SCOPE Work Package 7
Quality Management Systems

Compliance and Performance: Management and Indicators

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SCOPE

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Contents

Acknowledgments

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1. Introduction

1.1 Purpose of the document

The purpose of this document is to provide definitions and clear distinction between compliance and performance management and to provide some examples of indicators. It is at the discretion of each NCA whether to consider any examples presented in this document, if relevant and suitable to their work methodologies.

1.2 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
AR	Assessment Report
BSC	Balanced Scorecard
CAPA	Corrective Action and Preventive Action
EC	European Commission
EPITT	European Pharmacovigilance Issues Tracking Tool
EU	European Union
GVP	Good Pharmacovigilance Practices
HCP	Healthcare Professional
ICSR	Individual Case Safety Report
KPI	Key Performance Indicator
KRI	Key Risk Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MS	Member State
NCA	National Competent Authority
NUI	Non Urgent Information
PASS	Post-Authorisation Safety Study
PSUSA	Periodic Safety Update Single Assessment
PV	Pharmacovigilance
QMS	Quality Management System
RA	Rapid Alert

Terminology	Description
RMP	Risk Management Plan
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
WP	Work Package
WHO	World Health Organisation

1.3 Background

In the SCOPE (Strengthening Collaboration in Operating Pharmacovigilance in Europe) survey for Work Package (WP) 7, National Competent Authorities (NCAs) were asked to provide information on their workflow tracking system used for pharmacovigilance (PV) purposes and to share their experience on compliance management, including the type of indicators monitored, the frequency of compliance checks as well as the method of recording the results.

As highlighted in the SCOPE survey report for WP7, from the responses of 26 Member States (MSs) given questions on workflow management, it could be concluded that a fully functional workflow tracking tool or system for all PV processes was uncommon (only 7 NCAs – 26.9%). Partial solutions are more widespread (12 NCAs – 46.2%) and 7 NCAs (26.9%) do not have a workflow tracking system in place. Integration of the workflow tracking tool with document management is present in slightly more than half of the surveyed NCAs with a complete or partial tracking system in place.

Compliance and performance management are tightly coupled to workflow management/tracking because data feeding into such activities derives from the workflow by recording and evaluating pre-defined indicators of effectiveness and quality.

NCAs were asked to provide information on the most commonly monitored quality attributes in association with PV activities. The top three answers indicated the monitoring of (1) legally defined timelines, (2) the quality and completeness of assessment and adverse drug reaction (ADR) reports, and (3) working hours spent on each activity. The responses given by MSs have demonstrated that there is a difficulty in distinguishing between compliance and performance indicators, as these concepts are linked but do not have the same content. One of the objectives of this document is to provide clear definitions on compliance and performance management, as well as examples of indicators from NCAs.

MSs indicated that data monitoring for compliance and performance checks were conducted both via manual and automated queries, with manual methods prevailing over automated techniques. The frequency of compliance (and performance) checks varied on a wide spectrum, being dependent on the characteristics of each process and activity, on how stable the process is and the controls already in place. All responding MSs indicated that there was some degree of Corrective Action and Preventive Action (CAPA) put in place and followed up until resolution of deficiencies. This CAPA procedure was fully functional in 22 MSs (84.6%).

2. Concepts

2.1 Compliance management

Compliance is the fulfilment of a requirement defined in the legislation, guidelines and/or specific documents (for example, of the Quality Management System (QMS), contracts of outsourced services, etc.).

From an outward look, compliance management is about providing accountability for the performance of the PV department, risk management and stakeholder engagement, in short having the appropriate systems in place to provide the required information in a timely manner and to the appropriate quality standards.

From an inward perspective, compliance is related to monitoring and supervision. Reporting, analysis, ongoing review and corrective actions are steps that also contribute to achieving compliance.

2.2 Performance management

Performance can be defined as the accomplishment of a given task measured against present known standards of accuracy, completeness, cost (human resources allocated), and speed (fulfilling deadlines).

It includes the activities which ensure that goals are consistently being met in an effective and efficient manner.

Performance management can focus on the performance of an organisation, a department, an employee, or even the processes to build a product or deliver a service.

2.3 Performance versus Compliance

Performance and compliance do not always go together. One can comply with requirements but perform badly. Performance and compliance should be considered as a holistic approach to be integrated in NCA activities in order to get the best from the NCA's work.

