SCOPE Work Package 7
Quality Management Systems

Quality Standards of Pharmacovigilance Assessment

2016

SCOPE

SCOPE Work Package 7
Quality Management Systems
Quality Standards of Pharmacovigilance Assessment

Contents

1. Introduction

1.1 Purpose of the document

The purpose of this document is to provide practical guidance for Pharmacovigilance assessors arising from the work in Work Package 7 – Quality Management Systems, Understanding national quality systems in the context of the quality of assessment reports.

1.2 Definitions and abbreviations

Terminology	Description
ADR	Adverse drug reaction
AR	Assessment report
EU	European Union
EPITT	European Pharmacovigilance Issue Tracking Tool
EV	EudraVigilance
MS	Member State(s)
NCA	National Competent Authority
PASS	Post Authorisation Safety Studies
PSUSA	Single assessment of Periodic Safety Update Reports
PV	Pharmacovigilance
QC	Quality control
RMP	Risk Management Plan
RSI	Request for Supplementary Information
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SOP	Standard Operating Procedures
WP	Work Package

1.3 Background

In the SCOPE (Strengthening Collaboration in Operating Pharmacovigilance in Europe) Project, Work Package (WP) 7 is responsible for Quality Management Systems in the area of Pharmacovigilance (PV).

During the survey for WP7 – Understanding national quality systems, NCAs were asked to provide information on the quality standards of assessment of PV data, considering the work and practices by which the high quality of scientific conclusions and the consistency and timeliness of decision making can be ensured.

As highlighted in the survey report, 76.9% of the respondents reported that they have standards or methods in place to ensure the quality of scientific assessment work. Details of these methods were further investigated which revealed that only 61.5% of the NCAs have a fully functional QC in place in terms of 7 criteria investigated during the survey, e.g. the fulfilment of timelines, the compliance with templates, and conflict of interests. The consistency of ARs with previous decisions and presentation of conclusions in a clear, concise and logical manner were the most critical aspects identified.

Peer review and team meetings (i.e. review with all assessors concerned by the issue) were the most common practices of quality control. Additionally, results of the survey suggested that quality control of scientific assessment work is usually not a single person responsibility, but a shared effort highlighting the significance of high quality reports.

The extent of quality control at NCAs regarding PV assessment procedures depends generally on the nature, priority and criticality of the issue. This approach presumes from a quality management point of view that a well-defined prioritisation method is in place in order to be able to decide which procedures and outputs should be subject to quality control.

It is of primary importance that high quality assessment reports are produced by NCAs during PV activities, particularly in procedures concerning the whole EU regulatory network. A common and unified set of criteria to establish and control the quality of assessment reports will improve the scientific decision making process in the EU.

1.4 Context and scope of the toolkit item

The SCOPE survey report for WP7 highlighted the importance of the high quality assessments reports produced by NCAs in association with PV activities, particularly in procedures concerning the EU regulatory network.

One of the recommendations that arose from analysis of these results and during internal discussion among contributors to WP7 was the proposal to develop a guidance checklist for PV assessors to perform quality control of their assessment reports (self-assessment). Additionally, this checklist could be adapted to be used by a peer reviewer in order to streamline criteria of QC. The checklist once filled in could be used as a record of a quality control activity.

This document was written to offer some practical guidance on key aspects regarding the quality control of assessment reports. It is acknowledged that there are different structures in place for pharmacovigilance assessment across the MSs. However, the focus of this paper is on the actual assessment reports and not the workflow of the PV procedures, for which guidance is already available, nor on the scientific guidance for PV assessments and competencies of assessors which are in the scope of WP8 – Lifecycle Pharmacovigilance.

This document can be applied horizontally to all PV procedures whenever it is necessary to write an assessment report, independent of the nature of the assessment process, quality of data submission, therapeutic area or the safety issues under review.

Ultimately, this tool may also be important in underlining and assessing the needs of each assessor in terms of relevant additional training.

2. Establishing Quality Standards for PV Assessment

Pharmacovigilance assessors need to be familiar with the relevant legislation, guidelines, SOPs and templates guidance, and refer to these, as appropriate, throughout each assessment process.

These guidance documents can and should be used for quality control of ARs, within the NCAs' daily life, considering their main responsibilities in every procedure in which they are intended to participate.

The most practical way to define quality standards is establishing and measuring indicators. In general terms, these will provide the outcome on the quality of the work being developed. Here, the relevant indicators are completeness and consistency of PV assessment.

