (NCAs) regarding Quality Management Systems (QMS) in pharmacovigilance (PV). This is part of the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action, which aims to support each European Union (EU) Member State (MS) in operating their PV systems. Each MS was asked to complete a questionnaire covering the following main topics:

- Understanding national quality systems
- Resource management
- PV inspections

The questionnaire on Resource Management was part of SCOPE Joint Action WP7and was answered by 26 MSs. This report discusses those responses and tries to identify areas of good practice and areas where NCAs might optimise their QMS.

1.4 The survey results

The first section of the questionnaire addressed general NCA views on PV resources, including the number of staff employed and how duties and workload were assigned and managed. The number of staff assigned to PV activities varied significantly across the 26 MSs. This highlighted the different organisational structures of the PV departments in the NCAs.

Just over one half of respondents use a formal documented process to reference NCA business goals and PV department needs, in workload assignment. Half of the respondents estimated workload on historical changes and/or planned applications. In addition, only half of NCAs follow a formal capacity management plan.

The second section of the questionnaire focused on how NCAs recruit and train new employees and the career development of existing PV staff. Generally graduate degrees and relevant experience are requirements for any PV role, although some NCAs hire administrators with higher education qualifications only. It is possible that the scope and responsibilities of the administrator role are different across NCAs. Computer literacy and a good command of the English language were also requirements for some NCAs. Less common attributes included requesting new starters were medically registered or had taken various job-related exams.

Training new starters almost always involved both internal and external training sources for all NCAs; with three quarters of NCAs tailoring this training to the individual's background experience and education. Most MSs identified mentorship programs as important sources in PV training, with NCAs implementing this for training new starters. All NCAs identified the use of external training for continuous development of their PV staff, utilising internal and on-the-job training to some extent. Formal performance evaluation systems are in place for almost all NCAs, although a system to measure the effectiveness of the training is assessed to a lesser degree.

The amount and frequency of training provided for continuous development is rarely systematically monitored, with training assigned on an 'ad-hoc' basis, and no set number of hours required by staff members.

Resource allocation questions were the focus of the third section of the questionnaire, addressing how staff were assigned to tasks, how NCAs rank the importance of such tasks and how they respond when the workload is significantly increased. There was a big variation in the way that PV staff are assigned PV activities, some referring to therapeutic area, some on the type of procedure and others, staff experience. The three most influential factors referenced in task assignment included regulatory legislation, public impact and whether the MS is the EU lead for a particular case.

Generally NCAs rated Adverse Drug Reaction (ADR) and signal management as the most important PV tasks, with ADR management increasing in priority when NCA resources are limited. The assessment of risk management plans and post-authorisation safety studies were ranked as having the lowest priority, both during normal working conditions and during times of limited capacity. NCAs seem to handle peak periods by re-assigning staff, increasing working hours and/or hiring short term staff.

The fourth section of the questionnaire addressed career development, and how PV staff members are helped to progress within the agencies. Interestingly there was little focus on this, staff were primarily assigned more interesting work to keep job interest high. Some agencies provided financial incentives and some provided external training, although most NCAs primarily supported managers and senior staff in career succession.

The final section of the questionnaire aimed to extract good practice examples from NCAs, surrounding resource management, thus tying together the main survey sections. Some NCAs highlighted their limitations in managing resources due to austerity measures. Others suggested the hiring of staff with experience across multiple areas increased their flexibility in responding to workload. The mentorship system was highlighted again to facilitate an increase in knowledge sharing. Although the hiring of short-term staff was proposed as an option to manage peak periods, NCAs identified the challenges in using this method as the training of new staff can be time consuming for existing PV staff.

1.5 Good practice

Proposing good practice methods for NCAs is a challenging prospect, given the significant variation in existing resources and processes. For this reason it is difficult to measure what 'good practice' is, and how effective the proposals might be across Europe. Nevertheless the most common practices highlighted by the collective NCAs that took part in the survey are a good reference. The deliverables for good practice approaches may be delivered through face-to-face training, e-learning or as part of a QMS toolkit that NCAs can use as a reference.

The current proposals for additions to good practice in resource management are summarised below:

- Create training development plans for all PV staff
- Regular review of the effectiveness of training materials and methods
- Improve mentorship schemes for new-starters
- Consider the use of formal planning tools to support decision making for resource management
- Improve resource management processes, for example through a capacity management plan
- Improve forecasting capabilities, for example through horizon-scanning.

1.6 Future work

In light of these proposed approaches to 'good practice', the following next steps will be implemented to gather the information required to include as part of the toolkit for WP7 and to provide training on these good practices:

- Develop practical guidance on resource management, highlighting PV aspects
- Identify a good case study of a training development plan, including 'Vigilance Competency Framework' to be part of the WP7 QMS toolkit
- Request additional information from the NCAs who have a mentoring program for new staff
- Identify a good case study of risk assessment in PV activities, to be part of the QMS toolkit.

1.7 Background

The legal requirement for quality systems was introduced by Directive 2010/84/EU[1] and Regulation (EU) No 1235/2010 to strengthen PV in the EU. The minimum requirements of these quality systems are set out in the European Commission (EC) Implementing Regulation (EU) No 520/2012[2].

The Guideline on Good Pharmacovigilance Practice (GVP) Module I provides guidance on the establishment and maintenance of quality assured PV systems for stakeholders[3]. The principles for GVP include ensuring that resources and tasks are organised through structures and processes in a manner that will support the proactive, risk-proportionate, continuous and integrated conduct of PV. Management of resources dedicated to operating PV systems is essential in order for NCAs in MSs to be able to meet their PV legal obligations and responsibilities, which forms part of a quality management system (QMS). Responsibility for the quality system within an organisation includes ensuring that a sufficient number of competent and appropriately qualified and trained personnel shall be available for the performance of PV activities [IR Art 1091), Art 14(1)].

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action aims to support EU MSs in operating their PV systems as part of the EU Network making the best use of experience and practices to achieve the most effective use of available national resources. SCOPE is gathering information and expert knowledge on how MSs run their national PV systems. Using this information, SCOPE will develop and deliver tools, guidance and training to support MSs in their PV activities. Through this approach SCOPE aims to support consistency across MSs to provide greater knowledge and help to identify and promote their strengths, thereby strengthening the protection of public health[4].

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[1] Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use

[2] Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament

[3] Guideline on good pharmacovigilance practices: Module I – Pharmacovigilance systems and their quality systems EMA/541760/2011, 22 June 2012

[4] http://www.scopejointaction.eu/ downloaded: [10/06/2015]

SCOPE is divided into eight Work Packages (WP). WP7 focuses on the development and function of national PV systems from a quality management perspective. There are three topics within WP7. The focus of Topic 2 is to fully understand the resources that MSs have in place which are dedicated to PV tasks. Information will be gathered regarding what PV tasks exist and how work-load and responsibilities are allocated, to more fully understand the burden these activities place on MSs.

The overall deliverables from WP7 are to develop introductory training materials on QMS for PV staff together with a quality toolkit presenting case studies of good practice from MSs, practical guidance documents and specific tools to share expertise and set priorities for EU NCAs, thus allowing further development depending on their resources and maturity of quality systems.

A number of EU NCAs were visited in 2014 as part of a data gathering exercise of WP7 to consider how a PV quality system was run in practice at NCAs. Information shared during site visits served as a basis for a comprehensive questionnaire on the quality management practices of EU MSs focusing on the general structure and functioning of the QMS and that of PV, resource management and interface of PV assessors with PV inspectors.

One of the WP7 Sub-packages aimed to contribute to this through delivery against the following:

- Development of a questionnaire on resource management
- Analysis of responses and production of a summary report
- Identification of areas of good practice.

1.8 Context and scope of report

The report summarises and analyses information obtained from the survey to contribute to the final deliverables of WP7. Responses are not attributed directly to responding MSs, so as to preserve confidentiality.

1.9 Main goal

This report provides a review summary and analysis of responses from the NCAs in the EU Network on the WP7 survey on resource management. A web-based questionnaire was used to gather information on resource management in participating EU MSs. It was not an audit exercise but an information-gathering activity. The results of the survey will provide the basis for further work in WP7, identifying solutions and drafting recommendations for the good practice guidance.

1.10 Objectives

Results from the survey have been used to identify the range of practices across EU MSs, and will be used to produce guidance and tools to support MSs to meet the requirements set out in EU PV legislation.

1.11 Challenges

The harmonisation of results and comparison of responses between MSs could be impacted by differences in interpretation. For the recommendations themselves, there may be challenges in national applicability with the significant range of contexts, stakeholders and factors relevant in different MSs.

Responses to the survey have been anonymised to safeguard the confidentiality of the information. In addition, careful communication and planning was required to avoid unnecessary duplication of work in other ongoing EU initiatives.

2. Methodology

2.1. Tool and survey method

WP7 used questionnaires to gather information from NCAs of MSs in the EU on the topics investigated. A questionnaire, as a tool for collecting information, has advantages over other methods like interviews:

Responses to questions are gathered in a standardised way

They allow information to be collected quickly (via an online survey tool)

Information can be collected from a large portion of the target group (NCAs of MSs in the EU).

The following three questionnaires were developed in the frame of QMS in SCOPE WP7:

- General (49 questions)
- Resource management (28 questions)
- Pharmacovigilance inspections (27 questions).

2.2 Data collection methodology

In the first step of the development phase, objectives and types of information to be collected for each questionnaire were defined and identified. Next, all possible questions were collected using brainstorming sessions with SCOPE WP7 team members via face to face meetings, teleconferences and emails. These collections were considered as source data for the three planned questionnaires.

2.3 Preparing draft questionnaires

In the second step of the development phase, the proposed questions were restructured using the following principles:

- Keep questions as simple as possible
- Avoid ambiguous, leading questions or those asking two questions in one
- Avoid questions on overly sensitive topics in order to get accurate responses
- Limit the number of questions to those absolutely necessary, so that questionnaires were not too long, but still able to fulfil their purpose

All three questionnaires contained closed[5] and open-ended[6] (free-text) questions.

Closed and open-ended questions are appropriate in different contexts and provide different types of information. Closed questions should be used where alternative replies are known, limited in number and clear-cut. Open-ended questions are used where the issue is complex, where relevant dimensions are not known and where the process/issue is being explored.

The main advantage of closed questions is that they are less time consuming for respondents to complete, and avoid misinterpretation. The main disadvantage of closed questions is that they may mislead if poorly designed.

The main advantage of open questions is their flexibility, however, the respondent may require more thought and time to answer.

As such, the three WP7 questionnaires primarily contained closed questions (Yes/No, Yes/No/Partially, single and multiple choice, and rating scales). Nevertheless, to get as much information as possible from MSs and not to limit response options unnecessarily, an 'Other' option in closed questions was generally included to allow for additional information and for NCAs to provide context to their answers, in case the selectable options were not appropriate. Furthermore, closed questions with a 'Yes' option were frequently accompanied by a gentle request to provide more details in free-text to reduce misinterpretation and maintain short, to-the-point, flexible questions. Nevertheless, it has not been evaluated whether adding these options carried any excess gain in the level of granularity of responses.

2.4 Piloting draft questionnaires

In the third step of the development all three questionnaires were tested using a PILOT trial, in order to avoid the problems mentioned above and improve global quality. Testing a questionnaire prior to use is strongly advised[7], following five general criteria:

- **Purpose**: One has to be absolutely clear about the purpose
- **Directness**: The questionnaire should ask questions that address as directly as possible the issue wished to be evaluated
- **Utility**: This criterion relates to the practicalities of implementing and using the questionnaire
- **Reliability**: A questionnaire is reliable if similar results would be obtained by others using the same questions and using the same sampling criteria (repeatability)

[5] **Closed or closed-ended question with ranked answers:** Questions in which all possible answers are identified and the respondent is asked to choose one or more of the answers.

[6] **Open or open-ended question:** Questions that allow the respondent to answer in any way they wish.

[7] M. Bloom and J. Fischer (1982) Evaluating practice: Guidelines for accountable professional. Prentice Hall, pp. 45-69

- **Validity**: A questionnaire is valid if it actually measures what it sets out to measure. Validity much depends on the quality of the questions themselves. Validity is not an absolute quality. A questionnaire can be valid to a certain degree in certain circumstances, and developers must decide (a priori) what degree of validity is considered sufficient[8].

Testing reliability was not applicable by the PILOT trial as all members of the target group (NCAs of EU MSs) were involved in the WP7 surveys.

Regarding the validity of questionnaires, the main purpose of the PILOT trial was to improve the content and linguistic validity of the three WP7 questionnaires. These two kinds of validity have an impact on internal validity of the questionnaire (a subject will respond to similar questions in a similar way). They also affect the likelihood of producing false positive or negative answers.

