SCOPE Work Package 7
Quality Management Systems

Quality Planning and
Quality Objectives

2016

SCOPE

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Contents

Acknowledgments

1. Introduction

1.1 Purpose of the document

The purpose of this document is to introduce a specific process of Quality Management to pharmacovigilance (PV) assessors and any interested parties at National Competent Authorities (NCAs): Quality planning and the selection and management of quality objectives. The document covers basic definitions and introduces the topic through several practical examples from PV as collected by an online survey and through written and face-to-face follow-up activities from NCAs participating in the SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe) project.

The purpose is to share experience with and disseminate good practice across Member States (MS) and to increase the level of awareness of PV assessors and interested staff on specific areas of quality management instead of providing exhaustive guidance. Practices described in this document may not cover all relevant issues and may not be suitable for every NCA. It is at the discretion of each NCA whether to consider any practices presented in this document relevant to their work, and there is no obligation to adopt any practices.

1.2 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
BEMA	Benchmarking of European Medicines Agencies
BSC	Balanced Scorecard
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures – Human
DHPC	Direct Healthcare Professional Communication
EPITT	European Pharmacovigilance Issues Tracking Tool
EMA	European Medicines Agency
eRMR	electronic Reaction Monitoring Report
EU	European Union/Europe
GVP	Guideline on Good Pharmacovigilance Practices
HALMED	Agency for Medicinal Products and Medical Devices of Croatia
HCP	Healthcare Professional

Terminology	Description
INFARMED	National Authority of Medicines and Health Products (PT)
ISO	International Organisation for Standardisation
IMPACT	Implementing Pharmacovigilance Actions team
IT	Information Technology
MAH	Marketing Authorisation Holder
MEB	Medicines Evaluation Board (NL)
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
KPI	Key Performance Indicator
MS	Member State
NCA	National Competent Authority
OGSM	Objectives, Goals, Strategies and Measures
PDCA	Plan-Do-Check-Act
PRAC	Pharmacovigilance Risk Assessment Committee
PV	Pharmacovigilance
QMS	Quality Management System
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SOP	Standard Operating Procedure
SMRM	Signal Management Review Meeting
SWOT	Strengths, Weaknesses, Opportunities and Threats
VRMM	Vigilance and Risk Management of Medicines (MHRA)
WIN	Work Instruction
WP	Work Package

1.3 Background

The effective and efficient operation of any organisation, organisational unit, management system or subsystem is primarily dependent on a consistent planning process. Goals relevant for the strategic direction of the organisation have to be carefully planned together with measurable indicators to check for the realisation of targets within a defined timeframe, and results have to be fed back to the system for correction and improvement. Furthermore, planning ensures that available resources that are usually limited or restricted in nature are used in the most effective and efficient manner. Although NCAs are operating in the public sector, which makes them different from the private sector in many ways, a key sense of direction, good strategy and effective implementation of strategic plans is essential to achieve success.

Quality management adds a further dimension by ensuring that the organisation works in compliance with statutory and internal requirements, makes every effort to satisfy the needs and expectations of its customers, aims at continuous improvement of its services and maximises its performance. Introduction of quality management is the decision of the top management of an organisation and an effective PV quality system cannot function in isolation, but rather as an integral part of the global organisational quality system.

In public organisations, quality is often defined as the minimum that a supervisory body (e.g. government) demands, and cost reduction is usually more important than quality improvements which may not lead to an increase in customer demand.[1] Nevertheless, based on the results of the online survey conducted by WP7, some NCAs who decided to follow available international quality standards (i.e. ISO 9001 and others) to assist them in the development of their quality systems, benefited from such an approach considering both the global organisational and the PV quality systems.[2] Furthermore, GVP Module I is consistent with the general principles of the ISO 9000 Standards on good quality management practices, specifically the ISO 9001:2008 Standard[3] on quality management systems, issued by the ISO.

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[1] Pejovic G, Filipovic J, Tasic L, Marinkovic V. Int J Health Plann Mgmt (2014) DOI: 10.1002/hpm.2265

[2] Pálfi M, Cserjés Zs. SCOPE Work Package 7 – Survey Report (2015)

[3] Please note that from 15 September 2015, ISO 9001:2008 has been cancelled and replaced by the newest edition ISO 9001:2015.

Results of the online survey[4] conducted by WP7 specific to the topic of this document pointed out that although planning activities are in place at several NCAs as regards PV, it seems to be ad hoc in a number of cases. Additionally, some discrepancies have been observed in the understanding of certain quality concepts related to the planning process (e.g. quality objectives, performance and compliance indicators) which highlights the need for clear definitions and explanation via practical examples. Specifically, the relationship between business and quality planning, the place of PV planning in the planning activity of the organisation, and the relationship of PV quality objectives to indicators, especially that of compliance and performance management were identified as requiring further explanation.

1.4 Context and scope of the toolkit item

One of the deliverables of WP7 is to assemble a quality toolkit, a diverse collection of case studies, good practices, templates and guidance for NCAs to aid the understanding of quality management and the establishment and operation of their PV quality systems. This toolkit is not intended to be exhaustive and should be used to supplement legal requirements and already existing guidance.

This document constitutes an item of the quality toolkit that outlines the importance and features of the quality planning process as an integral part of a well-functioning QMS. The document discusses the relationship of business and quality planning and its various levels (strategic and operational). It will be explained how quality objectives – the primary foci of quality plans – may be derived from and related to the quality policy of the NCA and the business planning process. Practical examples and case studies will be provided to demonstrate how PV activities are represented at various levels of the planning process, including the selection and management of objectives related to the quality and business management cycle.

In line with the information presented in the previous section (1.3 Background), quality planning and quality objectives will be interpreted and discussed with reference to relevant international standards, where applicable, so that organisations may see the added value of organising work along with recognised quality principles, but without any obligation to follow such principles.

This document will not go into details of business management systems, and the methodology of strategic or operational business planning. It will focus only on the place and added value of quality management in the overall panning process and will handle PV quality system as part of the organisation's QMS.

The information sources of this document are data provided by NCAs during the online survey, conducted by WP7 among SCOPE active partners; site visits, face-to-face and written follow-up activities at some NCAs, websites of NCAs and the scientific literature.

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[4] Pálfi M, Cserjés Zs. SCOPE Work Package 7 – Survey Report (2015)

1.4.1 Objectives

This document will cover specific subtopics supported by practical examples coming from the practice of NCAs that are summarised as follows:

- The concept of planning and the relationship of quality and business planning

- Various levels of planning from strategy to individual employees

- The concept of a quality policy

- The concept of quality objectives, factors to be taken into account during their selection and their documentation

- The relationship of quality objectives to indicators

- Inputs of the planning process

- The contents of quality plans

- Monitoring and evaluation of implementation

- Communication of strategies, the quality policy and objectives to staff and their feedback and involvement in the planning process.

When presenting examples, the '*golden thread*' will be followed that connects top management with individual employees, i.e. how strategic objectives of the organisation are cascaded down to the work of each and every individual employee with specific focus on PV activities and the contributory role of PV staff.

1.4.2 Limitations

Participation in SCOPE was voluntary for MSs, and the type of information and level of details provided during the online survey or follow-up activities was at the discretion of each participating NCA. Good practices and case studies chosen by the author to be presented in this document are based on the information provided by MSs and the willingness to share experience and practices, and are therefore not representative of all EU NCAs. Further to the examples described, most probably there are other NCAs where the planning process as a whole or any sub-processes are robust and functioning well. Additionally, good practices presented in this document may not be suitable for every NCA, as operation of a QMS should respect a variety of local or internal factors, and should be adapted to the needs of an organisation.

2. Introduction to quality planning and the selection of quality objectives

2.1 The concept and significance of planning

Planning is the process of thinking about and organising the activities required to achieve a desired goal. The activity of planning has to be distinguished from forecasting. Forecasting can be described as predicting what the future will look like, whereas planning predicts what the future should look like for multiple scenarios. Planning combines forecasting with preparation for scenarios, and how to react to them.[5]

In an organisation, planning is a management oriented process, which increases the rational use of its resources, identifies and reduces the risks and recognises and takes advantage of opportunities involved in its business activities.

Planning is strongly associated with the **management of resources**[6] within an organisation, as resources are often limited and careful consideration is needed to define goals and find and allocate sufficient resource for realisation of the objectives.

2.2 Business planning, quality planning and their relationship

There are various types of plans that help organisations achieve **effectiveness** and **efficiency**.[7]

A **business plan** is an essential roadmap for an organisation that outlines its goals and targets; i.e. *what* to be achieved in order to manage business, develop and grow.

A **quality plan** outlines *how* business plans should be realised so that the organisation (1) meets the needs and expectations of its customers and stakeholders; (2) complies with legal and organisational requirements; and (3) continually improves the effectiveness and efficiency of its capabilities. High quality is achieved by planning for it rather than by reacting to problems ad hoc after they have been identified. Incorporating quality into the activities of an organisation increases credibility and accountability and builds trust among its stakeholders.