Prior to measuring performance and compliance, the process landscape should be mapped, describing and viewing core organisational processes to help understand organisational relationships, identify references and supporting processes. Once this is in place, other elements such as measures, risks, people, and technology can start to be aligned to the processes.

It is relevant to: 1) identify the key processes – steps that impact on the final outcome, the processes and the variables to measure; 2) understand the risks that may negatively impact performance and to make plans to control and mitigate them.

3. Indicators

Indicators are used to monitor the operation or condition of a system, a network, or equipment. In general, indicators provide quantitative data that are compared against agreed expected values or metrics. There are also qualitative indicators.

A good indicator should be objective, measurable, well defined, relevant for the process, easy to obtain, inexpensive to accumulate and potentially predictive.

The type of indicators used to monitor the objectives and to evaluate the NCA should include effectiveness, efficacy and quality perspectives.

In order to gather the information that will allow the NCA to monitor compliance and performance, it is important to have records of the several steps of the key procedures, in terms of who is responsible for each activity, timelines (foreseen, real dates and deviations) and summary of outcomes.

One of the best ways to gather all the required information is using databases. As some databases can be expensive, particularly those that are purpose built, similar results can be achieved in a more cost-efficient manner by using simpler methods like excel spreadsheets. These methods will allow information to be obtained, while reviewing indicators, of the status of procedures and to identify where the process failed or highlight issues that require further exploration to determine why such failures have occurred. This further analysis may be conducted for example within the QMS in order to determine the root causes of failure and if it is still possible to take measures to fulfil the objectives.

It should be taken into account the limitations related to the use of the excel spreadsheets, namely the vulnerability to lose or unintentionally modify data.

These records of the key steps of the procedures, although seen sometimes as an extra burden, are essential for the ongoing assessment of the NCA´s work in the task of guaranteeing traceability, achievement of compliance and performance to meet regulatory and quality management system requirements.

The results should be assessed in order to decide if it is necessary to take some CAPA to ensure that objectives and targets are achieved. The effectiveness of the implementation of these CAPA should also be monitored. Therefore, the results should be monitored at least on a quarterly basis. However, monitoring on a monthly basis provides an opportunity to prevent/correct deviations in a timelier manner.

3.1 Key performance indicators (KPIs)

Key performance indicators (KPIs) represent a set of measures of the organisational and operational performance that are critical for the success and mission of the NCA, including the Pharmacovigilance department.

The KPIs should allow the NCA to define measurable objectives, identify, monitor and foresee trends in order to implement corrective, preventive and improvement actions when necessary. The Top Management should select the KPIs considered more suitable to support the strategic decisions. The KPIs should in turn be properly deployed in performance indicators to the relevant functions and levels within the NCA, in order to support the accomplishment of the high level objectives.

The KPIs should be appropriate to the nature and dimension of the NCA, its processes and activities. They have to be consistent with the objectives of the NCA, which should be in turn consistent with the strategies and policies. The selection of the KPIs should also take into account the specific information regarding the risks and opportunities identified by each NCA.

When defining the KPIs, we should ensure that they provide data that is measurable, accurate and reliable and that can be used for implementing corrective actions, when the performance is not in alignment with the objectives or when the efficacy and effectiveness of the process needs to be improved. This data should take into account:

- The needs and expectations of the customers and other stakeholders
- The relevance of the process for the Agency, in the present and in the future
- The efficacy and effectiveness of the processes
- The rational use of the resources
- The profitability and financial performance
- Legal requirements, if applicable

The KPIs will allow continual assessment of the NCA's performance as a whole, as well as the PV department's performance in particular.

3.2 Key Risk Indicators (KRIs)

In order to better understand and define performance indicators consideration should be made to those indicators that can detect the possibility of any future adverse impact on the continuity of the activity.

A key risk indicator (KRI) is a measure used in management to define the risk associated to an activity. This indicator becomes quite useful in the scope of PV as it gives an early warning to identify potential events that may affect/delay the continuity of the activities and allows placing of controls to prevent, mitigate or reduce the risks.

Defining the KRIs is crucial to obtain success and to fulfil the mission of the Agency.

While defining KRIs the following aspects should always be considered:

- Stakeholders
- Balanced selection of risk indicators, covering performance indicators, lead indicators and trends
- Selected indicators should detail the root cause of events
- High relevance and high probability of predicting important risks (high business impact, easy to measure, sensitivity, correlation with the risk)
- Thresholds and triggers
- Data sources
- Methods of measurement

Risks may vary in both impact and likelihood, as processes, people and technology change. Effective risk management is an essential element of a sound internal control system. The measure of KRIs may provide an early warning and consequently proactive actions can be considered. Additionally, it provides a retrospective view on risk events enabling changes to be made so that the same errors do not reoccur. Since these indicators estimate the potential for some form of harm, risk assessment should be conducted whenever a change has been introduced to the process or inputs, and the outputs differ from previous. All this information will provide real time actionable intelligence to decision makers and risk managers ensuring that controls are in place to manage risks.