Nine NCAs (BG, CZ, ES, HR, HU, IT, LT, PT, UK) were invited in the testing phase of the development including NCAs participating in WP7 and agencies involved in other work packages (PILOT trial). They were asked to complete all three questionnaires via the online survey tool and asked to give feedback via email. All comments and proposed modifications received by email were analysed by the WP7 team and modifications/changes to the questionnaires were made.

2.5 Development of final questionnaires

As a result of this PILOT trial, final versions of the three questionnaires were produced by 22 January 2015 in online survey tools.

In the final step of the development phase, an introduction text was added to each questionnaire in order to support respondents. These texts described the purpose of the questionnaire, together with simple instructions on how to complete them, the deadline of responding/completing and a note of thanks to respondents for completing.

2.5.1 Setting and participants

Data capture

A single contact person was identified with his/her email address for each NCA. Only one response was accepted from each NCA via SurveyMonkey (an affordable, user-friendly web-based application for survey creation, distribution and analysis).

Twenty-nine invitation emails were sent from SurveyMonkey to contact persons on 23-24 January 2015. Twenty-seven of these invites were sent to active SCOPE partners, with two invites send to non-active SCOPE partners.

[8] K. Howard (2008) Validating questionnaires, Kestrel Consultants, Inc.
http://kestrelconsultants.com/reference_files/Validating_Questionnaires.pdf [Accessed 04/11/2015]

The questionnaires were also sent to the contact persons in Portable Document Format (PDF) format via email in order to discuss/delegate certain groups of questions with/to suitable person(s) within or outside a given NCA.

A one month period was left for respondents to complete the questionnaires. The deadline was set at 25 February 2015.

Two reminder emails were sent to all contact persons (on 16 and 23 February 2015).

Requests were received from some NCAs via email to modify the deadline for completing questionnaires (reasons included change of contact person). Therefore the deadline was extended twice in order to collect as much information as possible. The second and third (final) deadlines were set at 15 March 2015 and 15 April 2015, respectively.

General response rates

After the 1st and 2nd deadlines the response counts and rates were as follows (**Table 1** and **Table 2** below).

Table 1. Response counts and rates by the 1st and 2nd deadlines. Twenty-seven MSs were included in the survey.

Topic – Title of questionnaire	1st deadline		2nd deadline	
	Number of responses	Response rate (%)	Number of responses	Response rate (%)
1 – General QMS	19	70.4	25	92.6
2 – Resource management	18	66.7	21	77.8
3 – PV inspections	16	59.3	23	85.2

All twenty-seven active SCOPE MSs were expected to answer (100%); the response rates (%) by the final deadline were as follows (**Table 2**).

Table 2. Response counts and rates by the final, 3rd, deadline for the twenty-seven active SCOPE partners and 2 non-active partners

Topic – Title of questionnaire	Response count from 27 active SCOPE partners	Response count from 2 non-active SCOPE partners	Response count from all partners	Response rate (%)*
1 – General QMS	25	1**	26	92.6
2 – Resource management	26	0	26	96.3
3 – PV inspections	26	1**	27	96.3

*Response rates were calculated for active SCOPE partners (n=27)

**Although Topic 1 had a total of 26, and Topic 3 of 27 responses, there were only 25 and 26 responses from active SCOPE partners, respectively, with 1 additional response from a non-SCOPE partner in both cases. This additional response from a non-SCOPE partner is included in the survey discussions, but not in the response rate calculation as this was not an anticipated respondent.

The trend in responses justified the extension of deadlines given the high response rates and allowed a large amount of information to be gathered by the final deadline. **Figure 1** summaries these findings graphically and **Table 3** lists the MSs taking part in the survey.

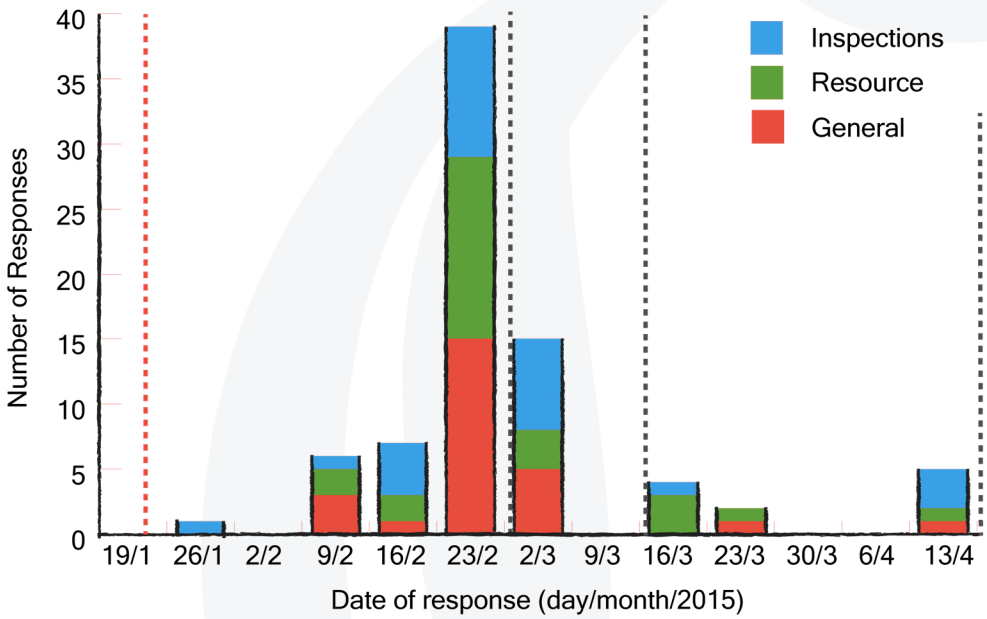

Figure 1. Trend of responses with starting dates and deadlines of responding

Far left, red dotted line = start date, with the following three grey lines = 1st, 2nd and 3rd deadlines, respectively.

Table 3. List of MSs who took part in the survey

Denmark	Croatia	Bulgaria	Latvia
Spain	Slovenia	Slovakia	Norway
Poland	Czech Republic	Belgium	Greece
Ireland	Finland	Romania	Hungary
France	Sweden	Portugal	Estonia
Malta	Austria	UK	
Lithuania	Netherlands	Italy	

Response rates of closed- and open-ended questions

Closed questions were mandatory to complete, but open-ended questions were not. Thus, the response rates were 100% regarding the closed questions but considerably less for open-ended. For example, the last two open questions (**Q48** and **Q49**) in the questionnaire were completed by only 16 and 14 respondents, respectively. Nevertheless success of the questionnaire was not judged on the rate of response to each question, as there were several questions linked and thus required a positive response for a lead question in the series to be able to proceed with the others. NCAs who provided a negative answer to the first question in a set of linked questions were therefore expected to skip the remaining associated ones. Furthermore, response rates of mixed (open and closed) questions were difficult to assess. Finally, responding to a question did not imply that the response given was relevant to the question. Several examples were found where MSs indicated 'Not applicable' or 'No' instead of leaving the response blank.

Factors that contributed to the success of the surveys

One important factor that contributed to the success of the WP7 surveys was the high response rate across the three questionnaires. Another is the careful preparatory work together with a PILOT phase allowing the exclusion of ambiguous questions. A third factor may be that the mixture of closed and open questions allowed MSs to add items to lists most relevant to their situation, and thus give more detailed explanations.

Challenging factors and limitations

Overall the survey reached its intended objectives. Nevertheless, there could have been improvements if some of the limitations had been eliminated or addressed.

Using too many free-text questions can be risky, as the willingness of respondents to give detailed responses cannot be predicted, i.e. the level of granularity of responses cannot be communicated to respondents. More active contributions from respondents and more detailed explanations on potential good practices and good examples were expected. Furthermore, free-text questions were skipped by a considerable amount of respondents (probably as they were defined as 'not mandatory').

Additionally, it was hard to control the content of free-text answers, and keep respondents linked to the issue in question. Interpretation of responses may also be difficult, in particular when responses are brief. In order to overcome these challenges, a consistent approach in data analysis was developed and is presented in the next section. Furthermore, when responses were ambiguous but essential to record, respondent NCAs could be contacted to clarify answers.

2.5.2 Data analysis

Methodology and display of results

SurveyMonkey was used for the WP7 questionnaires, and has inbuilt plotting capabilities. However, for all of the analyses in this report, questionnaire responses were exported into excel, and downstream data processing performed here.

Files were extracted from SurveyMonkey with the responses of each NCA, as identification of NCAs and linking them to their answers were necessary for assessors to have a deeper understanding and to present and discuss data in the most comprehensive way. Nevertheless, as already stated, data are presented and discussed in an anonymised way.

Data obtained from the questionnaire has been analysed by two assessors independently to ensure an unbiased assessment and presentation of data, paying special attention to free text questions and questions where answers required adjustments (detailed later on). When assessors were not in agreement, issues were discussed. Both assessors had a background in PV with some knowledge of quality management, for a better understanding and interpretation of responses. Assessors were cautious not to add any further meaning to any of the responses.

Single and multiple-choice, closed questions

For the display of results, pie charts were used for single choice questions and bar graphs for multiple choice. Tables were generally (but not in all cases) used for free text inputs to extract, summarise and present relevant responses.

Open-ended questions

There are many methods for evaluating open-ended (free-text) questions, e.g. to extract important keywords and visualise relationships among sentences[9] or to summarise results using hierarchical classification[10].

Our approach to the assessment of free-text responses used the following principles:

- Responses that were considered equivalent to leaving the question blank (i.e. responses of '-', 'No', 'Not applicable', No comments', etc.) were excluded.
- Content of responses were analysed by searching for keywords relevant to the question.
- Responses that, based on content analysis, did not add relevant information to the question were excluded.
- Relevant information from responses were summarised and presented arbitrarily by assessors to the best of their knowledge. The cross-checking of assessor interpretations were performed in all cases.
- Questions were free text responses are summarised are marked by an asterisk (*).

Challenges in data interpretation

Assessors encountered a number of challenges while analysing the data, including the following examples:

- Concise, list-like responses or keywords were hard to interpret by assessors not familiar with the internal procedures of a given MS.
- Analysis of a response where the question had been misinterpreted by the respondent.
- Response was uninterpretable for the assessor.

Usually, such responses were rejected or included only to a limited extent in the analysis. Furthermore, some questions might be interpreted only in context with other types of information that might or might not be available for the assessors. This was partially overcome by using data collected during a Work Package 1 (Project Coordination) survey in which MSs were asked general NCA operational questions. For example **Q9** in this survey asked NCAs to comment on whether their PV assessors and inspectors were based in the same departments or whether based in separate institutions (data not published).

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[9] Y. Uchida *et al.* (2009) Extraction of important keywords in free text of questionnaire data and visualisation of relationship among sentences, FUZZ-IEEE, pp. 1604-8.

[10] M. Garcia-Constantino, F. Coenen, PJ. Noble and A. Radford. (2012) Questionnaire free text summarisation using hierarchical classification. Research and Development in Intelligent Systems XXIX, Springer London. pp35-48

Definition of criteria for inclusion of topics for further investigation

In line with Section 1.10 (objectives), data obtained from the survey has been screened and analysed to identify any areas and information that could potentially be included in any of the three categories listed as objectives: good examples and practices, challenges, and lack of unified understanding of quality concepts requiring further clarification and guidance.

No specific inclusion criteria were defined, to avoid loss of information by setting up unnecessary limitations. A higher weighting was allocated to the interpretation of questions where multiple MSs provided the same response. These were flagged for inclusion in the proposals for further investigation.

3. Results/Findings

In total, 26 MSs responded (of a total of 29 invited) to the questions in this survey. Questions that were not answered by all 26 are highlighted.

3.1. High-level overview (Q1-7)

Summary points

- Approximately three quarters of respondents considered the number of Full Time Equivalents (FTEs) in their PV team were insufficient
- Over half of respondents have a formal documented process for feeding resource requirements into the annual business planning arrangements, based on the agency business plan and PV department needs
- Generally, workload forecast is based on planned applications, historical trends, industry forecasts, agency strategy and upcoming legislative requirements

The first set of questions aimed to gather high level information about EU NCAs in order to provide background data for the analysis of results. NCAs were asked to provide an organogram in **Q1**, highlighting the organisation structure of the PV department; however, these are not included in the report.

In **Q2**, which asked NCAs to provide the number of FTEs employed for PV activities, 26 MSs provided responses. Respondents were asked to provide the number of administrative staff, PV assessors and PV inspectors for each type of role and were given the option to include other roles.

The total number of staff for PV activities (administrative staff, PV assessors and PV inspectors) ranged from 2 to 46.2. The breakdown of staff counts into each respective role is shown in **Figure 2**, with the exact numbers presented in the Annex.