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[5] https://en.wikipedia.org/wiki/Planning; downloaded [23/08/2015]

[6] For further information on resource management in association with PV activities, please consult Toolkit item: **Resource Management**

[7] For an explanation of **Effectiveness vs Efficiency** please refer to the Additional Information.

Quality planning can be a part of **business planning** or treated as an independent entity depending on the organisational structure and decision of the top/quality management of the organisation. Nevertheless, some EU NCAs (HR, NL, PT, UK) with a very robust planning process are concordant in that business and quality planning should be kept integrated as much as possible. There is a tendency that international quality standards (e.g. ISO 9001:2015) also promote the existence of one management system within an organisation. The quality policy should fit for the purpose and context of the organisation and support its strategic direction.[8] Top management is recommended to integrate and keep quality management policies and objectives consistent with strategies, policies, and objectives for other business areas.[9]

As a consequence, the upcoming sections of this document will focus on the added value of quality planning and quality objectives to business planning, keeping in mind that there may be no rationale in strictly separating business and quality planning and related objectives.

2.3 Levels of planning

There are various levels of planning. On the **strategic level**, a plan generally encompasses a period of 3-5 years ahead and outlines the route an organisation intends to take.[10] A strategic business plan includes the *mission* and *vision* statements[11], core values of an organisation, strategic areas of focus, and strategic goals with a high level action plan. Strategic objectives may include both business and quality objectives. Strategic goals of the QMS are outlined in the **Quality policy** which is the vision on quality management in the organisation. The quality policy has to be translated to measurable objectives and requirements during the quality planning process.[12]

Since the introduction of the current PV legislation in July 2012, PV has increasingly been recognised as a strategic area for NCAs with a significant place among current strategic goals.

Implementation of each strategic goal may concern several or all units in the organisation. At the **tactical** and **operational level**, strategic goals should be broken down to operational objectives, steps and targets and cascaded down to organisational units, and eventually, to individual employees who carry out the work. This is generally put in place in the form of annual plans. Each operational objective should have a connection to the strategic goals.

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[8] ISO 9001:2015

[9] Beecroft GD, Duffy GL, Moran JW (eds) The Executive Guide to Improvement and Change, ASQ Quality Press, Milwaukee, Wisconsin, (2003) p36.

[10] https://www.sba.gov/writing-business-plan; downloaded: [23/08/2015]

[11] A **Vision statement** defines the optimal desired future state of what an organisation wants to achieve over time. A **Mission statement** defines the present state or purpose of an organisation; its activities, stakeholders and the way it achieves its tasks. Source: https://www.psychologytoday.com/blog/smartwork/201004/vision-and-mission-whats-the-difference-and-why-does-it-matter; downloaded: [07/01/2016]

[12] http://www.businessdictionary.com/definition/quality-planning.html; downloaded: [15/10/2015]

Quality plans may also manifest as relevant **written quality documents** at all levels of the planning process such as quality manuals, SOPs or WINs that give framework to the quality system, define basic common supportive (e.g. control of documented information, internal audit, handling of risks and opportunities, etc.) or specific procedures performed by single or multiple departments. These 'plans' ensure robustness of everyday activities and an easy and effective handling of non-conformities or deviations from plans.

2.4 Quality policy

The quality policy of an organisation defines its high level goals for quality management. A quality policy should include a commitment to comply with requirements and continually improve the effectiveness and efficiency of the quality management system.[13] Each statement in the quality policy may result in one or more quality objectives. The quality policy should be reviewed periodically for continuing suitability.[14]

2.4.1 Examples of quality policies of EU NCAs

Some NCAs make quality policy of their organisations publicly available on their websites. Typical summaries are provided in the following examples.

[13] ISO 9001:2015

[14] http://askartsolutions.com/quality-objectives.html; downloaded: [15/10/2015]

Agency for Medicinal Products and Medical Devices (HALMED), Croatia[15]

- Correct, confident and ethical execution of work processes by respecting professional confidentiality, good professional practice and quality of work. This should be maintained at the highest level when providing services which is achieved through permanent education, both in professional and scientific field and supporting employees to acquire new skills

- Improvement of the quality system according to various national and international quality standards and benchmarking with the EU Agencies

- Continuous improvement of the QMS, promotion of the Agency's quality policy and values by each and every employee

- Cooperation with the EU Network, national and international competent authorities in the field of medicinal products and medical devices. Implementation of EU law and continuous monitoring and harmonisation with any changes. To achieve this, proper internal infrastructure in terms of human resources and technical support will be developed and provided

- Continuous improvement of transparency of the regulatory system and communication to facilitate access to the safest medicinal products and medical devices to every citizen.

Health Products Regulatory Authority (HPRA), Ireland[16]

To help us to achieve the goals set out in our mission statement, we will ensure that quality is central to all aspects of our work by:

- Establishing, implementing and maintaining a documented, effective quality management system in line with best international practice

- Incorporating HPRA corporate quality objectives, essential to the implementation of strategy and based upon our customers' needs and expectations, into functional targets and work plans

- Monitoring our performance against these quality objectives, and reviewing and revising them as necessary to ensure that we achieve our aims for continuous improvement

- Ensuring that a trained and experienced team of HPRA personnel, committed to achieving our quality objectives, is available and that these staff members are provided with appropriate resources, in terms of infrastructure, to achieve these objectives

- Complying with the requirements of all relevant financial reporting standards, legislation, and Board and government policies

- Aiming to maximise the reuse and recycling of materials and minimise the production of waste material.

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[15] http://www.almp.hr/fdsak3jnFsk1Kfa/ostale_stranice/Quality_Policy_Statement.pdf; downloaded: [16/01/2016]
[16] https://www.hpra.ie/homepage/about-us/quality-management; downloaded: [16/01/2016]

State Institute for Drug Control (SÚKL), Slovakia[17]

In relation to customers:

- Prompt and professional handling of requests and on qualified, uniform and consistent performance of professional activities in all organizational units of SÚKL, including electronic data processing
- Impartiality, objectivity, transparency and confidentiality when providing services
- Developing of professional communication, including requests for customers' feedback regarding the quality of provided services.

In relation to stakeholders:

- Active participation of SÚKL management in the national drug policy in cooperation with the Slovak Ministry of Health
- Developing of cooperation with organisations ensuring the quality of medicines and medical devices: on both the national level (professional organisations – Slovak Pharmaceutical Chamber, Slovak Medical Chamber, Association of Slovak companies in the field of drug regulation, regional governmental bodies, and other ministries of SR) and on the international level (EU and Pharmaceutical Inspection Convention Scheme)
- Obtaining of a stable and reputable position among medical agencies and related bodies (EMA, EDQM, and WHO)

In relation to SÚKL employees:

- Creating conditions for adequate education and professional development of employees
- Objective, impartial and motivating evaluation of employees' performance
- Effective communication of information and increasing of staff involvement in SÚKL activities either individually or as a team
- Improvement of SÚKL management system documentation in order to ensure systematic, goal-oriented and high-quality performance of assigned tasks
- Increasing employees` conciseness of their personal commitment to quality, as well as their compliance with the Code of Ethics of SÚKL
- Systematic evaluation of SÚKL activities, elimination of gaps and deficiencies and dynamic improvement of all activities
- Open communication within SÚKL using all available forms and implementation of findings.

In relation to patients/citizens of Slovak Republic:

- Availability of high quality and safe medicines and medical devices on the market
- Availability of information regarding authorised medicinal products and those withdrawn from the market

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[17] http://www.sukl.sk/en/about-sidc/quality-policy?page_id=1018; downloaded: [16/01/2016]

2.5 Quality objectives and their selection

Objectives are crucial to the planning process, as they represent the goals to be achieved in a measurable format. To avoid confusion or an improper use of terminology, **goals** should be distinguished from **objectives**. One approach for distinction is presented here. Although, they both represent things a person or an organisation wishes to achieve, goals stand for an action that may be long term, and may not be strictly measurable or tangible. On the contrary, objectives assume specific action on a shorter term, and support attainment of the associated goal. A strict criterion is that objectives are *measurable* and *tangible*.[18] Generally, a goal is likely to be associated with a number of objectives.

A **quality objective** is a specified level of quality that must be met by a product, process, service or any project outcome, to be considered acceptable[19]. Quality objectives should provide information on (1) conformity to legal obligations or organisational requirements; (2) fulfilment of customers' needs and expectations; or (3) the effective and efficient operation of a system or process or implementation of a project. As mentioned earlier, quality objectives may be interpreted in conjunction with, integrated into or supplementary to business objectives.

Quality objectives should derive from the quality policy of the organisation.

Objectives are set at various functional levels (strategic, tactical or operational, e.g. organisation, departments, processes, individuals) and should be documented. As such, objectives should be carefully cascaded down from the strategy to organisational units and individual employees and broken down and set for shorter, definite time periods to continuously achieve concrete results.