Managing risks is about managing the chain of:

- Detecting/predicting threats and/or opportunities
- Estimating the probability that risks will happen
- Controlling the impact/outcomes

Normally, it is difficult to map all these aspects of the risk in one KRI, so we may need three indicators:

1. Indicator that measures **probability**
2. Indicator that measures the **impact**
3. Indicator that measures **action plan**.

For example, if we define a KRI such as "Insufficient autonomy of new PV staff" we would have:

1. **Probability indicator**: "Time spent on coaching per week (hours)" – fewer hours spent coaching others, the more likely the NCA will face this risk
2. **Impact indicator**: "% of new PV staff autonomy"- less coaching means less autonomy from the new PV staff
3. **Action plan indicator**: "Leadership training spent (hours)" – teach managers a proper leadership paradigm that would include coaching.

4. Examples of compliance and performance indicators

These examples were provided by some WP7 active partners (BG, ES, HU, IT, PT and UK) and HR.

However, there are some differences between NCAs regarding for instance the strategic objectives, the work methodologies and also the number of human resources allocated to each activity. Therefore, each NCA should consider which of these examples are more appropriate and meaningful to use in their context, bearing in mind their own strengths and/or limitations. Please find below some points to consider in each example.

As a general consideration, when the results of a certain indicator are consistently achieving the defined target, the NCA should focus their monitoring activities on other areas that still require further improvement and define new relevant indicators.

Example 1

Objective:

- Increase the efficiency of the main business processes of <NCA> (fulfilment of defined timelines).

Indicators (compliance):

- No. of educational materials approved in the defined timeline vs total No. of approved educational materials
- No. of ADR reports sent to the Marketing Authorisation Holders (MAHs) and the EMA within the legal timelines vs total No. of ADR reports sent to the MAHs and EMA
- No. of Rapporteur/Lead MS Assessment Reports (ARs) for Periodic Safety Update Single Assessment (PSUSA), Risk Management Plan (RMP) and Post-Authorisation Safety Study (PASS) circulated within the timelines defined vs total No. of ARs circulated.

Considerations to take into account:

- The achievement of 100% of compliance with the legal or defined timelines is sometimes precluded by the lack of human resources allocated to those PV activities; the monitoring of results of these kind of indicators can be useful to identify areas where resources are lacking and to obtain evidence to trigger more prompt actions regarding the allocation of resources.

Example 2

Objective:

- Organise training events for all stakeholders involved in the national system of pharmacovigilance

Indicator (performance):

- No. of courses organised vs total No. of planned courses

Considerations to take into account:

- The stakeholders' needs and expectations are important to plan the training courses that should be organised
- Complementary to this indicator, it can also be useful to have another indicator regarding the level of satisfaction of the stakeholders with these courses.

Example 3

Objective:

- Continuous training for the PV staff through internal and external courses

Indicator (performance):

- No. of courses attended by each resource vs total No. of planned courses

Considerations to take into account:

- The training plan of the PV staff should be developed and regularly reviewed in order to maintain a skilled workforce to deliver objectives with high quality standards; if this indicator has poor results, it can be a sign that the plan should be reviewed or that, although the plan reflects the real needs of the PV staff, the workload doesn't allow everyone to attend the courses
- Complementary to this indicator, it can also be useful to have another indicator regarding the effectiveness of the training, which is sometimes more difficult to measure.

Example 4

Objective:

- Conduct PV inspections of MAHs to verify compliance with legal and regulatory requirements in the PV field

Indicator (performance):

- No. of PV inspections performed vs total No. of planned PV inspections

Considerations to take into account:

- The plan of PV inspections has to consider the risk assessment performed by the NCA to prioritise inspections; if this indicator has poor results, it can be a sign that the plan should be reviewed and/or that more human resources are needed.

Example 5

Objective:

- Conduct joint PV inspections of MAHs with EU and extra EU inspectorates to exchange experiences

Indicator (performance):

- No. of joint PV inspections performed vs total No. of planned joint PV inspections

Considerations to take into account:

- Please see the previous example.

