SCOPE Work Package 7
Quality Management Systems

Stakeholder Feedback and Customer Satisfaction

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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 outline the basic concept of gathering stakeholder feedback and measuring customer satisfaction with special focus on pharmacovigilance (PV) and highlight its importance in the context of quality management. This enables experiences to be shared and good practices disseminated across Member States (MSs), and in addition increases the awareness of PV assessors and any interested parties at National Competent Authorities (NCAs) level on this specific area of quality management.

The document covers basic principles, definitions and methods, illustrated with practical examples from the field of Public Administration and particularly PV as collected by an online survey and further follow-up (written and face-to-face) activities with NCAs participating in the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) project.

Practices described in this paper may not cover all relevant issues and may not be suitable for every NCA. It is at the discretion of each NCA to consider if the practices presented in this document are relevant to their work, and there is no obligation to adopt any practices.

1.2 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
AIFA	Agenzia Italiana del Farmaco, The Italian Medicines Agency (IT)
BDA	Bulgarian Drug Agency (BG)
DHPC	Direct Healthcare Professional Communication
DSU	Drug Safety Update
EMA	European Medicines Agency
EU	European Union
EU-QPPV	Qualified Person Responsible For Pharmacovigilance in the EU
GPQ	Gabinete de Planeamento e Qualidade, Quality and Planning Office of INFARMED, I.P.
GVP	Guideline for Good Pharmacovigilance Practices
HALMED	Agencija za lijekove I medicinske proizvode, Agency for Medicinal Products and Medical Devices of Croatia (HR)
HCP	Healthcare Professional

Terminology	Description
INFARMED, I.P.	Autoridade Nacional do Medicamento e Produtos de Saúde I.P., National Authority of Medicines and Health Products (PT)
IR	Implementing Regulation
ISO	International Organisation for Standardisation
IT	Information Technology
Lareb	Landelijke Registratie en Evaluatie van Bijwerkingen, The Netherlands Pharmacovigilance Centre (NL)
MAH	Marketing Authorisation Holder
MEB	Medicines Evaluation Board (NL)
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MS	Member State
NCA	National Competent Authority
NHS	National Health Services
OGYÉI	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet, National Institute of Pharmacy and Nutrition (HU)
PV	Pharmacovigilance
QMS	Quality Management System
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SOP	Standard Operating Procedure
WP	Work Package

1.3 Background

Guidance on quality systems in the Guideline for good pharmacovigilance practices (GVP) Module I is consistent with the general principles of the ISO 9000 Standards on good quality management practices, specifically the ISO 9001:2008 Standards on quality management systems (QMS), issued by the International Organisation for Standardisation (ISO). According to the basic principles laid down in these standards, one of the primary goals of the functioning of an organisation is to meet the requirements of its customers so that customers feel satisfied by the goods and services provided.

In the frame of the revised legislation on pharmacovigilance (PV) for human medicinal products in the EU that came into force in July 2012 the following obligations of EU National Competent Authorities (NCAs) relating to stakeholders are defined. As set out in the Implementing Regulation (IR) Section 3 (Minimum requirements for the quality systems for the performance of PV activities by NCAs and the Agency):

Article 15(1) Compliance management section (d): effective communication among NCAs and between the NCAs and the Agency (European Medicines Agency – EMA) as well as with patients, healthcare professionals (HCPs), marketing authorisation holders (MAHs) and the general public should be ensured.

While there has to be compliance with these legal requirements, the implementation of a quality system should be adapted to the respective organisation. In accordance with the quality cycle, customer requirements and the needs and expectations of relevant interested parties (other stakeholders) should inevitably being taken into consideration. In the planning phase it can be used as a pivotal outcome indicator of the NCAs QMS e.g. measuring customer satisfaction.

Customer satisfaction in general means the customer's perception of the degree to which their expectations have been fulfilled. Therefore, customer satisfaction is a subjective term, but it can be measured and highlight areas for improvement.

With the new PV legislation, NCAs are faced with the challenge of needing robust and rapid decision–making processes, increased expectations and enhanced involvement of stakeholders in PV to increase transparency. The ultimate goals of PV are the rational and safe use of medicines, the assessment and communication of the risks and benefits of medicines on the market, and educating and informing patients, HCPs and other stakeholders concerned.

The "public" reasonably expect NCAs to keep them well informed about medicines safety, in order to reduce the risks associated with medicines and to feel safe and confident in the usage and consumption of medicinal products. However, the patients' needs and expectations may be different from that of HCPs. For example, an individual patient wishes to enhance his/her quality of life with highly effective and safe medicinal products, whilst HCPs expect evidence-based authorisation processes, an ability to access reliable medicines information and to experience less administrative burden related to PV activities, such as adverse drug reaction (ADR) reporting. The success or failure of any spontaneous reporting system depends on the active participation of reporters, both patients and HCPs. Underreporting of ADRs is a common issue across the EU, therefore raising awareness of reporting to stakeholders and implementing efficient processes to decrease administrative burden would help alleviate this problem.

The primary goal of PV activities performed by an NCA or other responsible regulatory body or organisation is to ensure that marketed medicines are safe and they meet the needs and expectations of its customers. Notwithstanding, the needs and expectations of the individuals are not always met considering that medicinal products are evaluated on population based data, with results not always applicable at individual level. Clear and mutual understanding of responsibilities and expectations are of great importance.

In order to achieve the above goals there should be a constant exchange of information between the organisation and its customers/stakeholders to receive feedback on whether expectations have been met and how stakeholders perceive the performance of the organisation. An organisation has to be open for queries, complaints, or any type of feedback by establishing and making publicly available the channels via which stakeholders can provide such communication.

1.4 SCOPE project

SCOPE is a European-wide Joint Action among NCAs to share experiences and create PV tools and guidance to maximise the effectiveness of regulatory activities in the network and in each MS. As a consequence, SCOPE aims to strengthen and improve the protection of public health across Europe. SCOPE is divided into eight separate work packages (WPs), each dealing with different subtopics. The overall main objective of WP7 – Quality Management Systems is to understand the added value of implementation of quality management and to apply it in everyday work for improving the performance of PV. WP7 is further divided into three topics: Understanding national quality systems; Resource management; and Interaction with PV Inspectors.

In the frame of WP7 first topic, an online survey was conducted to gather information on the practices of participating MSs concerning their quality management principles in PV activities and the operation of the national PV system, as required by the EU PV legislation. The survey was focused on selected areas of quality management which were considered the most important, based on experience gathered during site visits and as agreed by the active participants of WP7.

As part of the survey, in section “Stakeholder feedback”, MSs were asked to provide information on their practices of communication with their stakeholders, including the availability of the NCA for any queries or feedback, and any activities in place to actively survey stakeholders’ perception and expectations on drug safety, and on general PV issues.

MSs were asked to provide information on the availability of contact points for a variety of stakeholders and the availability of PV colleagues or any other solutions to register incoming information either inside or outside working hours. In line with the legislation MSs confirmed the existence of contact points for the EU regulatory network, the pharmaceutical industry and the public (including HCPs and patients). Besides a single common contact point in some MSs, there are also dedicated contact points or special corresponding fora dealing with media queries, ADR reporting, and other PV issues. However, resources are a critical aspect across EU agencies with approximately half of the responding agencies being available for receiving feedback, queries or notifications only during office hours. This may be set against the requirement of continuous availability (7/7 days, 24/24 hours) of the Qualified Person Responsible for Pharmacovigilance in the EU (EU-QPPV) as defined by the legislation. Constant availability of regulatory agencies to catch drug safety issues may well be justified.

The survey also addressed whether the agencies actively survey the stakeholder's needs, expectations and perception on safety related issues, and if so, was there a mechanism or process in place for managing stakeholder feedback.

Results of the survey highlighted diverse practices in MSs in the approach to getting feedback from stakeholders to assess their level of satisfaction. Using a proactive approach, several MSs compile and conduct stakeholder surveys and customer satisfaction questionnaires on a regular basis, making the results available on their websites.

Regular targeted meetings and information days are organised for exchanging experience and addressing the needs of stakeholders. Nevertheless, the majority of the responding MSs operate a reactive system managing 'spontaneously' incoming feedback, complaints and queries.

The results of the survey conducted by WP7 have shown that some NCAs with more mature PV systems have more experience with the proactive approach of surveying customers' needs and expectations.

1.5 Aim and scope

This paper constitutes an item of the quality toolkit, as part of the WP7 deliverables, and outlines the basic concept of measuring customer satisfaction and information exchange with stakeholders focusing on the importance of stakeholder feedback and its added value in the evaluation of the organisations' performance as well as continuous improvement.

Apart from highlighting its importance, this document will not examine the effectiveness of medicines safety communications (this is covered by SCOPE WP6), but will focus on general customer's/stakeholder's satisfaction, communication aiming at gathering information on stakeholders perceptions, opinions and suggestions with proactive approaches for ensuring continuous improvement of the NCA's services. Complaint management will be mentioned as an alternative channel to obtaining feedback from stakeholders.