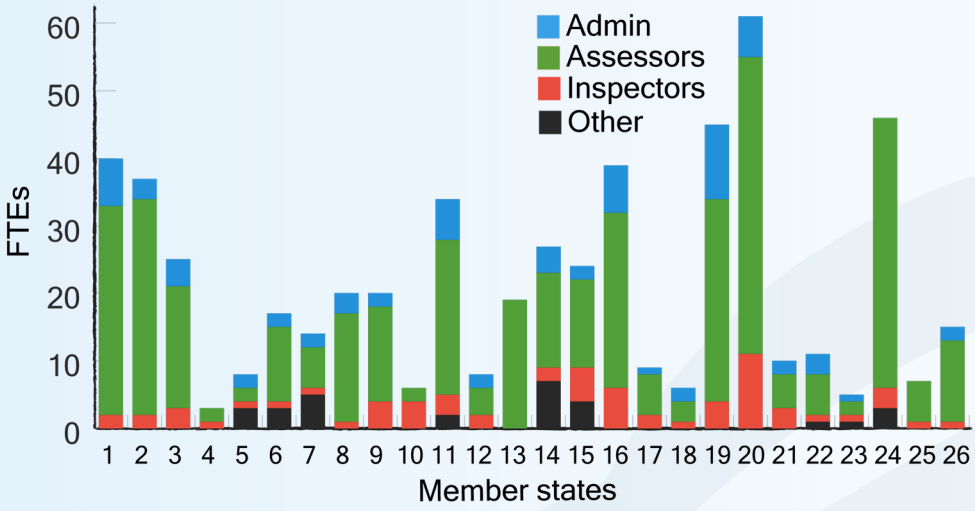

Figure 2. Responses to Q2: How many full time equivalents (FTEs) are employed for PV activities?

Some of the FTE counts were provided by MSs as non-integer values, this may account for staff that work across multiple departments. Apart from one MS who employs 61 FTEs, all remaining agencies employ fewer than 46 FTEs for PV activities. In fact, 8 MSs reported having <10 FTEs across all PV roles. The number of administrative staff tends to be lower, ranging from 0 to 11. The number of PV inspectors ranged from 0.5 to 11.

This information suggests that it is quite possible that the scope of the functions and responsibilities of the administrative role is different across NCAs.

Respondents also specified other roles such as pharmacists, physicians, data-managers, ADR case processing team, divisional head, quality officer, scientific officers, clinical assessors, graduate student, biostatistician and pharmacoepidemiologists.

Furthermore, it should be noted that several MSs have regional PV centres. Six MSs confirmed that medicinal products could be reported to regional centres in response to the survey for WP4 on ADR Collection, although it is difficult to determine whether respondents included FTEs for regional PV centres in response to this question. One respondent commented in free text that a separate organisation is responsible for ICSRs, highlighting different organisational structures of PV departments.

Q3 aimed to gather a high level understanding of the resources for operating PV systems across the EU network (**Figure 3**).

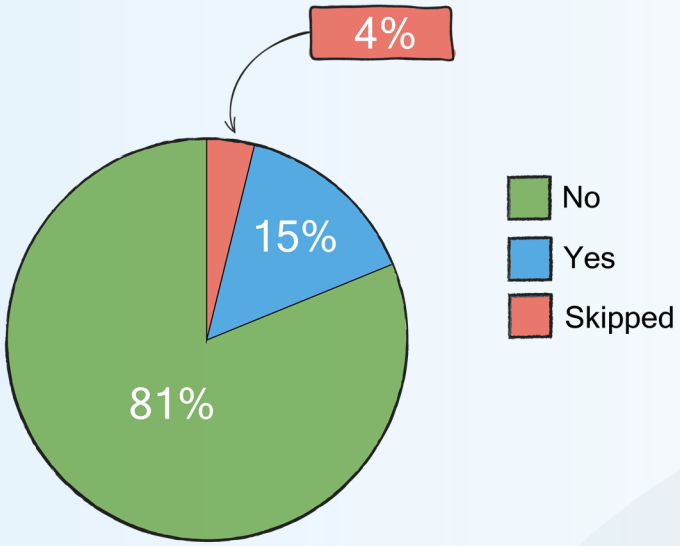

Figure 3. Responses to Q3: Do you feel that the number of FTEs you have allocated to PV is sufficient?

Twenty-one MSs responded that the number of FTEs was insufficient. The average number of FTEs involved in PV for these 21 MSs was 19.4 ± 15.9, however, the large standard deviation suggests that many agencies have this opinion irrelevant of the number of FTEs they employ. Indeed, one of the NCAs that suggested they required more PV staff had a total of 61 FTEs already allocated to them. As might be expected, this confirms that resources management dedicating to operating PV systems is a challenge for the majority of MSs.

Respondents who selected 'No' were asked to propose the number of additional FTEs required for a fully effective PV team. The number of additional FTEs ranged from 1 to 20. One respondent noted that it was difficult to answer this question as they are generally able to manage their workload, delivering high quality within deadlines, however, sometimes PV work that falls outside of regular procedures could benefit from more FTEs. The same NCA referenced earlier, who had 61 FTEs associated with PV activities suggested an additional 10 were required. Whereas an NCA who had a total of 8 PV FTEs only suggested an additional 3 FTEs was required. This highlights the different organisational structures of the PV departments in the NCAs and differences in the volume of procedures between different NCAs.

The next set of questions (**Q4-7**) aimed to understand how resource requirements for PV are determined within NCAs.

Q4 asked MSs if there is a formal resource management process within the quality management system (QMS) for feeding resource requirements into the annual business plan (**Figure 4**).

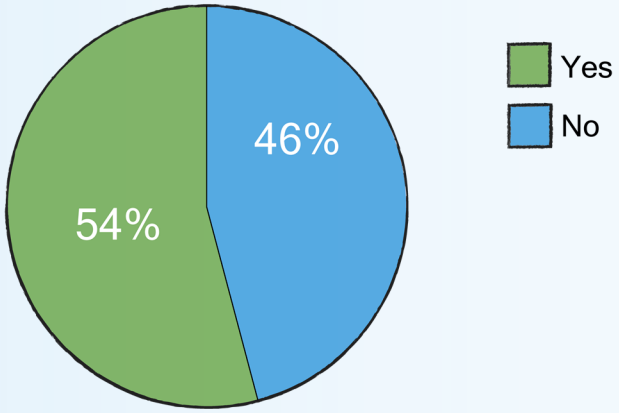

Figure 4. Responses to Q4: Is there a formal documented process within your quality management system for feeding resource requirements into the annual business planning arrangements?

The response to this question was almost equally divided, with 14 (54%) of respondents confirming that they have a formal documented process within the QMS and 12 (46%) confirming their processes are not documented.

Q5 explored this topic further by asking MSs how resource requirements fed into their agency's planning cycle, aiming to understand if resource requirements are based on the PV department needs.

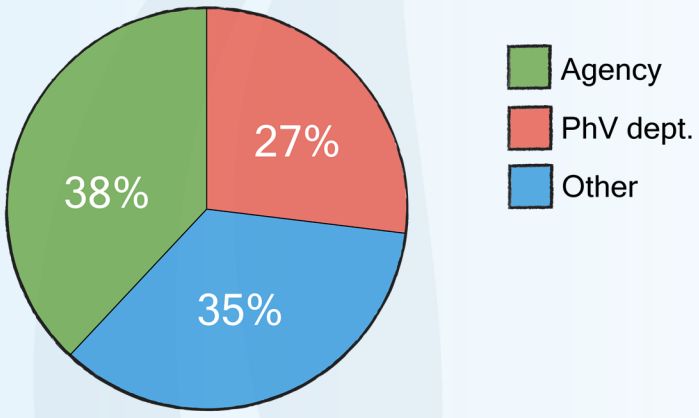

Figure 5. Responses to Q5: How do resource requirements feed into your Agency's business planning cycle?

Ten (38%) respondents stated that resource requirements are based on the priorities of the agency business plan and seven (27%) respondents stated that resource requirements were based on their PV needs. Many of the comments in free-text stated that both the agency's business plan and PV needs applied. In addition, several respondents commented on restrictions imposed by governments. Interestingly, this could possibly explain the response to **Q4** with the number of MSs stating that they do not have a formal documented process within the QMS for resource requirements. One NCA commented that resource requirements should ideally be based on the PV department needs, but that their agency business plan has a strong influence.

One particularly detailed response was considered an example of good practice.

Example

'Each unit head makes an annual (department) plan with goals (put into practise strategic business plan ambitions at Agency level) including a budget proposal. Internal resource allocations are based on needs and expectations and are attached to the defined objectives/goals in the annual plans of each unit. For flexibility and knowledge building temporary employees are contracted and an appeal is done on covenants (academic institutions and university hospitals). Priorities, goals and measures are set after several rounds of talks with the Management Team. Resources needed from subcontractors are also part of this budgeting process. Subcontractors (infrastructural resources, human resources partly) are evaluated or a Service level agreement is in place.'

Forecast of workload is a challenging yet critical component of business planning for PV. MSs were asked about how they estimate/forecast workload in **Q6**.

Q6: How do you estimate/forecast workload?

Answer options (multiple choice)	Response percent	Response count
Based on planned applications	34.6%	9
Based on historical trends	23.1%	6
Other, please specify:	42.3%	11
Answered question		26

The majority of MSs stated that forecasting is based on planned applications, while 6 MSs estimate/forecast workload is based on historical trends. Additionally, in the free-text comments many respondents indicated that they used both planned applications and historical trends to estimate workload. Other factors used to estimate/forecast workload included industry forecasts, upcoming legislative requirements and agency strategy/internal priorities.

Q7 asked MSs whether their organisations had a capacity plan. A capacity plan describes how to make the best use of the available resource in order to achieve the intended outcome, and where appropriate to define the need for additional resource. Fourteen MSs confirmed that their organisations have a capacity plan.

Q7: Does your organisation have a capacity plan?

Answer options (single choice)	Response percent	Response count
Yes	53.8%	14
No	46.2%	12
Answered question		26

3.2 Recruitment, training and development (Q8-17)

Summary points

- Internal, external, on-the-job training and mentoring are used to develop PV staff
- Nearly three quarters of respondents develop a unique training plan for new staff
- Nearly two thirds of respondents develop a continuous development plan for experienced staff
- Just over three quarters of respondents have a performance measurement system in place
- Just over a third of respondents measure the effectiveness of training through 'formal evaluation'
- Around two thirds of respondents provide training on an 'ad hoc' basis

Questions 8 to17 aimed to gain an understanding of the recruitment, training and development of PV staff.

The responses to **Q8** for the essential selection criteria used when recruiting administrative staff, PV assessors and inspectors are presented in Table 4.

Table 4. Responses to Q8: What are the essential selection criteria when recruiting new staff?

Example: education/qualification (graduate, diploma specific experience), 1-2 yrs/3-5 yrs experience? Any additional information provided by MSs is also presented in the 'other' column. Those answers that were summarised are highlighted with an *.