Selection of objectives is recommended to follow the **SMART principle**. SMART is an acronym that stands for Specific, Measurable, Achievable, Realistic and Time bound[20]. In summary, a SMART objective is well-defined and focused rather than being too general; the results can be assessed qualitatively or quantitatively; is realistic and achievable for employees; is consistent with the mission/role/context of the organisation, or the employee's place in the organisation, and is achieved within a defined time period to ensure accountability. It is also of primary importance that objectives neither impose extreme workloads on employees, nor require efforts below standard performance.[21]

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[18] http://www.diffen.com/difference/Goal_vs_Objective; downloaded: [07/01/2016]

[19] http://www.businessdictionary.com/definition/quality-objective.html; downloaded: [21/10/2015]

[20] Please note that the acronym may be interpreted slightly differently by various sources.

[21] Government of Canada – "SMART" objectives and performance indicators. http://www.tbs-sct.gc.ca/psm-fpfm/learning-apprentissage/ptm-grt/pmc-dgr/smart-eng.asp; downloaded: [06/01/2016]

2.6 Measurement of (quality) objectives, setting of indicators

It is important that progress made in terms of strategic goals and specific objectives (i.e. the implementation of processes or projects, achievement of desired outcomes, performance or impact of interventions) are systematically measured during continuous monitoring. Planning, monitoring, evaluation, correction/improvement are closely linked and sequential activities of the quality planning cycle.

Objectives become assessable when relating them to certain values that can be measured. These values can either be measures or indicators. Measures and indicators are different from a conceptual approach[22], but this document will use the term 'indicator' when referring to the measurement of objectives.

Indicators measure to what extent an objective has been met, and may be associated with implementation of a process, achievement of an outcome, performance or impact of an intervention. As such, performance indicators – perhaps the most commonly encountered – are an important class of indicators that relate strongly to quality management, but it should be realised that as objectives may vary largely among organisations, types of indicators should not be restricted to ones measuring performance[23].

Indicators have limitations, and cannot convey information on several aspects of an implementation process (e.g. complex relationships and reasons, why and how change occurs); therefore, indicators should be chosen carefully to be relevant for the objectives and the organisation. Indicators are sometimes easily quantified (numbers or percentages, i.e. quantitative indicators), but sometimes more descriptive qualitative indicators are needed to assess more complex scenarios (i.e. changes in attitudes and behaviour) or a mixture of qualitative or quantitative aspects may be used within the same indicator.[24, 25]

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[22] Jones P. What is the difference between a measure and an indicator? (2012 May 19)
http://www.excitant.co.uk/2012/05/what-is-the-difference-between-a-measure-and-an-indicator.html downloaded: [06/01/2016]

[23] For performance and compliance indicators used in PV, please consult Toolkit item: **Compliance and performance management and indicators**

[24] IBIS Manuals – The programme management manual. Monitoring toolbox – Tool 8. Guidance on objectives, indicators and annual objectives. http://ibis-admin.org/promm/3-tp-monitoring-guidelines/; downloaded: [06/01/2016]

[25] Lennie J, Tacchi J, Koirala B, Wilmore M, Skuse A Equal Access Participatory Monitoring and Evaluation Toolkit. Module 2 Setting objectives and indicators. (2011 Feb)
http://betterevaluation.org/sites/default/files/EA_PM%26E_toolkit_front_pages%26introduction_for_publication.pdf; downloaded: [06/01/2016]

Indicators should always be used in the context of objectives, not in isolation; therefore without the definition of appropriate objectives, indicators cannot be assigned to them. A reverse order, setting of indicators without understanding their relationship to local or strategic objectives is likely to result in failure. When selecting indicators the already mentioned SMART principle can be applied. Similarly to objectives, indicators are chosen so that they are appropriate and relevant to the scope and context of the organisation, department, process or project, fits in the way the organisation is managed, and is preferably free from external influencing factors. Indicators should be kept simple, they should be clear, easy and feasible to collect without the measurement being too time-consuming or demanding on resources. They should be objective, accurate, useful and unambiguous to interpret. It should be clear what to do when the indicator indicates a favourable or unfavourable scenario. On the other hand, as good indicators are simple, there may be a temptation to use them to simplify complex situations and use measurement instead of managing the issue; this should be avoided. Finally, the number of indicators is recommended to be kept to a reasonable minimum, as regular and careful evaluation is more important than having a larger number of indicators which may result in information overload without a learning perspective and any added value.[26, 27, 28]

In summary, indicators useful and relevant for one organisation may be inappropriate for another; therefore, general examples are hard to provide without having extensive knowledge of what is important for an organisation and what context it works in. Carefully chosen and communicated indicators will help manage business, and encourage positive behavioural patterns of employees and contribute to improvement; whereas indicators used as simplification of complex situations, without a clear link to strategic or operational objectives will not improve effectiveness and efficiency.

[26] Jones P. The KPI substitution heuristic – or why use a KPI in first place. (2014 Oct 26) http://www.excitant.co.uk/2014/10/the-kpi-substitution-heuristic-or-why-use-a-kpi-in-the-first-place.html; downloaded: [06/01/2016]

[27] IBIS Manuals – The programme management manual. Monitoring toolbox – Tool 8. Guidance on objectives, indicators and annual objectives. http://ibis-admin.org/promm/3-tp-monitoring-guidelines/; downloaded: [06/01/2016]

[28] Lennie J, Tacchi J, Koirala B, Wilmore M, Skuse A Equal Access Participatory Monitoring and Evaluation Toolkit. Module 2 Setting objectives and indicators. (2011 Feb) http://betterevaluation.org/sites/default/files/EA_PM%26E_toolkit_front_pages%26introduction_for_publication.pdf; downloaded: [06/01/2016]

2.7 Quality objectives defined for PV activities

GVP Module I provides MSs with guidance on the operation of their quality system as an integral part of their national PV systems. This includes the planning process and the setting of quality objectives. GVP I.B.4. provides the **overall quality objectives of PV systems** as follows:

- *Complying with the legal requirements for pharmacovigilance tasks and responsibilities*

- *Preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure*

- *Promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public; and*

- *Contributing to the protection of patients' and public health.*

[…]

In order to have a systematic approach, the organisation should define in advance:

- *Quality objectives specific to their organisations in accordance with the overall quality objectives and the structure- and process-specific quality objectives in accordance with each Module of GVP; and*

- *Methods for monitoring the effectiveness of the pharmacovigilance system.*[29]

Supporting the strong relationship to business management, the overall quality objectives defined by GVP may be interpreted as integrated quality and business objectives. Furthermore, some MSs indicated in the online survey of WP7 that these objectives were considered as general guiding principles and were not included directly in operational objectives.

GVP Module I remains silent on **process-specific PV quality objectives** and how to measure such objectives. Despite this, GVP Modules of PV specific processes may contain hints on quality requirements. Furthermore, based on specific GVP Modules, the Pharmacovigilance Audit Facilitation Group defined objectives to support internal audit of PV processes in the form of checklists. According to NCAs' practice, specific PV (quality) objectives are either incorporated in the NCAs' strategic or annual organisational or divisional plans; or quality requirements for PV activities are defined in relevant SOPs, the quality manual or other written quality documents.

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[29] Guideline on Good Pharmacovigilance Practices (GVP) Module I – Pharmacovigilance systems and their quality systems EMA/541760/2011 – 22/06/2012

Further to the above, it may be difficult to provide general examples of PV objectives. It should be emphasised that there are no limitations as to what a business or quality objective may be – as long as they fulfil the previously mentioned criteria, can be monitored and measured; their selection should be based on a good understanding of what is important for the organisation or organisational units. Therefore, it might not be possible to provide NCAs with general indicators as they are dependent on specific objectives. Vice versa, without a deep insight into and a thorough assessment of the context, adoption of general examples may not be recommended either. For examples of indicators used by NCAs, consult the Case studies, where indicators used are put in context.

2.8 The quality planning process

Quality management can be envisaged as a cycle which is the basis of corrective action as well as continuous improvement. The methodology called **PLAN-DO-CHECK-ACT** (PDCA) can be applied to all processes and the system as a whole (dynamic cycle). The cycle starts with planning activities.

At the organisation level, quality planning addresses development, maintenance and improvement of the overall QMS. At lower levels, quality plans (e.g. written procedures) set specific procedural quality objectives and the quality assurance and control activities to be performed in day-to-day operations. During the realisation of plans, they are transformed from documents to *records*[30].

Quality planning may be applied prior to the introduction of new structures, processes or projects; or when **changes** to the existing processes included in the QMS are required. The continuity and integrity of the QMS must be maintained in the event of significant changes in the QMS or organisation. Changes must be carefully planned so as not to disturb the organisation's ongoing capability and responsibility to effectively meet customer and regulatory requirements.[31] Potential consequences of the change shall be investigated well in advance (impact analysis). Preliminary studies may be conducted to compare the new structures or processes to the old one to verify its suitability. Following implementation, new structures and processes should be evaluated and adapted as necessary. For examples of such an approach, refer to the Case studies.

A quality plan describes how an organisation will achieve its quality objectives.

Plans are documented outcomes of the planning process at a given point of time. To maintain flexibility, planning should be an ongoing, active process and plans should be evaluated on a regular basis for continuing suitability and updated as necessary.