Practical examples derived from the SCOPE survey and provided by active MSs illustrating a proactive approach of surveying customers' satisfaction and obtaining stakeholders' feedback via survey/satisfaction questionnaires are provided, among general guidance.

This paper is considered a useful tool to give details and raise awareness of different methods of obtaining and measuring feedback from stakeholders on new and/or already existing PV processes, aiming at continuous improvement of the performance of the organisation and satisfying the customers.

1.6 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. Practical examples chosen by the author to be presented in this paper 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.

2. Guidance and good practice examples

2.1 Identification of customers and stakeholders in the Public Sector

Organisations providing a service for their customers need to be in close contact and in a two way information exchange with the stakeholders in order to proactively assess their needs and expectations, and explore their perceptions on the performance of the organisation. Public health and drug safety are highly sensitive areas, and lack of transparency and communication with stakeholders creates distrust and may hinder the operation of national healthcare systems.

In public organisations, quality is often defined as the minimum that a supervisory body (e.g. government) demands, and cost reduction can often be deemed more important than quality improvements, which may not lead to an increase in customer demand.

The widely used definition of the customer and the stakeholder in general are the following:

- The **customer** is a party that receives or consumes products (goods or services) and has the ability to choose between different products and suppliers. From a quality perspective, the customer is defined as an entity within a firm who establishes the requirement of a process and receives the output of that process from one or more internal or external suppliers. A customer can be internal or external to the organisation.
- The **stakeholder** is a person, group or organisation that has a significant interest in services provided or has concerns in an organisation. Stakeholders can affect or be affected by the organisation's_action, objectives and policies. Stakeholders can be of any form, size and capacity. They can be individuals, organisations, or unorganised groups.

Service users are those who use or may use services. The involvement of service users may be direct or through representatives.

2.1.1 Who are considered to be the customers/stakeholders of the NCAs?

Does the organisation serve society as a whole or just the individuals who use the services?

According to the general definition, the customer means a particular individual participating in the market by buying goods and services for their own purposes. In the regulatory perspective the term general public (the whole society), consisting of individual citizens, should also be considered.

In the current PV legislation (Directive 2010/84/EU), a wide range of customers and stakeholders such as patients, HCPs, marketing authorisation holders (MAHs), NCAs, the EMA, general public, social health insurers, as well as organisations representing patients, consumers, HCPs, and other interested parties are addressed in relation to different PV processes, however, exact definitions are not provided.

In general, patients and HCPs are ultimately the end users (customers) of medicinal products; however, they also play a pivotal role in PV as stakeholders. All regulatory efforts should lead to patient protection, however, the concern of public organisations will not be their direct users' individual needs but the needs of the society as a whole.

Patient groups or public interest groups can contribute to these efforts by participating as stakeholders in the development of regulatory policies and in regulatory activities. These groups can act and may protect the public from undue pressure from industry or regulatory bodies. However, due to the highly technical nature of medicinal products and information, patients need support from the NCAs and other organisations to empower themselves and make appropriate contributions.

Pharmaceutical companies also have a crucial role in medicines regulation and PV, thus also constitute as key stakeholders, together with other players within the medicines regulatory network such as the EMA and other regulatory agencies including the NCAs.

Stakeholders may be divided into two main groups:

- External stakeholders and groups include (but not limited to):
  - HCPs
  - Patients, and their carers
  - National health services
  - Patient organisations
  - Academic and scientific boards
  - MAHs
  - Other regulatory bodies (i.e. other agencies, ministries)
  - General public Within the group of general public 'media' is a high priority stakeholder requiring special attention due to PV activities' potential impact on public health.
- Internal stakeholders within the organisation include (but not limited to):
  - Staff
  - Multidisciplinary teams, peer reviewers
  - Departments interfacing with PV activities and processes
  - Management Boards, committees.

Adequately trained PV staff are an important internal group of stakeholders involved in the daily provision of PV services and, having close contact with the stakeholders, they can exert considerable positive impact by strengthening relationships and building trust. Members of the public also have their own health interests and views.

Each stakeholder or stakeholder group have different characteristics, roles, needs, expectations and interests which vary according to the process or issue under evaluation.

2.1.2 In which quality document can NCAs define their stakeholders?

Organisations may define their stakeholders in their Quality Manual/Policy, Communication Policy, or Business Plan.

An example of defining principle stakeholders and key accounts for communication within the organisation is provided and highlighted below (quoted from the published Communication Policy of HALMED, the Croatian NCA).

*"HALMED's principal stakeholders are **general public, patients, healthcare professionals, pharmaceutical and medical devices industry representatives**, other **national** and **EU regulatory bodies** and **media representatives** as **external stakeholders**, and **HALMED's employees** as **internal stakeholders**. HALMED's Public Relations Office, in cooperation with other HALMED employees, is responsible for performing tasks related to the communication, providing information and maintaining relationships with the HALMED's stakeholders. /…/ In addition, HALMED encourages a two-way communication and engagement of its stakeholders."*

2.2 Why should customers' and stakeholders' satisfaction be measured?

One of the key elements of organisational success is the customer's satisfaction with the organisation and its products and services. Therefore, it is necessary to monitor and measure customer satisfaction.

Customer satisfaction is the degree of satisfaction provided by the goods and services of a company as measured by the number of returning customers. Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction. Customer satisfaction is a subjective term and is not always proportionate to the quality of services provided. Even when requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction. In the business world this term is more straightforward compared to the public sector.

The level of customer satisfaction highly depends on the level of knowledge and understanding of the individuals on the services provided by the regulators. For that reason, regulators should keep their customers well informed on their services, processes and limitations in order to avoid unrealistic expectations and unmet needs. In order to achieve this goal there should be a continual exchange of information between the organisation and its stakeholders to receive feedback on whether expectations have been met and the stakeholder's perception on the performance of the organisation.

In order to pursue this goal the organisation should:

- Identify their stakeholders
- Provide information on products and services provided by the organisation
- Identify stakeholders' expectations
- Gather stakeholders' satisfaction data
- Analyse stakeholders' satisfaction data
- Provide feedback on obtained results for improvement
- Continuously monitor the level of satisfaction
- Appropriately handle enquiries and complaints from the stakeholders.

The purpose and objectives influence what, when, how and from whom the data is gathered. They also influence how the data is analysed and how the information is ultimately used.

2.2.1 What benefits may be obtained?

The information obtained from monitoring and measuring customer satisfaction can help identify opportunities for improvement of the organisation's strategies, products, processes and characteristics that are valued by customers, and serve the organisation's objectives. Such improvements can strengthen customer confidence and result in increased trust and other benefits such as better compliance with legislation.

Benefits may be obtained by:

- Gathering information on new expectations
- Resolving complaints to the satisfaction of the complainant and the organisation
- Identifying trends and therewith eliminate causes of complaints
- Taking a customer-focused approach to resolving complaints
- Encouraging personnel to improve their skills in working with customers
- Creating a basis for continual review and analysis of the complaints-handling process.

An organisation has to be open for queries, complaints, or any type of feedback by establishing and making publicly available the channels via which stakeholders can reach the organisation. The organisation shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.

The high rate of satisfaction is one of the guarantees of customer loyalty. The organisation should plan and establish processes to listen to the voices of their customers effectively. It should define and implement methods of data collection, including information sources, frequency of collection and data analysis review. The information gained can guide the organisation to take actions which can help to sustain or enhance customer satisfaction.

2.3 What channels and tools may be used for engagement with stakeholders?

Monitoring and measurement of customer satisfaction is based on the review of customer-related information. The collection of such information may be active or passive.

Management should recognise that there are many sources of customer-related information, and should establish effective and efficient processes to collect, analyse and use this information for improving the performance of the organisation. The organisation should identify internal and external sources of customer and user information, available in written or verbal forms. The process of requesting, measuring and monitoring feedback on customer satisfaction should provide information on a continual basis.

Different communication channels, tools, and activities are used in practice by NCAs for internal communication such as intranet, email, telephone, published strategic plans, reports, meeting minutes, regular face-to-face meetings (for example the "Italian Medicine Agency" launched the "OPEN-AIFA initiative" dedicated to the institutionalisation of meetings with all stakeholders to ensure a direct and transparent dialogue: patient groups, civil society representatives, pharmaceutical companies and any other interested party may submit a reasoned request for participation in the meetings that will take place on a monthly basis); however for external communication generally the organisations' website is used as a primary channel in most of the cases. Other tools and activities for engaging and informing external stakeholders include organised lectures, webinars, conferences, workshops, regularly distributed newsletters, brochures and leaflets.

Examples of sources of information on customer satisfaction may include:

- Customer feedback
- Customer complaints
- Communicating directly with customers on specific processes
- Questionnaires and surveys

- Subcontracted collection and analysis of data
- Focus groups
- Reports from customer organisations
- Reports in the media
- Industry studies.

