SCOPE Work Package 7
Quality Management Systems

Resource Management
Best Practice
Guidance

2016

SCOPE

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Quality Management Systems
Resource Management Best Practice Guidance

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Acknowledgments

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1. Introduction

1.1 Purpose of the document

The purpose of this document is to provide examples of good practice in the area of resource management presenting Member State (MS) case studies and guiding principles. This paper has been developed and approved by all WP7 active partners (BG, ES, HU, IT, PT and UK).

1.2 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
AIMS	Access and Information for Medicines and Standards
AIFA	Italian Medicines Agency
BDA	Bulgarian Drug Agency (BG)
CAP	Centrally Authorised Products
CDF	Competence Development Framework
CMDh	Co-ordination group for Mutual recognition and Decentralised procedures – human
CHMP	Committee for Medicinal Products for Human Use
CV	Curriculum Vitae
EEA	European Economic Area
EO	Executive Officer
EU	European Union
EMA	European Medicine Agency
EURD	European Union Reference Date
EV	EudraVigilance
EVDAS	EudraVigilance Data Analysis System
FTE	Full Time Equivalent
GVP	Guideline on Good Pharmacovigilance Practices
HALMED	Agency for Medicinal Products and Medical Devices (HR)
HEO	Higher Executive Officer
HMA	Heads of Medicines Agencies
HR	Human Resources

Terminology	Description
HPRA	Health Products Regulatory Authority (IE)
ICSR	Individual Case Safety Report
IMI	Innovative Medicines Initiative
IT	Information Technology
KPI	Key Performance Indicator
L&L	Label & Leaflet
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MEB	Medicines Evaluation Board (NL)
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MS	Member State
MRP	Mutual Recognition Procedures
NAP	Nationally Authorised Products
NCA	National Competent Authority
PDCA	Plan-Do-Check-Act
PASS	Post Authorisation Safety Study
PRAC	Pharmacovigilance Risk Assessment Committee
PROTECT	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
PSUR	Periodic Safety Update Report
PSUSA	Periodic Safety Update Single Assessment
PV	Pharmacovigilance
QMS	Quality Management System
RCT	Randomised Controlled Trial
RMP	Risk Management Plan
RMS	Reference Member State
RPPS	Regulatory Pharmacovigilance Prioritisation System
SEO	Senior Executive Officer
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SOP	Standard Operating Procedure

Terminology	Description
VCF	Vigilance Competence Framework
VIRG	Vigilance, Intelligence and Research Group
WP	Work Package

1.3 Resource management and QMS

Resource management is the process of being as efficient as possible with an organisation's resource, encompassing a variety of factors, including staff, equipment and finances[1]. This includes determining the resources that are needed to meet the organisation's objectives. Overall quality objectives for pharmacovigilance (PV) include promoting the safe and effective use of medicinal products and contributing to the protection of public health through strengthened vigilance.

The Guideline on Good Pharmacovigilance Practice (GVP) Module I states that the 'management of resources is essential in order for National Competent Authorities (NCAs) to meet their PV legal obligations and support the proactive and risk proportionate conduct of pharmacovigilance'[2]. GVP Module I also states that 'resources and tasks should be organised as structures and processes in a manner that will support the proactive, risk-proportionate, continuous and integrated conduct of pharmacovigilance'.

Quality management systems (QMS) cover the organisational structure, responsibilities and accountabilities, procedures, processes and resources for managing the workflow. Implementing a quality management system should drive an organisation to consistently meet statutory and regulatory requirements and can help improve performance and customer satisfaction. The potential benefits of working to a formal QMS is that it provides a structured approach to activities that are documented, provides a benchmark against which to audit and measure performance, and a means for identifying and implementing improvement.

Furthermore, the GVP module I also states that 'achieving the required quality for the conduct of pharmacovigilance processes and their outcomes is intrinsically linked with the availability of a sufficient number of competent and appropriately qualified and trained personnel.' PV is a discipline that requires a range of skills from scientific and assessment skills through to regulatory knowledge. NCAs recognise the importance of recruitment, training and development in order to maintain a skilled workforce to deliver objectives and fulfil regulatory obligations.

[1] http://www.businessdictionary.com/definition/resource-management.html

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

1.4 Background

The European Union's (EU's) PV legislation[3] that came into force in 2012 has increased the burden on NCAs, drastically affecting the efficient management of resources[4]. The changes to the PV legislation aimed to further strengthen the protection of public health through more clearly defined roles and responsibilities of Marketing Authorisation Holders (MAHs) and NCAs with respect to PV systems, more focus on proactive and risk proportionate safety monitoring and robust and timely decision making.

Consequently, implementation of the legislation has required many changes to procedures and processes at both a European and national level.

In addition, the legislation introduced a range of new tasks, from the introduction of patient reporting of suspected Adverse Drug Reactions (ADRs) to requiring risk management plans for all Marketing Authorisation Applications (MAAs), including generics. Furthermore, changes to the definition of the term 'adverse reaction' means that this now covers noxious and unintended effects resulting not only from the authorised use of a product at normal doses, but also from medication errors, occupational exposure and uses outside the terms of the marketing authorisation, including overdose, the misuse and abuse of the medicinal product. A significant increase in the numbers of submitted Individual Case Safety Reports (ICSRs) has been observed following the introduction of the new legislation. There was an absolute increase of approximately 51,000 European Economic Area (EEA) reported post-marketing ICSRs received in the data collection period compared to approximately 169,000 ICSRs received in the same year before the PV legislation was implemented. A 60% increase in spontaneous ADR reporting by patients in the EEA was reported in the year following implementation of the PV legislation (a total of approximately 25,000 compared to approximately 15,000 in the previous year[5]).

Robust and rapid EU decision-making is an important aim of the PV legislation with a focus on greater transparency. The introduction of legally binding timelines has also placed additional pressures on the system e.g. Periodic Safety Update Report (PSUR) Periodic Safety Update Single Assessments (PSUSAs) and Post-Authorisation Safety Studies (PASS).

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[3] 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

[4] 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

[5] One-year report on human medicines pharmacovigilance tasks of the European Medicines Agency

1.4.1 SCOPE project

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action was created to help NCAs comply with the new PV legislation in all aspects. Work Package 7 (WP7) of the SCOPE project tackled QMSs in European Member States (MSs), using surveys to collect data on how NCAs manage the quality of their PV operations (Annex). WP7 reviewed how MSs are addressing resource management.

As part of the SCOPE survey, MSs were asked to identify any particular challenges that they face in resource management. Many MSs identified the difficulties in managing staff, particularly being restricted in the number of staff that they are allowed to hire due to austerity measures. Others identified the difficulties in incentivising staff in order to retain them, where trained employees often move into industry where the salaries are higher.

Results of the survey highlighted the different organisational structures of the PV departments in the NCAs and differences in volumes of procedures. Some MSs do not have formal documented resource management processes in place. The importance of training and development was evident from the survey, although many NCAs do not measure the effectiveness of training. In addition, the necessary competence to conduct PV processes is a key element in improving quality, consistency and efficiency.

The nature of unplanned ADR work, delays in submissions, and EU contributions were highlighted as a key challenge, as was trying to recruit into specialised areas to help cope with these fluctuations. Some resolutions were to cross-train staff in multiple areas of PV to better allow staff reassignment when needed. These points highlight the difficulties experienced by NCAs in trying to adequately assign resources, not just within, but outside of the Agencies as well, specifically freezes in head counts by national Ministries.

1.4.2 SCOPE guidance document

As part of the WP7 deliverables, a toolkit has been developed to include this guidance document, which will present examples of good practice across Europe, and aim to help NCAs optimise their resource management processes and where possible to overcome their major challenges.

This guide will cover all topics mentioned above: predicting workload, allocating resources and managing staff resources. Each factor is of course interconnected, for example, the need to hire new staff could only be identified if an evaluation of workload allocation highlighted areas lacking staff resources. An effective plan to predict workload, can be used to develop business plans to hire staff thus efficiently managing the fluctuations in PV activities.

Guiding principles will be presented in this document, together with NCA case studies and the results from the SCOPE survey. It should be noted that the implementation of these good practices is not mandatory, but that the aim is to provide NCAs with practical advice in resource management. This guide aims to present feasible guidance and recommendations for applicability across all NCAs in Europe. However, WP7 recognises that NCAs may only reference guidance that is appropriate within their current systems. The WP7 outputs provide ideas and suggestions for NCAs to optimise quality management, and comply with PV legislation, within their own means.

1.5 Capacity management and forecast of workload

A capacity plan describes how to make the best use of available resources in order to achieve operational objectives, and where appropriate to define the need for additional staff. This may include evaluation of historical data, identification of future needs, targeted recruitment, staff competencies and expertise and analysis of business performance through performance indicators.

Predicting the flow of work for NCAs is one of the most challenging areas of resource management. Certain areas of work can be well predicted, for example, PSUSAs, which have set submission dates. In addition, the anticipated number, nature and submission dates for new MAAs for which Risk Management Plans (RMPs) will need to be assessed is a further area where workload can be predicted to some degree by referring to data on planned Centrally Authorised Products (CAPs), and historical data on Nationally Authorised Products (NAPs). However, more ad-hoc issues, for example, urgent action required as a result of critical safety signals cannot be predicted. This highlights the importance of effective resource management processes, assessing stakeholder expectations, and managing those appropriately.

1.6 Hiring, training and retaining staff

Identified during either workflow prediction or during capacity management tasks, the hiring of new staff into an organisation can be fundamental in allowing efficient resource management e.g. targeted recruitment with an evaluation of the skills and competencies required for the role. However, the adequate training of such staff is equally important for their integration and can encompass a variety of techniques, including mentorship and training courses. Actively seeking opportunities to develop competence and sharing experience is also essential. The retention of existing staff is just as vital in maintaining consistency, and often there is no one method appropriate for incentivising all staff, although a framework for career progression is an important aspect. The limit of resources available to provide such incentive is an important consideration for NCAs.

1.7 Allocating resources

Appropriate allocation of resources is a highly multifaceted process, and has to take into account factors like the complexity of the task and the skills and experience of the staff for which the task is to be allocated. In addition, there are also Agency, divisional and annual business models that must be fed into. Efficient resource allocation is a critical process, if NCAs are to maintain high quality outputs in all required areas and adapt to changing priorities e.g. in the event of an urgent safety issue.

2. Guidance and best practice examples

2.1 Capacity management

Key points

- Capacity management ensures that the NCA's capacity is matched to business performance through performance indicators
- Improving forecasting abilities, for example through horizon scanning, is recommended
- Historical data, industry forecasts and planned applications can be used to estimate demand. For example, resource for PSUSAs can be predicted several months in advance
- Formal tracking tools can be used for capacity planning and to measure business performance
- Capacity management should include continuous review to optimise performance

Capacity is determined by the available human resource, Information Technology (IT) services, facilities, finance and information used to achieve agreed goals. For human resource, factors that contribute to capacity include the number of staff available to each process and their level of competence.

The capacity plan describes how to make the best use of available resources in order to achieve the intended outcome and, where appropriate, to define the need for additional resource. Successful capacity planning is based on:

- Determining stakeholder needs and expectations, including statutory obligations
- Analysing current capacity and balancing it with required outputs
- Planning to accommodate future changes, such as changes to the regulatory process.

The Plan-Do-Check-Act (PDCA) can be applied to ensure that processes are planned, adequately resourced and managed. The PDCA cycle can be described as:

Plan	Establish the objectives of the system and its processes, and the resources needed to deliver results.
Do	Implement what was planned.
Check	Monitor and measure processes.
Act	Take actions to improve performance.[6]

2.1.1 Capacity planning

Some of the principles mentioned here may be useful to help predict the more predictable processes, and to identify discrepancies in staff resources.

