Stakeholder feedback and customer satisfaction: Guidance and good practice examples

Introduction

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 a lack of transparency and communication with stakeholders creates distrust and may hinder the operation of national healthcare systems.

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.

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.

This module outlines the basic concept of gathering stakeholder feedback and measuring customer satisfaction with a special focus on pharmacovigilance (PV) and highlights its importance in the context of quality management.

The module covers the basic principles, definitions and methods used to gather stakeholder feedback, 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 National Competent Authorities (NCAs) participating in the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) project.

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.

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 NCAs level on this specific area of quality management.

Identifying customers and stakeholders in the Public Sector

Before moving on, please write down your thought in general who do you think the customers and stakeholders are?

Now, let's look at a general definition of who a customer is and who a stakeholder is. Select the headings below.

Customers

Stakeholders

Who are the customers and stakeholders of NCAs?

Consider this - does an organisation serve society as a whole or just the individuals who use their services?

In general a customer is defined as a particular individual participating in the market by buying goods and services for their own purposes. From a regulatory perspective the term 'the general public' (i.e. all of society), consisting of individual citizens, should also be considered.

The current PV legislation (Directive 2010/84/EU) addresses (in relation to different PV processes), a wide range of customers and stakeholders such as patients, healthcare professionals (HCPs), marketing authorisation holders (MAHs), NCAs, the European Medicines Agency (EMA), the general public, social health insurers, as well as organisations representing patients, consumers, HCPs, and other interested parties. However, the PV legislation does not provide exact definitions.

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 but the concern of public organisations will not be their direct users' individual needs but the needs of 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 NCAs and other organisations to empower themselves and make appropriate contributions.

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

Each stakeholder or stakeholder group has different characteristics, roles, needs, expectations and interests which vary according to the process or issue under evaluation. Therefore measurements of their needs, expectations and satisfaction requires different approaches.

Stakeholders may be divided into two main groups – external and internal. Who do you think your external and internal stakeholders are? Write your thoughts in the boxes below before moving on.

External stakeholders

Internal stakeholders

Select the headings below to find out more.

External stakeholders

Internal stakeholders

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 other stakeholders, can exert a considerable positive impact by strengthening relationships and building trust.

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.

> *"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."*
>
> (Quoted from HALMED's (NCA of Croatia) published Communication Policy)

Why measure customer/stakeholder satisfaction?

A key element 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.

> **Note**
>
> Customer satisfaction is the degree of satisfaction provided by the goods and services as measured by the number of returning customers.

Customer complaints are a common indicator of low 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.

Important note

The level of customer satisfaction very much depends on the level of knowledge and understanding of the individuals about 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 of the stakeholder's perception on the performance of the organisation.

What do you think the organization should do to achieve the above goals? Write down some examples in the box below before selecting the headings on the next page for more information.

What does the organisation need to do to pursue this goal?

What benefits may be obtained?

The information obtained from monitoring and measuring customer satisfaction can help identify opportunities for improving 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. Select the heading on the next page to find out more.

How can these benefits be obtained?

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.

Important note

The organisation should monitor customers' perceptions as to the degree to which their needs and expectations have been fulfilled.

A 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.

Processes should define and implement methods of data collection, including:

- Information sources
- Frequency of collection
- Data analysis review

The information gained can guide the organisation to take actions which can help to sustain or enhance customer satisfaction.

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

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

What do you think about the active and the passive collection of information? What type of communications do you consider passive and what are active? Write down your thought in the box below before moving forward on.

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 intranets, e-mail, telephone, published strategic plans, reports, meeting minutes, regular face-to-face meetings. However, for external communication generally the organisation's 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.

For example, the Italian Medicines Agency (AIFA) 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.

Select the heading below.

Sources of information

Different methods of engagement

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

- **Customer satisfaction questionnaires**
- **Stakeholder 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, communication divisions**

- **Contacting patient organisations**
- **Follow-up of safety communications (response to statements in the media, request for further information of interviews)**

Hints and Tips

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. Select the headings below to find out more.

Written consultation

Oral consultations

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 and questionnaires

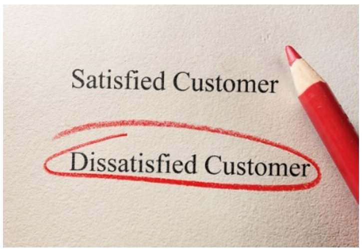
Customer surveys and questionnaires are considered quantitative research providing measurable feedback on pre-set questions.

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.

Measuring customer satisfaction

Customer satisfaction may be measured by the calculation of improved ratings based on regularly performed stakeholder satisfaction surveys (see details in the practical examples section).

Complaints-handling process



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 the practical examples section).

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.

Focus groups

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.

Advisory committees

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

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.

However, to enable all to have an opportunity to speak and be listened to, workshops need to be highly structured and skillfully facilitated.

Which of the above measures do you think may be used for qualitative and quantitative research? Write down examples of both categories in the box below before moving on.

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

Important note

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

1. **What is the purpose and the objectives of expected outcomes? Think about the scope and frequency of the survey – are you going to repeat it or is it only going to be done once?**
2. **Who is the target audience - which stakeholders or groups will be addressed and how representative the sample will be (e.g. customer sampling)?**
3. **You need to find the most suitable method that best fits the purpose and your target audience.**
4. **When developing your questions consider asking simple, targeted questions i.e. those that are easy to understand and that do not lead to the respondent answering in a directed way and (or instead) ask open questions with free-text response fields to gain individual stakeholder opinions.**
5. **You must assign responsibilities, set the timelines and allocate resources and decide if the survey can be performed by your organisation's own staff or whether it needs to be outsourced (internal/external sources).**
6. **You must determine an appropriate method of analysis; one that can describe, summarise and compare the gained results.**
7. **Think also about how you are going to report the results to the participants, the general public, the management board and staff (always factual but with a different approach).**
8. **Determine how you will use the results as an input for improvement processes and how the results may be suitable as a basis for comparative and repetitive surveys.**
9. **Finally, be prepared for customer expectations or queries of that cannot be addressed or fulfilled by your organisation.**

Hints and Tips

Always choose the best timing for the performance of the survey engaging stakeholders!

Surveys and questionnaires can be administered in a number of ways: by post and by telephone or in-person interviews using trained individuals. The telephone and in-person interviews 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.

Examples from MSs on stakeholder feedback and customer satisfaction measurements

In this section, examples obtained from specific 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

Select each of the individual NCA examples below to see how they approached measuring stakeholder feedback and customer satisfaction.

Croatia: Agency for Medicinal Products and Medicinal Devices (HALMED)

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

The Netherlands: The Netherlands Pharmacovigilance Centre (LAREB)

United Kingdom: Medicines and Healthcare products Regulatory Agency (MHRA)

Bulgaria: Bulgarian Drug Agency (BDA)

Summary and conclusion

This module 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.

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