Despite it being acknowledged that there are different structures in place for PV assessment across the MSs, the quality of reports should be standardised as much as possible, which will ultimately provide a more common and accurate evaluation throughout PV activities in the European context. Consequently, it is important to use common "tools" that will hopefully allow the quality improvement of the assessment reports of the PV assessors, as well as give a glance on what is expected from an external pool of other assessors (e.g. clinical), when applicable.

The checklist proposed in Annex 1 will allow a common, unified and accurate self-assessment of the quality of assessment reports prior to, or while preparing, the assessment reports by assessors and ultimately will contribute to the overall quality of the assessments throughout PV procedures.

It is of primary importance that the assessment report of any PV procedure presents a comprehensive, concise and critical analysis of the data/information under assessment, with clearly justified conclusions and recommendations, based on the submitted data and other relevant information, as applicable. It is acknowledged that work patterns and practices vary amongst assessors. However, it is important that assessment reports are clear and consistent with the submitted data.

In order to comply with the quality standards of PV assessments, the overall evaluation of the assessment report should address, as a minimum, the following issues:

- Scope of the AR
- Structure and clarity of the AR
- Findings and analysis/evaluation
- Conclusions
- Recommendations

One of the most prominent criteria is 'Findings and analysis/evaluation' as good analysis and credible findings are considered the backbone of a high quality report.

In fact, a PV assessment report containing clear presentation of a critical appraisal of all relevant data is useful in order to get robust conclusions and recommendations and provide the reader with accurate information on the scope of the procedure being assessed as well as, potentially, useful lessons learned.

Additionally, clarity of the assessment report is also crucial in order to communicate the rationale of the analysis, the conclusions and recommendations in a logically structured way, with comprehensive and clear language.

Annex 1: Guidance Checklist for Pharmacovigilance Assessors

Title of the Assessment Report:

SCOPE:

Objective	Yes	No	Difficulties & other observations
1. Structure, completeness, clarity and presentation of the assessment report *To ensure that the AR is user-friendly, comprehensive, logically structured and drafted in accordance with approved templates*			
AR completed			
AR logically structured and the contents in line with the approved templates			
AR reflects the relevant information of data under assessment including issues raised in the procedure or previous conclusions			
Information is provided in a language that can be easily understood			
2. Scientific findings and analysis/evaluation *To ensure consistent analysis/evaluation and reliable findings*			
Analysis of the scientific findings clearly explained and understandable			
Limitations of the data submitted by the MAH or of the responses to RSI (if any) clearly highlighted/discussed and appropriate measures proposed			
3.Comments received *To assess how comments have been acknowledged and assessed*			
Assessment of all comments (including clear discussion and grounds for agreement or disagreement)			

Objective	Yes	No	Difficulties & other observations
4. Conclusions *To assess the robustness of conclusions*			
Conclusions well-structured and organised in priority order (from the critical ones to the minor ones regarding the risk-benefit of the medicinal product)			
Conclusions reflect clearly the evaluation of scientific data			
Limitations (if any) clearly pointed out and appropriate measures proposed to prevent the same in future procedures			
5. Recommendations *To assess the usefulness and clarity of recommendations*			
Logical flow from the conclusions to recommendations			
Recommendations presented in a priority order, consistent with the prioritisation of the conclusions			
Recommendations detailed and supported by the correct grounds (e.g. scientific findings)			
All issues addressed and measures/actions proposed are feasible and proportionate			
6. Communication and interdisciplinary working *To assess the importance/necessity of interdisciplinary assessments*			
Report reflects the discussion of the multidisciplinary assessment team and/or the peer review comments (if applicable)			

Objective	Yes	No	Difficulties & other observations
7. Documentation to be consulted by assessors *To ensure that assessors are aware of the requirements and standards of each assessment and that they gather every effort to make the report as complete and grounded as possible*			
Checklist for assessors (e.g. National checklists for different procedures, if existing)			
Legislation (National and/or European)			
Literature (e.g. PubMed, Micromedex)			
Guidelines (regulatory and clinical)			
SOPs			
Previous decisions and outcomes on similar issues / other procedures involving the medicinal product or the therapeutic class			
Practical Guides developed by SCOPE WP8 (scope: PASS, PSUSA, RMP and Referrals)			
Databases (e.g. EPITT, EV, National Databases for ADR or Drug utilization patterns, …)			