Understanding stakeholder and regulatory requirements

An important factor in capacity planning is to reference the corporate, annual-agency and annual-division business plans which generally set out stakeholder requirements and expectations as performance targets. Where regulatory targets are not included in key performance indicators (KPIs) these should also be included in the goals that inform the capacity plan relating to each process.

Determining resource requirements

The resource requirements for work that contributes to a single output (for example an assessment) should be determined. This can be done by reference to metrics that link the volume of outputs with inputs in terms of number of staff employed at each stage, timelines and the effect of planned or unplanned interruptions to the process.

Linking capacity with target

The resources required maintaining the output necessary to satisfy the target qualitatively and quantitatively per unit of time and process should be determined. For example this might relate to the input required to achieve the relevant performance targets and work volumes specified in the annual business plan. At a divisional level this might relate to a local target that contributes to a high-level Agency target. The resources required to meet the target should be compared with the resources that are available and a risk-based 'capacity plan' drafted to determine how best to use these resources to achieve the required output. The plan should be sufficiently flexible to take account of challenges that may affect achievement of the target.

[6] ISO 9001:2015 Quality management systems

Identifying action and failure points

A capacity plan should include an indication of the challenges that are likely to affect the achievement of the target. The trigger points at which action should be taken to mitigate the effect of those challenges and the nature of the action that could be taken should be specified. Contingency plans (such as the temporary diversion of staff from other duties) should also be defined.

Changes impacting capacity

Anticipated changes to legislation and/or stakeholder needs and expectation should be taken into account during capacity planning where there are resource implications.

Monitoring the implementation and effectiveness of the capacity plan

Monitoring the implementation and effectiveness of the capacity plan should be carried out at regular intervals against set criteria.

2.1.2 Forecast of workload

The purpose of predicting workload is planning the right amount of resources (e.g. number of staff) in place to handle tasks. There are various steps that can be used to predict workload, for example using

historical trends as a reference, ideally looking at two or more years' worth of data[7]. Separation of PV processes into milestones and key areas can more accurately allow prediction and tracking of timelines for tasks.

From the SCOPE survey, MSs were asked how they forecast PV workload. 9 MSs (35%) stated that they use planned applications to predict workload; 6 MS (23%) use historical trends, and in some cases MSs use both. Some other methods used include industry forecasts, upcoming legislative requirements and agency strategies. 14 MSs (54%) confirmed that they have formal documented processes within their QMS for feeding resource requirements into the annual business planning arrangements.

Figure 1 below summarises an overall process of PV resource management, with a feedback loop between resource allocation and PV outputs, thus allowing for optimisation of resources. The identification of insufficient resources could either be predicted as part of anticipating workload, or as the tasks are allocated and completed, identifying poor quality or delayed outputs.

[7] Reynolds P (2003) Forecasting fundamentals: The art and science of predicting support desk workload. *Call Centre Staffing: the complete practical guide to workforce management.* Call Centre School Press.

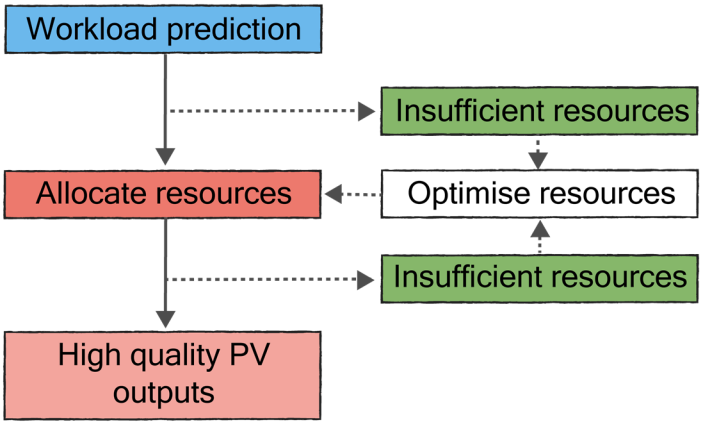

Figure 1 Summary of the resource management process, from predicting workload through to measuring PV outputs

'Insufficient resources' included factors like insufficient staff number and staff training.

Staff resources

An important area of predicting workload is identifying whether there is the required capacity available to complete PV tasks i.e. that the staff resource is sufficient. One method to explore staff resources for available tasks is to construct a skills matrix, although this does require a prior estimate for the number of staff required per task.

A skills matrix can be interpreted in many ways and can be tailored to a NCAs preferences and needs. The primary structure of a skills matrix is to display the experience of employees, and to identify whether they require additional training to be able to perform PV tasks. This is discussed in more detail in Section 2.2.

Historical trends

As mentioned in the SCOPE survey, some NCAs use historical trend setting to predict areas, and time periods, which may require additional resources. This involves looking back on previous peak periods and making predictions on the resource capacity required to cope. Often it is most accurate if there is more than 1 years' worth of data to accurately predict. For example, historical trends for Type IB variations can be used, to justify the hiring of contract staff in order to manage predicted fluctuations.

The anticipated number, nature and submission dates for new MAAs, for which RMPs will need to be assessed, is a further area where workload can be predicted to some degree by referring to data on planned CAPs, and historical data on NAPs.

Planned applications

There are various avenues from which NCAs can monitor planned applications.

PSURs are examples of planned applications that NCAs can account for. A case study example of this is discussed in **Example 1** below. In addition, RMPs for generic medicines is an area where workload can be planned to some extent by identifying products going off-patent.

A further example includes national immunisation programmes where it may be possible to estimate the number of ADR reports based on previous experience with major programmes. Although immunisation schedules are invariably dynamic, there is a need for constant, proactive horizon-scanning to anticipate likely issues based on past experience and promote confidence in safety surveillance systems. Proactive and tailored vaccine risk management strategies should be planned well in advance with a need to optimise data collection and make the best use of all available data sources. It may be necessary to consider the need for a business case for additional resource and costs to implement an effective proactive risk management strategy. For example, an increase in ADR reporting may require additional staff requirements (e.g. PV scientists, assessors, epidemiologist and support from the press office) in order to process, follow-up, assess and share data as quickly as possible to detect signals and communicate accurate information on safety to stakeholders.

2.1.3 NCA good practice examples

Example 1: monitoring planned applications

The Medicines and Healthcare products Regulatory Agency (MHRA) predicts the number of single assessment procedures expected to start each month several months in advance using the submission date on the European Union Reference Date (EURD) list and the list of NAP only procedures provided via CMDh.

Any subsequent change to the frequency of the PSUR submission may not be accounted for in these predictions and for PSURs on a 6-monthly cycle, volumes are predicted on the 'next submission date' as well as the 'submission date' on the EURD list to ensure that all submissions in the period are taken account of.

In addition, the total number of procedures expected in order to predict the resource required to review PSURs and assessment reports when the UK is not the lead, are also reviewed (**Figure 2**) to determine any peaks in work and to re-direct and re-prioritise work accordingly.

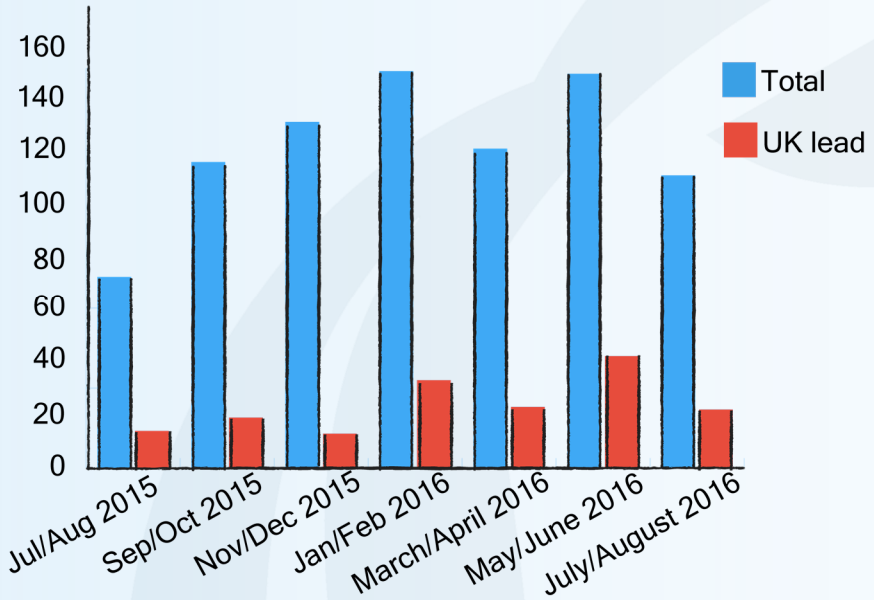

Figure 2. Total PSUSA procedures expected to start July 2015 to August 2016 at the MHRA
The bar graph presents both those in total, and those which were UK led.

For procedures where the UK is not the lead the MHRA operate a triage system to identify PSUSAs where the benefit-risk may have potentially changed, where changes are required to the product information or where new safety issues are identified. Resource is directed to such procedures in order to ensure that any issues are reviewed and the PV Risk Assessment Committee (PRAC) rapporteur is briefed for discussion at PRAC plenary, where appropriate.

For procedures where UK is the lead the procedures are broken down by type i.e. centralised, CAP/NAP and NAP only (Figure 3).

Where peaks are detected, for example, the number of procedures due to start in May and June 2016, the expected procedures can be looked at more closely. Procedures which may involve assessment of PSURs from a number of different MAHs may require more resource than a procedure which involves the assessment of one product.

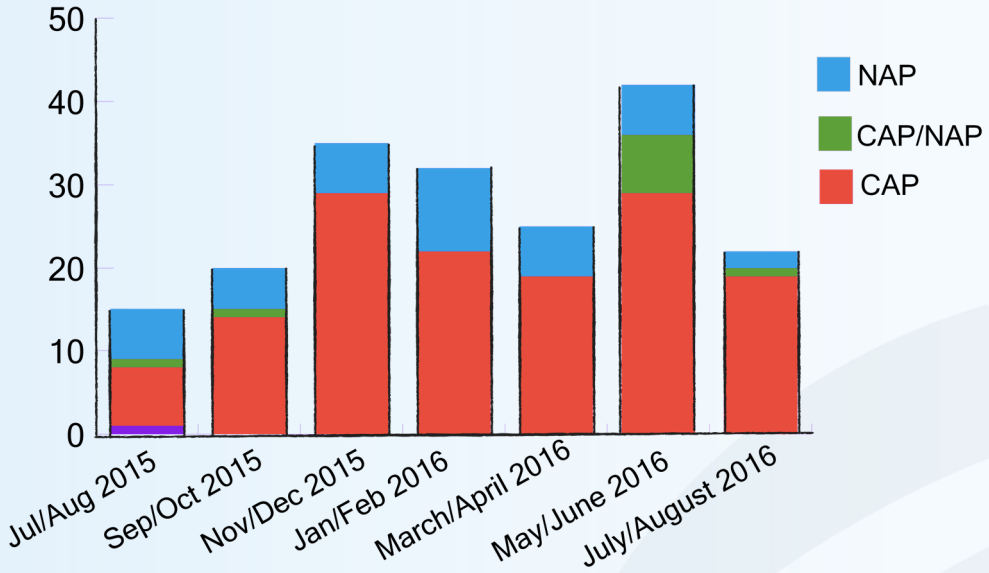

Figure 3: UK lead procedures expected to start July 2015 to August 2016

The graph highlights the breakdown of PSUSA procedures at the MHRA into NAP, CAP/NAP and CAP categories.