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[30] Record is used in the previous ISO version 9001:2008. In ISO 9001:2015, it is uniformly referred to as documented information.

[31] http://isoconsultantpune.com/iso-90012008-quality-management-system/iso-9001-requirements/iso-9001-clause-5-4/; downloaded: [15/10/2015]

2.8.1 Input to planning

During the planning process a variety of factors are recommended to be considered. Some examples are provided in the following list:

- External and internal relevant influences with an impact on the strategic direction and ability of the proper functioning of the QMS in an organisation:
  - Legal requirements (national and international)
  - Benchmarking activities (e.g. BEMA)
  - Strategic concerns in the EU
  - Specific organisational requirements
  - Cost-benefit analysis: the cost of poor quality, the cost of quality improvement and the cost of benefits to be achieved
  - Resources available (infrastructure, human, financial)
  - Risk assessment, analysis of risks and opportunities
  - Potential/anticipated impact.

- Performance or compliance data of an existing system:
  - Review of system, or process data, if available (audit findings, process performance and status of preventive and corrective actions, follow-up actions from previous management reviews, and recommendations for improvement).

- Stakeholder requirements and expectations, evaluation of information relating to customer perception as to whether the organisation has met the customer requirements, customer satisfaction data, and staff feedback, if applicable.

2.8.2 Contents of the plan

In the following list, examples are provided on what items are to be included in a quality plan:

- **Quality objectives** and **indicators**, method and frequency of data collection and method of evaluation of indicators including acceptance and rejection criteria

- **Process steps**: inputs, outputs, value adding or conversion activities, sequence of steps

- Nature, method, frequency and timing of **interaction with other processes** and where this interaction will occur

- **Process owner, responsibilities and accountabilities**

- **Resources** needed (facilities, equipment, human, materials, time, financial, etc.)

- **Process controls**: Controls to detect and manage any non-conformities (audits, management review); measures to be taken if non-conformities or deviations occur

- **Process documentation** (e.g. written procedures with reference to WINs, forms, templates, records to be generated, etc.)

- **Schedule** (the timeframe in which the work will be achieved together with major milestones)

- **Methods to monitor, analyse and address risks and opportunities** (what could go wrong together with strategies for risk reduction and deployment of opportunities).

2.9 Monitoring and evaluation

Monitoring should be a regular and ongoing process to collect and analyse information on the functioning of structures and processes or the progress of projects over time. Monitoring is key to good planning; it identifies strengths and weaknesses in a timely manner, and the results of this analysis can be quickly and directly fed back to the planning process.

Evaluation is determining, through systematic, regular research, the value and outcomes of activities (e.g. on stakeholders of the organisation), in order to improve effectiveness, better reach of objectives, and make informed decisions about future plans.

If monitoring systems are working well, evaluation of the achievement of goals is needed less often and is much easier to carry out.

Monitoring and evaluation may be accomplished via various means, e.g. management reviews, internal or external audits, stakeholder surveys or staff feedback for continuous improvement and corrective action.

Continuous achievement of quality objectives, improved customer satisfaction ratings, or a reduction in the number of significant audit/inspection findings may indicate that an effective quality cycle is in place.[32]

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[32] Lennie J, Tacchi J, Koirala B, Wilmore M, Skuse A Equal Access Participatory Monitoring and Evaluation Toolkit. Definition of key terms (2011 Feb)
http://betterevaluation.org/sites/default/files/EA_PM%26E_toolkit_front_pages%26introduction_for_publication.pdf;
downloaded: [06/01/2016]

2.10 Communication and staff involvement

The internal communication process of the organisation should cover how the quality policy and strategic goals are communicated throughout the organisation. Personnel must understand the direction of an organisation and the impact and importance of the primary quality principles on the work they do.

Objectives need to be communicated to people at all levels of the organisation so that each employee understands how their job supports the realisation of business objectives and contributes to high quality work. The message of the strategy should be preserved top-down so that there is no gap between high level objectives and local indicators which helps create clarity for staff, better commitment and ownership.[33, 34]

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[33] IBIS Manuals – The programme management manual. Monitoring toolbox – Tool 8. Guidance on objectives, indicators and annual objectives. http://ibis-admin.org/promm/3-tp-monitoring-guidelines/; downloaded: [06/01/2016]

[34] Jones B. Effective KPI development (2012 Jan 27) http://www.excitant.co.uk/2012/01/effective-kpi-development.html; downloaded: [06/01/2016]

3. Case studies

In this section, case studies obtained from 4 NCAs (HR, NL, PT, UK) are presented with a specific focus on PV activities. Case studies bring examples to demonstrate that/how:

- PV is currently defined among the strategic goals of NCAs

- Strategic goals are broken down to measurable objectives (indicators), what action steps, responsibilities and timeframes are assigned to them

- Annual goals of PV may be related to strategic objectives (operational planning)

- Various departments (including PV) may relate their objectives to the same strategic goal

- PV staff may contribute to strategic/operational planning

- NCAs interpret and make use of quality objectives

- NCAs derive their quality objectives from the quality policy and what indicators they measure

- Examples of quality objectives used by NCAs

- The planning process is monitored and evaluated

- A new procedure is planned

- A change to an existing procedure is planned

- The quality policy, organisational strategy and performance are communicated to individual employees.

3.1 Agency for Medicinal Products and Medical Devices (HALMED), Croatia

3.1.1 Strategic and annual (operational) planning

At HALMED, long term business and quality goals are defined at the agency level in the Development Strategy document for the period of 5 years (2014-2018) which is published on the agency's website[35]. This document defines 5 general strategic goals, each comprising of several specific strategic objectives (**Table 1**).

A Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis[36] has been performed based on the self-assessment of organisational maturity in accordance with the BEMA requirements. The results of the analysis were used to define the goals and specific objectives of the Development Strategy.

For each specific strategic objective the strategic document defines strategy, action steps, prerequisites, responsibility, indicators and timelines.

Table 1. Strategic goals for HALMED between 2014 and 2018 and related strategic objectives

	Strategic goals	Objectives
I	To contribute to the safety and quality of medicines and medical devices through effective risk management and market surveillance	1. **To ensure the continued and high quality monitoring of adverse reactions/events concerning medicinal products and medical devices in the territory of the Republic of Croatia*** 2. **To improve managing the risks of medicinal product use** 3. **To ensure the continuous monitoring of medicine consumption and their rational use** 4. Market surveillance 5. Collaboration with key stakeholders on the reduction of unauthorised medicinal products in legal supply chain 6. The establishment of a Pharmacopoeia Committee
II	To improve the provided services within a high quality, risk-based regulatory framework	1. **Contribute to the assessment of the quality, efficacy and safety of medicines on an EU level** 2. **Establishment of new processes in the area of medicine safety** 3. *Meet agreed timelines for all procedures***

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[35] http://www.almp.hr/fdsak3jnFsk1Kfa/ostale_stranice/Development_strategy_2014-2018.pdf; downloaded: [16/01/2016]

[36] For an explanation of **SWOT analysis (Strengths, Weaknesses, Opportunities and Threats),** refer to the Additional information.

	Strategic goals	Objectives
III	To deliver transparent, pertinent and well-timed communication to patients, public and HCPs	1. *Prompt public oriented communication on safety and quality issues* 2. *Strengthen HALMED's transparency* 3. Patient associations, HCP organisations, and public engagement strengthening in the activities of HALMED 4. Ensure the public and stakeholder perception of HALMED as an effective, independent and reliable regulatory agency
IV	To strengthen capacities as a response to developing regulatory requirements and scientific/technological advances	1. *Further development of the QMS* 2. *Further development of the Information Management System* 3. *Improve expertise across the Agency and use the gained knowledge for academic purposes* 4. Ensure balance between income and costs 5. Construction of new office building
V	To participate in medicines and medical devices policy and legislation development for the benefit of public health at the national and EU level	1. *Influence the strategic direction of new legislation and regulation as well as strategic discussions at the EU and international level* 2. Influence IT developments within the EU regulation network

*Objectives in bold are related primarily to PV (the Head of the PV Unit being fully or partially responsible for fulfilment)

**Objectives in italics affect all divisions (thus including PV)

For a thorough understanding of setting objectives, planning the implementation process and assigning indicators, an extract from the current Development Strategy is outlined in **Table 2**: a strategic objective related to PV (Objective 1.1) associated with the first strategic goal. For more examples or the complete strategic document, please refer to HALMED's website.