MS	Administrative staff	Pharmacovigilance assessors	Pharmacovigilance inspectors	Other, please specify
1	Academic staff	Graduate staff	Graduate staff Lead auditor education*	
2	Education General experience	Education Relevant experience*	Education Relevant experience*	
3	Admin experience Computer literate*	Graduate degree in medicine/pharmacy Full registration Clinical experience* Research experience*	Graduate science degree* 2 yrs relevant experience	Scientific Officer: 3rd level science degree 2 yrs relevant experience
4		Graduate degree in medicine/pharmacy 5 years relevant experience*	Graduate degree in medicine/pharmacy 5 years relevant experience*	
5	Higher education*	Graduate degree Regulatory experience	Graduate degree 3 yrs regulatory experience	
6		Education English language	Education English language	
7	Higher education* Computer literate English language	Graduate/Post-graduate degree in biological sciences* Computer literate English language Relevant experience	Graduate/Post-graduate degree in biological sciences* Computer literate English language 3 yrs relevant experience Communication skills	

MS	Administrative staff	Pharmacovigilance assessors	Pharmacovigilance inspectors	Other, please specify
8		Graduate education Relevant experience	Graduate education Certification exams (inspector, offence proceedings)*	Requirements are defined by the internal Rule on Organisation and Systemisation All staff involved in administrative procedures are obliged to pass exam on General Administrative Procedure Act*.
9	Interpersonal skills*	Graduate degree in medicine/pharmacy *	Relevant experience	Personal interview to assess qualities such as brainpower, work ethics, interest and motivation
10	Graduate/Post-graduate degree in science*	Graduate degree in medicine	Not employed by PV department	
11	Education	Education Relevant experience*	Graduate pharmacist or pharmaceutical experience PV/ audits experience	
12	Higher education	Graduate education 2 yrs Relevant experience*	Graduate education 2 yrs Relevant experience*	
13		Graduate degree in medicine/pharmacy /statistics English language		
14		Graduate degree in medicine/pharmacy /science* Relevant experience* English language Computer science*	Graduate degree in medicine/pharmacy /science* Relevant experience* English language Computer science*	

MS	Administrative staff	Pharmacovigilance assessors	Pharmacovigilance inspectors	Other, please specify
15	Graduate degree	Graduate education 1-2 yrs relevant experience	Graduate education 1-2 yrs relevant experience	
16	Graduate degree*	Graduate education* Relevant experience	Graduate education* Relevant experience	
17	Higher education* Computer literate	Graduate education 1-2 yrs relevant medical experience Computer literate	Graduate education 1-2 yrs relevant medical experience Computer literate	
18	Higher education*	Graduate degree	Graduate. New staff have a specific training period of qualification as an observer and inspector (6 months) and as a coordinator inspector (1 yr)	
19	Graduate degree Interpersonal skills* Experience in customer service* Research skills*	Graduate degree in chemistry/medicinal chemistry/pharmacology/nursing/physiology Analytical skills	Graduate degree in a life science Relevant experience in a pharma regulatory environment and/or auditing	Associate signal assessor: Graduate degree in pharmacy/pharmacology/nursing/physiology/toxicology/science*
20	Higher education or Graduate degree	Graduate/Post-graduate degree* Computer literate English language	Graduate/Post-graduate degree* Computer literate English language	Some jobs require specific skill sets*
21	Education	Education 3 to 5 yrs relevant experience	Education General experience	
22	General experience	Graduate degree Relevant experience	Relevant experience*	

MS	Administrative staff	Pharmacovigilance assessors	Pharmacovigilance inspectors	Other, please specify
23				Public sector personnel (administrative and scientific) are selected by an independent authority based on qualifications and experience
24	English language Experience in life sciences/medicine is an advantage	English language Degree in life sciences/medicine is an advantage*	Graduate degree in medicine/ pharmacy	No specific criteria Experience in life sciences/medicine is an advantage
25	Medical doctor 3 yrs relevant experience	Medical doctor	Medical doctor/pharmacist	

In general, for administrative staff, the majority of NCAs specified the essential selection criteria included high school graduate/diploma, knowledge of the English language and computer literacy. NCA 25 indicated that their criteria includes *'medical doctor, with at least 3 years' experience'* and NCA 10 specified a post-graduate science degree, specifically a *'master of science'*. Both of which may require clarification, it's possible that the administrative staff also perform assessor duties and therefore require graduate education. Indeed, in **Q2** this MS reported 0.25 FTEs covered administrative work, suggesting that there is significant sharing of responsibilities in their PV department. NCA 8 stated that all staff involved in administrative procedures are obliged to pass an exam on the *'General Administrative Procedures Act'*.

For PV assessors, most respondents confirmed that the essential selection criteria include graduate staff with a degree in medicine, pharmacy or closely related scientific discipline. Good command of the English language and computer skills were also required by some NCAs. In addition, three NCAs also specify 1-2 years relevant experience with two NCAs specifying greater than 3 years.

For PV inspectors, most respondents confirmed that the essential selection criteria include both a degree and specific work experience. Work experience is an important essential selection criterion for PV inspectors e.g. pharmaceutical orientated regulatory environment and/or auditing experience. One NCA commented that applicants are required to pass both an inspector certification exam within the first six months and a certification exam related to offence proceeding. One NCA commented that there is a training period as an observer, as an inspector (6 months) and as a coordinator inspector (1 year). Good command of the English language together with computer skills were also listed as additional criteria.

In **Q9**, MSs were asked what training takes place to induct new staff, and if a unique training plan is developed for new staff is it tailored to their education and work experience in **Q10**.

Q9: What training takes place to induct new staff?

Answer options	Response count
Internal training	25
External training	25
On-the-job training	25
No training	0
Other, please specify:	5
Answered question	26

There was a uniform response to **Q9** (multiple choice) on training to induct new staff. Internal, external and on-the-job training were all selected by 25 respondents. Two MSs use mentoring to induct new staff. Other responses included auto training based on GVP modules and the European Medicines Agency's (EMA) assessor training.

Q10: Is a unique training plan developed for new staff tailored to their education and work experience?

Answer options (single choice)	Response percent	Response count
Yes	73.1%	19
No	26.9%	7
If Yes, please provide an anonymous example		14
Answered question		26

In response to **Q10** on whether a unique training plan is developed for new staff, 19 MSs responded 'Yes'. 14 MSs provided feedback on the request for anonymous examples and mentioned mentoring, individual training and development plans, EudraVigilance training, EudraVigilance Data Analysis System (EVDAS) training and basic training with the individual study of some Standard Operating Procedures (SOPs) followed by questionnaire based training for new staff.

MSs provided the following detailed examples of good practice regarding training plans for new staff.

Example 1

'Each new staff member is provided with an individual induction plan relevant to his/her education and work experience and tailored towards the specifications of his/her new role. This plan includes training on the quality management systems, practical training on the document management and workflow systems and comprehensive guidance, training and mentoring on all pharmacovigilance activities that he/she will be engaging with as part of the new role. Training plans are developed both for induction training of new entrants and for task specific training for core pharmacovigilance processes. Whereas training plans are standardised according to QMS templates, the plan is adapted for the individual staff members according to previous experience.'

Example 2

'Every new employee is provided with the 6 month education plan under mentorship. The educational plan is developed by the mentor and approved by the head of division prior to the first working day of the new employee. The educational plan during mentorship includes only internal training. It is tailored to cover general and specific areas relevant for the new employee.

The general areas include:

- *The most important structures and processes within the Agency,*
- *Legal and regulatory environment in general and specifically regarding pharmacovigilance (both EU and national)*
- *General overview of all pharmacovigilance processes and relevant SOPs.*

Specific areas of training of an employee are decided upon on a case-by-case basis, based on the requirements of the specific position and the working experience of the new employee.'

Example 3

'General training for all new staff: presentation of the Agency and the tasks (visiting all departments of the Agency), SOPs and working instructions (general), legislation (Medicinal Products Act, General Administrative procedure Act…), conflicts of interests….

On-the-job training depends on the working area: SOPs and working instructions of the area, legislation, plan for trainings and seminars to gain specific knowledge is made by head of relevant sector/department; senior assessor as mentor work with new employee; peer review, self-training.

New employee has probation job training (3 to 6 months), this is reviewed at the end of the provisional time period.'

MSs were asked what ongoing training takes place for experienced PV staff (**Q11**) and if there is a continuous development plan for staff, tailored to their needs or career aspirations (**Q12**).

Q11: What ongoing training takes place for experienced pharmacovigilance staff to ensure professional development?

Answer options	Response count
Internal training	21
External training	26
On-the-job training	22
No training	0
Other, please specify:	3
Answered question	26

The majority of MSs provide ongoing training for experienced PV staff, with all NCAs using external training sources for this. On-the-job training takes place in 22 MSs and internal training in 21 MSs. In free-text comments respondents indicated that there is regular internal training to continue professional education, presentations on all aspects of regulatory and clinical developments, and peer review and assessor's training.

Q12: Is a continuous development plan developed for staff tailored to their needs of career aspirations?

Answer options (single choice)	Response percent	Response count
Yes	65.4%	17
No	34.6%	9
If Yes, please provide an anonymous example		12
Answered question		26

In response to **Q12** on whether a unique training plan is developed, the majority (65%) responded 'Yes'. In comparison, this response rate is slightly lower than for the same question asked of new staff (see **Q10**). In free text comments respondents mentioned examples such as continuous development plans, Individual Professional Development Programmes, cyclical performance programmes, individual training and development plans, personal development plans, programmes for leadership and senior expert careers and three year training planning.

One MS provided the following example of a continuous development plan.

Example

'There are two basic types of learning and development in our Agency:

- *Scientific (academic) development (education)*
- *Training*

Scientific (academic) development is defined in Agency Ordinance on scientific development which describes the terms and conditions. The annual program of this development is a part of Annual Business Plan and is approved by Management Board of the Agency.

Training is managed as defined in the SOP "Staff training". Training can cover different aspects/areas such as:

- *Training of new staff/staff that changed position within the Agency (with appointed mentor that has to create specific training plan, and monitor implementation of the plan)*
- *Continues improvement designed for specific job position (participation on congresses, seminars, workshops, counselling, courses)*
- *Health & Safety training*
- *IT training*
- *Foreign language courses*
- *Additionally, special team building trainings are used as a tool for staff motivation.'*

Q13 asked MSs whether their organisation has a performance measurement system, such as an appraisal system, for staff development.

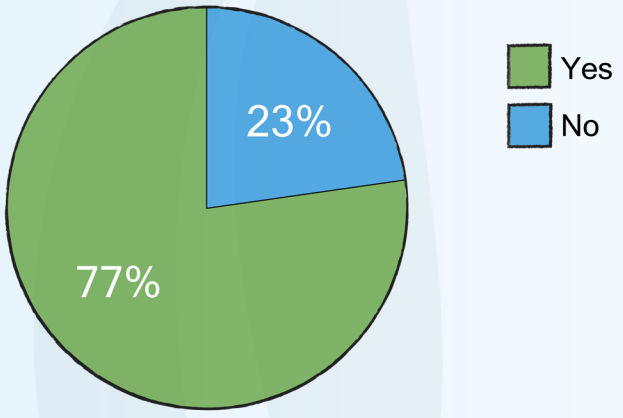

Figure 6. Responses to Q13: Does your organisation have a performance measurement system, such as an appraisal system, for staff development?

Twenty-six MSs (77%) confirmed that they have a performance measurement system in place. Most NCAs have annual evaluations with a focus on continuous improvement and individual development. In free-text comments respondents explained the use of key performance indicators (KPIs), evaluation parameters in terms of results and skills and assessment of performance through scores.

However, it should be noted that six MSs (23%) indicated that they do not have a performance measurement system in place. One MS indicated that the implementation of the performance measurement system had been initiated within their agency within the last year. In the latter case, training had been provided and career development discussions were planned for later during the year to define group education.

Q14 asked MSs to specify courses/sources of information considered the most important for training in PV (**Figure 7**).

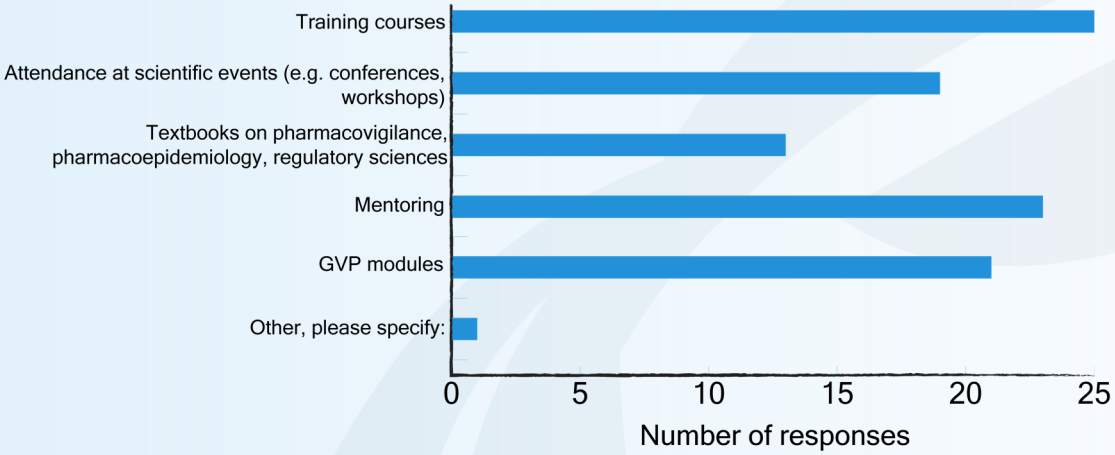

Figure 7. Responses to Q14: please specify what courses/sources of information you consider the most important for training pharmacovigilance.

There was an even spread of responses with 25 for 'training courses', 23 for 'mentoring', 21 for 'GVP modules', 19 for 'attendance at scientific events (e.g. conferences and workshops)' and 13 for textbooks on PV. In free-text comments respondents mentioned on-the-job training and the opportunity to present at EU meetings where appropriate as most important for training in PV.

Questions 15 to 17 were a series of questions asking MSs about the measures they have in place to monitor the effectiveness of training, the frequency of training and the minimum number of training days set for staff.

Q15: What measures are in place to monitor the effectiveness of training?