It must also be borne in mind that in reality resource can be impacted up to 60 days after the start of the procedure, until preparation of the preliminary assessment report, and therefore assessor workload over this time period needs to be taken into account. However, by identifying peaks in workload it can be identified where additional resource is required and resource can be redirected from other areas if necessary. In addition, some procedures will require substantial work following the preliminary assessment report. Although it is not possible to predict which procedures will be more involved in advance, due to the clarity of the timetable, the time period in which it may be required is known and assessor time can be allocated accordingly.

Example 2: a formal planning tool

The Health Products Regulatory Authority (HPRA) of Ireland uses a Gantt chart to illustrate any planned procedures where they have a lead role (PRAC Rapporteur, Lead MS, RMS, etc.). This chart allows the tracking of all ongoing procedures and allows users to quickly identify areas of high and low capacity from the populated Gantt chart.

Figure 4 and **Figure 5** highlight the structure of the excel file used by HPRA. Figure 4 is a template showing the information included in the table; including product, active substance, procedural role, proposed resource in terms of assessor, and milestones, all based on a timetable proposed at the time of entry.

However, even if this is tentative when populating the chart, there is a column (T) which allows this to be captured with a Y/N response.

								Milestones														Gantt Chart				
								D0	D87	D101	D107	D120	D121	D150	D159	D167	D180	D181	D187	D197						
	Application type	Product	Active substance	Role	Assessor 1	Assessor 2	T	Start	PAR	Updated AR	PRAC Adaptation 1	CS	CRS	AR	AR	PRAC Adaptation 2	CS	CRS	AR	PRAC Adaptation 3	End	Oct-15	Nov-15	Dec-15	Jan-16	Feb-16
1																										
2																										
3																										
4																										

Figure 4. Template for the HPRA process planner, with the Gantt chart highlighted on the far right.

The milestones are automatically calculated based on the specific timetable of the procedure. Once the start date is entered into the table, the Gantt chart automatically populates the milestones and allows a quick and easy visualisation of expected applications and periods of high and low capacity (including clock stops and active phases during the procedures). Although automatically populated, the dates can be manually edited, should there be a delay or to enter restart dates following clock stops. Areas of active and inactive (clock stopped) times within procedures can be colour-coded in the Gantt chart.

This set-up allows HPRA to include planned procedures in advance of the start date and to allow efficient prediction of resources. To maintain clarity the chart allows filtering, for example by start date and planned resource allocation etc.

The planner also includes useful links such as to the EURD list for PSUSA submission timelines and planning files for other departments within HPRA to whose assessments they make a contribution (**Figure 5**).

VA Planner

Expand | Condense | PRAC Rapp Folder | EURD List | HPAR Outgoing Work Folder | View Gantt Chart | View Case Milestones | View All Milestones | Add Milestone Calcs

							Milestones													Gantt Chart	
Application Type	Product	Active Substance	Role	Assr 1	Assr 2	T	D0 Start	D87 PAR	D101 Updtd AR	D107 PRAC Adptn 1	D120 CS	D121 CRS	D150 AR	D159 AR	D167 PRAC Adptn 2	D180 CS	D181 CRS	D187 AR	D197 PRAC Adptn 3	End	Oct-14	Nov-14
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD		26/11/14	20/02/15	06/03/15	12/03/15	25/03/15	26/07/15	24/08/15	02/09/15	10/09/15	23/09/15	21/10/15	03/11/15	13/11/15	13/11/15		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD	n	26/02/14	23/05/14	06/06/14	12/06/14	25/06/14	28/12/14	04/02/15	12/02/15	12/02/15	25/02/15	24/03/15	29/03/15	10/04/15	10/04/15		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD	y	28/05/15	22/08/15	05/09/15	11/09/15	24/09/15		24/10/15	02/11/15	10/11/15	23/11/15		30/11/15	10/12/15	10/12/15		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD		24/09/14	19/12/14	02/01/15	08/01/15	21/01/15	24/05/15	22/06/15	01/07/15	09/07/15	22/07/15	25/08/15	30/08/15	10/09/15	10/09/15		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD	y	27/10/16	28/01/17	11/02/17	09/02/17	22/02/17	22/05/17	20/06/17	29/06/17	07/07/17	20/07/17		27/07/17	06/08/17	06/08/17		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD	n	26/11/14	20/02/15	06/03/15	12/03/15	25/03/15	22/05/15	29/06/15	03/07/15	09/07/15	26/08/15	08/09/15	17/09/15	27/09/15	27/09/15		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD		28/05/15	29/08/15	10/09/15	10/09/15	23/09/15		23/10/15	01/11/15	09/11/15	22/11/15		29/11/15	09/12/15	09/12/15		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD		28/05/15	29/08/15	10/09/15	10/09/15	23/09/15		23/10/15	01/11/15	09/11/15	22/11/15		29/11/15	09/12/15	09/12/15		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD	n	25/06/15	26/09/15	09/10/15	09/10/15	22/10/15	26/01/16	02/03/16	11/03/16	12/03/16	25/03/16		01/04/16	11/04/16	11/04/16		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD		01/10/15	02/01/16	14/01/16	14/01/16	27/01/16	27/04/16	01/06/16	10/06/16	11/06/16	24/06/16		01/07/16	11/07/16	11/07/16		
New Outg CAP PRAC Rapp	xxxxxx	yyyyy	Rapp	AB	CD	y	20/08/15	21/11/15	03/12/15	09/12/15	22/12/15		21/01/16	30/01/16	07/02/16	20/02/16		27/02/16	08/03/16	08/03/16		
Outg PASS Report	xxxxxx	yyyyy	Rapp	AB	CD		24/08/15													23/10/15		
Outgoing PSUSA	xxxxxx	yyyyy	Rapp	AB	CD		13/11/14		22/02/15											13/03/15		
Outgoing PSUSA	xxxxxx	yyyyy	Rapp	AB	CD		12/02/15		24/05/15											11/06/15		
Outgoing PSUSA	xxxxxx	yyyyy	Rapp	AB	CD		11/06/15		20/09/15											08/10/15		
Outgoing PSUSA	xxxxxx	yyyyy	Rapp	AB	CD		11/06/15		20/09/15											08/10/15		
Outgoing PSUSA	xxxxxx	yyyyy	Rapp	AB	CD		14/05/15		22/08/15											10/09/15		
Outgoing PSUSA	xxxxxx	yyyyy	Rapp	AB	CD		13/11/14		22/02/15											13/03/15		
Pharmacovig Review	xxxxxx	yyyyy	Rapp	AB	CD		12/01/15													13/03/15		
Outgoing PSUSA	xxxxxx	yyyyy	Rapp	AB	CD		12/02/15		24/05/15											11/06/15		
Outgoing PSUSA	xxxxxx	yyyyy	Rapp	AB	CD		12/03/15		21/06/15											09/07/15		

Figure 5 Screenshot of a populated HPRA planner, listing ongoing procedures

Example 3: Optimising ADR signal detection

The Innovative Medicines Initiative (IMI) Pharmacoepidemiology Research on Outcomes of Therapeutic by a European Consortium (PROTECT) project[8] aimed to strengthen the monitoring of benefit-risk for medicines in Europe. The MHRA identified a need to adjust signal detection thresholds to reflect changing volumes and types of cases received, as well as to incorporate new best practice identified in published literature and studies within the project. As general guidance the following steps can be followed in order to base any changes to signal detection thresholds on scientific evidence:

1. Specify the need/reason for the change (increase in volumes of cases received, new evidence emerged which recommends an updated process)
2. Develop study plan with relevant experts (e.g. Pharmacoepidemiology staff, signal detection group, scientifically trained staff). The plan should include the methods that will be tested, timelines and testing methods, and any pre-analysis that is necessary to facilitate the study.
3. Approve the study plan by relevant persons.
4. Conduct the study. From previous experience, at least 6 weeks of direct comparison of the old and new methods is recommended as well as a retrospective analysis to ensure signals previously identified will not be missed.
5. Discuss the results in a meeting with the relevant persons, including assessors involved in signal management, including positive and negative impacts of making each change (if multiple changes are tested).

If the changes are proven successful, the next steps would be:

- Agree a proposal for implementation
- Seek feedback from the managers
- Implement changes when agreement is attained[9].

[8] http://www.imi-protect.eu/partners.shtml

[9] SCOPE WP5 – Signal Management Best Practice Guidance

2.1.4 Discussion of Capacity Management

It is essential to make the best use of available resources and to plan for additional resource as appropriate in order to fulfil regulatory obligations in promoting the safe and effective use of medical products, and contributing to the protection of public health. Successful capacity planning should ensure that there are adequate resources to meet statutory obligations. It is evident from the survey that some NCAs do not have a formal process to document resource management processes, although many follow strategy or plans for resource management so that there is re-assignment to deal with peaks in workload. Case studies from two NCAs were presented (UK, IE). These examples demonstrate:

- Planning to predict PV workload e.g. PSUSA procedures
- A formal tool for monitoring the current workload by using a set-timeline for completion of tasks
- Optimising individual PV processes in order to streamline and better cope with fluctuating workload

The use of tools for capacity planning can be helpful to define the optimum number of staff during a given time period. Furthermore, resource requirements should be based on PV department needs to meet performance targets, although many respondents indicated a top-down approach, as agency business plans having a strong influence.

Anticipated effects of changes to legislation and/or to stakeholder needs and expectation should be taken into account during capacity planning where there are resource implications to develop a more proactive approach. Improving forecasting capabilities, for example through horizon-scanning is important. Historical data, industry forecasts and planned applications can be useful in estimating demands and to anticipate issues that may arise. For example the number of single assessments for PSURs can be predicted several months in advance using the submission date on the EURD list. In addition, the anticipated number, nature and submission dates of applications for new MAAs for which RMPs will need to be assessed is a further area where workload can be predicted to some degree by referring to information on planned CAPs and historical data for NAPs. Workload can also be planned for RMPs for generic medicines by identifying products going off-patent. In addition, previous experience with major immunisation campaigns can be used to estimate the number of ADR reports and to develop proactive risk management strategies. Finally, it is may also be possible to predict the number of expected variations in some circumstances e.g. the number of expected variations following referral procedures and therefore plan resource in advance of the Commission decision and following a PSUSA procedure which concludes with regulatory action.

Nevertheless, it is acknowledged that it is often difficult to predict PV workload in some circumstances e.g. urgent emerging safety issues or variations submitted by MAHs. A flexible and collaborative approach may be appropriate for dealing with unplanned work or peaks in workload e.g. cross-training of staff.

2.2 Hiring, training, and retaining staff

Key points

- A skills matrix can be useful for monitoring the need for hiring, training and retaining staff
- Individual training plans should be regularly assessed
- The effectiveness of training materials and methods should be regularly reviewed
- Shadowing, secondment and mentoring can offer development opportunities
- A solid career progression plan could ensure that NCAs continually develop the necessary competence to deliver high quality assessments
- Employee engagement is a strong predictor of organisational performance
- Key potential drivers in staff retention include basic needs of pay and benefit, development opportunities and clear career progression

Predicting workload is a good way to identify whether the current resources in place are sufficient for the tasks ahead. If staff resources are not sufficient, then NCAs can take action to rectify this. Some of the key potential drivers include basic needs of pay and benefit, development opportunities and clear career progression.

2.2.1 Skills Matrix

As discussed previously, a skills/competency matrix is a good tool in identifying whether the current staffing resources are sufficient. This includes hiring, training and retaining staff. A skills matrix can display the number of people required for the day-to-day running of a particular process, as well as the current staff number, and competencies, available. **Figure 6** presents an example structure of such a matrix.