Table 2. Implementation of a strategic objective at HALMED related to PV activities

Objective 1.1 Strategy	Ensure that medicines and medical devices on the market in Croatia are regularly and actively monitored due to possible ADRs/events and the consequent impact assessment on health issues (supported by PV and vigilance of medical devices).
Action steps	• Develop a training programme to support the increase in patient and HCP reporting ADRs for medicines and adverse events for medical devices by enhancing public awareness on the importance of reporting • Support scientific efforts in the field of PV and rational pharmacotherapy with the inclusion of information on pharmacogenomics in written responses to ADR reporters, where relevant • Collaborate with other competent authorities in the EU involved in signal detection activities • Collaborate with HCP bodies, patient associations and academia in education training programmes • Collaborate with national and international health institutions in the development of mutual interoperable system and the sharing of relevant information of common importance • Develop new tools such as database for pharmacoepidemiology and an on-line application dedicated to HCPs for medicines ADR reporting.
Prerequisites	• Sufficient and well-educated trained staff • Allocation of financial resources • Adequate IT tools • Preparedness and willingness for collaboration on the part of national and international institutions and bodies, as well as HCPs and patient associations
Responsibility	• Head of Department for PV and Rational Pharmacotherapy • Head of the Department of Medical Devices
Evaluation of indicators	• Increased number of ADR reports, including serious cases with higher quality information received from patients and HCPs • Increased levels of ADR assessments connected to pharmacogenomics issues • An increased number of signals detected that are assessed according to the EMA's active substance list for signal management work sharing • Strong links with other national and regional institutions and patient associations involved in patient safety and close collaboration to maximise patient safety • A database for epidemiological data is used in benefit-risk assessments and ongoing therapeutic risk management • With the help of an on-line tool, ADR reporting by HCPs is increased and report quality is improved • HALMED is recognised as a relevant and useful source of information on safe medicines by HCPs and patients.
Time	Actions start in 2014 and are supposed to be finished by the end of 2018.

From the strategic plan, annual business plans are assembled (according to the SOP 'Annual Planning') in which strategic objectives are cascaded down to the divisions and departments. Annual business plans are mandatory in the organisation.

3.1.2 PV (quality) objectives

Overall PV quality objectives are defined in the PV quality manual and are in line with the objectives presented in GVP Module I.B.4. which are considered as guiding principles.

Specific PV objectives are derived from the overall objectives and are incorporated into strategic (long term) or annual (short term) plans, or broken down for each relevant PV procedure in respective SOPs. **Table 3** presents some examples of short term PV objectives relevant for the recent years.

Table 3. Short term objectives at HALMED in PV (examples from recent years)

- Full implementation of GVP Modules
- Establishing the active involvement in the EU regulatory network after joining the EU
- Establishing the GVP inspectorate within the Agency (previously it was within the competence of the Ministry of Health)

3.1.3 Planning of new procedures or changes to existing ones

An Action Plan needs to be developed with the definition of responsibilities, specific objective, tasks, milestones and deadlines. After completion of an action plan, final conclusion on the effectiveness is always brought with possible recommendation for further improvements. The preparation of action plans is defined in SOPs.

In addition, common changes to procedures (updating SOPs) are done in order to streamline processes and improve compliance and outcomes. This is done either following the result of an internal audit or when possible improvements are defined at the level of the PV Department.

3.1.4 Monitoring and evaluation

Evaluation is done either for a specific important change or on an annual basis against the predefined indicators; these approaches are complementary. Various monitoring tools are summarised in **Table 4.**

Reports of audits carried out in the Agency are made publicly available on HALMED's website.

Table 4. Activities for monitoring and evaluation at HALMED

- Internal meetings of the Department (PV) at least every six months, and in the case of risk assessment as required and more often
- Internal/external audit of the PV quality system
- Management review
- Implementation of procedures for managing compliance
- Assessment of risk minimisation activities.

3.1.5 Communication of strategies, quality policy and organisational performance to staff

Performance results are communicated within the agency from the top to the bottom, and vice versa. Top management informs middle/low management and the staff about the fulfilment of the goals and specific objectives obtained, while at the same time the information related to the individual performance results is presented to the middle/low and top management too.

There are regular meetings between the Head of Agency with his/her deputy and heads of units where the most important issues regarding set goals, objectives and plans are discussed. Final conclusions are met giving the answers to open questions and direction for further performance.

There are also regular division/department meetings where the most important issues regarding the strategic objectives of concern, plans and activities are discussed. Participation of staff in the discussions is strongly encouraged and regarded as a valuable tool for possible improvements of processes and the QMS. Final conclusions encompass the staff suggestions and proposals. Through direct and open communication the heads ensure that the staff has a good understanding of strategic direction and operational priorities.

The heads are involved daily in realisation of business plan objectives and they communicate constantly in formal and informal ways with the staff in order to resolve any possible issue that could arise, and to define operational priorities. In specific processes like marketing authorisations and PV, coordinators are nominated that cooperate closely with heads and co-workers responsible for scientific assessment. This communication is open to any kind of suggestions and proposals that are mutually discussed. The staff informs the heads and coordinators about realisation of operational priorities through pre-set monitoring, and heads discuss weekly with staff about realisation and further actions. The results are always discussed at top level and presented to the Management Board.

3.1.6 Involvement of staff in organisational improvements

PV staff are encouraged to participate in defining business projects and business plan activities. This activity may be realised via an official template or email. As an example, PV staff were involved in the preparation of the first draft of specific PV strategic objectives as described above.

3.2 Medicines Evaluation Board (MEB), Netherlands

3.2.1 Strategic planning

Another way of strategic planning is represented by MEB. The Dutch NCA considers business and quality objectives one and the same at the policy level. The strategy planning is the responsibility of MEB management, chair of the Board and senior staff like the CHMP, the PRAC and the CMDh members. They include stakeholders in their discussion on the developments in the field and society regarding medicines, and the role and position of the MEB.

Table 5. Extract from the Strategic Business Plan (2014-2018) of the MEB

Strategic goals	• Patient-oriented evaluation • Proper use • Innovative development
Ten ways of realisation of goals	• Attention for specific patient groups • Individualised regulation • Risk-driven evaluation • Information on proper use • Timely informed and prepared • Better use by looking at medicine in practice • Advice and dialogue • European collaboration • Regulatory science • Independence and transparency

Implementation	• Improvement of flexibility, effectiveness and efficiency via
	  – Strategic personnel planning
	  – Continuous process improvement
	  – IT strategy
	• Collaboration
	• Communication

Furthermore, MEB has carried out a scenario analysis on the position of MEB in 2030. Information obtained from the 4 scenarios anticipated, is reflected in the Strategic Business Plan (2014-2018) that is available at the MEB website.[37]

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[37] http://english.cbg-meb.nl/about-meb/documents/publications/2013/06/05/sbp-2014-2018; downloaded: [20/10/2015]

In its Strategic Business Plan (see **Table 5** above for a high level extract) the MEB defines its high level goals (i.e. patient oriented evaluation, proper use and innovative development), and elaborates 10 concrete ways to promote progress in terms of the strategic goals. Rather than focusing on predictions on production, productivity and capacity that are no longer realistic in an unpredictable environment, the MEB focuses more on collaboration, effective communication and continuous monitoring of its surroundings to improve flexibility, effectiveness and efficiency.[38] Programmes and objectives are elaborated at lower levels and in annual business plans.

Once the strategy is finalised, it is used as a framework to set annual goals in the annual business plan. This is done by discussion between top management and middle management. Middle management (department level) is responsible for involving staff in the draft department plan (or even department overarching project plans). It is an iterative process resulting in a plan that is supported by management and staff.

A strategic objective always applies to more than one department (for an example, refer to Table 6), leading to activities for multiple (or all) departments. The MEB translates and cascades strategic objectives to departmental objectives which are described in an operational (quantitative) manner.

Table 6. Breakdown of organisational (strategic) goals to departmental objectives in Annual Plans

Strategic goal	• To become more patient oriented
Organisational level	• A new website designed by the communications department with a stakeholder dedicated approach (patients, HCPs and industry) is to be implemented
PV Department	• Do research (cooperation with universities) on the effectiveness of risk communication to patients (DHPCs and educational materials), and to publish more information on the MEB website (summaries of risk management plans)
Legal Department	• Strengthen patients involvement in the development of guidelines
HR Department	• Launch a program to educate all staff to become more communicative
Board level	• Have a representative of patient organisations as a Board member

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[38] http://english.cbg-meb.nl/about-meb/documents/publications/2013/06/05/sbp-2014-2018; downloaded: [20/10/2015]

3.2.2 Annual (operational) planning

The strategic objectives are the basis for defining operative annual goals, which lead to the yearly plan at organisational and department level (work programme). The process for the yearly plan development is described in a policy cycle document, which is revised every year. The management review is included in the yearly plan which addresses the progress made on the objectives defined in the strategic plan. For the development of the yearly plans and budget, standard formats are in place.

The policy cycle document includes deadlines for each stage of the annual planning process, the process owner and the deliverables. Every department provides a year plan, key elements of which are highlighted in **Table 7**.

Table 7. Key elements of Annual Plans at MEB

- Achievement of previous year's goals and areas for improvement; management review
- External and internal relevant influences
- Goals for next year
- Means to achieve those goals
- Risk management
- Budget.

Planning is bottom up and top down, through an iterative process. First draft of plans ensures that dependencies are known between departments. Dependencies are also discussed and agreed on in Management Team meetings. Objectives should be SMART.