Answer options	Response percent	Response count
Formal evaluation	42.3%	11
None	26.9%	7
Other, please specify:	30.8%	8
Answered question		26

Table 5. Free text responses provided by MSs in Q15: 'Other'

Respondent	'Other'
1	Formal evaluation of the quality of training is assessed by the attendee. However there is no formal evaluation of training effectiveness.
2	Mentoring of staff during ongoing procedures, one-on-one meetings, peer review of assessment reports, discussion of assessments and issues at regular team and interdepartmental meetings. Following the completion of a formal training course each staff member is required to complete a training evaluation form to rate the usefulness and relevance of the training course.
3	The effectiveness of training is evaluated every year during the process of evaluation of employees.
4	Follow-up by manager
5	Formal evaluation of external training is monitored by back to office reports to colleagues Fulfilment of annual training plan is monitored in appraisal interviews
6	Ad hoc evaluation depending on the specificity and the objectives of the training
7	Formal and/or informal evaluation

From **Q15**, 11 (42%) MSs stated that they measure the effectiveness of training through 'formal evaluation'. In free text comments respondents indicated that some MSs have formal evaluation of the quality of the training but not the effectiveness or that there is formal evaluation but this is not standardised (**Table 5**). Other MSs commented that there is both formal and informal evaluation within their agencies or that that there is 'ad-hoc' evaluation.

In **Q16** Over half of responding 16 (62%) NCAs confirmed that the frequency of training is 'ad-hoc' with only 7 (27%) MSs providing regular training. One NCA noted that the frequency of training is both regular and 'ad-hoc' and a further MS noted that regular training includes continuing professional development sessions.

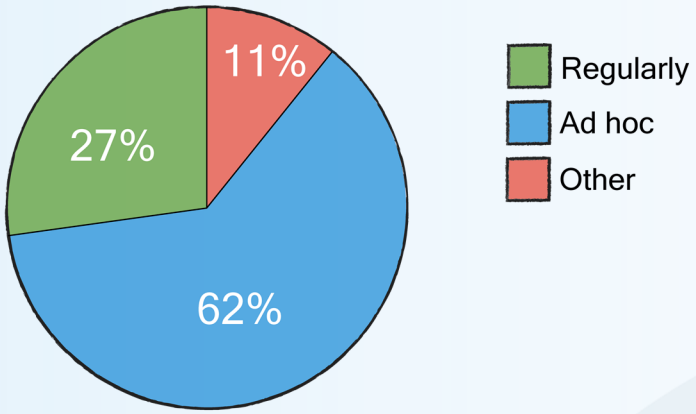

Figure 8. Responses to Q16: How frequently do you provide training?

MSs were asked to specify how often training is provided if marked 'regularly' in **Q16** (**Table 6**).

Table 6. Free-text responses from Q16: Comment on how often training is provided

Respondent	Comment on how often training is provided
1	Ad hoc training as monthly seminars, specific pharmacoepidemiological training with an external provider
2	In house continuing professional development training on a monthly basis (regulatory and scientific topics)
3	Annual education plan based on individual need
4	External training at least once per year, internal training on an ad-hoc basis
5	5 times a year, full or half day training organised on particular topics
6	Annually especially for pharmacovigilance inspectors
7	At least yearly, but in general 2 to 3 times a year
8	Internal lectures on medical/regulatory topics 2-4 times a year

Q17 asked MSs about whether there is a minimum number of days training and to specify the number of days when applicable.

Q17: Do you have a minimum number of days training set for your staff?

Answer options	Response percent	Response count
Yes	30.8%	8
No	69.2%	18
If Yes, please specify the number of days per year:		7
Answered question		26

Approximately two thirds 18 (69%) MSs do not have a minimum number of days training set for the year. Approximately, a third of respondents, 8 (30%) MSs have a set number of training days for staff and further information on the minimum number of days is provided in **Table 7**.

Table 7. More details regarding the minimum number of days training provided

Respondent	If Yes, please specify the number of days per year
1	For pharmacovigilance inspectors 10 days a year, others as required
2	10 days
3	At least 15 days on the job for initial training
4	All staff are recommended to have a minimum of 5 days a year
5	10 days for inspectors, 7 days for assessors, 2 days for administrative staff
6	For new staff – 4 months of training period, depending on tasks

3.3. Resource allocation (Q18-23)

Summary points

- Legal and regulatory requirements, the impact on public health, public interest and the role in the assessment process are taken into account when allocating resources
- If there is limited resource, cases where the NCA is the lead MS/PRAC rapporteur for the procedure are prioritised
- Commonly used methods to meet peaks in workload include re-assigning staff and additional working hours. Cross- training and short term contracts are also used but these may have a short term negative impact on established resource as new team members are supported and settled in.

The next set of questions (18-23) aimed to gain further understanding of resource allocation within NCAs.

Q18 asked NCAs to confirm how PV staff were assigned to PV activities (**Figure 9**).

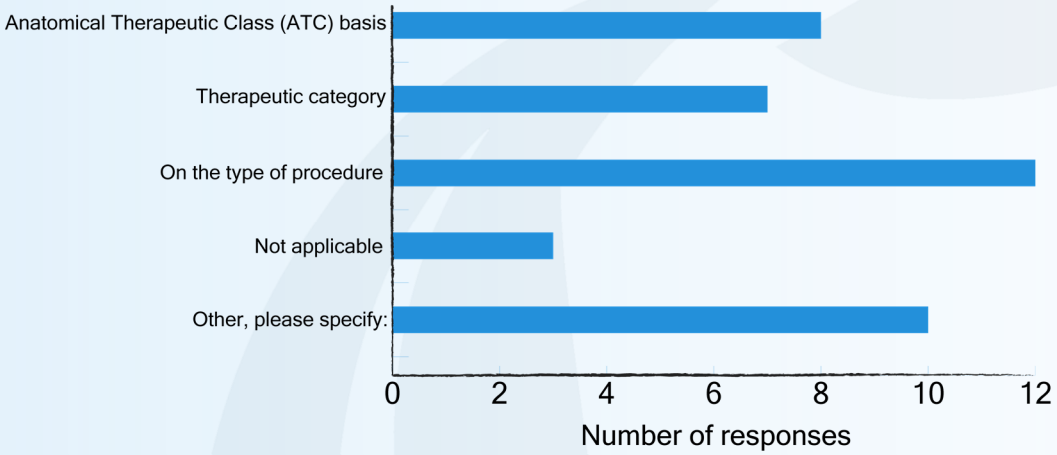

Figure 9. Responses to Q18: How are pharmacovigilance staff assigned to pharmacovigilance activities?

Twelve respondents assign PV staff to activities based on the type of procedure, eight respondents based on anatomical therapeutic class and seven based on therapeutic category.

In free-text comments respondents mentioned that staff are assigned to PV activities based on the experience with certain types of PV issues/specific products, specific expertise e.g. toxicology, medication errors, pregnancy, addiction and also depending on availability and urgency of the matter. Others indicated that there is no special assignment.

In **Q19** NCAs were asked to describe any tools used to support decision making for allocation of resources and asked how workload is prioritised (**Figure 10**).

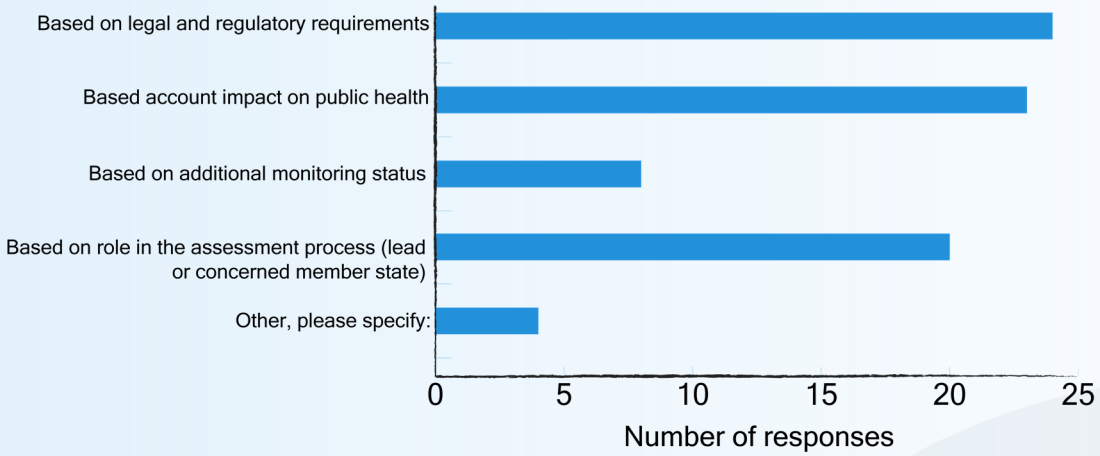

Figure 10. Responses to Q19: Please describe any tools used to support decision making for allocation of resources. How do you prioritise workload?

Overall, legal and regulatory requirements, the impact of public health, and the role in the assessment process are taken into account when allocating resources by at least two thirds of MSs. Only eight NCAs take into account the additional monitoring status of the product when allocating resource.

There were no comments on tools to support decision making for allocation of resources. In free-text comments respondents explained that workload is prioritised based on availability, on specific products (case by case basis), expected media impact and that priority is given to issues with great public interest and attention.

Q20 asked NCAs to select the priority of the nine PV activities (from low 1 to high 5) and **Q21** asked NCAs to answer the same question in cases of insufficient resource. NCAs were also given the option to include other PV activities (**Figures 11** and **12**).

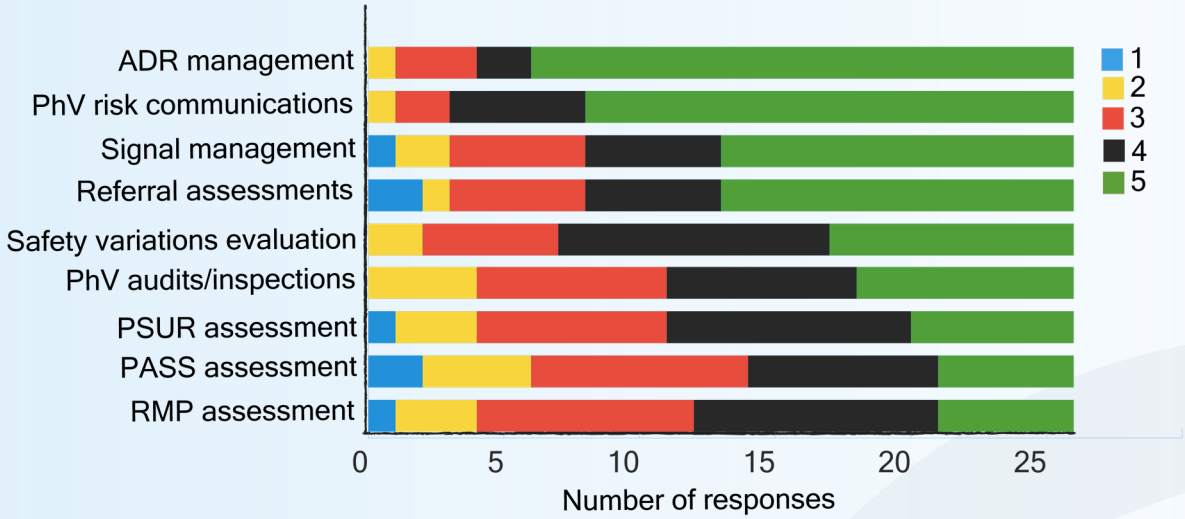

Figure 11. Responses to Q20: Could you please select the priority of the following pharmacovigilance activities.