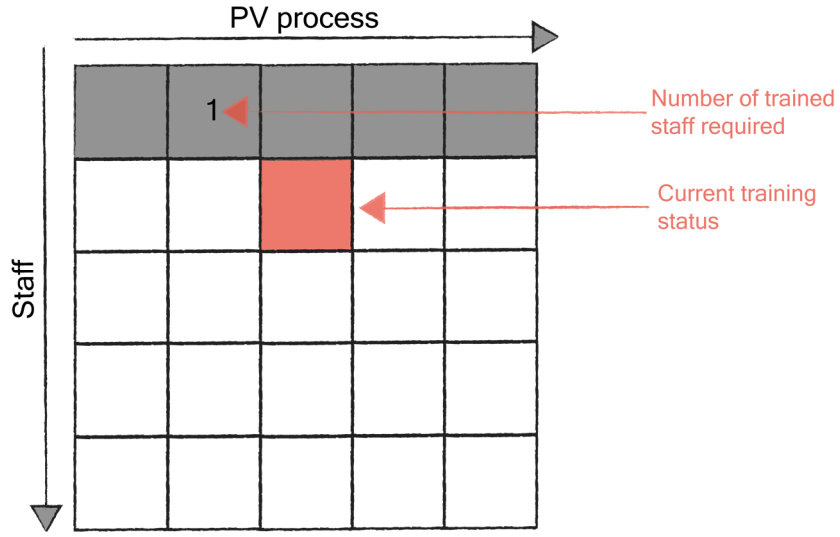

Figure 6. Example skills matrix

Each PV process can be listed in columns along the top, with an associated number of trained staff required to perform each task. The rows are then populated with individual staff members, where their current level of training/competence can be graded, shown here using colour.

This can allow users to identify areas where resources are lacking, whether this is a lack in numbers or in competencies. For example, for a 'PV process 1' an NCA may require 4 people to be trained, yet currently only has 3 trained people to a high enough grade, however, 2 of these trained staff are experienced enough to train others. Therefore an additional person is required for this process, and can be trained by either of the two experienced employees. A skills matrix can be structured in such a way to track these types of decisions.

As workload increases, a skills matrix could be updated to reflect the increase in number of people required for each task. For example, a 'PV process 2' only requires 1 employee to be trained, however, there is a second person trained who could be utilised should the workload shift and this process start to require more than 1 person.

Figure 7 highlights how the skills matrix can be integrated into the general resource management process, together with the hiring, training and motivating of staff.

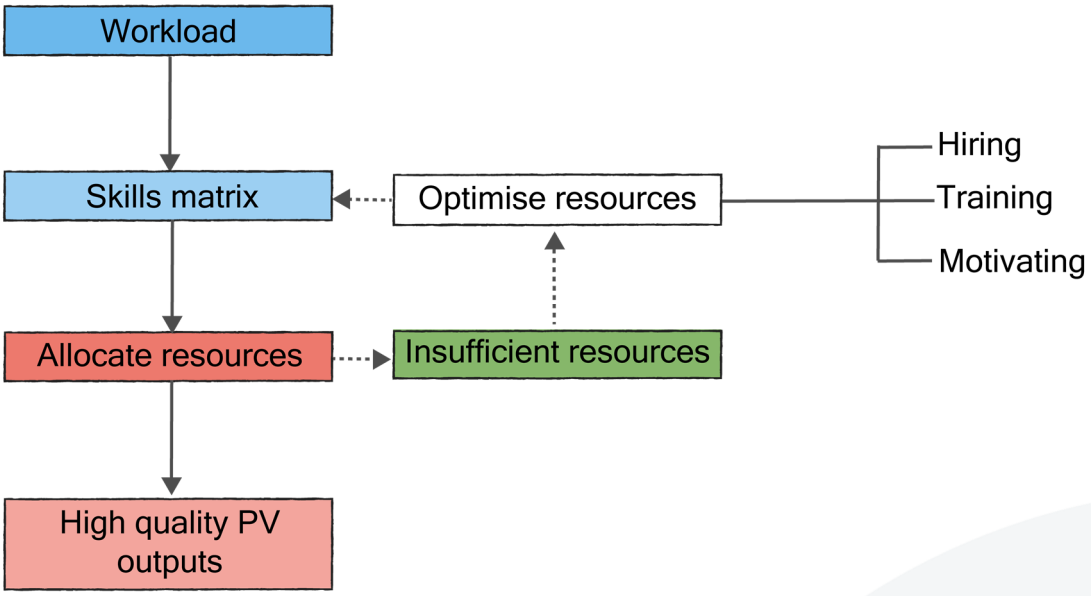

Figure 7. The resource management process, highlighting the use of a skills matrix, and how it can be updated as a result of resource assessment and optimisation

As resources are optimised, the skills matrix can be updated, and the allocation of resources adjusted appropriately. One of the points to highlight is the importance of motivation in staff resource optimisation. There is a multitude of ways that a skills matrix can be structured, for example it could also include employees associated interest in a given PV task. Section 2.2.3 explores methods for incentivising staff.

Such a system can be used to accurately monitor and predict the training and hiring requirements of a NCA, even monitoring the motivation of employees. Below are described some more practical details in hiring, training and retaining staff.

2.2.2 Staff hiring

There are multiple basic steps required when hiring new staff, below are some examples of these considerations:[10]

Identify business need

Identifying the need to hire a new PV employee is a fundamental aspect of resource management. During this process, NCAs can decide what type of post they wish to hire for e.g. permanent, temporary, internship, apprentice etc. Temporary staff are more applicable if the workload fluctuates, with internships designed to hire more long term employees.

[10] http://www.acas.org.uk/index.aspx?articleid=4216 [Accessed 21st December 2015]

Ideal candidates

NCAs could write down a checklist of all the ideal qualities that a new employee might have. It is often good to keep flexibility in this checklist to account for applicants with skills that may not match exactly the expectation, but may in fact excel in an area that could be beneficial in developing the role for the future.

Considering the personality of a potential employee can be just as important as work experience. For example, for an industry or governmental facing PV role, an employee may need to have a better communication skillset, and be more relaxed and confident under on-the-spot pressure situations.

Advertise

Advertising the role can be the key to finding the right candidate. Deciding where you advertise the role is equally important, and should have an impact on the content and structure of the advert. Examples include:

- Schools, colleges and universities
- Job Centres
- Recruitment agencies
- Newspapers
- Online sources e.g. agency websites and social media.

Where it is difficult to fill PV roles, the use of social media-driven campaigns to publicise the work and the benefits of working at an NCA may be considered in order to reach a wide audience. This may include key messages about why the role is important, career options e.g. progression through competency framework, job satisfaction and the wider impact of the role on public health.

SCOPE survey questions

From the SCOPE survey, 21 MSs (81%) stated that they do not feel that the number of full time employees they have is sufficient for their PV activities.

NCAs were asked to provide details as to the qualifications and experience required of any new hires, specifically for PV administrators, assessors and inspectors. The requirements for an administrator were generally for applicants to have graduated from high school, to have good knowledge of the English language and to be computer literate. However, for some NCAs there is an overlap in administrator duties with more specialist PV roles, in such cases more education and experience is required.

Assessors and inspectors were required to have more experience, including graduate degrees in a scientific or medical discipline as well as relevant work experience. More focus was placed on the need for work experience in inspector roles. In addition, some NCAs ask candidates to pass internal exams after a certain period of employment within the Agency.

Given the requirements for specialised education and experience, NCAs have to consider the sources for finding new staff in order to interview and hire the most appropriate employees within their MSs.

NCA good practice examples

Example 4: recruiting using a pool of applicants

The National Authority of Medicines and Health Products in Portugal (INFARMED, I.P.) approaches recruitment in the most transversal way in the public tender context, by maintaining a 'pool' with potential recruits available for 18 months.

This pool has several benefits:

- Due to some restrictions INFARMED, I.P. cannot recruit whenever needed, but only when possible
- The recruitment procedure itself is time consuming
- INFARMED, I.P. can address the staff turnover without a huge impact since the candidates are already selected.

INFARMED, I.P. has a 'Personnel map' that reflects the human resources allocated to the activities of each Directorate. This document is fundamental for recruitment and is approved by the Executive Board and by two Ministries (Health and Finance). The performance of the NCA has an impact on the number of new staff allowed to be recruited.

The recruitment process aims to ensure compliance with the national legislation regarding labour and the appropriate methods and techniques in the recruitment and selection of human resources, in order to guarantee equality of opportunity and treatment to all applicants. This is achieved by normalising activities, involvement and responsibility of employees who participate in recruitment services and selection of staff. The final objective is to determine the most suitable candidates or the ones likely to acquire skills to perform the duties required to the fulfilment of the mission of the NCA.

The process is broken down into the following steps:

1. Recruitment decision

   The NCA executive board identifies the need to recruit staff, based on the personnel map and the requests from the directorates.

2. Preparatory acts

   The human resources directorate prepares the proposal for opening the public tender procedure. The executive board approves the proposal and nominates the jury for the public tender. The jury defines the requirements of the public tender, taking into account the personnel map and the manual with job descriptions for all kinds of functions performed at the NCA, which also defines the skills, experience, education and qualifications needed for each function and is also responsible for the assessment of candidates.

3. Publicity

   The human resources directorate ensures that the announcement of the public tender procedure is published on the NCA website, the electronic legislation diary and several national journals, stating clearly the reference to the number of jobs to be filled, the characterisation of the activity to perform and the requirements of the candidates in terms of skills, experience, education and qualifications.

4. Assessment of candidacies

   Each candidate must send several documents, such as: a certificate of competence, an updated curriculum vitae (CV), a motivation letter, the form of the public tender and a statement that all information provided is true.

   In a public tender, usually the candidates are assessed through 3 types of selection methods and ranked: psychometric tests, exams regarding general and specific knowledge, and an interview. The jury is responsible for applying all the selection methods, with the practical support of the human resources directorate.

5. Elaboration of the unitary list of final ranking

   The final note is given considering the partial note obtained in each selection method and the relative weight of each one. The jury elaborates the unitary list of final ranking of the candidates, which is published on the NCA website, and notifies the candidates, giving them the possibility to pronounce themselves about the final note.

6. Homologation of the final ranking

   The executive board of the NCA homologates the final ranking of the candidates and all the jury's deliberations regarding the procedure.

7. Negotiating the remuneration position

   The executive board of the NCA negotiates the remuneration position with the candidate according to what is defined in the national legislation regarding labour in Public Administration.

8. Recruitment

   The human resources directorate of the NCA has to ensure the compliance with the rules legally established for recruitment in terms of priority and to deal with the candidates who refuse the recruitment, remuneration or the position offered, or deliver inadequate documents or failure to attend to the award of contract.

9. Welcome

   The human resources directorate has a "welcome manual" to all new staff with an overview of the NCA that includes the mission, the vision and the values, the organogram, the introduction to the Quality Management System and some practical information regarding services, work schedule, rules of procedure, among others.

There is a probationary period of 6 months. The assessment is made by a panel of senior colleagues and considers not only the daily performance but also the integration in the team, among other predefined skills. New staff must also submit a report at the end of this period covering the activities developed, experienced difficulties and opportunities for improvement in the directorate and in the NCA. If someone was not approved after the probationary period of 6 months, the pool with potential recruits can be used. This is available for 18 months after the finalisation of the public tender procedure, to choose the next candidate in the final ranking list. The agency goes directly to the negotiating of the remuneration position step because the candidate assessment is already done.

When the restrictions imposed by the government do not allow recruitment by public tender, INFARMED, I.P. has two possible alternative ways in order to address staff turnover or peaks in workload:

1. In Portugal's Public Administration, there is a possibility of exchanging employees from one Public Institute to another – it's called internal mobility. This possibility is also applicable within INFARMED, I.P., among the different directorates, always subject to the Directors' authorisation.