Recently MEB has changed its annual business planning cycle and introduced the Objectives, Goals, Strategies and Measures (OGSM)-method[39] to lower the administrative burden, achieve consistency between plans at department level, monitor plans during the year and define SMART objectives. For examples of annual objectives of the PV Department for 2015, see **Table 8**.

Table 8. Annual objectives for the PV Department (2015)

- Develop national policy for Implementation and evaluation of additional risk minimisation measures
- Translate insights gained through Regulatory Science project to daily practice
- Strengthen risk communication via DHPCs (content, uptake and timeliness)
- Strengthen collaboration with national PV centre LAREB for signal detection and signal validation.

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[39] For an explanation of the **OGSM method (Objectives, Goals, Strategies and Measures)**, refer to the Additional information.

3.2.3 PV quality objectives

In the (organisation-wide) quality manual all PV processes are described; nevertheless, no quality objectives are explicitly defined at process level. Instead, pre-requisites are put in place around the processes to support high quality output.

For pre-requisites with regard to which processes are defined, refer to **Table 9**.

Table 9. Definition of processes at MEB

Prerequisites	• Workflow
	• Tasks and responsibilities
	• Review and escalation
	• Decision making
	• Qualification of staff
	• Training new staff
	• Assessment policy – criteria based on procedure and role of MEB in the EU.

3.2.4 Planning for and implementation of a new procedure

Factors to be taken into account and considered relevant by MEB when developing a new procedure are summarised in **Table 10**. An example of the newly developed procedure on signal detection based on eRMRs is demonstrated in **Table 11**.

Table 10. Factors pointing to the need of a new process at MEB

- It is legally required
- It reduces the risk of failure in the implementation process
- It increases the detectability and traceability of results
- The process description is required cf. ISO 9001
- The complexity of the process demands it
- It is necessary for exchange of knowledge
- The degree of detailing follows staff competence
- It achieves consistency (alignment) between staff/departments.

Table 11. Example of planning for and implementation of a new procedure at MEB

Signal detection based on eRMRs – Action steps
1	Assess the nature of the new procedure to be implemented by looking at the process itself (e.g. can it follow a similar workflow as other procedures, or is another workflow required), the people (required expertise, impact on other departments and/or external stakeholders), and the tools (assess use of existing tools and/or IT systems, need to adapt tools or develop new tools).
2	Assess the need for training.
3	Assess the need for internal/external communication.
4	Check whether GVP and/or other EMA documentation is available; are there aspects that need further clarification? What level of effort is needed to comply with the law; is there a need/benefit to go beyond that level or can it be kept to a minimum? Check with other MSs what they are doing.
5	Assess the need to develop new or adapt existing SOPs and/or WINs. Create a working group with participation from different departments (if these are impacted); responsible for the SOPs, WINs and delivery of training (if applicable). If possible, use a pilot period for checking if the new procedures work, if instructions are clear, etc.
6	After implementing the new process, evaluate what can be improved, and adapt as necessary.
	In this context, also monitor any relevant changes made by EMA/EU Regulatory Network that may have impact (e.g. changes in guidance documents, changes to EPITT, templates)
	If possible, monitor what other MSs are doing (for Signal Management, the MEB monitored EPITT and PRAC Minutes) and use this as a reference to review the process and outputs.
	Review the comments made by other MSs on Signal Assessment Reports written by MEB staff, and feedback any learning points to the PV department. The MEB also consulted the Dutch PRAC delegates on how they perceive the quality of the signals entered into EPITT by the MEB, and the Signal ARs delivered by the MEB.

3.2.5 Planning for and implementation of a change in an existing procedure

The PV Department annual plan (2015) included a goal to strengthen risk communication via DHPCs regarding content, uptake and timeliness (**Table 12**). Proposals were included in a policy document that was published on the MEB website for public consultation. The goal is to improve collaboration with HCP organisations to actively involve them in the communication strategy for urgent safety restrictions.

Table 12. Example of planning for and implementation of a change in an existing procedure at MEB

Objective	To strengthen risk communication via DHPCs
Triggers	• Link to the MEB strategic business plan ('proper use of medicines') • Findings from a PhD thesis with MEB involvement on risk communication • Recommendation following an internal audit on DHPCs • Current procedure being outdated (not completely in line with GVP) • External signals indicating that the content of DHPCs could be improved by consulting relevant HCPs and/or 'expert patient' groups before distributing the DHPCs
Action steps	**Improve content of DHPCs:** • Explore possibilities for consulting HCPs before DHPCs are distributed • Update guidance for MAHs • Review internal WINs and procedures • Address DHPCs in education of PV staff and other staff involved
	Improve uptake of DHPCs: • Improve recognisability by introducing a new logo which should avoid that HCPs consider the DHPC to be promotional material. MAH logos will no longer be allowed on the DHPC and envelope • Explore possibility for distributing DHPCs via email • Explore possibilities for including DHPCs in knowledge systems used in clinical practice
	Improve timeliness of risk communication

3.2.6 Monitoring and evaluation

The implementation of the planning process at the policy level is monitored by reports on the status of goals and objectives (3/year), and preparing for the ISO recertification (management review) every year.

Performance is monitored in several ways, and at different levels.

At the operational level, peer review mechanisms are in place for PV processes within the PV division, but review also takes place through discussion of reports in meetings with the Board in which the assessors have to reflect with the Board members on the assessment reports. After each meeting the Board gives feedback on the quality of the reports and the discussion being held.

At the business level, several management reports are available at the department level, at the process/procedure level, and at the individual level. Also a balanced scorecard (BSC) is monthly available. For the business planning, management also performs a yearly forecast on the resources required by the MEB. PV activities are included in this forecast.

Regarding the quality of work/performance in daily processing of procedures, training of new staff and reviewing work is done by senior staff, or even at the level of department meetings.

3.2.7   Involvement of staff in organisational improvements

Some staff members are involved in defining annual goals regarding PV.

Most staff members are mainly involved at the operational level regarding ongoing QMS matters: WINs, templates and internal audits. For the QMS documentation the MEB has internal working groups for most parts of the quality manual, e.g. there are working groups for mutual recognition, centralised procedure, medical devices, validation and site clearance, legal affairs, and PV. Staff from all departments can volunteer (intrinsic motivation) to become a member of one or more groups. The chair of the group is responsible for keeping all documentation under their responsibility up-to-date. The chair can ask group members to do a certain amount of work. For all group meetings there is an agenda and an action list or minutes.

3.3 National Authority of Medicines and Health Products (INFARMED), Portugal

3.3.1 Strategic planning

The Executive Board of INFARMED defines the mission, vision, values, quality policy and strategic objectives for INFARMED based on (1) the government program, (2) guidance documents of the National Health Plan, (3) other guidance documents of the Health Ministry, and (4) strategic map of the Heads of Medicines Agencies.

INFARMED has a 5 year strategy road-map that defines 6 strategic objectives. PV activities are included in 2 strategic objectives of INFARMED.

3.3.2 Annual (operational) planning

The Planning and Quality Office of INFARMED communicates the strategic objectives to all directorates, including the PV Directorate.

The directorates identify the operational objectives, in line with these strategic objectives and their relative weight (also defined by the Executive Board), and give input to the Annual Business Plan, which includes the INFARMED's **Balanced Scorecard** (BSC)[40].

The BSC presents the most relevant performance indicators for each directorate (strategic objectives, operational objectives, weight of each indicator, method of calculation and goals).

The Annual Business Plan and another national model of evaluation of performance (QUAR)[41], which has three chapters of key performance indicators (KPIs) (Efficacy, Effectiveness and Quality), are approved by the Executive Board of INFARMED and by the Health Ministry. The Planning and Quality Office of INFARMED communicates to all directorates that the Annual Business Plan and QUAR were approved.

The directorates' operational objectives are then reflected by cascading them to the individual staff objectives. In **Table 13**, an example is provided on how quality objectives are derived from the quality policy of INFARMED and the relationship of strategic and operational objectives is demonstrated. Furthermore, indicators are assigned to each objective. PV specific indicators are highlighted in bold.

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[40] For an explanation of the **BSC (Balanced Scorecard)**, refer to the Additional information.

[41] QUAR (Quadro de Avaliação e Responsabilização) is part of the Integrated System for Management and Performance Assessment in Portugal, and is related to health services. QUAR contains the most important key performance indicators of INFARMED. INFARMED's performance is evaluated by the Health Ministry based on the results of the indicators included in the QUAR.