Example 6

Objective:

- Improve the efficiency of the local signal detection activity

Indicator (performance):

- No. of (local) confirmed signals which are logged into European Pharmacovigilance Issues Tracking Tool (EPITT) for further assessment vs total of local detected signals

Considerations to take into account:

- The monitoring of results of this type of indicator can provide us with an insight into the quality and robustness of signal detection and validation activities.
- The knowledge and experience of the PV assessors are important factors.

Example 7

Objective:

- European collaboration: increase the quality and completeness of assessments across MS (e.g. PSUSA AR, RMP AR, PASS AR, signal confirmation/ assessment AR, referral AR)

Indicators (performance):

- No. of procedures/ARs to which comments have been submitted by <NCA> which are agreed by the Rapporteur/Lead MS vs total No. of procedures/ARs to which comments have been submitted by <NCA>.
- No. of Rapporteur/Lead MS ARs of <NCA> for which comments from MSs (excluding endorsement comments) were adopted vs total No. of Rapporteur/Lead MS ARs of <NCA> for which comments from MSs were received (including endorsement comments).

Considerations to take into account:

- These indicators, related to the peer review across MSs, can highlight the level of quality and completeness of the NCA's comments and assessments: if these indicators have poor results maybe there is a need for further training/mentoring of the PV assessor; on the other hand, if the results are good, this indicates that the assessments are appropriate and risk proportionate
- The knowledge and experience of the PV assessors are important factors; these indicators can be used as a measure of the evolution of the new staff's performance.

Example 8

Objective:

- Increase the efficiency of the exchange of information process across MSs, EMA and the European Commission (EC) through the Non Urgent Information (NUI)/Rapid Alert (RA) system

Indicators (compliance):

- No. of responses sent by <NCA> to NUI/RA vs total No. of NUI/RA circulated
- No. of responses sent by <NCA> to NUI/RA in the defined timeline vs total No. of responses sent

Considerations to take into account:

- The capacity to achieve 100% of responses and compliance with the defined timelines is sometimes precluded by the lack of human resources allocated to those PV activities; the monitoring of results of these kind of indicators can be useful to identify areas where resources are lacking and obtain evidence to trigger more prompt actions regarding the allocation of resources.

Example 9

Objective:

- Increase the level of ADR reporting

Indicator (performance):

- No. of ADR reports received from (a) healthcare professionals (b) the public

Considerations to take into account:

- This indicator can highlight the ADR reporting rate trends, which should be followed by a proper analysis of the root causes (existence of a previous campaign to encourage ADR reporting, need of more informative sessions for healthcare professionals (HCPs) and/or patients)
- The quality of the ADR reports received is also an important performance indicator, although it can be more difficult to measure
- The existence or not of regional units of PV, the population of each geographic area are also factors that can influence the context of ADR reporting
- We can also consider comparing the level of ADR reporting regarding the medicinal products under additional monitoring and the others, as a measure of the effectiveness of the black triangle in the product information.

Example 10

Objective:

- Reduce the timescale between receipt and analysis of the most serious ADR reports

Indicators (performance):

- % of fatal adverse drug reactions analysed within 24 hours
- % of fatal adverse drug reactions analysed within 72 hours
- % of serious adverse drug reactions analysed within 72 hours
- % of serious adverse drug reactions analysed within 5 days

Considerations to take into account:

- The resources available, in terms of number and experience, are critical factors for these kind of indicators because the quality of the analysis cannot be jeopardised
- These indicators can give us evidence of the capacity to act more promptly regarding the protection of public health, if needed, and/or of the possibility of reallocating (temporarily or even cumulatively) resources for other activities.

Example 11

Objective:

- Reduce the timescale between detection and analysis of all local potential signals (from whatever source)

Indicator (performance):

- % of local potential signals initially evaluated within 5 working days

Considerations to take into account:

- Please see the previous example.

Example 12

Objective:

- Increase the completeness (clinically relevant information) of Individual Case Safety Reports (ICSRs) sent to the World Health Organisation (WHO)

Indicator (performance):

- Completeness score (based on the WHO vigiGrade™ – ranges from 0.07 to 1)

Considerations to take into account:

- The monitoring of the results of this indicator can give us an insight regarding the quality of our analysis of ICSR, which should be followed by a proper analysis of the root causes (the number of ADR reports received and the number of human resources available to analyse them, the capacity to perform follow up activities to ensure that the clinically relevant information is as complete as possible, the need to provide further training to the ADR reporters).