2. Sometimes, there is also a possibility for internships. These internships are usually a result of collaboration with universities, but pharmacists (or other professionals with relevant education) can also apply, even if they have never worked in this area. Usually internships do not last longer than 9 months and are not paid.

Example 5: a promotional campaign for recruitment

In order to raise awareness for pharmaceutical assessor roles, the MHRA has launched a campaign strategy, which is largely driven by social-media. The campaign directs people to a stand-alone campaign page[11] which provides additional information about the role and about the MHRA in general, even providing real-life examples from existing pharmaceutical assessors. The advert was posted on the MHRA Facebook, LinkedIn and Twitter pages, using designated hashtags like #MHRA jobs and encouraging existing MHRA staff to re-post and extend circulation.

This is a good example of how useful social media can be for recruitment in the future, even if only to publicise hard-to-fill positions in the first instance.

2.2.3 Training and development

Induction training for new hires

NCAs will have their own specifications for the training of new hires, based on their new role. A few example areas are listed below:

- Legal and regulatory framework, both national and European
- PV processes
- Standard Operating Procedures (SOPs)
- Scientific skills e.g. pharmacoepidemiology, pharmacokinetics
- IT skills e.g. the European Medicine Agency (EMA) databases.

The tailoring of induction training can be for a new role and/or for new training for experienced employees. The level of expertise for a new hire can dictate the detail of the training given as well as the number of training sessions provided.

There are various methods for the delivery of induction training materials, normally as presentations by internal subject matter experts, or as e-learning modules. It is unlikely that new hires would be exposed to external visitor seminars for the purpose of induction; these are more likely part of ongoing interest and development for the entire agency or department.

[11] https://mhra-pharmaceutical-assessor.pgtb.me/wcs5dJ

Mentorships

Mentorship schemes can be a useful method of both inducting new staff into the agency and training existing employees in a new area of PV. This method can be as simple as shadowing a member of staff on a particular process, to having a hands-on mentor, who designs and closely monitors all aspects of the new hires induction. These different methods will have vastly different timelines associated, with the latter taking months to complete and requiring a significant amount of time and effort to be dedicated by a mentor. It is often beneficial for mentors themselves to undergo specific training before taking on a new hire e.g. leadership, influencing skills.

Types of training

There are different types of training which are required for a person to be competent at their job, and which is designed to be useful in the future as part of career development, or as part of cross-training to help with peaks in workload.

Continued training and development is an important part of retaining employees in any organisation. There are various different approaches that can be taken when developing the career of employees, and these may differ depending on their grade. The most important aspect is to tailor career development programs to the employee's career aspirations and interests, more detail on this is discussed in Section 2.3.

Identifying the need for training can be acknowledged during regular reviews between manager and employee, often as part of goal setting for future roles. It may be difficult to predict too far in advance the training that may be required, so goals should be re-addressed on at least a yearly basis. Developing and adapting an official training program can be a good way to track and assess progress.

Training can take many forms, ranging from participation in international conferences to team building exercises with fellow colleagues. Some training made available to employees may result in a qualification; justifiable based on the employee's current or planned job roles. Internal training generally takes three forms:

- Self-service learning (e.g. e-learning programs)
- Instructor led training (e.g. workshops and presentations)
- On-the-job training (e.g. mentorships).

Mentorship training is generally reserved for new hires or employees changing roles, however self-service learning and workshop-type training are commonly used as part of ongoing training programs. Shadowing, secondments and mentoring can offer opportunities for staff to gain a wider understanding of the agency's goals for public health protection and to learn new skills.

It is important to measure the effectiveness of training delivered to employees, not only to make sure staff are appropriately trained for their jobs, but also to make sure that future training is optimised. Training is often evaluated with a questionnaire completed by trainees at the end of a training session, which asks for ratings and comments on how it may be improved going forward.

The effectiveness of training can also be assessed during employee appraisals, assessing the quality and timeliness of the work produced after training. This would be assessed on a case-by-case basis based on each agencies internal processes and quality monitoring.

SCOPE survey answers

The SCOPE survey asked MSs to comment on the training and induction process for new staff. Twenty five NCAs identified the use of internal, external and on-the-job training to induct new hires. As for training programs, 19 MSs (73%) create unique training programs as per the new employees' background and experience. NCAs provided more detail on these training programs as described below in the good practice examples. Most NCAs (16) stated that training is provided on an ad-hoc basis, with 7 providing training regularly. Regular forms of training were given on at least a yearly basis, and included external and internal teaching. Interestingly, 8 MSs have a set number of training days per year for their staff, ranging from 2 to 15 days depending on role and period of employment.

It is not only important to provide training to PV employees, but also to monitor the effectiveness of this training. Nineteen MSs have an evaluation process of some description from manager follow-ups to attendee assessment though training evaluation forms.

NCA good practice examples

Example 6: a career development framework for PV scientists

The Medicines and Healthcare products Regulatory Agency (MHRA) has developed a Vigilance Competence Framework (VCF) for PV scientific staff. Although there is a Competence Development Framework (CDF) for assessors and inspectors, the aim of the VCF was to develop a clear career progression pathway for PV scientific staff and strengthen opportunities for learning and development. Entry level scientists are initially employed as 'Associate Signal Assessors' and then progress to the level of 'Signal Assessor' following a minimum of twelve to eighteen months experience of working in PV and by applying for positions through open competition.

Associate Signal Assessors are responsible for the classification of ADR reports, PV signal detection and assessment procedures to ensure drug safety issues and risks to public health are identified and evaluated. Additional activities for this role include responding to PV enquiries from stakeholders and provision of ADR data to researchers. Progression to Signal Assessor accreditation requires demonstration of performance of the Associate Signal Assessor responsibilities at a consistent level of output and quality as outlined below:

- Ability to consistently meet targets for the ADR workflow steps over a six month period
- Proven high level of quality in ADR processing as demonstrated by QA Audit results over a six month period
- Ability to draft responses to lay queries with minimal input
- Ability to source information from different areas of the Agency in response to a wide range of enquiries
- Ability to consistently extract and validate ADR data from different systems
- Identify and assess signals on a weekly basis, including making recommendations to relevant signal meetings
- Proven examples of taking forward a signal, for example review of other data sources, within appropriate time frames

Additional responsibilities for Signal Assessors include quality assurance of ADR reports, training new Associate Signal Assessors and preparation of assessment reports for committees. Signal Assessors are expected to work in close partnership with other assessors in the Agency particularly with assessing safety issues. The experience gained means that staff are often well placed to apply for a wide range of positions within the Agency, such as assessor posts within the Benefit Risk Management Group when vacancies become available.

Examples of career options for PV Scientific Staff are described in **Figure 8** below.

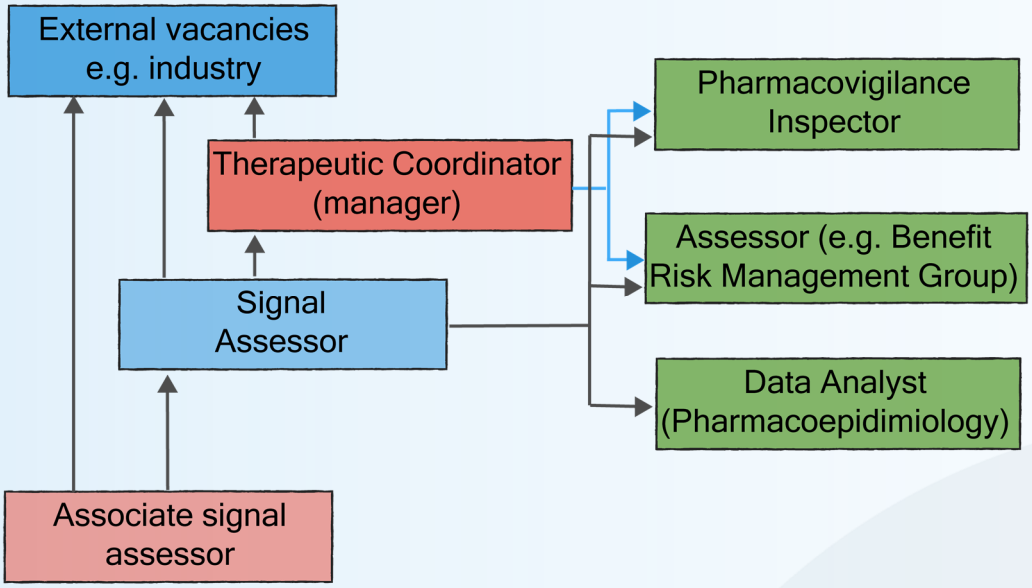

Figure 8. Possible movement of an Associate Signal Assessor through different roles and departments across the MHRA

The framework has been in place at the MHRA since 2012 and has successfully enabled progression for over 15 Associate Signal Assessors to Signal Assessor accreditation. Feedback from one member of the Agency who has since progressed to an assessor position in the Benefit Risk Management Group (BRMG) was that:

"VCF provided a solid structure to my training as an Associate Signal Assessor, and the framework set clear goals for my development. This helped me to understand the core requirements for progression and a motivation to work towards attaining Signal Assessor status. The focus on developing skills such as robust scientific assessment of signals has helped me in my further career within the Agency too, where I have used this experience as groundwork to my current role of Associate Scientific Assessor in BRMG."

Example 7: a training development plan

Training and professional development at the Bulgarian Drug Agency (BDA) is based on a developed National Health Strategy (2014-2020); a consensus among experts from the healthcare sciences and institutional and informal structures of the civilian society. Two of the objectives detailed in the strategy cover management of resources and the development of the capacity of the employees from the healthcare sector.

These two goals are developed as strategic objectives for the whole agency with respect to the three years budget plans. Each is measured and performance indicators are applied.

An annual analysis of training is conducted on the basis of an indicator for self-assessment; fully achieved objective, satisfactorily achieved objective, unsatisfactory achieved objective. The self-assessment indicators are:

1. Fully achieved at 100% performance
2. Satisfactory achieved in 50% and over 50% performance or
3. Unsatisfactory achieved in 50% performance.

An overall number of the trained employees are provided in the annual report of the agency. Determination of the specific needs for the training of an employee is dictated by the BDA appraisal system for assessment of excellence for completed work.

Different sources for funding the training are used. During 2014/2015 the BDA was a European project beneficiary "Competent and effective administration" and received budgeting for training. As a result of the project, 100 (approx. half of the agency staff) BDA employees received training in English, teamwork effectiveness and strategic planning.

Annual appraisal that took place at the BDA sets out criteria for calculation of fare remuneration of the staff according to individual skills and contribution towards agency's activities. Yearly, the head of the department develops a work plan, jointly with the employee, with a maximum 7 objectives (concrete, measurable by volume, quality and deadlines) and requirements towards performance.

At the end of the year in a joint meeting with the employee their achievements and need for further training are discussed. The result from the appraisal serves as basis for promotion.

Training provided at BDA is divided into mandatory and specific (on-the-job training).

Mandatory training

Mandatory introductory training is performed by the Institute of Public Administration and is directed to newly employed, or appointed for the first time on a managerial position or into the civil service. This includes the structure and functioning of the administration, rights, obligations and the responsibilities. For employees in managerial positions, the training course is focused on developing skills for planning, organising, directing and controlling the activities of structural units.