Table 13. Relationship of strategic and operational quality objectives with the quality policy

Quality policy	Strategic objectives	Operational objectives	Indicators
Ensure the compliance with the applicable legal and regulatory requirements	Continuous improvement and internal efficiency: Develop a culture of continuous improvement and creation of added value for the several clients and stakeholders of INFARMED and to the public in general, optimising processes and ensuring efficiency of resources.	Increase the efficiency of the principal business and support processes of INFARMED (responses' timelines)	Percentage of ADR reports sent to the MAHs and EMA within legal timelines (PV specific)
	Market compliance and risk management: Strengthen the monitoring/inspection instruments, quality assurance and proactive risk management	Increase the reporting levels and strengthen the proactive risk management	Number of drug safety monitoring activities (PV specific)
Satisfy the needs and expectations of INFARMED's clients and stakeholders	Continuous improvement and internal efficiency: Develop a culture of continuous improvement and creation of added value for the several clients and stakeholders of INFARMED and to the public in general, optimising processes and ensuring efficiency of resources.	Increase the satisfaction of INFARMED's clients and partners / stakeholders	Percentage of INFARMED's external clients' satisfaction (transversal)
Optimise and improve INFARMED's processes as well as the efficacy of its QMS	Continuous improvement and internal efficiency: Develop a culture of continuous improvement and creation of added value for the several clients and stakeholders of INFARMED and to the public in general, optimising processes and ensuring efficiency of resources.	Increase the quality and continuous improvement of the principal business and support processes of INFARMED (QMS)	Number of preventive and/or corrective and/or improvement actions implemented / considered effective (transversal)
Provide qualifications for staff	Reinforcement of the positioning in the international context: Strengthen the presence of INFARMED in EU and international contexts, following scientific innovation and market development and providing qualification and differentiated skills to human resources	Promote the development and retention of human resources	Percentage of INFARMED's staff that attended to professional training sessions (transversal)

3.3.3 PV quality objectives

When defining the objectives the PV department considers the strategic objectives defined by the Executive Board, the 3 types of KPIs (Efficacy, Effectiveness and Quality), the legal requirements and the historical data on the performance achieved in order to decide which indicators need close monitoring.

The general quality objectives are transversal to all directorates of the Portuguese NCA, which includes PV processes and are related to registries of non-compliances, corrective/preventive/improvement actions and complaints, their implementation and effectiveness, external and internal clients' complaints. For examples of annual specific PV quality objectives/indicators at INFARMED, see **Table 14**.

Table 14. Examples of annual PV quality objectives/indicators at INFARMED

- Number of ADR reports assessed and finalised in the database
- Percentage of ADR reports sent to the MAHs and EMA within the legal timelines
- Percentage of approved educational materials within the timeline defined
- Percentage of assessment reports for PSUR, RMP and PASS delivered within the timelines defined
- Number of drug safety monitoring activities
- Number of communication documents produced on PV issues (communication to HCPs, public, press, health institutions)

3.3.4 Monitoring and evaluation

The BSC results are monitored at least on a quarterly basis. INFARMED monitors several objectives/indicators internally, but only the most relevant are included in the BSC.

Performance data is electronically submitted by each directorate into the business intelligence tool and automatically the dashboard shows all INFARMED's results regarding strategic objectives, operational objectives, indicators and the results of each directorate. These results are also documented in the Summary Executive document (with an analysis and justifications regarding the deviations from targets) that is sent by the Planning and Quality Office to the Executive Board, the directorate's managers and quality managers. The results are assessed by the directorates in order to decide if preventive and/or corrective actions are necessary to ensure that objectives and targets are achieved. INFARMED also monitors the effectiveness of the implementation of these preventive and/or corrective actions. This way, INFARMED has updated information about the status of performance, if objectives are being met or not and so resources can be adjusted whenever necessary.

INFARMED's self-evaluation is also approved by the Executive Board of INFARMED and by the Health Ministry.

3.3.5 Communication of strategies, quality principles and organisational performance to staff

The quality policy of INFARMED is part of the quality manual, available to every employee in the informatics' tool of QMS and also available for the public on the website. Additionally, posters are placed with the quality policy in almost every INFARMED office.

There is a 'welcome manual' to all new staff that includes the quality policy. Additionally, new PV staff always have an initial training plan that includes information on the QMS of INFARMED, highlighting the following aspects: (1) quality policy; (2) description of the operational processes with the objectives associated; (3) the importance of optimisation and improvement of INFARMED's processes, through the involvement of all staff, in order to facilitate the work on a daily basis.

The head of the PV directorate sends quarterly, by email, the Performance Evaluation Report regarding the specific PV quality objectives (with an analysis and justifications regarding the deviations of the targets) to all staff. The quality manager of the PV directorate sends quarterly, by email, the results of the performance in terms of the general quality objectives (related to registries of non-compliances, corrective/preventive/improvement actions and complaints, their implementation and effectiveness, external and internal clients' complaints) to all staff.

3.3.6 Involvement of staff in organisational improvements

All PV staff can contribute to the definition of indicators and monitors monthly all the performance indicators: the ones included in the BSC and other internal indicators considered relevant for the monitoring of PV activities. The PV directorate collects the data from several databases related to the operational processes and compiles it in the PV dashboard (Excel file). Then, the head and the quality manager of the PV directorate are responsible for submitting electronically the PV performance data that is included in the BSC into the business intelligence tool of INFARMED.

If there is a need to implement some preventive/corrective/improvement actions, staff are involved in the definition of the action, responsibilities and the timelines of implementation.

3.4 Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

3.4.1 Strategic and annual (operational) planning and its relationship with the quality policy

The MHRA has a corporate plan for 2013-2018 which sets out the strategic direction of the agency over the five year period. It highlights the key areas where efforts need to be focused and business developed, in keeping with its core aim to protect and improve the health of patients. Every year an annual Business Plan is produced which sets out in detail how to achieve ambitions in the corporate plan. This is supported by divisional and centre plans. Individual staff objectives are linked to these plans to help deliver strategic aims as well as core business.

Vigilance and Risk Management of Medicines (VRMM) to which PV belongs, has a divisional plan which brings together its contributions to the work of the agency and to the delivery of the Agency Business Plan for 2015-2016 and the Corporate Plan for 2013-2018. Key strategic priorities for the annual and divisional business plan are summarised in **Table 15**.

Table 15. Strategic priorities for MHRA

- Vision and scope of the Agency's role
- Bringing innovation and new products speedily and safely to patients
- Strengthening surveillance
- Safe products and secure supply in globalised industries
- Achieving excellence – a well-run, efficient and effective organisation.

The MHRA established a formal QMS which is certified to ISO 9001:2008. The divisional, agency and corporate business plans take into account all quality objectives (see next section), as referenced in the quality documents (quality manual and SOPs). Examples of the integration of these set quality objectives into each business plan are described below (**Table 16**).

Table 16. Example of the association of corporate, agency and divisional objectives

Strategic priority (corporate)	Strengthening surveillance
Strategic goal	Development of a Joint Patient Safety and Surveillance Strategy (to establish a common vigilance platform which maximises synergies while allowing for local differentiation in order to protect public health).
Strategic objective	The effective capture of information from incident reports and also the wider scientific evidence base, including social media information and other technologies such as the Yellow Card App.
Agency business plan (2015/16)	Lead the further development of incident reporting systems to embed Yellow Card reporting into National Health Service (NHS) and the care system, working with UK healthcare bodies to ensure safety measures for medicines and devices contribute to safe care and reducing avoidable harm.
Divisional business plan (2015/16)	Lead the further development of incident reporting systems to embed Yellow Card reporting into NHS and the care system, and champion reporting as an indicator of safe care with NHS and Arm's Length Bodies stakeholders by end quarter four.

3.4.2 Quality objectives

Quality objectives are derived from annual agency and divisional business plans and strategies. A high-level description of the PV system and its quality system is provided in a quality manual, supported by documented SOPs.

The principal quality objectives of the QMS of MHRA are summarised in **Table 17**.

Table 17. Principal quality objectives at MHRA

- Satisfy the needs and expectations of its stakeholders
- Continually improve service to its stakeholders
- Improve the effectiveness and efficiency of its performance
- Ensure that its staff has the competencies necessary to discharge their responsibilities
- Comply with the requirements of the QMS
- Review the operation and effectiveness of the QMS at regular intervals and improve the system.

Specific examples of quality objectives in association with PV are summarised in **Table 18**.

Table 18. Examples of quality objectives relevant for PV at MHRA

ADR management	**Objectives**: • To capture information on suspected ADRs in high quality and structured manner that supports accurate detection and analysis of safety signals • To continuously improve the quality of PV data classified into the ADR database through conducting audits. **Performance targets**: Maximum timescale between receipt of reports and making them available for evaluation and analysis • For fatal UK ADRs: 90% within 24 hours and 100% within 72 hours • For serious UK ADRs: 95% within 72 hours and 100% within 5 days.
Contributing to the EU regulatory network	**Objectives**: • Facilitation of improvements to the ADR reporting systems • Membership in expert committees • Contribution to SCOPE Project • Contribution to work sharing activities.
Business performance	**In terms of**: • Work volumes (e.g. number of variations received) • Public health (e.g. number of Yellow card reports by HCPs and the public) • Capacity, efficiency and capability (e.g. HR metrics such as staff in post).

3.4.3 Planning for and implementation of a new procedure

A project, IMPACT (Implementing Pharmacovigilance Actions team) was designed to identify where the MHRA had gaps in its PV activities as per the new PV legislation. An initial gap analysis was performed by multidisciplinary project teams including areas like IT, communications and policy.