Example 13

Objective:

- Increase the NCAs involvement in the PV activities of the European Union (EU) regulatory network

Indicator (performance):

- No. of biddings sent by <NCA> to act as Rapporteur/Lead MS vs total No. of biddings sent to <NCA> for application to act as Rapporteur/Lead MS (e.g. new Marketing Authorisation Application (MAA), PSUSA, PASS, referral procedures)

Considerations to take into account:

- The areas of expertise of the PV assessors, as well as their availability, are critical factors for achieving this objective
- This specific indicator only shows us the level of proactivity/commitment of the NCA to pursue the objective of increasing the lead the European assessments.

Example 14

Objective:

- Improve the contribution of PV staff to stakeholder satisfaction and involvement

Indicators (compliance/performance):

- No. of complaints the PV department addressed vs total No. of received complaints by the PV department
- No. of complaints addressed in the defined timeline vs total No. of addressed complaints
- No. of stakeholder satisfaction surveys responses with positive feedback vs. total No. of stakeholder satisfaction surveys responses

Considerations to take into account:

- These kind of indicators provide us with some evidence of the level of satisfaction of the stakeholders and also of the involvement of the PV staff in increasing that level
- However, the capacity of addressing 100% of the complaints within the defined timelines is sometimes precluded by the workload and/or the complexity of the issues and the respective root causes' analysis.

Example 15

Objective:

- Continuous improvement of the PV quality system

Indicators (compliance/performance):

- No. of (serious/critical) audit findings detected in the internal audit of the QMS of PV or specific processes vs total No. of audit findings detected in the internal audit of the QMS of PV or specific processes
- No. of non-compliances which arise from the internal audit of the QMS of PV or specific processes vs total No. of non-compliances which arise from the PV staff
- No. of improvement opportunities/suggestions which arise from the internal audit of the QMS of PV or specific processes vs total No. of improvement opportunities/suggestions which arise from the PV staff

Considerations to take into account:

- The first indicator can give us an insight as to the maturity of the QMS or a specific process because, in general, the serious/critical findings will tend to decrease when the QMS is fully implemented and functional (i.e., the quality management is integrated and consistent with the PV business activities)
- The last two indicators can give us some information regarding the level of commitment of the PV staff with continuous improvement of the quality system of PV activities; the audits are a sampling exercise, so we can not rely only on auditors to find non-compliances and opportunities to improve; it's to be expected that the PV assessors are able to recognise more easily the constraints and the improvements that have an impact on their daily work.
- As a final note, this is not an exhaustive list of points to consider when defining relevant indicators to monitor compliance and performance. For further information regarding the measurement of (quality) objectives and setting of indicators, please consult also the Toolkit item: Introductory paper on quality planning, quality objectives and their use in pharmacovigilance.

5. Balanced Scorecard (BSC) – a tool for monitoring performance and compliance indicators

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

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 communication device to keep team members up-to-date regarding the accomplishment of the goals.

The BSC helps in translating strategy into operational and measurable actions and should present the most relevant performance indicators (strategic objectives, operational objectives, indicators and the weight of each one, method of calculation and goals). There are software applications, called business intelligence tools, designed to retrieve, analyse, transform and report data that can streamline the use of BSC.

Although the BSC should include the key PV activities, it does not mean that other activities should not be measured and monitored, using other management tools and methodologies, in order to guarantee the compliance and performance of all activities.

6. Summary and conclusions

This document is intended to provide definitions and clear distinction between compliance and performance management, as well as give examples of indicators used by some NCAs to monitor their PV activities.

Whereas compliance is the fulfilment of a requirement defined in the legislation, guidelines and/or specific documents, performance can be defined as the accomplishment of a given task measured against present known standards of accuracy, completeness, cost (human resources allocated), and speed (fulfilling deadlines). Performance and compliance should be considered as a holistic approach to be integrated into our activities in order to get the best from our work.

A good indicator should be objective, measurable, well defined, relevant for the process and easy to obtain. In general, indicators provide quantitative data that are compared against agreed expected value or metrics. There are also qualitative indicators.

It is important to have records of the several steps of the key procedures in order to gather the information that will allow the NCAs to guarantee the traceability of the PV activities and to monitor the achievement of compliance and performance to meet regulatory and quality management system requirements.

The results should be assessed regularly in order to decide if it is necessary to take some CAPA to ensure that objectives and targets are achieved. The effectiveness of the implementation of these CAPA should also be monitored.