Specific training

The Specific training is divided into:

1. **Introductory training**
   - Familiarisation with relevant legislative/normative documents and requirements
   - Reading of general (whole agency) and specific PV SOPs
   - Acquainted with ethical standards and confidentiality rules adopted by the agency
   - Identification of periodic meetings for providing employees with information for safe labour conditions
   - Introduction to the particular obligations of the employee (30 min session from the Head of the PV department).
2. **Professional development training**
   - Contributing to the improvement of the structural unit (directorate, department, sector)
   - Different modules are proposed e.g. improvement of computer and business skills, foreign languages etc.
3. **Training for career development**
   - Contributing to the professional development of staff
   - Necessary for specific work – such as electronic reporting of ICSRs, EudraVigilance (EV) Data Analysis System (EVDAS), mandatory training for PV inspectors etc.
4. **Mentoring**
   - Aims at acquiring key knowledge and skills for professional induction and support of new employees
   - Different styles of mentor
   - An Informal mentoring system is applied at the BDA
   - A senior employee is appointed to work with newcomers
   - No limits regarding the period of time for mentoring
   - The mentor relays back to the Director of the department when the mentee is ready for independent work.

The determination of the specific needs for the training of an employee are bound to the BDA appraisal system for assessment of excellence of completed work. Each employee can indicate the training that they wish to attend during the following year through completing a personal training plan (**Figure 9**). The form is agreed with the divisional Director for applicability and is transferred to Human Resources (HR) for consultation on available training. A record of the training completed is stored in a personal file for the employee in the form of training log.

PERSONAL TRAINING PLAN (BDA)

Name:
Position:
Department:
Agency:
Period:

I. Training needs

Type of training	*Mandatory*	*Specific*
Introductory training		
Professional development training		
Training for career development		
Mentoring		

II. Training Objectives

Include: purpose of training, what can be achieved, how it improves competency and knowledge

III. Consultation on learning opportunities with an employee of the Department for Human Resources

Include r: content, methods (short course, seminar etc.), technique (complete/partial absence from work)

IV. Coordination of content, method, technique, duration and site of training with the head of division

Content	*Method*	*Technique*	*Duration*	*Site*

V. Expected results and areas of application of lessons learned

VI. Financing of the training

Specify who will pay; administration (specific training), IPA (general), employee (individual), or other

Signature of the employee:	
Signature of the head of department:	
Agreed with: *HR department*	
Director of the division:	

Figure 9. Training development plan for employees at the BDA, showing the need for justification and the exact nature of the training request

When no certificate is gained from the course the employee is obliged to prepare short report for the training. Some examples of the training provided are:

- EudraVigilance (1 employee every year)
- EVDAS (2 employees every year)
- Webinars organised by EMA
- Training organised by PRAC

For all agency departments, all reports from business trips (the PRAC, the Committee for Medicinal Products for Human Use (CHMP), CMDh, working groups, other EMA/ Heads of Medicines Agencies (HMA) committees) are stored and available to everyone from the agency who is interested (the directory was created with training purposes). Sometimes the officer has to prepare a report and present to colleagues within the department (also used for internal training).

With the extensive training programs available at the BDA, a high level of efficiency and efficacy is expected in staff performance, along with more effective collaboration and better contribution to the assessment of the quality, efficacy and safety of the medicines in the EU.

Bulgaria, for a first time, in 2015 accepted to be Rapporteur at PRAC and conducted two PSUSA assessments as Lead Member State. Bulgaria was also reference MS in a work-sharing procedure for assessment of marketing authorisation updates with a new path for synthesising an antibacterial for systemic use, in addition to being reference MS for Mutual Recognition Procedures (MRP).

Owed to the development of the experience of its employees, BDA is recognised as a reliable partner by the Bulgarian professional's organisations in achieving safety and accessibility to pharmaceutical services, and ensuring safety in prescribing and dispensing of medicinal products. A signed memorandum for cooperation between BDA and the Bulgarian Pharmaceutical Union states that the two institutions will conduct information panels in which training sessions will be organised for the members of the association with the participation of representatives of the BDA.

Additionally the BDA is a side in two international memorandums for provision of expertise for the integration of two non-EU neighbourhood countries into the EU, with respect requirements of the European Drug regulation.

Example 8: Training development plans and resource qualification structure

The Italian Medicines Agency (AIFA) created a basic training plan for new staff in the PV Office. The basic training foresees the individual study of some main SOPs followed by a questionnaire for each SOP. The questionnaires are evaluated by the trainer responsible.

The SOPs included in the basic training are related to general procedure of the agency (e.g. conflict of interest) and some SOPs related to general basic information required by the assessor (e.g. the national PV network, training of assessors etc.). In case the staff member is already employed in the agency, they can skip the study of some general SOPs regarding the organisation.

AIFA has also developed a resource qualification structure based on three levels of experience (from new entry employee to medium and high experienced assessor). The three levels are set according to the expertise, the seniority, the on-the-job training (quantity and quality of assessments performed) and the theoretical training days.

New staff are supported by an interchangeable mentor who directs the work and evaluates the quality of the job. The overall performance (on-the-job, training days, seniority) of the assessor is considered by a committee composed by the mentors, the Head of the office and the quality PV responsible for eligibility to upgrade the level.

Example 9: A mentorship training plan

The Agency for Medicinal Products and Medical Devices (HALMED) of Croatia creates a 6 month education plan for new employees. This plan is created by a mentor, and is approved by the head of the division prior to the first working day of the new employee. The educational plan includes internal training and is tailored to cover both general and specific areas that are relevant to the new job role. The Quality Management Office supervises the appointed mentor. The more specific areas of training are decided on a case-by-case basis, based on the requirements of the position and the previous experience of the new employee.

General areas covered include the important structures and processes within the Agency, together with the legal and regulatory environment, specifically regarding PV, both central and nationally. In addition, a general overview of PV processes and the quality system and relevant SOPs are referenced. The head of division approves the Training Programme for new employees. Education within the Agency includes organising plenary lectures and divisional lectures, learning by performing tasks (under supervision and with guidance from the mentor) and self-education through reading relevant legislation (EU and national), guidance (such as GVP modules) and internal PV SOPs.

During the training and after completion of the training, the mentor assesses whether the employee is trained for independent performance of work tasks. To assess the independency of the employee, the mentor can define measurable criteria, for example, 10 successfully performed tasks in a particular analytical area such as independent assessment of cases etc. In the event of an unsatisfactory result (criteria not met) the mentor extends the training period. However, since the mentor continually assesses independence of the new employee during the mentorship period and makes adjustments to the learning process, a formal test is commonly not needed and the extension of the training period does not commonly occur. The results of the training for an individual employee are recorded on a form in line with the SOPs.

Example 10: Annual training development plan

The Agency for Medicinal Products and Medical Devices (HALMED) of Croatia creates annual plans of education for staff members. This lists the areas of training to be given to match the job title. An example of this education plan is shown in **Figure 10** below.

Name of employee	Working place	Training plan for 2014	Place of education
DEPARTMENT FOR SAFE USE OF DRUGS AND MEDICAL PRODUCTS DEPARTMENT OF pharmacovigilance and rational pharmacotherapy			
	The main coordinator of the National Centre and Pharmacoepidemiology	• Congress ISOP • Internal education / courses with an external lecturer • PSUR • RMP • DSUR • Signal Detection • Statistics • Pharmacoepidemiology • Pharmacogenomics • EU2P, http://www.eu2p.org/ - moduli	• HALMED • Outside agency • On-line
	Senior Adviser for pharmacovigilance and rational pharmacotherapy	• Internal education / courses with an external lecturer • PSUR • RMP • DSUR – non-interventional tests • Signal Detection • Statistics • Pharmacoepidemiology • Pharmacogenomics • MedDRA • EVDAS	• HALMED • Outside agency
	Senior Adviser for pharmacovigilance and rational pharmacotherapy	• Internal education / courses with an external lecturer • PSUR • RMP • DSUR • Signal Detection • Statistics • Pharmacoepidemiology • Pharmacogenomics • EVDAS	• HALMED • Outside agency
	Administrative Officer for pharmacovigilance and rational pharmacotherapy II degree	• Internal education / courses with an external lecturer • External courses / conferences / workshops	• HALMED • Outside agency
	Administrative Officer for pharmacovigilance and rational pharmacotherapy I degree	• Internal education / courses with an external lecturer • External courses / conferences / workshops • The person responsible for pharmacovigilance - Management Forum	• HALMED • Outside agency • Internal

Figure 10. Example of an annual educational plan in PV, as created by HALMED

This table shows that even for employees with the same job title, there may be differing training delivered. This is dependent on different tasks performed by staff members who have the same job title. Employees undertake self-education by following legal regulations, international standards, guidelines, pharmacopoeias, professional magazines, seminars and international meetings. Every employee is required to maintain their knowledge and skills through self-education in accordance with the development and requirements of their profession.

The head of division assesses the implementation of education plans. Once a year, the head of division prepares a report on the implementation of the annual education plan (which serves as the basis for preparing the education plan for the next calendar year). Training that was not carried out in the previous year is, if still considered needed, included in the annual plan for the next year. The Quality Management Office considers the reports during management review.

In addition, at least once a year, the senior head in the hierarchy assesses whether the desired goal has been achieved after completion of training. The impact of employee education on work is monitored continuously and promptly, and may include monitoring the success of tasks performed, monitoring the elimination of errors in work etc.

2.2.4 Staff Commitment

Staff commitment is a key aspect of maintaining a smooth running PV system. Staff commitment is evidently something wider than job satisfaction, although this forms an element of it. Staff commitment, engagement and motivation are all key factors that should help improve staff retention.

There are many definitions in the literature, all of them focused on two aspects: two-way nature and the extent to which an engaged employee is expected to have an element of business awareness. One example of a definition for staff commitment is:

"Employee engagement is a positive attitude held by the employee towards the organisation and its value. An engaged employee is aware of business context, and works with colleagues to improve performance within the job for the benefit of the organisation. The organisation must work to develop and nurture engagement, which requires a two-way relationship between employer and employee."[12]

There are many factors that can help motivate employees to stay within the agencies. The 3 most apparent factors are: career development, interest and salary.

Often for public-sector workers, the salary is the least flexible factor, however, there are many different methods that can be used to help employees maintain interest and to choose to develop their career within the agency. The key is to make the incentive program as flexible as possible to suit the employee's interests and ambitions.

[12] Robinson D., Perryman S., and Hayday S. (2004) The drivers of Employee Engagement Report 408. Institute of Employment Studies, UK

Drivers

There are many potential drivers; those listed here include the drivers highlighted by MSs participating in the survey and the most popular ones:

- Basic needs of pay and benefits
- Development opportunities
- Clear career progression
- Sense of meaning at work
- To be able to voice ideas
- Being kept informed about what is going on in the organisation.

Employee engagement is the outcome of personal attributes such as knowledge, skills, abilities, temperament, attitudes and personality, organisational context which includes leadership, physical setting and social setting and Human Resources practices that directly affect the person, process and context components of job performance.

Employee engagement strategies

Employee commitment or engagement is a strong predictor of organisational performance. It is interwoven significantly with important business outcomes: employee retention, productivity, profitability, visibility, customer-stakeholder satisfaction.

Ten points to consider:

1. Start on day one.
   Effective recruitment and general orientation which relates to the organisation, procedures and job-specific orientation (job duties and responsibilities, goals, current priorities of the department to which the employee belongs) in order to enable development of realistic job expectations and reduce role conflict that might arise in the future.
2. Start it from the top.
   Needs leadership commitment i.e. people from the top should believe in it. Employee engagement requires “Leading by Example”.
3. Enhance employee engagement through two-way communication.
   Managers should promote two-way communication which is clear and consistent with what is expected from employees. Sharing power through participative decision making will provide a feeling of belonging, increasing their engagement.