2.3.1 Different methods of engagement

Examples of methods and measures used to obtain stakeholder's feedback derived from the SCOPE WP7 survey results are:

- Customer satisfaction questionnaires
- Stakeholder's surveys (general and PV specific)
- Information days, sessions, targeted meetings
- Comments, suggestions, enquiries and complaints via any channel from any stakeholder
- Internal reviews of PV queries
- Feedback from staff
- Committees, focus groups, communications divisions
- Contacting patient organisations
- Follow-up of safety communications (response to statements in the media, request for further information of interviews).

It should be noted that stakeholders may differ within the organisation depending on the process under evaluation and the role played in a given procedure. Different methods of surveying customers' needs and opinions suit different situations and reflect the ability and willingness of an organisation to reactively or proactively monitor and measure customer satisfaction.

The different methods may be grouped based on the different channels used:

- Written consultation: comments, suggestions, complaints, customer surveys, questionnaires, customer feedback, and public consultations.
- Oral consultations: face-to-face interviews, public meetings, open days, formal/informal meetings, focus groups, user panels, advisory committees, public hearings.

2.4 How can customers' and stakeholders' satisfaction be measured?

A range of qualitative and quantitative measures can be used to evaluate and analyse feedback received or obtained from stakeholders.

- **Customer surveys, questionnaires** are considered quantitative research providing measurable feedback on pre-set questions. Web-based surveys are useful tools in gathering information about attitudes and feedback from customers, however other channels such as face-to-face or telephone interviews, and emails may also be used. This method is relatively cheap and can target representative audiences. However, limitations such as response rates can impact feedback.
- Customer satisfaction may be measured by the calculation of improved ratings based on regularly performed stakeholder satisfaction surveys (see details in the example section).
- Information from a **complaints-handling process** can be used to monitor and measure customer satisfaction. For example, the frequency and type of complaints can be an indirect quantitative indicator of customer satisfaction. Compliments, comments, suggestions, and complaints are common forms offering customers an immediate channel for providing feedback on the services they have received. The primary purpose of these mechanisms is to provide prompt information to staff enabling immediate response and opportunity for quick resolution of operative issues and implementation of corrective and preventive measures. A simply designed form serves this purpose (see practical examples). However, limitations include the fact that feedback is not fully representative due to self-selection of responses, and unrealistic expectations may be raised.
- Questionnaires and surveys are also used to collect basic descriptive information on customer/stakeholder attitudes and therefore can constitute a qualitative measure.
- A greater depth of understanding about people's perceptions and views can be obtained using **focus groups**. The group format can encourage a greater coverage of specific issues than a one-to-one interview and feel less intensive for stakeholders. However, the assessment can be time consuming.
- Through regular meetings, **advisory committees** may provide an on-going forum over a period of time. The designated committee will serve a number of functions within the broader aim of integrating stakeholder input more directly into decision-making, through a process of information exchange.
- **Workshops** have a specific purpose in facilitating solutions or recommendations in targeted topics. They can occur over a longer period of time and there is the possibility to involve a larger number of individuals and representatives. To enable all to have an opportunity to speak and be listened to, workshops need however to be highly structured and skilfully facilitated.

2.5 What basic principles should be considered in the preparation of a stakeholder survey or questionnaire?

When a survey or questionnaire is designed, a number of components should be considered:

- The purpose and objectives of expected outcomes
- The scope and frequency of the survey (i.e. repeated or single occurrence)
- The target audience: which stakeholders or groups will be addressed and how representative the sample will be (e.g. customer sampling)
- To find the suitable method to fit best the set purpose and audience
- When developing questions consider asking simple targeted questions that are easy to understand and do not lead the respondent to answer in a directed way and/or ask open questions with free-text response fields to gain individual opinion of stakeholders
- Assigning responsibilities and timelines
- The allocation of resources: whether the survey may be performed by the staff of the organisation or outsourced (internal/external sources)
- The appropriate method of analysis that can describe, summarise and compare the gained results
- Reporting the results to the participants / general public / management board / staff (always factual but with a different approach)
- Using the results as an input for improvement processes
- To be suitable as a basis for comparative and repetitive survey
- Being prepared for expectations or queries of customers that cannot be addressed or fulfilled by the organisation.

Surveys and questionnaires can be administered in a number of forms: by post, by telephone or in-person interviews using trained individuals. They can be useful for reaching those who would not normally respond to postal questionnaires.

Publishing the results is an important way of enhancing transparency and increasing trust as participants are reassured that their opinion and views have been taken on board and reflect the benefits of participation.

2.6 Examples from MSs on stakeholder feedback and customer satisfaction measurements

In this section, examples obtained from NCAs are presented to demonstrate:

- Reactive and proactive approaches of surveying customer satisfaction
- Different methods of obtaining and measuring feedback from stakeholders on new and/or already existing PV processes
- How to obtain information from customers on specific fields of PV to have a better understanding and ability to implement change in PV processes
- Added value of the above processes in the continuous improvement of the performance of an organisation.

2.6.1 Agency for Medicinal Products and Medicinal Devices (HALMED), Croatia

The Croatian agency stakeholders' needs, expectations and perception on safety related issues are proactively surveyed. Some of the applied processes are described below.

HALMED surveys its stakeholder's needs and evaluates customer's satisfaction with the following means and methods:

- Through a regular annual satisfaction survey, covering activities of the agency in general
- Registering and monitoring complaints, enquiries, comments and suggestions received daily by the HALMED's employees via the agency's website, email, telephone and fax
- Feedback from stakeholders collected by PV staff on related workshops, meetings
- Regular evaluation of feedback received in a common daily communication with stakeholders concerning PV processes (e.g. ADR reports, local QPPVs' communication)
- Seeks customer feedback via online form for questions and comments ("Ask us form").

2.6.1.1 General annual satisfaction survey

With an aim of actively obtaining the feedback from its external stakeholders, HALMED conducts an overall annual satisfaction online survey addressed at the users of all of its services, including the area of PV, according to the Standard Operating Procedure (SOP) "Customer satisfaction".

The data received in the survey, in particular the comments and suggestions provided by the respondents, is used for identifying and addressing the needs of users of the HALMED's services. The set of stakeholders' comments and suggestions serves as an input for the improvement and development of the agency's services.

The customer satisfaction survey is not specifically designed to seek responses relating to the PV area. Survey respondents are asked to identify themselves as a HCP, MAH, manufacturer, wholesale representative or provide another category. Therefore, different categories of respondents can be analysed separately.

The annual survey questions are listed below:

1. How well are you informed about the services that our Agency provides?
2. How would you rate the timelines of our staff's responses to your enquiries?
3. How would you rate the clarity of our staff's responses to your enquiries?
4. How would you rate the procedure of receiving your submissions?
5. How would you rate the speed of handling your requests?
6. How would you rate the competence of staff which provides the service for you?
7. How would you rate the degree of professionalism of staff responding to your complaints?

8. How would you rate the courtesy, kindness and approachability of Agency staff?
9. How would you rate the price/quality of service ratio?
10. Which of our current services do you consider need to be improved? – open question with field of free text response
11. Which additional services would you like to suggest? – open question with field of free text response
12. You are: (HCP, MAH, wholesaler, manufacturer, other etc.)
13. Your details: (name, company, address)
14. Your opinions, suggestions and comments – open question with field of free text response

For questions 1-9 respondents can choose between five pre-defined answers (Excellent, Very Good, Good, Satisfactory and Unsatisfactory).

The customers/stakeholders are defined in the document 'Communication policy of HALMED', and include the general public, patients, HCPs, pharmaceutical and medical devices industry representatives, other national and EU regulatory bodies and media representatives.

The list of customers/stakeholders for the annual customer satisfaction survey is maintained by the HALMED's spokesperson, as defined in a SOP on customer satisfaction. In addition, any interested party can apply for participation in the survey based on a call for participation which is published on the dedicated site of the agency's website, in the user satisfaction section. The feedback to the survey is most commonly provided by the pharmaceutical and medical devices industry representatives.

According to the related SOP, the analysis of data is performed by HALMED's spokesperson, who prepares the final report. An assigned member of the Information Technology (IT) unit provides help in releasing the survey and statistical analysis of the results.

Following the evaluation the results are presented to the Head of Agency and Quality Manager as well. These results are also presented at the Management review to the heads of divisions and departments, including the Head of PV, who can afterwards act upon the information received.

The set criteria for analysis are shown below.

Grade	Actions
Excellent and Very Good (more than 80%)	No preventive action is required
Good and Satisfactory (40% – 80%)	Corrective actions are required
Unsatisfactory (less than 30%)	Situation is alarming, urgent steps of improvement is required (corrective and preventive action plan / CAPA plan is required)

The analysis is performed question by question and then summarised. If the results are mainly "excellent" and "very good" no action is needed; if the results are mainly "good" and "satisfactory" there is a need for preventive or corrective action; if the results are "poor" there is a need for urgent corrective action as shown in the table above.

The summary result of the annual customer satisfaction survey along with the improvements that are undertaken based on the feedback are presented both to the agency's employees and to the stakeholders and general public via the agency's website User Satisfaction section.

The expectations of customers that cannot be addressed or served are managed in the way that it is clearly communicated to them what activities are, and what activities are not within the scope of work of the Croatian Agency.