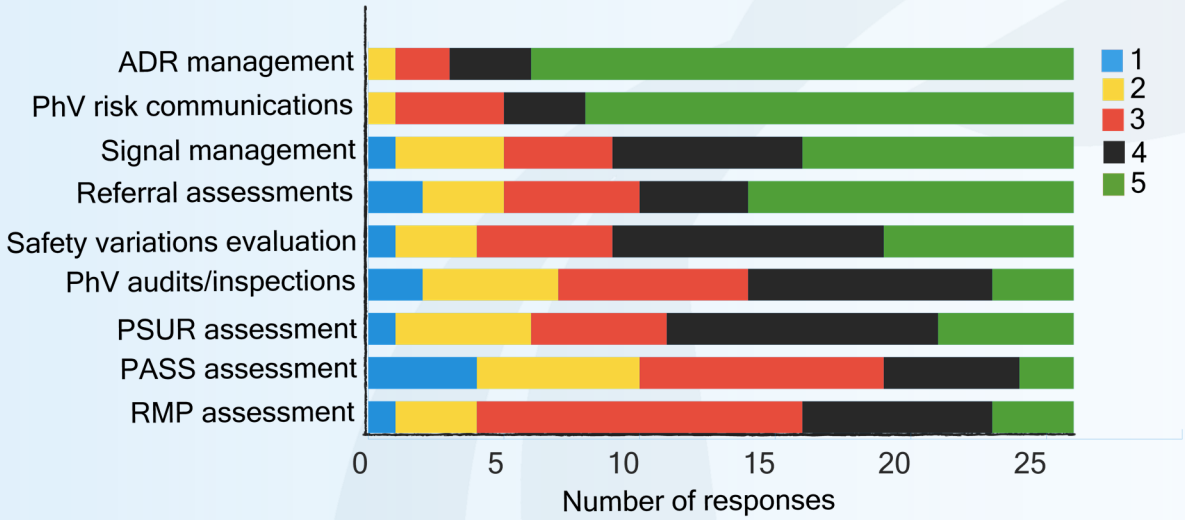

Figure 12. Responses to Q21: In the case of insufficient resource, could you please select the priority of the following pharmacovigilance activities in terms of allocation of resource.

Table 8. Mean ratings for each PV activity from Q20 and Q21, ± standard deviation (SD)

PV activity	Q20 (mean ± SD)	Q21 (mean ± SD)
Risk management plan assessment	3.54 ± 1.05	3.31 ± 0.95
Post-authorisation safety studies	3.35 ± 1.17	2.81 ± 1.14
Periodic safety update reports	3.62 ± 1.08	3.50 ± 1.12
PV audits/inspections	3.73 ± 1.06	3.23 ± 1.12
Safety variations evaluations	4.00 ± 0.92	3.73 ± 1.09
Referral assessments	4.00 ± 1.24	3.81 ± 1.33
Signal management	4.04 ± 1.16	3.81 ± 1.21
PV safety communications	4.54 ± 0.80	4.46 ± 0.89
ADR management	4.58 ± 0.84	4.62 ± 0.79

ADR management was ranked as highest priority by the majority of MSs, with safety communication closely behind. Post-Authorisation Safety Studies (PASSs) and risk management plans were ranked as the least important.

The average priority for the ratings for the listed PV activities were calculated for **Q20** and **Q21**. Under normal conditions, ADR management (average rating 4.58) and safety communications (average rating 4.54) were rated as high priority. Of note, the results for signal management, referral assessment and safety variations are the same (ca. 4). PV audit/inspection (3.73) was rated higher than Periodic Safety Update Reports (PSUR) assessment (3.62), risk management plan assessment (3.54) and evaluation of post authorisation studies (3.35).

The biggest spread of data (standard deviation) was associated with the rating scores for referral assessments, thus suggesting MSs have differing opinions on rating this task. Conversely, the most unanimous rating was for PV safety communications and ADR management.

In free-text comments respondents for **Q20** included additional PV activities such as PV assessment for registration branch (new authorisations, renewals, variations), answering enquiries about drug safety' and 'safety assessments (renewals, variations)'. One MS selected a priority of 1 for 'National implementation of risk minimisation'. Another MS selected a priority of 1 for 'training to stakeholders', 2 for 'internal development of IT systems supporting PV activities' and 3 for 'development of QM of PV'.

There were some subtle differences when the same question (**Q21**) was asked for rating processes in the cases of limited resource (**Table 8**). Interestingly, priority changes do not balance out in times of insufficient resources i.e. some tasks decreased in priority and others increased. Instead, all tasks apart from ADR management decreased in priority. Five MSs provided free-text responses for **Q21**. An observation noted by two MSs is that in times of insufficient resource any cases where the NCA is the lead MS/ Pharmacovigilance Risk Assessment Committee (PRAC) rapporteur for the procedure would be prioritised.

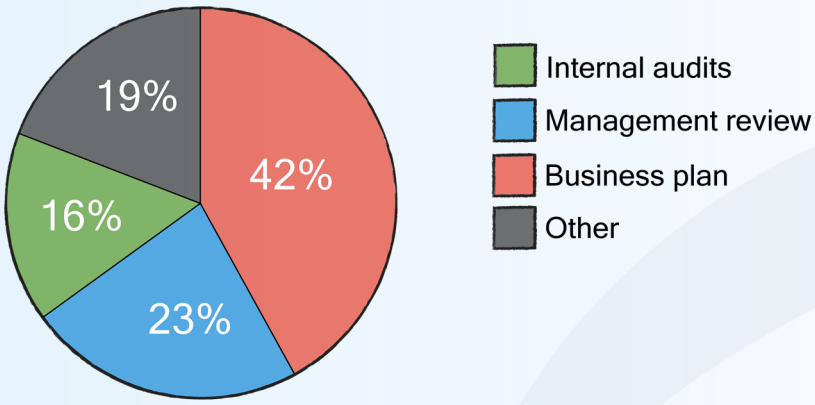

Figure 13. Responses to Q22: How often is resource allocated to pharmacovigilance activities reviewed?

In response to **Q22**, resource allocated to PV activities tends to be reviewed as part of the business planning process (11 MSs). Six MSs review resource allocation during management review and four during internal audit. In free-text comments respondents explained that the review process regarding resource allocation is ongoing and when possible due to the current restrictions of the public administration. In addition, two respondents indicated that resource allocation is reviewed annually as part of business planning, however also through management reviews and internal audit. One MS explicitly stated that allocation of resources in not based on workload and thus no review is carried out to adjust for workload changes.

Q23 asked MSs to describe any tools used to ensure optimum use of resources and whether arrangements are in place to meet peaks in workload.

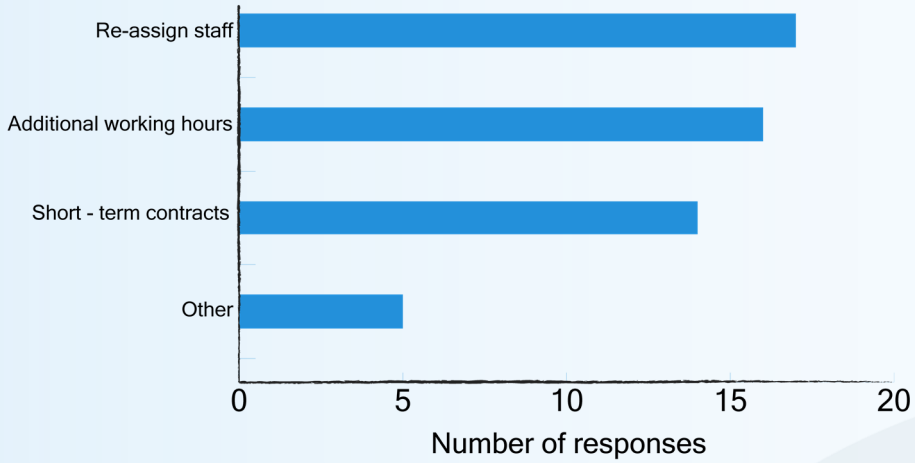

Figure 14. Responses to Q23: Please describe any tools you use to ensure optimum use of resources. What arrangements are in place to meet peaks in workload?

There was a good agreement regarding arrangements in place to meet peaks in workload: 18 respondents re-assign staff, 17 rely on additional working hours and 14 on short-term contracts. In free-text comments respondents provided details such as cross-training of staff to ensure competence in a number of process areas, prioritisation of activities when required, outsourcing to regional PV centres, contracts with external experts and staff re-assignment. One MS indicated that there are no formal arrangements in place due to restrictions of public administration.

3.4 Succession planning (Q24-25)

Summary points

- Allocation of interesting work, training and projects help to improve staff commitment and morale
- Most respondents have either a low or medium level of succession planning

Questions 24 and 25 aimed to develop an understanding of the level of succession planning within NCAs.

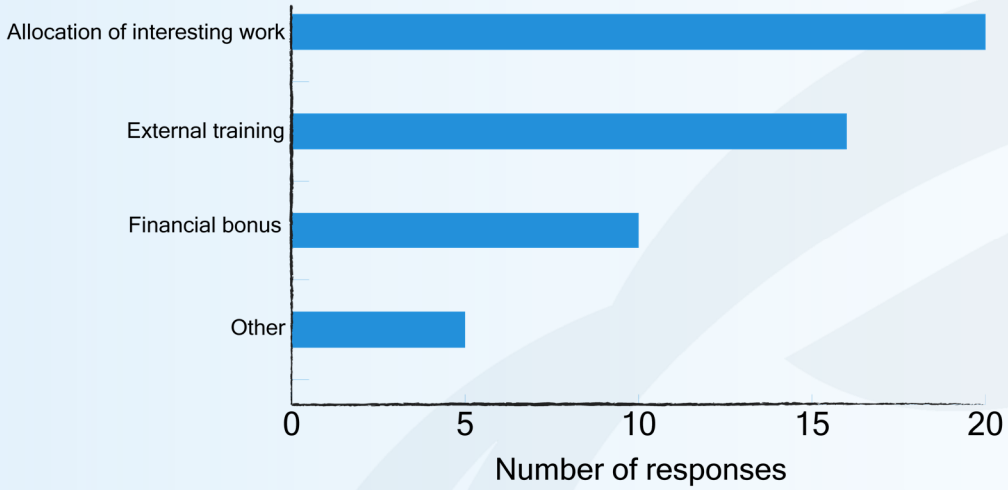

Figure 15. Responses to Q24: What arrangements are in place to improve staff commitment?

In response to **Q24**, in terms of what arrangements are in place to improve staff commitment, the highest factor was the allocation of interesting work (20 respondents) followed by external training (16 respondents). Less than half of respondents (10 respondents) considered financial bonus systems as an arrangement to improve staff commitment. In free-text comments respondents provided details such as 'career development plans', 'internal training' and 'projects to focus on areas of specific concern'. Two respondents commented that no arrangements are in place due to restrictions of the public administration.

Q25 asked MSs about the level of succession planning within their agencies. The following definitions were provided:

Planning	Definition
None	Dealt with after staff departs
Low	Only the most senior position considered
Medium	Manager positions considered
High	All positions considered

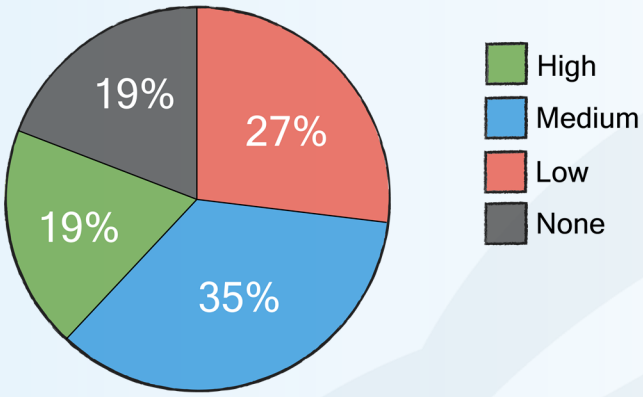

Figure 16. Responses to Q25: What level of succession planning does your organisation undertake?

The majority of respondents indicated that there is a medium or low level of succession planning. Five NCAs have a high level of succession planning and five NCAs have none.

3.5 Challenges and good practice in resource management (Q26-27)

Summary points

- Many respondents stated that austerity measures have impacted on the resources
- Challenges include managing peaks in workload and unplanned work
- Staff retention is an issue for many NCAs
- Good practice includes mentorships for new employees, staff rotation and the use of formal planning tools
- Solutions include short-term contracts, additional working hours, cross-training to ensure flexibility, much of this requires collaborative team work

The final two questions asked MSs to describe any challenges faced in managing resources and the solutions they impose to overcome them which may be used as good practice examples.

Q26 received 18 free-text responses and **Q27** received 14 free-text responses. The responses for **Q26** and **Q27** are provided in **Table 9** below.

Table 9. Free-text responses from MS regarding challenges faced during resource management

MSs	Challenges or problems you have encountered and solutions	Any aspects that you considered is particularly helpful or good practice
1	Trained staff usually move to industry	N/A
2	Difficult to find/ train staff for maternity cover (up to 4 years)*	High motivation for interesting work*
3	Limited resources due to austerity	N/A
4	In order to be able to fulfil the new requirements set by the pharmacovigilance legislation, a significant number of new staff were employed for approximately one year.	The mentorship system which lasts for 6 months for new employees is very useful for both training the new employee to be able to perform their tasks independently and for controlling the workload of the mentor.
5	Headcount is defined by the state Internal re-structuring would be an option to deal with this challenge No powerful incentive tool available.	PV assessors are in the same division as clinical assessors, therefore PV documents in those procedures where MS is CMS can be assessed by clinical assessors (matrix structure).