Tasks were identified and broken down into small work streams, each of which had a responsible owner who produced finding reports. There was independent oversight (Regulatory Board) to advise and consult on strategic decision making and stakeholder analysis was conducted to measure the internal and external impact.

Once the changes were rolled out, there was user testing and training, with various measurements used to assess the effectiveness of the new activity.

3.4.4 Planning for and implementation of a change in an existing procedure

The MHRA conducts preliminary studies on planned changes to existing procedures before implementation. Changes to procedures should be based on scientific evidence, tested and validated. An example of adjusting signal detection activities as a response to various triggers is presented in **Table 19**.

Table 19. Example of planning for and implementation of a change in an existing procedure at MHRA

	Adjustment of signal detection activities – Action steps
1	Specify the need to change. For example: • Incorporate new best practice identified in published literature and studies such as the IMI PROTECT[42] • Adjust signal detection thresholds to reflect changing volumes and types of cases received.
2	Develop a study plan with Pharmacoepidemiology Unit to include the methods that will be tested (including any preliminary analysis that is necessary to facilitate the study).
3	Approve the study plan at Signal Management Review Meeting (SMRM) – a weekly meeting responsible for management of the signal process.
4	Conduct the study, including at least 6 weeks of direct comparison of the old and the new methods, and a retrospective analysis to ensure signals previously identified will not be missed.
5	Discuss the results at SMRM, including positive and negative impacts of making each change (if multiple changes are tested).
6	Agree proposal for implementation.
7	Seek feedback from the Senior Management Team.
8	Implement changes when agreement is attained.

3.4.5 Monitoring and evaluation

There are multiple methods used to monitor and evaluate whether quality objectives are being adhered to: from risks register assessment to quarterly ADR statistics and individual management reviews.

The MHRA has an SOP in place to manage non-conformity and corrective action. This action is intended to prevent the recurrence of non-conformities or to avoid circumstances that resulted in an adverse situation. This document identifies different methods used to detect non-conformities (**Table 20**).

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[42] **IMI-PROTECT**: Innovative Medicines Initiative – Pharmacoepidemiological Research on Outcomes of Therapeutics. The project aims at developing innovative tools and methodological standards to enhance the monitoring of the safety of medicinal products and to better evaluate and communicate their benefit-risk profile throughout their lifecycle.

Source: https://www.imi.europa.eu/content/protect, downloaded: [19/08/2016]

TABLE 20. Methods for monitoring non-conformities at MHRA

Internal audits	Reviewed at divisional level
Customer complaint	Reviewed in line with agency procedures
Customer satisfaction measurement	Qualitative and quantitative data collected and reviewed to identify any repetitive adverse comments and direct performance improvements
Management review	Annual review to assess whether the system remains suitable and effective in the implementation of quality management; includes review of customer feedback, complaints, internal/external audits and performance against targets

Depending on the nature of the action needed, the corrective process may or may not make up a formal change control. A formal documented action will identify persons responsible for plan management, timelines, verification process and criteria for success measurements. The method of recording and assessing corrective action is documented in official SOPs.

VRMM management is responsible for reviewing PV and quality systems at regular internal meetings to verify they are fit for purpose and that all appropriate measures are in place to measure their success. Management reviews and internal/external audits identify improvement areas in PV systems. Self-assessments conducted as part of BEMA also inform system improvements.

3.4.6 Communication of strategies, quality principles and organisational performance to staff

The quality objectives defined in the annual and divisional business plan are circulated and agency-wide meetings are held biannually for staff to comment on the direction of the agency. Performance management reviews are also used to assist staff to conform to specified quality guidelines, and to suggest training where required. Quality policy and objectives may also be discussed in meetings and through team briefings. Team briefing is an agency-wide, coordinated system of communication where managers can inform on organisational and topical matters, with an opportunity for staff to feedback. In addition, there is a cross agency group responsible for maintaining and improving the QMS, including promoting awareness of QMS across the agency.

3.4.7 Involvement of staff in organisational improvements

All PV staff can contribute to the quality planning/business planning process. There are regular divisional, management and group meetings where issues regarding goals, objectives and performance are discussed. Group managers are accessible to staff and amenable to suggestions which can be taken forward. In addition, there is a yearly staff survey which assesses all aspects of staff working.

The MHRA holds biannually agency-wide meetings for staff to comment on the direction of the agency, comments which can be taken forward into the following year's business plans. The agency is committed to embedding strategic objectives in the day-to-day work. Staff are encouraged to further engage in developing strategic priorities. For example, plans to refresh the agency's corporate strategy including engaging staff through team briefings and a series of workshops.

4. Summary and conclusion

This toolkit item intended to raise awareness of PV assessors and interested staff at NCAs on quality planning and the selection and measurement of quality objectives. Quality planning was introduced in context with business planning, and it was demonstrated that quality management can add value when integrated to business processes in terms of achieving effectiveness and efficiency. Various levels of planning were described, and the importance of a clean-cut and visible 'thread' linking strategies to individual objectives was outlined. The concept and selection of quality objectives was detailed and the setting of appropriate indicators to measure such objectives. Finally, theory was put in practice by presenting case studies from 4 NCAs with a robust planning process in place, focusing on the place of PV in the planning process.

In conclusion, every employee of an organisation (including PV assessors at NCAs) should understand how his/her work contributes to the accomplishment of the organisation's mission and vision, and that quality management is not an extra burden, but an opportunity to improve. This may be achieved by the appropriate setting of objectives (and indicators) to work for (and monitor) at all functional levels and a good information exchange between management and employees, so that staff do not lose sight of the 'golden thread' and remain committed.

5. Additional information

This section contains basic definitions of some related concepts mentioned in the document. They are not intended to be in-depth clarifications, and readers are referred to the literature for further information.

5.1 Effectiveness versus Efficiency

These concepts are broad categories of performance management.

Effectiveness indicators measure the extent to which planned activities are realised and results achieved. They relate actual to expected values. A process is effective if its outcomes match the stated goals. These types of indicators require a plan: effectiveness cannot be measured without a set target.

Efficiency indicators measure how well resources (e.g. human, financial, equipment) were used to produce the output. It is rarely possible to describe in absolute terms. One process is 'more efficient' than another if it achieves the same outcomes at lower cost/time, etc.

Efficiency measures concentrate on how well a task is being performed, not whether the task itself is correct. Effectiveness concentrates on the correctness of the process and whether the process produces the required result.[43, 44, 45]

5.2 SWOT analysis (Strengths, Weaknesses, Opportunities and Threats)

SWOT analysis is a structured planning method to aid the identification of internal (strengths and weaknesses) and external (opportunities and threats) influencing factors that are favourable or unfavourable to achieve a defined objective. SWOT analysis helps organisations decide whether an objective is obtainable or not and therefore enables organisations to set achievable goals and objectives.[46]

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[43] Carmichael RM. Measures of efficiency and effectiveness as indicators of quality – a systems approach; downloaded: [15/10/2015]

[44] Terry Wireman: Developing performance indicators for managing maintenance, 2nd ed., Industrial Press, New York, 2005, p210

[45] http://www.cbsolution.net/techniques/ontarget/effectiveness_vs_efficiency; downloaded: [15/10/2015]

[46] https://en.wikipedia.org/wiki/SWOT_analysis; downloaded: [19/10/2015]

5.3 OGSM method (Objectives, Goals, Strategies and Measures)

The OGSM method is a strategic planning process that provides clear goals and identifies the strategic choices to achieve them. It defines the measures that will be followed to assure that goals are met and helps groups work together toward common objectives, across functions, geographical distance and throughout the organisation. A clear, concise objective drives the rest of the OGSM model. The objective should be worded as a customised, specific statement that is specific to the organisation. Goals should be numeric, usually over three to five years, financial and/or operational and should support the objective. The strategy should also use words which are focused and clearly written, typically around growth, productivity and people. Measures should be a numeric representation of the strategic objectives that are traceable and have one owner.[47]

5.4 BSC (Balanced Scorecard)

It is a strategic planning and management tool to align business activities to the vision and strategy of the organisation, improve internal and external communications, and monitor the organisation's performance against strategic goals. The BSC suggests that the organisation be viewed from 4 perspectives, and to develop metrics, collect data and analyse it relative to each of these perspectives: (1) learning and growth; (2) business process; (3) customer; and (4) financial.

The BSC can be used:

- To significantly improve the implementation of objectives and strategies

- To provide a mechanism for controlling and monitoring the organisational progress

- As a communications device to keep team members up-to-date regarding the accomplishment of the goals.

It helps in translating strategy into operational and measurable actions and achieve strategic implementation.[48, 49]

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[47] https://en.wikipedia.org/wiki/OGSM; downloaded: [20/10/2015]

[48] Balanced Scorecard Basics. http://balancedscorecard.org/Resources/About-the-Balanced-Scorecard; downloaded: [20/10/2015]

[49] Shehu S. Business performance management, balanced scorecards and the decision model. (2013 Jul 11) http://blog.bizzdesign.com/business-performance-management-balanced-scorecards-and-the-decision-model; downloaded: [21/10/2015]