Based on the results of the proactive annual survey, as well as other feedback, i.e. numerous enquiries, comments and suggestions received daily by the HALMED's employees via the agency's website, email, telephone and fax, the effectiveness of the Agency's services and the degree of the employees' cooperation with users are evaluated. Following the analysis, the survey results and findings from regularly received enquiries and comments are presented at the Management review meeting, where the ways in which the Agency's work could be further improved in accordance with the inputs received from the stakeholders are identified and thoroughly reviewed with an aim of optimising the quality of the Agency's services.

Based on the 2014 annual survey, a number of improvements have been performed, including:

- An upgrade of the web-application form intended for the payments for MAH submissions
- Publishing of a number of contacts of employees involved with authorisation procedures
- Publishing more information about the service of expert advice
- An increased number of workshops for MAHs has been provided about the topics that were requested (regulatory and distribution issues)
- Redesigning the website in order to improve the functionalities and increase the transparency (HALMED launched its redesigned web portal on 12 Nov 2015)
- New staff have been employed in order to increase the timeliness of approving safety variations etc.

2.6.1.2 Feedback from stakeholders collected by PV staff

Examples of mechanisms in place at HALMED for stakeholder feedback on PV issues:

In addition to general channels for feedback for the entire Agency ('Ask us' form and consumer satisfaction survey), PV staff also seek feedback at the workshops held on PV topics and in daily communication to HALMED's stakeholders. Feedback from workshop attendees (HCPs, PV staff from MAHs, patients) is sought both directly (orally) and in writing via a small questionnaire completed after the workshops.

This questionnaire asks the attendees to rate the usefulness for each of the topics within the workshop (grades from 1 to 5), to rate if the workshop was useful, clear, interesting and interactive overall. In dedicated free-text fields participants are asked to provide suggestions for topics of interest for future workshops and to provide further comments.

Relevant feedback received in a common daily communication to stakeholders (e.g. ADR reporters or local QPPVs, depending on the PV process) is communicated to the Head of the PV department directly or to the whole department at weekly meetings.

This feedback is then used to streamline the PV processes. For example, a requirement for sending the Direct Healthcare Professional Communication (DHPCs) and education materials to HCPs with the return receipt option (confirmation of receipt) was previously in place for MAHs to follow. This was not well accepted from HCPs who were absent when the DHPCs were delivered and therefore had to go to the post office to collect their mail. Because of the way the post service is organised, the receiver does not know the content of the letter or who the sender is before he/she collects it. It is of note that generally only a few types of letters are commonly sent with confirmation of receipt, which includes letters from courts and debt warning letters. The MAHs have shared with our Agency's PV staff their concerns about the HCPs' discontent with this type of dissemination of safety communication, and their feedback was the sole reason to lift the requirement for confirmation of receipt.

2.6.2 National Authority of Medicines and Health Products (INFARMED, I.P.), Portugal

In order to provide services with the highest quality, INFARMED, I.P. continuously assesses the level of satisfaction of its customers and partners on the services provided and evaluates the progress of the level of satisfaction throughout the years.

INFARMED, I.P. evaluates customer/partners satisfaction with the following means and methods:

- Through customer satisfaction surveys, focusing on core activities
- Registry and management of complaints
- Identification of constraints and opportunities for improvement during the periodic meetings of the agency's Advisory Council with the participation of stakeholder representatives.

2.6.2.1 The Customer Satisfaction survey

The INFARMED, I.P.'s Customer satisfaction survey, generally performed every two years, aims to:

- Capture the perception and evolution of the customer's vision regarding the quality of the different processes and services provided by the NCA
- Contribute to the process of monitoring the global and specific quality of processes and services provided by the NCA, with the aim to improve efficiency and effectiveness
- Identify the processes and services where there is more evolution in the level of satisfaction compared to previous diagnosis
- Identify the needs and expectations of customers, within the mission of INFARMED, I.P..

A brief description of the process followed and steps taken:

1. According to the NCA's objectives and mission, each directorate of INFARMED, I.P. identifies the relevant processes and services to be considered for evaluation in the survey. To guarantee the involvement of the relevant staff, meetings are held in all directorates, with the respective quality managers and the responsible person for each process, to establish the methodological framework and to discuss the format of the survey.
2. All directorates give their input to the Quality and Planning Office of INFARMED, I.P. (GPQ) who is responsible for compilation of all the requirements, adjusting them to the previous survey format in order to allow meaningful comparison of the results.
3. An external independent entity is responsible for the implementation of the surveys, using an online platform for the purpose.
4. An invitation is disseminated via email to the target groups for collaboration in the survey; responses are received online.

5. Follow up actions are conducted, if deemed necessary, in order to achieve the desired response rate.
6. The results are assessed by an external independent entity, using statistical analysis and graphic processing of data collected.
7. The quantitative grids obtained are interpreted in order to determine the level of satisfaction or dissatisfaction related to the different processes and services under analysis.
8. Performing signalisation of processes and services with better results (or further evolution), as well as those with worse results (or that need more improvement).
9. Conduct interviews with relevant associations of stakeholders to inquire about the assessment, expectations and needs of the institutional partners of the INFARMED, I.P..
10. The GPQ is then responsible for presenting the results of the customer satisfaction survey to the Executive Board of INFARMED, I.P., to the staff of all directorates and also to the Advisory Council of INFARMED, I.P.. Additionally, the results of customer satisfaction surveys are published at the Institute's website.
11. After this presentation, each directorate assesses the results of their processes and implements, where possible, the necessary changes and improvements, especially on the procedures with the lowest levels of satisfaction.
12. These actions are registered and treated/followed up in the scope of the quality management system of INFARMED, I.P., with the respective effectiveness evaluation.
13. Within the next survey these improvements are also addressed and reassessed by the customers/partners of INFARMED, I.P..

The extensive survey carried out involves the following target customers/partners:

- HCPs
- Pharmaceutical Industry and their national associations
- Pharmacies and their national associations
- Non-prescription drug stores
- Wholesalers
- Hospitals and other healthcare institutions (public and private)
- General public

The last evaluated and published survey was performed at the end of 2015. The overall assessment focused on existing processes and services of INFARMED, I.P.. It addressed general qualities such as co-operation with customers and partners, disclosure of activities and available services, innovation, modernity, transparency, competency, fulfilment of the Institute's mission. Organisational competencies (accessibility, capacity and response time of services), interpersonal skills (assistance and follow up), and communication skills (information, clarification and divulgation) were evaluated. Responses provided by the target audience with assigned values of very weak / weak / average / good / very good were summed up (%) and the results were compared to the results of previous surveys.

In the field of PV only four different processes of the Directorate of Risk Management for Medicines were evaluated in the 2015 survey: Monitoring and reporting of Adverse Drug Reactions (ADRs), Dissemination of Human Medicines' Safety Alerts, Assessment of educational materials and Validation of Direct Healthcare Professional Communications. These last two processes were evaluated for the first time in this 2015 survey. Annex 1 summarises the addressed questions and applied evaluation criteria for the four PV processes.

Overall, there was an improvement in the level of satisfaction regarding the processes evaluated in previous surveys and the level of satisfaction for the new two PV processes was high. Nevertheless, the comments provided in free text responses, are being assessed in order to decide if it is necessary (and possible) to implement some preventive/corrective/improvement actions to address the issues raised by the several target customers/partners.

2.6.2.2 Dedicated Customer satisfaction and complaint form

INFARMED, I.P. has a dedicated customer satisfaction and complaint form published on its website for online collection of customer complaints and/or suggestions concerning any of the following areas:

1. Services provided by INFARMED, I.P.
2. Services provided by other entities regulated by INFARMED, I.P.
3. Products regulated by INFARMED, I.P. (exclusively for complaints about Pharmacies please use this form available)

This initiative has the following objectives:

- To facilitate the submission of complaints/suggestions
- To improve the quality and timing of the resolution of problems and complaints from customers
- To ensure the collaboration of clients in improving the quality of service.

The aim is to ensure the immediate treatment of the complaints with an objective analysis, looking for the best solution.

INFARMED, I.P. faces complaints and/or suggestions as a positive contribution to prevent or repair errors and ensure the continuous improvement of its services.

The customers must fill the following fields: Name, email, subject, complaint/suggestions. There is an option to upload files/documents if needed.

Alternatively to this online submission, the customers can also send their complaints and/or suggestions by email (satisfacao.cliente@infarmed.pt; cimi@infarmed.pt), fax (217987316) and by post to INFARMED, I.P. – Parque de Saúde de Lisboa – Avenida do Brasil, 53 – 1749-004 Lisboa – Portugal.

There is also a “Complaints Book” (Yellow Book) available at the Public Relations Office of INFARMED, I.P. that may be requested by the customers.

2.6.3 The Netherlands Pharmacovigilance Centre LAREB

A site visit at the Lareb, the Netherlands Pharmacovigilance Centre, was performed and information on the QMS of the ADR management within the confines of SCOPE WP7 was collected.

On a separate occasion follow-up questions on the online survey was also conducted concerning the customer satisfaction topic. Obtained information and examples related to the topic of this paper are summarised below.