MSs	Challenges or problems you have encountered and solutions	Any aspects that you considered is particularly helpful or good practice
6	Challenges arise when applications/responses are submitted late/ early or not according to timetables. Additional resources may also be required for unplanned work e.g. an emerging safety issue. Assessors are cross-trained so that work can be reallocated but this remains a challenge for resource management. Recruiting expertise in specialised areas is challenging.*	Formal planning tools put in place to illustrate forecasted timescales and sequence of planned work. PV assessors are very aware of legal timelines in relation to applications and internal timelines are built into SOPs in order to ensure that processes run as smoothly as possible. Staff cross-trained to ensure flexibility. Careful planning for outgoing work and managing peaks in reporting is required for allocation of resources.
7	Different level of expertise among assessors overcome by creating teamwork to exchange experience and harmonise criteria; Detailed SOPs; Peer review of the work.	Involve national external experts in some procedures. Planning of training at central level.
8	We have no specific national educational program in pharmacovigilance. Therefore we learn by doing.	N/A
9	The Medicines Authority was stretched for resources but is currently recruiting new pharmacists and trainees in pharmacovigilance.	Flexibility in resource allocation.
10	Timelines change, it is difficult to plan resources based on European roles	Using overviews of deadlines/procedures/tasks during weekly planning meetings
11	Long term planning difficult because of restricted budgets and lack of clear priorities. Too frequent use of short-term contracts.	Good collaborative environment in the department ensures motivated staff and low turnover.
12	At the moment unable to hire resources based on pharmacovigilance needs due to the restrictions of the Public Administration. For now, the short term solution is to receive trainees at the pharmacovigilance department, when possible.	Since we are assigned to pharmacovigilance activities by the therapeutic category, we are able to have a more comprehensive knowledge of the medicinal products and to do several types of procedures. The participation in European working groups to increase the motivation of the staff.

MSs	Challenges or problems you have encountered and solutions	Any aspects that you considered is particularly helpful or good practice
13	Lack of human and financial resources. Short-term contracts, additional working hours, organised work	N/A
14	The underfunding of pharmacovigilance activities and the generally higher salary levels in industry, which can pose difficulties in attracting qualified staff.	N/A
15	Difficult to predict workload, means difficult to manage appropriate resource. Sudden changes/peaks in workload also pose a challenge to manage. These are managed through various means, usually flexibility of staff to help in different areas, or sometimes use of contract staff, or overtime. Bottlenecks due to a number of procedures worked on by one assessor converging at the same time. Inflexibility of timelines and delays in data submission. Combining urgent unexpected national issues with timetabled EU work. There is difficulty with retention of pharmacovigilance inspectors. Cross-trained internal staff and offer development opportunities where possible for example training courses, attendance at conference and symposia.	Cross training of staff helps provide flexible resource when needed. Identification and prioritisation of IT changes which can help tackle 'bottle-necks' in workflow, to help reduce burden on existing staff. For pharmacovigilance inspectors-developing provisional annual inspection plan, allowing for flexibility. Pharmacovigilance Service team includes a more service centred area, aimed at providing high quality service to enquirers Triage of work according to public health importance and legislative responsibilities Work-sharing between assessors and teams.
16	The agency may propose the need for additional staff, but the final decision is made by the Ministry. The promotion program and employees benefits provided by a national agency cannot compete with those from the private sector. However, the challenge of being on top of public health issues and being "excellence" in our work for the public health protection is quite attractive.	Assessors are trained in different procedures and activities, which allows for re-allocation of resources when needed. People may rotate through different Units of the Division if they request so and the time and work planning allows. This increase the knowledge sharing and foster team building.
17	Challenges: workforce planning strategy implementation Solution: workforce planning project ongoing, including staff training plan for new and senior staff	N/A

Generally, a key theme emerged that many agencies have limited resource due to austerity measures and therefore have little influence on headcount. Other issues identified by MSs include managing peaks in workload, challenges when applications are not submitted according to timetables and managing resource for unplanned work e.g. emerging safety issues or combining urgent unexpected national issues with timetabled EU work. Frequent use of short term contracts, issues with staff retention and recruiting expertise in specialised areas were also considered challenging. Agencies also commented on the difficulty of competing with the private sector despite the interesting nature of the work and appeal of 'protecting public health'. Participation in European working groups was considered to increase the motivation of staff.

MSs were asked to share solutions and suggest any aspects they considered as helpful or 'good practice'. These included internal restructuring, peer review, short-term contracts, additional working hours and cross-training to ensure flexibility. Furthermore, the use of formal planning tools to illustrate timescales and sequence of planned work, together with internal timelines in SOPs were noted as good practice. Some NCAs have weekly planning meetings to provide an overview of deadlines and undertake triage of work (according to public health importance and legislative responsibilities).

Other areas of good practice included a six-month mentorship for new employees and rotation of staff between units with benefits of increasing knowledge sharing and foster team building. One agency has recently initiated a workforce planning project which will include training for new and senior staff.

4. Discussion

4.1 Strategic overview

There were 26 responses from 27 active SCOPE MSs, which was considered a good response rate and suggested NCAs have a good interest in this area. The large amount of information provided by MSs allows a more accurate and complete proposal of 'good practice' in resource management. The responses offered a rich insight into some of the challenges encountered by MSs and the diversity in maturity of PV systems and practice.

Clearly there are different organisational structures across the PV departments and differences in the volume of procedures, however insufficient resource was a common theme not only in WP7, but also in WP5 on Signal Management and WP8 on Lifecycle Pharmacovigilance. The findings from WP7 are closely linked with both of these WPs, where lack of expertise and inexperienced assessors were identified as challenges. In WP7, NCAs highlighted the difficulty in managing peaks in workload and the challenge of combining unexpected national issues with timetabled EU work. This is also reflected in WP8 on Lifecycle Pharmacovigilance with difficulties in prediction for upcoming workload as an issue and the implementation of quality systems as one of the recommendations from the survey report.

Effective management of resources to achieve objectives requires having processes in place to identify, plan, allocate, monitor and evaluate resources within an organisation. Risks to the effective management of resources may include the availability of adequately trained and experienced PV staff e.g. due to significant turnover of staff, deficiencies in training and also unplanned work e.g. emerging safety issues or peaks in workload. The introductory questions from the survey highlighted the issue of limited resource for PV activities faced by some MSs, many commenting on the changing environment due to restrictions imposed by governments. In particular, the number of staff assigned to PV activities varied significantly, with eight MSs reporting having less than 10 FTEs across all PV roles.

The changes to the PV legislation that came in to force in July 2012 sought, amongst other things, to achieve greater clarification on the roles and responsibilities of Marketing Authorisation Holders (MAHs) and NCAs with respect to PV systems, more focus on proactive and risk proportionate safety monitoring, robust and timely decision making. Consequently many changes to procedures and processes have been required at both a European and national level. Also there are some areas which have resulted in additional work load (including risk management plans for all Marketing Authorisation Applications (MAAs) including generics, introduction of patient reporting of suspected ADRs) and others where the introduction of legally binding timelines have placed additional pressures on the system (PSUR single assessments and post-authorisation safety studies). It is evident that many NCAs struggle under the burden of the new legislation, particularly given that these requirements need to be fulfilled in the current climate of austerity measures.

4.2 Capacity management and forecast of workload

The capacity of an agency is a measure of the amount of work it can handle and capacity management ensures that the agency's capacity is matched to service demands. The capacity plan describes how to make the best use of available resources in order to achieve the intended outcome and operational objectives, and where appropriate to define the need for additional resource. This may include evaluation of historical data, identification of future needs, targeted recruitment, staff competencies and expertise available and analysis of business performance through performance indicators. In the survey many MSs indicated that they do not have formal documented resource management processes in place, or a capacity plan as part of the QMS, although MSs follow a strategy or plans for resource management, and that is why re-assignment can be done at peak times.

Successful capacity planning is based on determining stakeholder needs and expectations, including statutory obligations, analysing current capacity and planning to accommodate changes, such as changes to the regulatory process. Determining resource requirements can be done by referencing metrics e.g. volumes of work and taking into account the effect of planned or unplanned work. The resources required to achieve performance targets and working volumes specified in the annual business plan should also be determined and compared with the resources available. This information can be used to draft a risk-based capacity plan to determine how best to use these resources and include some form of predictive analysis.

Of note, NCAs with formal documented procedures for feeding resource requirements into their agency's business planning cycle tend to rely on both PV department needs and agency business plans. Ideally, resource requirements should be based on the PV department needs, although it is apparent that agency business plans have a strong influence. Furthermore, forecast in demand and workload is usually based on planned applications, historical trends, industry forecasts, upcoming legislative requirements and agency strategy/internal priorities, giving a mix of both lagging and leading indicators. However any forecast plan should remain an active document subject to continuous review to allow refinement in resource forecasting.

Improving forecasting capabilities, for example through horizon-scanning is particularly important for effective resource management. This is critical in determining the staff resource and expertise required for PV activities taking into account peaks in workload and the need to re-prioritising work accordingly. One area where this may be of benefit is the number of single assessment procedures for PSURs, taking into account the submission dates on the European Union Reference Date (EURD) list and the list of Nationally Authorised Product (NAP) only procedures. However, it is important to note that some procedures will require substantial work following the preliminary assessment work and it may not be possible to predict this in advance. In addition, the anticipated number, nature and submission dates of applications for new MAAs for which Risk Management Plans (RMPs) will need to be assessed is a further area where workload can be predicted by referring to information on planned Centrally Authorised Products (CAPs) and historical data for NAPs. It is recommended that practical guidance on resource management, highlighting PV aspects, should be developed as part of the quality toolkit. This document could be used to provide 'hints and tips' on resource management, including predicting workload where possible and resource allocation.

Proposal

- Develop good practice guide on resource management, highlighting PV aspects.

4.3. Recruitment, training and development of pharmacovigilance staff

4.3.1 Recruitment

Recruitment of staff is critical for efficient resource management, recognising the need for a sufficient breadth of expertise to enable NCAs to fulfil their regulatory obligations. In the survey, NCAs were asked to list the essential criteria when recruiting new staff e.g. education/qualification and level experience e.g. 1-2 years/3-5 years etc. Responses to the essential selection criteria for recruiting new employees offers an insight into the education, level of skill, knowledge and relevant experience required for positions in PV across NCAs. The GVP Module I states that *'achieving the required quality for the conduct of pharmacovigilance processes and their outcomes by an organisation is intrinsically linked with the availability of a sufficient number of competent and appropriately qualified and trained personnel.'*

In general, for administrative staff, the majority of NCAs stated that the essential selection criteria included high school graduate/diploma, knowledge of the English language and computer literacy. For PV assessors, most respondents confirmed that the essential selection criteria included graduate staff with a degree in medicine, pharmacy or closely related scientific discipline and relevant experience. The essential criteria for PV assessors are also broadly in line with the survey results from WP8 on Lifecycle Pharmacovigilance, which also noted significant diversity in the requirements for assessor's roles and recommends important characteristics for assessor profiles. For PV inspectors, most respondents confirmed that the essential selection criteria include both a degree and specific work experience. Some MSs referred to exams, particularly for PV inspectors. In addition, generic skills required by most NCAs include computer skills and good command of the English language.

4.3.2 Training and development

PV encompasses a wide range of activities requiring scientific assessment skills, regulatory knowledge and relevant experience. High quality training for the continuous development of assessor's knowledge and skills is essential in ensuring that NCAs have a good level of expertise. GVP Module I states that *'all personnel involved in the performance of pharmacovigilance activities shall receive initial and continued training' and 'training plans and records for documenting, maintaining and developing the competences of personnel should be kept. Training plans should be based on training needs and should be subject to monitoring.'*

NCAs commitment to training and development is evident from the high response rate to questions on training and good examples of training plans. The survey results showed that NCAs use internal and external training for new employees. Mentorship programmes were also identified as effective in training new employees and it is recommended that additional information on the survey response on mentorship schemes should be requested and reviewed. All respondents identified the use of external training for continuous development of PV staff, with internal and on-the-job training to some extent. Around 73% MSs develop training plans for new staff, although this is slightly less for experienced PV staff.

In addition, the report on WP8 on Lifecycle Pharmacovigilance also confirmed that almost all NCAs have a quality system in place with a mentoring system, introductory training and sharing of experience for new employees. NCAs also recognised on-the job training and formal training as the principal methods for ensuring that assessors knowledge is kept up to date and the implementation of quality systems to ensure a good level of expertise. Training on new or changing procedures was also highlighted. This finding is further strengthened by the survey report from WP5, concluding that there is a need for training in the signal management field, with lack of expertise identified as one of the challenges. In WP6 on National Methods of Communication, NCAs noted the added value of external experts in media training.