4. Give satisfactory opportunities for development and advancement.

   Encourage independent thinking by providing more job autonomy, so long as they are producing expected results. Manage through results rather than trying to manage all processes by which results are achieved.

5. Ensure that employees have everything they need to do their jobs.

   Managers should ensure that employees have all required resources e.g. physical, material, and financial and information in order to effectively do their job.

6. Give employee appropriate training.

   Increase their knowledge and skills as when employees get to know more about their job, their confidence increases, which in turn builds their self-efficacy and commitment.

7. Have a strong feedback system.

   Perform engagement surveys for employees to determine all factors that drive engagement in the organisation. Identify the factors that make the most difference and try to improve them; developing action-plans that are specific, measurable, accountable and time-bound.

8. Incentives have a part to play.

   Financial and non-financial benefits are important. Employees who get more pay, recognition and praise tend to exert more effort into their job. There should be a clear link between performance and incentives given.

9. Build a distinctive corporate culture.

   Organisations that build mutual respect, and promote a strong work culture in which goals and values of managers are aligned will keep their existing employees engaged.

10. Focus on top-performing employees.

    Many studies have shown that high performing companies are focusing on engaging their top-performing employees, this reduces the turnover of these employees and as a result leads to top business performance.

SCOPE survey answers

NCAs were asked to comment on their approach to professional development for employees, specifically whether ongoing training is in place. 21 MSs confirmed that internal training takes place, 26 that external training is offered, and 22 that on-the-job training is available. When asked whether a continuous development plan is tailored for existing employees, 17 MSs confirmed that it was.

MSs identified the allocation of interesting work to be a commonly used method to improve staff commitment as well as providing external training. Interestingly, only 10 MSs identified the distribution of financial bonuses to be a useful method. Few NCAs have Agency-wide succession planning, most reserving this for manager/senior positions only.

NCA good practice examples

Example 11: career development for incentivising

The MHRA has in place a framework for the development of assessors and inspectors called the Competence Development Framework (CDF). The CDF describes a pay scale for the progression of medical, bio-statistical, pharmaceutical, scientific, and non-clinical assessors, together with inspectors through a career path into senior positions.

The CDF was created to recruit candidates with the necessary skills and experience to deliver a safe regulation process. It was designed as a specific procedure to address the pay situation of highly experienced people from outside the Civil Service applying for posts with the MHRA. Employees enter into the framework in an associate position, into one of the subject tracks based on their previous experience (e.g. medical, scientific etc.).

Staff can take a variety of routes to progress through the CDF depending on management or specialist interest, but primarily the progression will follow one of the routes as described in CDF recruitment rounds for senior and expert posts that take place twice a year. Using this type of career progression framework can incentivise staff members to stay within the MHRA, knowing that there is a set path, and knowing in advance the pay scales in which they can expect to move through.

Example 12: Exit interviews

Another important aspect of retaining staff is to identify why there is staff turnover and why employees had decided to leave the agency. The Netherlands Pharmacovigilance Centre (Lareb) organises an exit interview to be performed between the employee leaving and an external HR consultant. This consultant will then provide interview feedback to Lareb. This process can help identify reasons for staff turnover and ways to improve processes in order to retain more staff in the future.

2.2.5 Discussion on hiring, training and retaining staff

It is important for NCAs to consider the processes in place for recruitment and training to ensure that there is a sufficient range of expertise for PV assessment. It is evident that many NCAs face competition from the private sector and that recruitment and retention of staff is a significant challenge, particularly given the current climate of austerity measures. MSs participating in the survey noted that recruiting expertise in specialised areas can be difficult. In these circumstances, it can be helpful to consider strategies for raising awareness for assessor's roles and to convey key messages such as why the role is important, career options e.g. progression through competency framework, job satisfaction and the wide impact of the role on public health. A skills matrix is also a good tool for hiring, training and retaining staff.

It is acknowledged that the good practices should be adapted to the needs of the organisation. NCAs will have their own specifications for training, based on their new role and topics usually include legal and regulatory framework, PV processes, SOPs and scientific skills. It is also recommended that there should be regular review of the effectiveness of training materials and methods. Mentorship schemes can also be a useful method for inducting new staff into the agency. Shadowing, secondments and mentoring can also offer opportunities for staff to gain a wider understanding of the Agency's goals for public health protection and also to learn new skills. Case studies from five NCAs were presented (PT, UK, BG, IT, HR). These examples demonstrate:

- Recruitment using a pool of applicants
- Career development framework for PV scientific staff
- Training development plans
- Mentorship training plan
- Competence development framework for assessors and inspectors.

The development of a rolling programme of training presentations covering the core PV topic areas is a further method for opening opportunities more widely. This can offer development opportunities both to new staff and also to existing staff that require refresher training or are interested in expanding their knowledge outside the topic area in which they work.

Finally, staff commitment is a key aspect to help improve staff retention, focused on a two-way relationship between an employer and employee. Some of the key potential drivers include basic needs of pay and benefit, development opportunities and clear career progression.

2.3 Resource allocation

Key points

- Legal and regulatory requirements, the impact on public health, public interest and the role in the assessment process are key factors when prioritising workload
- Staff training and qualification is also an important factor, as is knowing the staff requirements for each role to better assign to appropriate staff
- A more collaborative approach is recommended when allocating work to create interest and career progression across teams
- Assessing the risk of a given process is also vital to effective allocation with agencies i.e. those processes with high risks could be prioritised
- Resource allocation should be examined to identify any unbalanced use of resources over time

Resource allocation is an economic or productive factor required to accomplish an activity, or as means to undertake an enterprise and achieve a desired outcome. Resource allocation refers to the distribution of staff, time and money to achieve the goals of the agency. It is the scheduling of activities and the resources required by those activities while taking into consideration both the resource availability and the timeframe. The most efficient method is to not allocate randomly, but to allocate by need and by skill set.

The process of allocating resources follows on from the process of predicting workflow and maintaining a sufficient pool of staff resources. However, it is an iterative cycle, where identifying areas of weakness in resources, during allocation, can inform resource planning and staff management going forward. The allocation of money is an important consideration in resource allocation, although for the purpose of PV and for this guidance document, staff will be counted as the biggest expense, and not materials available.

The basis for allocation of PV work should ensure the most appropriate use of scientific expertise. This is likely to be influenced by the organisational structure of PV departments, number of staff employed and volume of work. MSs participating in the survey confirmed that staff are assigned to activities based on their role in the assessment process, therapeutic alignment or specific expertise e.g. pregnancy, toxicology. Assignment to PV activities by therapeutic category can help develop sufficient depth of expertise amongst assessors with a more comprehensive knowledge of medicinal products.

Finally, it is also important to ensure that there is an appropriate skills mix within teams to ensure the right level of expertise and flexibility. Review and optimisation of resource allocation and skill base should be a continuous process as part of the annual business planning and management review.

2.3.1 Resource Allocation Plan

Criteria that may be taken into account when allocating work may include: impact on public health, the type of work, volume of work, knowledge and skills, qualifications, legal and regulatory requirements. MSs participating in the survey stated that they consider the legal and regulatory requirements, the impact on public health, public interest and the role in the assessment process when allocating resource. The 'type of work' can simply be described as the exact task to be completed e.g. RMP, signal management, PSUSAs etc. However, there are many considerations that need to be factored in when determining the type of work, for example, whether the task is individual or collaborative in nature. The latter may have a greater demand on resources, and require wider allocation considerations.

The knowledge, skills and qualifications are other important factors and can be well managed with a skills matrix-type set up. The matrix is assessed to identify who is best to perform a task, and the task is delegated to that person. The process of staff resource allocation can also be used to adapt and optimise a skills matrix, i.e. it may only be possible to identify that a process actually needs more trained people once that process is allocated and underway.

When allocating work, a more collaborative approach can help ensure that opportunities are opened up to more staff and the ability to seek support from other teams when the workload is exceptionally high. Contingency plans (such as the temporary diversion of staff from other duties) should also be defined and may include a priority ranking of activities.

2.3.2 Prioritise work based on risk assessment exercise

An important aspect of resource management is assessing the risk and the impact of a particular process; this allows Agencies to prioritise the allocation of processes, particularly in times of limited resource. Risks can tie together Agency business plans and PV tasks, identifying those which have a higher probability to disrupt business objectives and goals. Risk registers are a standard way of recording, and monitoring an identified list of risks. This is discussed further in **Example 13** below.

The 'Guidance on Network Risk and Ratings of Pharmacovigilance Process Areas' paper[13] was created by the HMA's Pharmacovigilance Audit Facilitation Group, and was designed to provide advice on assigning risks to PV processes for the purpose of audits. The recommendations and direction identified in the paper could help NCAs to assign risk during resource allocation. The paper highlighted the requirements of the GVP Module IV in developing an audit strategy based on a risk assessment for PV processes. The output of the risk assessment is used to allocate audit resources on the basis of risk to determine the frequency, order or scope of audits. The paper encouraged the further development of this risk assessment into a more formal process, in the context of audit strategies. Although the paper emphasised that each Agency should set its own risks as per its own processes and resources. This document could be used as guidance as it reflects the risks foreseen from the European level, based on how it has been implemented and its maturity. Agencies were encouraged to use an EU-wide perspective when exploring the assignment of risks.

Risk assessment must be a repeatable process that integrates into regular business practices, adapts to change, and delivers value. Risk assessment should be based on selected data captured in an organised way following templates and guidance, allowing for capturing quality data for assessment and reporting. Risk indicators should be developed.

Identified risks could be clearly formulated and transparent recommendations linked to them. Clear objectives must be defined and owners should be assigned to the action items related to risk responses, as well as to milestones and timelines for completion, which serve as triggers for any necessary follow-up.

Example ratings were provided in the paper for measuring the likelihood and the impact of risk occurrence for PV processes, a simplified matrix is shown in **Figure 11**.

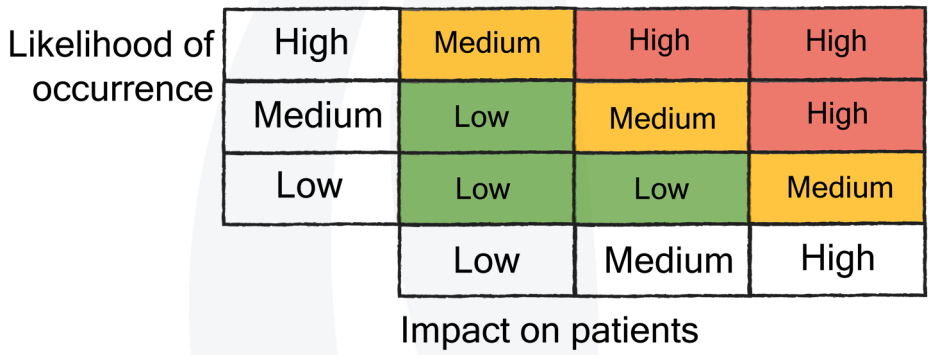

Figure 11. The 3x3 risk matrix presented as part of the audit risk management paper.

[13] Guidance on network risk ratings of pharmacovigilance process areas

Agencies would need to think about what a 'low', 'medium' and 'high' rating would mean internally, encompassing factors like: availability of SOPs, IT system capabilities, financial resources etc. Below in **Table 1** are some examples that the MHRA uses when grading risks as 'insignificant', 'moderate' and 'critical'.