Within the Lareb's five yearly set policy, among the ten point list of main tasks of Lareb is sharing knowledge about side effects, promoting the reporting of ADRs by HCPs and patients, and structured consultation between Lareb and collaborating parties.

The quality policy of Lareb (detailed in the Quality Manual) covers all activities performed by the centre. Once a year the quality policy is evaluated as a whole in the context of a management review. The management review evaluates the previous year and makes decisions and actions to take to improve the effectiveness of the QMS and associated processes, the improvement of the products and services, and required resources. The policy of Lareb is decided together with input from the employees and stakeholders. For this purpose internal and external evaluations are performed, including feedback from customers, employees and regular measurement of their satisfaction.

Special emphasis is put on surveying customer satisfaction (all partners) therefore all stakeholders are regularly interviewed about what they think about Lareb. Lareb place special emphasis on surveying and satisfying the needs of its partners by educating stakeholders (in particular HCPs and patients) on drug safety in general, providing up-to-date information on current PV issues, promoting reporting on ADRs, providing and requesting feedback on their functioning and public perception. Information is exchanged via various channels, e.g. via the website, newsletters, publications and web-based surveys.

Information shared with the public not only serves as means of education or communication, but it also supports transparency by sharing as many elements of the internal decision making process with respect to the protection of personal data and any confidential information.

Notification of complaints and suggestions (e.g. on reporting forms, websites) are collected in a structured way. A complaint form is available internally and the complaint list is discussed weekly with the director. Regular meetings are held with employees/head of departments/management to discuss operational delivery. All complaints are analysed and initiate improvement if deemed necessary.

There is a good relationship with various professional groups and patients' organisations. Regular consultations are held, during which new initiatives can be discussed, contributing to improving the reporting process and/or knowledge sharing.

Complaints or suggestions from both patients and healthcare providers are registered by employees systematically and discussed between the management, organisation and communication divisions, and also by the steering committee. Additionally customer needs are assessed in order to better respond to the needs of various healthcare providers and patients. This exercise can be repeated at regular intervals for various target groups.

2.6.3.1 Customer satisfaction survey

An example of a customer satisfaction survey designed in SurveyMonkey (an online survey tool) was provided by Lareb. The aim of the survey was to investigate what information is needed by different categories of HCPs regarding adverse drug reactions. Additional questions about the HCPs' level of acquaintance with Lareb were also asked. The responses fostered development in effective communication, enhanced ADR information already published on the Lareb's website and served a basis for changing processes to increase customer satisfaction.

Lareb questionnaire* concerns the following three main area of interest:

Information on side effects of drugs/vaccines	Drug safety during pregnancy and lactation	Reputation of Netherlands Pharmacovigilance Centre Lareb; Lareb reporting centre; Lareb Knowledge Centre
The following questions look at your experiences with searching for information on side effects 1. Do you find it easy to locate information on side effects of drugs/vaccines? Suppose you have a patient with symptoms that you suspect to be a side effect of a drug/vaccine. 2. Which sources of information do you usually consult when looking for information on side effects? 3. What information are you usually looking for? 4. Are you able to find sufficient information on side effects of drugs / vaccines?	**The following questions are about your experience with searching for information about drugs in combination with conception, pregnancy or lactation.** 7. How often do you require such information? 8. Do you find it easy to obtain information on drugs in combination with conception, pregnancy or lactation? 9. Which sources of information do you usually consult when searching for information on drug safety during pregnancy and lactation?	**The following questions look at the reputation of the Netherlands Pharmacovigilance Centre Lareb (Nederlands Bijwerkingen Centrum Lareb) and your experiences in reporting side effects.** **How do you know about Lareb?** 14. I know about Lareb from: **You can report side effects to Lareb** 15. Have you ever submitted a report to Lareb? 16. How often have you submitted a report to Lareb in the past 2 years? **The seriousness of a side effect may vary. Thus side effects may be serious for a number of reasons. For example, because they lead to hospitalisation, death, permanent disability, life-threatening situations or birth defects or side effects considered to be serious for other reasons.** 17. I report a non-serious, known side effect: 18. I report a non-serious, unknown side effect:

Information on side effects of drugs/vaccines	Drug safety during pregnancy and lactation	Reputation of Netherlands Pharmacovigilance Centre Lareb; Lareb reporting centre; Lareb Knowledge Centre
5 What are potential problems in finding information about side effects? 6. How do you obtain information on side effects?	10. What information are you usually looking for? 11. Can you find sufficient information on drug safety during pregnancy and lactation? 12. What are potential problems in finding information on drug safety during pregnancy and lactation? 13. How do you obtain information?*	19. I report a serious, known side effect: 20. I report a serious, unknown side effect: 21. What motivates you to report a side effect to Lareb? 22. Did you receive a response on the report you submitted? 23. What did you think of the response to your report? 24. What hinders you from reporting side effects? 25. What can Lareb improve so that you do report, or continue to report, side effects? **The following questions are about the Lareb website** 26. Apart from the report form, do you visit the Lareb website to look for information? 27. Why do you not make use of the information on the Lareb website?* 28. Why do you visit the Lareb website? 29. What information would you like to find on the Lareb website? 30. Lareb informs healthcare-providers via a digital newsletter. What do you think this should include? 31. How would you like to be kept up-to-date with the latest news on side effects? That was the end of the questionnaire. Thank you for your cooperation. For further information on Lareb, visit www.lareb.nl 32. Please give any tips or suggestions for Lareb on the provision and dissemination of information below. 33. Do you want to sign up for the newsletter from Lareb? If so, fill in your email address.

*The entire questionnaire with pre-set responses options is provided in Annex 2.

2.6.3.2 Employee satisfaction

Lareb is a small organisation with an open structure. Employee satisfaction is discussed during performance reviews, but also within consultations held during the year. Attention is also paid to the professional development of employees.

Staff meetings are organised annually, during which small groups of employees discuss several issues with the director. Results from these studies may lead to changes in the organisation or human resources policy and possibly staff regulations.

2.6.4 Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

The MHRA uses several surveys in order to obtain external and internal feedback. The MHRA is currently developing a more customer focused approach with a working group to review customer service standards across the agency. In 2015 the MHRA also held a series of staff workshops inviting input on the level of customer service currently offered by the agency, and suggestions for how the service could be improved. Alongside this, and for the first time, the annual staff survey included two questions about customer service which invited comments on this topic. A group has been formed to review the feedback from these two exercises in more detail; the aim is to develop recommendations in conjunction with the refresh of the IT and digital systems to ensure the MHRA delivers excellent customer service to all its stakeholders.

As stated in the MHRA Business Plan 2014-15, important initiatives are undertaken in relation to PV. One of these initiatives is the enhancement of the collaboration with external stakeholders to deliver medicines information which meets the needs of all patients and HCPs to enable delivery of the wider medicines optimisation strategy.

2.6.4.1 Customer feedback survey on Drug Safety Update

The customer feedback survey on Drug Safety Update (DSU) provided by the MHRA illustrates the initiatives mentioned above.

The questionnaire was compiled to address feedback of customers on the DSU monthly newsletter issued by the agency containing alerts and recalls for drugs and medical devices. Re-accreditation of DSU had been recently given to DSU by National Health Services (NHS) Evidence, a search engine for health and social care professionals to obtain access to evidence-based health information.

The questions in the survey address why, when and how customers access the DSU; what kind of evidence they search for; what their expectations and preferences are, and are they met; what they do with the information obtained from DSU; are they satisfied with the accessibility of the DSU.

There is also an option for HCPs to select whether they would like to take part in future activities to provide feedback including:

- Usability testing
- Face to face interviews
- Focus groups
- On-site testing at their place of work
- Telephone interviews
- Remote/online usability testing

There are also questions on the customers' awareness about the MHRA safety warnings and messages for medicines made publicly available. The results of the survey provide a basis for implementing changes if deemed necessary to enhance effectiveness of the DSU publication as well as to increase the level of satisfaction of the customers. The full questionnaire with the pre-set choice of responses is enclosed in Annex 3.

2.6.4.2 General stakeholder feedback

General stakeholder feedback is also obtained regularly by the MHRA, using a questionnaire at the bottom of service emails. In this survey, the PV Service Team ask the following multiple choice question: "Overall how satisfied were you with the service you received from the Pharmacovigilance Service Team?" Options are given to choose from answers of very satisfied, satisfied, dissatisfied, and very dissatisfied. An open question with a free-text response field is also asked: "Do you have any feedback about the service you received, or suggestions as to how the services could be developed?" The Pharmacovigilance Service team reviews all responses received to identify the extent to which the service is meeting the needs of their customers, and how the service could be developed to meet their future expectations. The survey is enclosed in Annex 4.

2.6.4.3 Staff surveys

The MHRA has an internal communications team that supports the business by keeping staff informed on what is happening in the organisation and encouraging their feedback using a variety of channels such as team briefings and all staff meetings. The team is also responsible for supporting staff engagement in the Agency. Staff within the MHRA are asked to complete an annual staff satisfaction survey covering a multitude of topics. The results of this survey are published on the agency website and are used by managers to improve agency processes. As a result of the 2015 survey, the MHRA will be holding a series of staff meetings in order to explore and optimise the impact that the work conducted by the staff has on the agency as a whole.