From the survey, a tailored induction plan was identified as an example of good practice, relevant to the new staff's education and work experience. In this specific example, training not only covered core PV processes but also QMS, standardised according to QMS templates. In addition, it is evident that training tends to be provided on an 'ad-hoc' basis and that many NCAs do not measure the effectiveness of training through formal evaluation. It is recommended that a good practice approach should involve regular review of the effectiveness of training materials and methods.

Finally, it is also important to note the role of the EU Network Training Centre[11] which is an initiative aimed to create a European central platform for exchange of information and supply of regulatory and scientific training across the EU regulatory network. The EU Network Training Centre is committed to the improvement of quality, consistency and efficiency of the work of the European Regulatory Network by promoting the harmonised operation of the regulatory framework and guidelines and fostering science based, pragmatic and consistent assessment, inspection, PV and decision making. It will also provide continuous professional development for regulatory agencies and possibly other stakeholders involved in the development of medicines regulation.

4.3.3 Competency frameworks and performance measurement

It is important to ensure that agencies have the necessary competence to conduct PV processes. Consequently, it is recommended that a competency development framework for PV assessors may help develop and improve the competency levels across the network and clarify expectations for competency requirements. This topic will be considered by SCOPE WP8 on Lifecycle Pharmacovigilance, together with a training package for assessors in order to further improve quality, consistency and efficiency. The WP7 quality toolkit will include a case study of a 'Vigilance Competence Framework', demonstrating an NCA's approach to developing a transparent career progression pathway for scientific staff working in PV by a formal planned process to create opportunities for learning and development.

The majority of NCAs have a performance measurement system in place, such as an appraisal system, for staff development. This is an important opportunity to express and plan for personal development goals. Nevertheless, six respondents indicated that they did not have a performance measurement system in place, highlighting a varying level of maturity in the system although this question may have been subject to differences in interpretation.

Proposals

- Case study of training development plans to be developed as a toolkit item including 'Vigilance Competence Framework'.
- Request and review additional information on mentorship for new employees

[11] http://www.hma.eu/otsg.html

4.4 Resource allocation

Allocation of resources takes into account a variety of factors including staff expertise, complexity, priority of work, legal and regulatory requirements and role in the assessment process. Ideally, NCAs should regularly review resource requirements to ensure optimum use of resources. From the survey results, most NCAs reported that PV staff were assigned based on the type of procedure and Anatomical Therapeutic class basis. Other methods for staff assignment included specific expertise e.g. toxicology, medication errors, pregnancy and also the urgency of the issue. Many NCAs confirmed that they consider the legal and regulatory requirements, the impact on public health, public interest and the role in the assessment process when allocating resources. Resource allocated to PV activities is usually reviewed as part of the annual business planning process and management review for over half of the NCA respondents.

In the survey, NCAs were asked to prioritise nine core PV activities to gain an understanding of how resource is allocated, particularly to identify any trends or changes in prioritisation in the case of limited resource. ADR management, PV safety communications, signal management and referral assessments were rated as the most important PV tasks, with a slight increase in priority in ADR management when NCA resources are limited. There was a decrease in priority for all other PV activities when NCA resources are limited. Under such circumstances, several respondents commented that priority would usually be given to cases where the NCA is the lead MS/PRAC. The assessment of post authorisation studies and risk management plans were rated as having the lowest priority during normal working conditions. In addition to these PV activities, PV audits/inspections were also rated as lowest priority during times of limited capacity. The WP8 survey report notes that the methods for prioritisation varied across NCAs, according to whether urgent/non-urgent and according to procedure and whether the NCA is Rapporteur/Co-rapporteur or only concerned MSs.

4.4.1 Risk based regulatory approaches

Risk based approach to regulation is where the level of activity in an area is proportionate to the risks associated with the activity procedures or issue. In PV inspections, 'risk-based inspection planning' is based on a systematic and risk-based approach to make the best use of surveillance and enforcement resources whilst maintaining a high level of public protection[12]. ICH Q9 Quality Risk Management defines the foundation for risk based approach, noting that *'it is becoming evident that quality risk management is a valuable component of an effective quality system'* and that this can facilitate better and more informed decisions.[13] Risk based approaches can provide useful information that might be helpful for allocation of resources. The Heads of Medicines Agency's (HMA's) Working Group of Quality Managers (WGQM) have drafted guidelines on risk-based regulatory approaches from a network perspective which are due for adoption.

[12] Guideline on Good Pharmacovigilance Practices Module III - Pharmacovigilance Inspections

[13] ICH Q9 Quality Risk Management, 9 November 2005

Clearly prioritisation of PV tasks is essential for NCAs, particularly when resources are limited, nevertheless the question arises as to whether a more systematic approach could be developed for allocating resource to PV activities at highest risk is of benefit. One NCA described the development of a risk analysis during a WP7 site visit, with the identification of risks for PV activities. Although this process was developed to determine the frequency of audits in line with the GVP Module IV[14], such an approach could potentially also be relevant for allocation of resources. This approach may be helpful in demonstrating the rationale for prioritisation, particularly relevant in light of the development of an agreed network risk ratings of PV process areas[15]. However, any risk based approach for resource allocation should be considered within the context of meeting all legal and regulatory requirements. It is recommended to include the example from the WP7 site visit as good practice within the quality toolkit.

4.4.2 Managing peaks in workload/unplanned work

In terms of challenges faced in resource management, many NCA highlighted difficulty in managing peaks and unplanned work e.g. applications not submitted within timetables or an emerging national safety issue. Commonly used methods to meet peaks in workload include re-assigning staff, staff rotation and additional working hours. Cross- training to improve flexibility and short term contracts are also used but these may have a short term negative impact on established resource as new team members are supported and settled in. A further issue identified was 'bottlenecks' due to a number of procedures worked on by one assessor converging at the same time, although it was suggested that prioritisation of Information Technology (IT) changes could help manage the workload.

It is interesting to note, that WP8 on Lifecycle Pharmacovigilance also highlighted 'down prioritising' issues, for example national procedures and overtime work as a common way of meeting deadlines, noting that both may lead to new problems further down the line and reinforcing the importance of the availability of sufficient competent assessors as a key for effective high quality assessments.

4.4.3 Planning tools

Although MSs were asked to identify useful tools, only one NCA described the use of formal planning tools to illustrate forecasted timescales and sequence of planned work where the NCA has a lead role (PRAC Rapporteur, Lead MS etc.). The Gantt chart used by the NCA provides a simple overview of expected applications, product, active substance, procedural role, proposed resource in terms of assessors and milestones, all based on a timetable proposed at the time of entry. It is recommended to request and review additional information on this formal planning tool with a view to including this in the WP7 toolkit as an example of good practice.

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[14] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/08/WC500191778.pdf

[15] WGQM Pharmacovigilance Audit Facilitation Group: Guidance on Network Risk Ratings of Pharmacovigilance Process Areas.

Proposals

- Case study of risk assessment of pharmacovigilance activities to be developed as a toolkit item.
- Request and review additional information on formal planning tool.

4.5 Staff retention

Many NCAs face issues around staff retention, particularly due to underfunding of PV activities, and generally higher salary levels in industry. NCAs operating an effective risk management framework, will regularly review risks including issues such as staff recruitment and retention. Recruiting expertise in specialised areas was also noted to be a problem and this was also highlighted in WP5 and 8.

In terms of succession planning, allocation of interesting work, training, and career development plans and projects help improve staff commitment and also develop appropriate skills and expertise. Participation in European working groups was also considered to increase staff motivation. The survey highlighted that most NCAs have a low (defined as only the most senior positions considered) or medium (defined as manager positions considered) level of succession planning. One agency stated that they had initiated a workforce planning project.

4.6 BEMA

Finally, it is important to recognise that NCAs may have already provided information on management of interfaces as part of their submission for the Benchmarking of European Medicines Agencies (BEMA) assessment[16]. BEMA is a HMA initiative involving an assessment of the systems and processes in individual agencies against a set of indicators, to identify strengths and best practices in Agencies and any opportunities for improvement. The initiative aims *'to contribute to the development of a world-class pharmaceutical regulatory system, based on a network of agencies, operating to best practice standards.'*

The BEMA methodology includes both self-assessment and peer review assessment by trained BEMA assessors against a questionnaire of set predefined performance indicators. A scoring system, based on the maturity levels described in ISO 9004 are applied in order to provide a benchmark against which to measure improvements. The outcome of each visit is an anonymised report produced by the assessment team and agreed with the visited Agency. All results are uploaded to a database and a report is generated for the agencies to use as a tool for identification of best practices and for improvement. The third cycle of BEMA is based on visits to agencies between 2012 to 2014.

[16] http://www.hma.eu/bema.html Accessed: [12/06/2015]

- **KPI 1.4 – Allocating resource**
  Allocating the necessary resources to the different work areas provides the basis for achievement of the Agency's goals and objectives. A dynamic allocation mechanism ensures the maximum effectiveness of available resources.
- **KPI 8.1 – Capacity management**
  Managing capacity at an operational level ensures there are adequate resources to meet legislative requirements and the fluctuating demands arising in each area of activity, providing consistent service delivery and performance, and efficient use of resources across the whole organisation.
- **KPI 8.3 – Resource allocation**
  A sound basis for allocating work to staff ensures the most appropriate use of scientific expertise and contributes towards timeline compliance.

In comparison, analysis of assessor reports from the third cycle of BEMA broadly support the SCOPE survey results. The forecast of workload at many NCAs is based on planned applications, the EMA for centralised procedures, industry forecasts and historical data. Some NCAs take forward capacity management during management review assessing peaks in the previous year, while others hold monthly capacity management meetings. In addition, gap analysis, the development of Capacity Planning Tools to integrate data from different sources, and Lean Six Sigma approach were also noted as important initiatives.

With respect to resource allocation, prioritisation is evident across the network. Approaches described include a risk based approach taking into account importance to the organisation and public health, complexity of work and splitting tasks into mandatory and non-mandatory. In terms of performance relative to resource allocation, review through KPIs are described, with numeric targets defined for each type of procedure and estimated assessment times. If procedures can be given a numeric target, then it may be possible for agencies to develop a workforce capacity tool to help define the optimum number of people in each department during a given time period.

In some NCAs, cross department resources are regulated by Service Level Agreements. Arrangements in place to meet peaks in workload include shadowing, cross training, development of databases listing all staff and competencies to allow better resource allocation and recruitment strategy in a three year rolling plan.

5. Conclusions and future work

Following the introduction of the PV legislation that came in to force in July 2012, the greater demands on MS regulatory systems means that there is a need to support best use of available resources, developing skills and capacity across the network, supported by effective quality management systems. From the survey it is clear that there is considerable diversity in the availability of resource, expertise and volumes of work across the network. Some MSs do not have formal processes for resource management or a performance management system, suggesting differences in maturity of PV systems, particularly in the management of resources. Nevertheless, MSs recognise the need to ensure adequate resource and effective allocation of that resource. Within the current climate of austerity measures, this remains a significant challenge.

Furthermore, NCAs also recognise the need for a sufficient breadth of expertise for ongoing business needs and the recruitment and retention of staff not only to fulfil their regulatory obligations, but also to cope with a constantly changing regulatory and scientific environment. In practice, this is achieved through ad hoc training to suit the needs of individual staff members together with 'on-the-job training'.

Following the information collected from the survey a number of additional steps will be used to collect some specific additional information from MSs to help identify good practice with specific examples. Practical guidance on resource management highlighting PV aspects will be developed for the quality toolkit. The guidance will focus on capacity management, forecast of workload, training and development and resource allocation. Practical examples or case studies will include the 'Vigilance Competency Framework', mentorship schemes for new employees, training systems, formal planning tools, forecast of PV workload and risk assessment of PV activities, aimed at improving NCA efficiencies.

Annex: Table of FTEs across PV activities

MS	Other	Administrators	Assessors	Inspectors	Total
1		6	31	2	39
2		3	32	2	37
3		4	18	3	25
4			1.5	0.5	2
5	2.5	1	1	0.5	5
6	2.5	1.5	11	1	16
7	5	2	6	0.5	13.5
8		4.1	15.5	1	20.6
9		2	14	3.5	19.5
10			2	4	6
11	2	7.3	23	3	35.3
12		2	4	2	8
13			19		19
14	7	5	14.5	2	28.5
15	4	2	13	5	24
16		9	26	6	41
17	0	1	6.5	1.5	9
18		1.5	2.8	0.2	4.5
19		11	30	4	45
20		7	43	11	61
21		2	5	3	10
22	0.75	1.75	7	1	10.5
23	1	0.25	1.75	1	4
24	3	0.2	40	3	46.2
25			6	0.5	6.5
26		2	12.5	0.5	15