Table 1. MHRA risk assessment grading

Impact	Description of impact	Probability
Critical	Prevents achievement of The Agency objectives or has highly damaging impact on Agency operational effectiveness or reputation.	Almost certain
Moderate	Impacts at local level on elements of efficiency, output and quality which impacts on the outcome of long term Agency corporate objectives. Potential for negative local media coverage.	Possible
'Insignificant'	Minor and containable impact on achievement of local (establishment / business area) objectives.	Rare

This type of system could be applied when managing capacity, to identify the processes that need to be tackled first i.e. the most high risk processes. Many MSs highlighted that they prioritise workload in their agency during the SCOPE survey; the examples presented here build on this and propose the use of formal risk/prioritisation methods. **Example 13** highlights the use of this risk-based approach with numeric ratings for different PV processes.

2.3.3 Resource Allocation Analysis

Resource allocation often leads to over-allocation (resource has been assigned more work than can be completed during normal work hours), overtime and overspending on financial resources. Therefore resource allocation should be examined to identify any unbalanced use of resources over time, and for resolving over-allocations or conflicts (**resource levelling**)

Levelling resources involves redistributing an imbalance of allocated work. It is to allocate resource efficiently, so that the work can be completed in the given time period. Resource levelling can be broken down into two main areas; tasks that can be completed by using up all resources which are available and tasks that can be completed with limited resources. Tasks which use limited resources can be extended for over a period of time until the resources required are available.

2.3.4 Resource re-allocation

The analysis of whether current staff resources are correct can sometimes be a difficult process, using factors like staff satisfaction as well as tangible metrics like timelines and quality of tasks delivered. Each NCA will have its own measure as to how resources fair in relation to the expected workflow. Staff satisfaction and work ethic can be explored during reviews.

The re-allocation of resources often means asking staff members to perform additional tasks outside of their normal job specifications. Cross-training is a way of helping staff to develop new skills and stay motivated in their work. This highlights the benefit of training staff in multiple areas of PV, as was highlighted by some MSs as part of the SCOPE survey.

When re-scheduling the resource allocation, it is vital to:

- Leave “breathing room” between tasks. A fine balance must be achieved between breathing room and not moving forward quickly enough
- Avoid the “putting out fires” approach. If one is consistently putting out fires, it makes it difficult to focus on the task.

SCOPE survey answers

The SCOPE survey asked MSs whether they had a capacity management plan in place to assist in resource management. Fourteen MSs (54%) stated that they did, with 12 (46%) identifying that they did not. When asked how staff were assigned to PV activities, the majority of MSs assign by the type of procedure, anatomical therapeutic class or therapeutic category. However, some stated that there was no special assignment of tasks.

MSs were asked to state which tools are used to support decision making i.e. how they prioritise workload. Twenty-four MSs base workload on legal requirements, 23 on public health impact and 20 on their role in the assessment process (lead or concerned MS). Only 8 MSs take into account additional monitoring status. MSs were asked how they respond to peaks in workload, and what tools are primarily used to cope with this. Eighteen MSs identified staff re-assignment as an important process, as well as working additional hours and hiring short term contracts. Some additional responses identified the use of cross-training to accommodate re-assignment of staff, as well as outsourcing to regional PV centres.

Prioritisation is an important aspect of resource allocation. MSs were asked to rate PV processes in order of importance with respect to resource allocation. ADR management was rated with the highest priority and PSUR, PASS and RMP assessments as the least. This highlights the difficulty in resource management for NCAs, where MSs have rated ADRs as the most important, however, ADR management can be challenging as MSs have no control over when ADRs are submitted and the impact they have. Conversely MSs rated PSURs as one of the least prioritised processes, yet these are one of the most easily predictable workloads.

2.3.6 NCA good practice examples

Example 13: a tool for prioritising PV issues

Signal prioritisation is required to focus the resources available on the most important signals. Signals with a potential important public health impact or which may significantly affect the benefit-risk profile of the medicinal product require urgent attention and should be prioritised for further management. A standardised approach based on the most important criteria that can be used should be in place and validated criteria should be employed as much as possible.

Seabroke et al.[14] in a recent publication, state that the prioritisation of drug safety issues for further evaluation or regulatory action is critical to ensure that acceptable timelines and appropriate resource allocation are defined to meet public health and regulatory obligations.

A novel tool for prioritising pharmacovigilance issues within the MHRA was developed and implemented, called the Regulatory Pharmacovigilance Prioritisation System (RPPS).

The RPPS tool provides a systematic approach to prioritise PV signals according to the following four broad categories, each with four inputs:

- Strength of evidence
  - Disproportionality measure/risk estimate
  - Data sources
  - Evidence from RCT or meta-analysis
  - Biological plausibility
- Public health implications
  - Drug/vaccine exposure
  - Frequency of ADR
  - Health consequences
  - Spontaneous case reports
- Agency regulatory obligations
  - Ministerial/public health authority concern
  - Recent parliamentary questions
  - European obligations
  - MAH application

[14] Seabroke S, Waller P. Development of a Novel Regulatory Pharmacovigilance Prioritisation System. http://link.springer.com/article/10.1007/s40264-013-0081-3#

- Public perceptions
  - Media attention
  - Factors likely to cause public anxiety
  - Public misperceptions
  - Other public concern

These categories comprise some points to consider in the prioritisation of signals and can help to reduce the subjectivity of reliance on individual judgement.

Example 14: a business plan for merging of assessment functions

This example details the business solutions used to manage the predicted fluctuations in workload at the MHRA. Type IB variation assessments as part of the Vigilance, Intelligence and Research Group (VIRG), and product label and leaflet (L&L) assessment as part of the Access and Information for Medicines and Standards (AIMS) Group, both result in amendments to statutory product information. The business therefore proposed to bring these assessment functions together as part of the AIMS workload.

It was stated that not only would this merging of functions help manage the workload of the MHRA, it would also foster cross-skilling and create interest and career progression across teams. It was highlighted that industry was already supporting proposals to combine variations and L&L applications, with a pilot underway.

This business case suggested that Executive officers (EOs) in AIMs would take on the workload for Type IB variations so that the higher and senior executive officers (HEOs & SEOs) in VIRG and AIMs could focus on the increasing demand from Type II variations, and article 61(3) L&L submissions respectively.

The business case then described the exact requirements for resource, citing the expected number of full time equivalents (FTEs) needed to handle Type II variations, Type IB variations and the article 61(3) L&L submissions. One EO was transferred to the new merged function and the business case proposed a further 5 EOs would be required. Therefore the request was to seek the employment of 5 fixed-term contract staff at EO level, for an initial 1 year period.

Example 15: a risk assessment tool

The Medicines Evaluation Board (MEB) of the Netherlands describes a process by which they assess the risks of internal processes i.e. what are the chances that it can occur and what is the impact to plan PV audits. Although MEB do not use this method for operational planning, the principle behind it could be adapted and could prove useful for ranking the risks of PV processes, as per NCA conditions.

The method described by MEB uses risk metrics, which quantitatively prioritise tasks assessing probability, impact, and risk management as factors. These three metrics are then used to calculate an overall risk score for a given activity.

As a tangible representation of these metrics, MEB has also assigned given metrics to cost, planning and quality outputs e.g. a high probability risk, with high impact would have the ability to increase the annual budget by over 10% of the prediction (or greater than €50k above the target).

The methods used by MEB for their risk assessment tool are described further below. **Table 2** outlines some details for a selection of PV activities, together with each of the 4 key risk metrics used by MEB: probability, impact, control and risk score.

Table 2. A selection of PV activities together with the various values assigned to each activity based on various risk parameters.

PV process	Risk description	Probability (1)	Impact (2)	Measure of control (3)	Risk score (4)
RMP	Lack of adequate trained staff could impact on the quality of the assessment and handling of RMP procedures	0.5	3	0.2	8
PASS	Recent and not fully developed at the European level, therefore not enough experienced and trained staff to assess PASS	0.3	2	1	1
ADR collection	Process is outsourced	0.2	4	1	1

(1) This determines how likely it is that the risk will actually take place. Use the following values: issue = 1, high = 0.6, average = 0.5 or 0.4, low = 0.3 or 0.2, negligible = 0.1

(2) This is interpreted what degree of impact this risk might actually take place. Use the following values: high = 4, average = 3, low = 2, negligible = 1

(3) This is interpreted what degree is that it affects CBG on the occurrence of the risk. Use the following values: no = 0.1, partial = 0.15, fair = 0.2, full = 1

(4) This is calculated according to the following formula: [(probability)(impact) / (measure of control)] = risk score. red > 15, amber 10 – 15, green < 10*

2.3.7 Discussion on Resource Allocation

The most efficient method to allocate resource is by need and by skill set to ensure the most appropriate use of scientific expertise. It is also important to establish an appropriate skill mix within teams to develop a flexible and integrated approach. Furthermore, the organisation structure of the department, the volumes of work, legal and regulatory requirements and impact on public health should also be considered. Some NCAs allocate PV activities by therapeutic category to develop a more comprehensive knowledge of medicinal products.

Risk based approach to regulation is where the level of activity in an area is proportionate to the risks associated with the activity to enable appropriate allocation of resources to areas of highest risk to public health. ICH Q9 Quality Management defines the foundation for a 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.[15] ISO 9001:2015 states that *'risk-based thinking is essential for an effective quality management system'*, addressing both risks and opportunities.

Resource allocation should be based on the needs of the organisation and should take into account internal factors. NCAs will have conducted a risk assessment of its own specific PV system processes to develop audit strategies. This includes determining in its system (i) the likelihood of occurrence of a non-conformance which may not be detected by other means and (ii) the severity of the outcome of the non-conformance on patients or public health.

For example, when considering risk, what makes the likelihood 'high' for one process and 'low' for another? This could for example be dependent on a lack of available training or significant staff turnover. A few examples of factors that NCAs could consider are listed below:

- Trained staff i.e. expertise
- Processes documented e.g. SOPs
- Changes in organisational structure or responsibilities for PV
- Turn-around-time
- Volume of work
- IT systems e.g. electronic document management system to track and store PV documents.

Signal detection is a PV process with a network risk rating of 'high'[15] on the rating that (i) the likelihood of occurrence of a non-conformance which may not be detected by other means is 'medium' and (ii) the severity of the outcome of the non-conformance on patient's or public health is 'high'. This rating is also reflected in the responses to the survey for prioritising PV activities.

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

Case studies from two NCAs were presented (UK, NL). These examples demonstrate:

- A tool for prioritisation of PV signals
- An example of merging roles and re-allocating resources through cross-training
- Metrics for assessing risk for PV processes, and proposals for introducing this into formal resource allocation.

3. Conclusion

The introduction of the 2012 PV legislation offers better protection of public health through greater clarification of the roles and responsibilities of MAHs and NCAs, more focus on proactive and risk proportionate safety monitoring, robust and timely decision making. Implementation of PV legislation has been challenging, with an increased burden on NCAs through several channels. This had a significant impact on how Agency's manage their resources, particularly given the current climate of austerity measures. A continuous quality improvement focus is essential in order to optimise NCA efficiencies. This guidance document has presented literature references in addition to NCA good practice examples to provide ideas and methods for NCAs to develop their own Quality Management Systems to better manage their resources.

Proposals have been made to predict capacity using historical trends, and skills matrixes, although notable some PV workload simply cannot be predicted. Managing staff was highlighted as an important area for development in the SCOPE survey responses, methods to adequately train and retain staff members were therefore discussed. Finally, assessing risk was highlighted as an important factor in efficiently allocating and re-allocating resources.

Each of these aspects to resource management are not mutually exclusive, and for an effective resource management system to operate all need to be optimised and working together. It is important to recognise that there are differences in resource, volumes of work and maturity of PV systems across the network. Each NCA will have different internal structure, and therefore no one solution will suit all. However, this guide should provide ideas for NCAs to adapt and learn from in order to develop further their own systems, and better cope with the challenges in resource management.

Annex

WP7 Resource Management Survey Report

WP7 DEL7 Resource Management Survey