2.6.5 General customers' satisfaction survey – Bulgarian Drug Agency (BDA), Bulgaria

The BDA's leading principle when completing activities is to ensure the customers' needs and expectations are met in a systematic and timely manner.

The current BDA interested parties/stakeholders are defined in the implemented "Quality manual" and consist of the following groups: European regulatory authorities, individuals/legal entities, BDA personnel, service providers/partners.

The methods and means used for receiving information aimed at meeting the requirements, wishes and claimed or presumed expectations of the stakeholders via direct contacts and through receiving feedback via information registered according to the requirements of the management procedure "Corrective actions" and SOPs applicable for employees from front office department.

Incoming opinions, suggestions for improvement and analysis of received complaints from the customers are managed according to the SOP "Proceedings on proposals and signals from individuals and organisations".

The BDA constantly strives to involve stakeholders and to inform them of the activities and plans of the organisation in order to create mutually beneficial relationships with suppliers, partners and stakeholders. This is achieved by a wide range of approaches like negotiations/discussions and mediation aimed at balancing the needs and expectations of customers.

As the high level of satisfaction of the customers' needs is a constant strategic objective at the agency, the BDA has implemented codes of conduct towards stakeholders. A section in the implemented ethics code is dedicated to the requirements for employees' behaviour with the BDA customers. These rules represent a set of commitments and injunctions towards management of personal data, confidentiality and availability of information, as well as management of complaints, and are made publicly available as a document named "Charter of the client".

The Charter contains in written form the obligations of the BDA for the provision of information; the tools for the collection and analysis of received complaints, praises, recommendations, suggestions and signals; rights and applicable obligations of the stakeholders; the BDA objectives in the field of the administrative services and the implemented standards of quality service that are divided into mandatory, common and typical for the BDA.

The customer satisfaction survey represents an integral part of the "Charter of the client". The questionnaire consists of 15 questions, formulated in order to get a clear and objective assessment of the quality of administrative services in the BDA based on the most common answers and prevailing opinion of the consumers.

The customers satisfaction survey is general (not PV related), anonymous and cannot claim to be representative, but still gives an indicative picture of the attitude of legal entities and individuals towards administrative services at the BDA.

Although the survey is available on the BDA's website and can be accessed freely, once in the year it is printed and is actively proposed to the customers by the employees from the BDA front office. The initiative lasts approximately one month. Every proposal or signal received outside the survey is registered by the officers from the front office. Customers are also allowed to make complaints or proposals verbally, by phone or by email. A bulletin issued by the BDA has a customer satisfaction form also.

In all cases a protocol/official file is compiled. A decision on a received proposal is issued no later than 2 months after the official filling and is communicated to the sender within seven days.

Results from the analysis of the survey are used as an input data for improvement of the quality system and provided services after management board meetings. Additionally the frequency and trends in complaints are used as indirect indicators for customer satisfaction, as well as media releases that show how the agency is perceived from the general public and letters of appreciation after attendance as lecturers at industry forums.

According to the results after the analysis of the customers' satisfaction survey almost all (92.19%) of the respondents address positive attitude towards electronic submission of documents. The BDA is working in the same direction after receiving funding from the operational programme "Administrative capacity". One of BDA's main goals is the implementation of electronic management.

A "one stop" administrative service desk is considered a preferable option for submissions to BDA meeting the expectations of BDA's customers for more efficient processes saving time and resources.

The significant number of the proposals received from customers highlights the demand for more accurate and up-to-date content of the BDA website. Based on customers' proposals for change a responsible person is appointed by the Executive Director at the department concerned with the issue to ensure that the content of the website is relevant. Information on the website is checked according to defined periods of time and outdated information is removed.

Good communication with experts and easier access to employees with specific expertise are considered by the customers as another opportunity the administrative services could improve. Due to this every department has issued a designated time when customers may ask for specific consultation. A hotline for PV questions was also issued.

Feedback and provision of information for the inner steps of the procedure is a significant indicator for good administrative service according to the respondents and their implementation is considered in the BDA document management system for which a stakeholder panel is under construction.

3. Summary and conclusion

This toolkit item intended to raise awareness of PV assessors and interested staff at NCAs on the importance of gaining information on stakeholder feedback and customer satisfaction. The theory was put into practice by presenting selected NCAs examples of different methods for obtaining stakeholders' feedback and measuring the level of customers' satisfaction. Focus was made on the added value of the proactive approach in collecting and analysing customer feedback for the purpose of improving the performance of the organisation and PV activities resulting in an enhanced customer satisfaction and shared knowledge.

It was demonstrated that stakeholders vary and measurements of their needs, expectations and satisfactions requires different approaches.

There is no one way to compose a customer satisfaction survey to measure all specific areas of PV and address different stakeholders. Customer surveys and questionnaires should be nationally tailored to consider basic principles highlighted in this paper and provide added value to the organisation.

In conclusion, every employee of an organisation (including PV assessors at NCAs) should understand how his/her work contributes to accomplishing enhanced customer satisfaction and at the same time improves the organisation's PV processes by implementing elements of quality management without extra burden. This may be achieved by a proactive approach in understanding the needs and meeting the expectations of the stakeholders at each level of the organisation.

Annex 1. The INFARMED, I.P.'s Customer satisfaction survey, PT

Detailed only for the PV four different processes

1. Monitoring and reporting of Adverse Drug Reactions (ADRs)

For MAHs, Pharmacies, Non-prescription drug stores, hospitals and other healthcare institutions (public and private) and general public:

- Have you ever reported an ADR to Infarmed or to the PV regional units?
- If yes: ……..

For Pharmacies, Non-prescription drug stores, hospitals and other healthcare institutions (public and private) and general public – Evaluation's criteria (weak/weak/average/good/very good):

- "Portal RAM" – electronic ADR reporting portal
- ADR reporting form
- Facility to contact with the PV department
- Courtesy of the attendance
- Clarity of the information provided
- Technical accuracy during the process' analyses
- Information's feedback
- Please highlight the reasons for your level of satisfaction and identify improvement proposals (free text response)

For the MAHs – Evaluation's criteria (weak/weak/average/good/very good):

- Facility to contact with the PV department
- Courtesy of the attendance
- Clarity of the information provided
- Technical accuracy during the process' analyses
- Transparency
- Update of the information provided in the website
- Please highlight the reasons for your level of satisfaction and identify improvement proposals (free text response)

2. Dissemination of Human Medicines' Safety Alerts:

For Pharmacies, Non-prescription drug stores, hospitals and other healthcare institutions (public and private) and wholesalers:

- Have you ever received information related to a Human Medicines' Safety Alert?
- If yes, how did you receive the information?
  1. Email sent by Infarmed
  2. Infarmed's website
  3. Media
  4. Via clinician and pharmacist
  5. Via attendance/information services of Infarmed

Evaluation's criteria (weak/weak/average/good/very good):

- Clarity of the information provided
- Completeness of the advice provided
- Timely update of the information
- Usefulness of the information
- Quickness of the information's release
- Please highlight the reasons for your level of satisfaction and identify improvement proposals (free text response)

3. Assessment of educational materials (new PV process in the survey of 2015):

For the MAHs – Evaluation's criteria (weak/weak/average/good/very good):

- Facility to contact with the PV department
- Courtesy of the attendance
- Clarity of the information provided
- Advice provided
- Technical accuracy during the process' analyses
- Transparency
- Time of response
- Please highlight the reasons for your level of satisfaction and identify improvement proposals (free text response)

For hospitals and other healthcare institutions (public and private):

- Did you ever receive educational material provided by MAHs?
- Overall, how do you classify the utility of the educational material received?
- Please highlight the reasons for your level of satisfaction and identify improvement proposals (free text response)

4. Validation of Direct Healthcare Professional Communications (new PV process in the survey of 2015):

For the MAHs – Evaluation's criteria (weak/weak/average/good/very good):

- Facility to contact with the PV department
- Courtesy of the attendance
- Clarity of the information provided
- Advice provided
- Technical accuracy during the process' analyses
- Transparency
- Time of response
- Please highlight the reasons for your level of satisfaction and identify improvement proposals (free text response)

For hospitals and other healthcare institutions (public and private):

- Did you ever received a Direct Healthcare Professional Communication provided by MAHs?
- Overall, how do you classify the utility of the communication received?
- Please highlight the reasons for your level of satisfaction and identify improvement proposals (free text response)

Annex 2. Customer satisfaction survey of LAREB, NL

Information on Side Effects of Drugs/Vaccines

The following questions look at your experiences with searching for information on side effects

1. Do you find it easy to locate information on side effects of drugs/vaccines?

- Very easy
- Easy
- Neutral
- Difficult
- Very difficult
- Not applicable

Suppose you have a patient with symptoms that you suspect to be a side effect of a drug/vaccine.

2. Which sources of information do you usually consult when looking for information on side effects?*

- PIL / SPC
- I consult with other colleagues and health care-providers
- Farmacotherapeutisch Kompas (Dutch pharmacopoeia)
- Website of the Netherlands Pharmacovigilance Centre Lareb (Nederlands Bijwerkingen Centrum Lareb)
- MEB (Regulatory authority) website
- RIVM (National Institute of Health) website
- Pubmed
- KNMP (Pharmacist's association) knowledge database / Informatorium
- Pharmaceutical industry
- Google
- Other sources of information, specify: ……

*maximum of three answers possible

3. What information are you usually looking for?*

- Whether it is a known side effect
- What is the course of the side effect
- How often the side effect occurs
- Whether the side effect also occurs with other drugs from the same group
- What is the treatment advice
- Whether there are alternative drugs
- Other, specify: ……

*maximum of three answers possible

4. Are you able to find sufficient information on side effects of drugs / vaccines?

- More than sufficient
- Sufficient
- Neutral
- Insufficient
- Highly insufficient
- Not applicable

5. What are potential problems in finding information about side effects? *

Sources of information..

- Give too little information
- Are contradictory
- I don't know where to find information
- I can't find what I am looking for
- Do not give a clear course of action
- It takes me a long time to search thoroughly
- I do not experience any problems
- I do not have access to sufficient sources of information
- Other, specify: ……

*maximum of three answers possible

6. How do you obtain information on side effects?*

- Via an easily accessible website with all available information
- Telephone consultation with an expert
- By email consultation with an expert
- An app where I can find information
- Other, specify: ……

*maximum of three answers possible

Drug safety during pregnancy and lactation

The following questions are about your experience with searching for information about drugs in combination with conception, pregnancy or lactation.

7. How often do you require such information?

- Weekly or more than once a week
- A couple of times a month
- A couple of times a year
- Less than once a year
- Never

8. Do you find it easy to obtain information on drugs in combination with conception, pregnancy or lactation?

- Very easy
- Easy
- Neutral
- Difficult
- Very difficult
- Not applicable

9. Which sources of information do you usually consult when searching for information on drug safety during pregnancy and lactation?*

- PIL / SPC
- Farmacotherapeutisch Kompas (Dutch pharmacopoeia)
- Pubmed
- The telephone help desk for care-providers from the Teratology Information Service (TIS)
- I consult with colleagues and other care-providers
- In the search system on the Lareb website with information on drug safety during pregnancy and lactation (TIS)
- MEB (Regulatory authority) website
- KNMP (Pharmacist's association) knowledge database / Informatorium
- "Medicinal products, Pregnancy and Lactation" manual
- Guidelines from professional associations
- I do not search for information
- Other sources of information, specify: ……...

*maximum of three answers possible

10. What information are you usually looking for?*

- The risk of birth defects

- The preferred medication in pregnancy
- The risk posed to the child during drug use in lactation
- The preferred medication in lactation
- The effects on lactation (volume or composition)
- The risk if the man uses a drug when conceiving
- Other, specify: ……

*maximum of three answers possible

11. Can you find sufficient information on drug safety during pregnancy and lactation?

- More than sufficient
- Sufficient
- Neutral
- Insufficient
- Highly insufficient
- Not applicable

12. What are potential problems in finding information on drug safety during pregnancy and lactation?*

Sources of information..

- Give too little information
- Are contradictory
- I don't know where to find information
- I can't find what I am looking for
- Do not give a clear course of action
- It takes me a long time to search thoroughly
- I do not experience any problems
- I do not have access to sufficient sources of information
- I do not experience any problems
- Other, specify: ……

*maximum of three answers possible

13. How do you obtain information?*

- Via an easily accessible website with all available information
- Telephone consultation with an expert
- By email consultation with an expert
- An app where I can find information
- Other, specify: ……

*maximum of three answers possible

Reputation of Netherlands Pharmacovigilance Centre Lareb (Nederlands Bijwerkingen Centrum Lareb)

The following questions look at the reputation of the Netherlands Pharmacovigilance Centre Lareb (Nederlands Bijwerkingen Centrum Lareb) and your experiences in reporting side effects.

How do you know about Lareb?

14. I know about Lareb from:*

- Reporting side effects
- Teratology Information Service (TIS)
- As a knowledge centre on side effects
- Looking for information on side effects
- I am not familiar with Lareb
- Other, specify: ……

*multiple answers possible

Lareb reporting centre

You can report side effects to Lareb

15. Have you ever submitted a report to Lareb?

- Yes
- No

16. How often have you submitted a report to Lareb in the past 2 years?

- I have not submitted a report in the past 2 years
- Once
- 2 – 3 times
- 4 – 10 times
- > 10 times

The seriousness of a side effect may vary. Thus side effects may be serious for a number of reasons. For example, because they lead to hospitalisation, death, permanent disability, life-threatening situations or birth defects or side effects considered to be serious for other reasons.

17. I report a non-serious, known side effect:

- Never
- Rarely
- Occasionally
- Often
- All the time

18. I report a non-serious, unknown side effect:

- Never
- Rarely
- Occasionally
- Often
- All the time

19. I report a serious, known side effect:

- Never
- Rarely
- Occasionally
- Often
- All the time

20. I report a serious, unknown side effect:

- Never
- Rarely
- Occasionally
- Often
- All the time

21. What motivates you to report a side effect to Lareb?*

- I want more information on the side effect
- My purpose in reporting is to promote drug safety; by reporting I am helping Lareb to draw attention to the relevant side effect(s)
- I consider it part of my duty of care
- Other, specify: ……

*maximum of three answers possible

22. Did you receive a response on the report you submitted?

- Yes
- No

23. What did you think of the response to your report?*

- It extended my knowledge of side effects
- It was helpful to the (ongoing) care of the patient
- It did not provide me with any new information
- It was not clear
- Other, specify: ……

*maximum of three answers possible

24. What hinders you from reporting side effects?*

- I don't think of it
- I don't see the use of reporting
- I don't have time
- The side effect is a known side effect
- I don't know whether it is worth reporting the side effect
- I only submit a report if I am sure that it is a causal relationship
- Someone else has already reported the side effect
- In my opinion it has nothing to do directly with the patient in question
- I hesitate to report because the side effect may be seen as my fault
- I find the reporting process cumbersome
- Other, specify: ……

*maximum of three answers possible

25. What can Lareb improve so that you do report, or continue to report, side effects?*

- Reporting via an App
- A shorter report form for side effects, with Lareb asking the informant for more information only where necessary
- Arrange training on side effects and drug safety
- I would like to be able to report by telephone
- Make reporting of certain side effects mandatory as part of the institution's accreditation or quality indicator
- More information on the outcome of the report
- A direct link from the care system to the Lareb report form in which all information is filled out in advance
- A report form that I can download and save on my computer and can send by email to Lareb
- No improvements are required
- Other, specify: ……

*multiple answers possible

Lareb Knowledge Centre

The following questions are about the Lareb website

26. Apart from the report form, do you visit the Lareb website to look for information?

- Yes
- Occasionally
- No

27. Why do you not make use of the information on the Lareb website?*

- I consult other sources
- It is hard to find information on the website
- I am not familiar with the Lareb website
- I can't find the information I am looking for on the website
- Other, specify: ……

*multiple answers possible

Lareb website

28. Why do you visit the Lareb website?*

- I am looking for information about a specific side effect of a vaccine
- I am looking for information about a specific side effect of a drug
- I am looking for information about drug safety during pregnancy and lactation
- I wish to contact Lareb
- I am looking for information about vaccines
- I wish to report a side effect
- I want to know whether a side effect has already been reported to Lareb
- I wish to keep up-to-date on news on side effects
- I wish to keep up-to-date on news on drug safety during pregnancy and lactation
- Other, specify: ……

*multiple answers possible

Lareb Knowledge Centre

29. What information would you like to find on the Lareb website?*

- Patient information that is known in the PIL / SPC
- What is known about the side effect in publications / literature
- What advice Lareb gives the MEB on reported side effects
- Whether a side effect has already been reported
- How often a side effect is reported

- I would not make any use of it
- Other, specify: ……

*maximum of three answers possible

30. Lareb informs healthcare-providers via a digital newsletter.

What do you think this should include?*

- New developments at Lareb
- News of side effects from drugs
- Ongoing research into side effects of drugs at Lareb
- News of side effects of vaccines
- Information on the latest publications from Lareb
- I have no interest in a newsletter
- Other, specify: ……

*multiple answers possible

31. How would you like to be kept up-to-date with the latest news on side effects?*

Newsletters

- RSS feed (a link that indicates that new information has been placed on the website)
- Through courses
- Publications in scientific journals
- Not applicable
- Other, specify: ……

*multiple answers possible

End

That was the end of the questionnaire. Thank you for your cooperation. For further information on Lareb, visit www.lareb.nl

32. Please give any tips or suggestions for Lareb on the provision and dissemination of information below. ……

33. Do you want to sign up for the newsletter from Lareb? If so, fill in your email address. ……...

Please note, that the above survey had different loops depending on how the different questions are answered.

Annex 3. Customer feedback survey on Drug Safety Update – MHRA, UK

Q1. Why do you read the Drug Safety Update (DSU)? Free text answer

Q2. How do you access the DSU?

a. *I am subscribed to the monthly DSU email bulletin*
b. *I look at/download the PDF from MHRA website*
c. *I visit the DSU homepage on MHRA website to see the latest edition*
d. *A colleague emails me the DSU*
e. *I use search engines to find the latest DSU*
f. *Other (please specify)*

Q3. Which do you prefer?

a. *DSU email*
b. *DSU PDF*
c. *MHRA website*
d. *Search (e.g. Google)*
e. *Other (please specify)*

Q4. Please explain your above choice Free text answer

Q5. Please select which statement most applies to you:

a. *I access/download the DSU PDF but do not print it*
b. *I access/download the DSU PDF when I need to print it*
c. *I access/download the DSU PDF when I want to look at previous issues*
d. *I never download the DSU PDF*
e. *Other (please specify)*

Q6. How do you decide whether the information in the DSU is relevant to you? Free text answer

Q7. What do you do with the information once you access the latest DSU?

a. *I only act upon articles that are relevant to my specialism*
b. *I pass on specialist information to colleagues*
c. *I search the MHRA website for additional information based on something I've read in the DSU*
d. *I search for additional information on the DSU homepage*
e. *I search for additional information within the DSU bulletin*
f. *Other (please specify)*

Q8. Why do you access past DSU bulletins or individual articles? Free text answer

Q9. When do you access previous DSU bulletins on the website?

a. *Daily*
b. *Weekly*
c. *Yearly*
d. *Bi-monthly*
e. *Never*
f. *Monthly*

Q10. How do you access previous DSU bulletins on the website?

a. *I browse through the MHRA website*
b. *I use the 'Search Drug Safety Update' function that is directly on the DSU homepage*
c. *I look through saved emails*
d. *I use the search box in the header of the main website*
e. *I use search engines*
f. *I look through DSU bulletin PDF archive*
g. *I have the page bookmarked*
h. *I don't*
i. *Other (please specify)*

Q11. When do you access previous individual DSU articles on the website?

a. *Daily*
b. *Weekly*
c. *Yearly*
d. *Bi-monthly*
e. *Never*
f. *Monthly*

Q12. How do you access previous DSU individual articles on the website?

g. *I don't*
h. *I browse through the MHRA website, e.g. starting at the home page and clicking links to get from 'A' to 'B'*
i. *I use the search box in the header of main website*
j. *I use the 'Search Drug Safety Update' function that is directly on the DSU homepage*
k. *I use search engines*
l. *I look through saved emails*
m. *I look through the DSU bulletin PDF archive*
n. *I have the page bookmarked*
o. *Other (please specify)*

Q13. Do you think the DSU could be made more accessible to meet your needs? If, yes, please explain how. Free text answer

Q14. Are you aware of the MHRA safety warnings and messages for medicines? If yes, describe what you think the differences are Free text answer

Q15. Please let us know if you would be interested in the following activities

p. *Usability testing*
q. *Face to face interviews*
r. *Focus groups*
s. *On-site testing at your place of work*
t. *Telephone interviews*
u. *Remote/online usability testing*

Q16. Name?

Q17. Location?

Q18. Email?

Q19. Company/organisation?

Q20. Choose the option that best describes you

v. *Member of the public*
w. *Government*
x. *Charity*
y. *Academic*
z. *Pharmaceutical*
aa. *NHS/public sector*
bb. *Healthcare professional*
cc. *Other (please specify)*

Q21. Occupation?

Q22. Please select your area of work (you can choose up to a maximum of three areas):

Annex 4. Pharmacovigilance Service Team Feedback Survey – MHRA, UK

Medicines and Healthcare Products Regulatory Agency

Pharmacovigilance Service Team Feedback

Overall how satisfied were you with the service you received from the Pharmacovigilance Service Team?

- ◯ Very satisfied
- ◯ Satisfied
- ◯ Dissatisfied
- ◯ Very dissatisfied

Do you have any feedback about the service you received, or suggestions as to how the service could be developed?

Thank you for taking the time to complete this, your feedback is very important to us. The Pharmacovigilance Service team will be reviewing all responses received to identify the extent to which we are meeting the needs of our customers at present, and how the service could develop to meet their future expectations.

https://www.surveymonkey.com/r/?sm=2hf%2fC0sOkjbvSW6f8u%2bjHSwMnR6dOiKYNZ3iqJkZopk%3d

Annex 5. Customers' satisfaction survey at Bulgarian Drug Agency, BG

QUESTIONNAIRE

Customers' Satisfaction of administrative services at BDA

DEAR CUSTOMERS,

Bulgarian Drug Agency, pursuant to Art. 24 of the Regulations on Administrative Services develops and provides information on the customers' satisfaction through collection and analysis of your proposals, reports, praise, complaints, etc.

We are convinced that the key to achieving this goal is the impeccable service and believe that you can con52tribute to this with your opinions and suggestions.

We would be grateful if you could share your impressions about the quality of service by completing the following survey.

1. Please identify yourself:
   - ☐ Individual
   - ☐ Legal entity
   - ☐ other
2. Since when you are using the services provided by the BDA?
   - ☐ Less than a year
   - ☐ More than two years
   - ☐ I never used them till now
3. What is your opinion about BDA initiative "one stop" service
   - ☐ Facilitates consumers
   - ☐ Impedes consumers
   - ☐ Improves the quality of the provided services
   - ☐ Worsens the quality of the provided services
   - ☐ Restricts corruption
   - ☐ Other, please specify..
4. What kind of access to the provided services do you prefer?
   - ☐ By electronic means

- ☐ By fax
- ☐ On desk
- ☐ By a certified postal operator
- ☐ By phone
- ☐ Other, please specify. ……

5. What services provided by the BDA you use most often?
   - ☐ Submission of documents related to services provided by the specialised directorates of BDA
   - ☐ Consultations with delegates from the BDA
   - ☐ Payment of fees
   - ☐ submission of complaint, signal or suggestions for improvements
   - ☐ Application for Access to Public
6. The written information (forms, letters, and press releases) is:

   Clear/easy understandable

   Excellent good satisfactory poor I can't decide

   Exact and complete

   Excellent good satisfactory poor I can't decide

   Up-to-date/timely provided

   Excellent good satisfactory poor I can't decide
7. In what terms was the required service provided by the BDA
   - ☐ Within the statutory deadline
   - ☐ Outside statutory deadline
8. Do you consider that the provided services by BDA meet the requirements for good administrative service?
   - ☐ Yes
   - ☐ No
   - ☐ My suggestion is. ……
9. Please rate the work, competency and diligence of the officers to cooperate during the process of providing service.

   Excellent good satisfactory poor I can't decide
10. How do you consider: of what aspect are the non-conformities/problems in the provided administrative services and do you need additional information/consultation?

    Politeness Access public Competency Failure to comply with the deadlines Other Civility to

11. How would you rate the quality of work, professionalism and competency of the officers from:

    "Front office"

    Excellent good satisfactory poor I can't decide

    "Back office" – Specialised administration

    Excellent good satisfactory poor I can't decide

12. Which elements of provided service need improvement according to you?
    - ☐ Access to information Suggestions ……..
    - ☐ Quality of performance of the provided administrative services Suggestions ……
    - ☐ Attitudes of the officers toward Suggestions ……..

13. How would you rate your satisfaction with our services?
    - ☐ Fully satisfied
    - ☐ Satisfied
    - ☐ Not satisfied

14. Your opinion and recommendations on the creation of a single portal for access to electronic administrative services in order to reduce the administrative burden and facilitate customers

15. Post a free text your opinion and give your proposal towards what would you like to improve in the quality of service provided by BDA

The survey is anonymous

The information from the questionnaires will be used exclusively by employees of the BDA in order to improve administrative services to individuals and legal entities.

Thank you for completing the questionnaire!

References

- ISO 9001:2015 https://www.iso.org/
- Commission Implementing Regulation (EU) No 520/2012
- Guideline on good PV practices (GVP) Module I – PV systems and their quality systems EMA/541760/2011 – 22/06/2012
- SCOPE-WP7-Topic-1-Survey-Report-2015
- Pejovic G, Filipovic J, Tasic L, Marinkovic V. Int J Health PlannMgmt (2014) DOI: 10.1002/hpm.2265
- https://www.bizmanualz.com/improve-quality/what-is-plan-do-check-act.html
- ISO 10001:2007 https://www.iso.org/
- ISO 10004:2012 https://www.iso.org/obp/ui/#iso:std:iso:10004:ed-1:v1:en
- http://www.halmed.hr
- http://www.businessdictionary.com
- AG-OP-0037 SOP on customer satisfaction including annual survey – HALMED, Croatia
- Site visit at the LAREB Foundation – Summary report – 22/05/2014
- MHRA Business Plan 2014-15
- Bijwerkingen Centrum Lareb Quality Manual version7, 2015
- http://www.infarmed.pt/portal/page/portal/INFARMED/SUGESTOES