Review of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products

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Contents

Executive summary

In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19, in which it decided to establish a Member State mechanism aimed at protecting public health and promoting access to affordable, safe, efficacious, and quality medical products, by promoting the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products and associated activities. This resolution[1] renewed and re-established a mandate for the Secretariat and Member States in addressing SSFFC medical products from a public health perspective in a transparent and inclusive way. The Member State mechanism is supported by WHO and facilitated by the mechanism secretariat.

The goal of the mechanism is to protect public health and promote access to affordable, safe, efficacious and quality medical products, through effective collaboration among Member States and the Secretariat, for the prevention and control of SSFFC medical products and associated activities.

The review of the Member State mechanism was mandated by resolution WHA65.19 to be conducted in 2016. The Health Assembly subsequently decided to postpone the review by one year to 2017.[2] At the fourth meeting of the Member State mechanism, held on 19 and 20 November 2015, there was agreement that the review process should be led by the WHO Evaluation Office, and that further details on the review, including on the questionnaire, would be provided to the Steering Committee of the Member State mechanism at its meeting in March 2016. Subsequently, the Steering Committee members agreed that, based on decision WHA68(12), the review should cover the period 2012−2016.

The overall purpose of the review was to estimate the extent to which the Member State mechanism had progressed in achieving its objectives in the period 2012–2016; to identify gaps and remaining challenges; and to make recommendations on the way forward.

The objectives of the review were to respond to the following four high-level questions:

- To what extent have the objectives of the mechanism been achieved?
- Which are the major gaps in the achievement of those objectives?
- Which are the principal factors that have either supported or hampered the achievement of the mechanism objectives?
- How could the mechanism be more effective in achieving its objectives?

The review sought the informed opinion of the primary stakeholders of the mechanism: all Member States (including health ministries and national/regional regulatory agencies), and WHO offices involved in supporting the implementation of the mechanism by Member States, such as the mechanism's secretariat and essential medicines regional advisers. Furthermore, nongovernmental organizations in official relations with WHO were made aware of this review and requested to express interest to participate in it, at which point, the Evaluation Office provided them access to the online survey. The survey for the review was managed online through a secure WHO electronic platform.

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1 The resolution further decided to review the Member State mechanism after three years of operation.

2 Decision WHA68(12).

The scope of the review covered the implementation of the eight strategies and action areas defined in the work plan of the Member State mechanism together with their relationship to the achievement of the objectives of the mechanism. The review estimated the extent of implementation of the work plan and explored its potential to achieve the corresponding objectives. The review also explored the factors that supported or hampered implementation of the work plan, and collected survey respondents' proposed options for improving the effectiveness of the mechanism.

The review was carried out through an online survey for the primary stakeholders of the Member State mechanism, key-informant interviews, an online survey for interested nongovernmental organizations and a document review.

There were 151 Member State representatives who responded to the survey, corresponding to 104 Member States across the six WHO regions. Of these, 36 countries provided two or more complete responses per country, and 68 other countries provided one complete response per country. The sample was adequate to generate useful estimates of stakeholders' views and experiences.

With regard to the distribution of respondents by the type of organization, national and regional regulatory agencies (77 respondents or 50%) and health ministries (65 respondents or 43%), were well represented. About 4% of respondents were from other governmental institutions.

Of the respondents, 91 (60%) were familiar with the work of the mechanism, either by serving on the Steering Committee (7 respondents), participating in one of the Working Groups (21 respondents) attending some of the mechanism's meetings (46 respondents), or advising the delegates to the mechanism (17 respondents). Another 37% of respondents had some exposure and were interested in its outcomes.

Eleven nongovernmental organizations in official relations with WHO responded to the survey. Seven of them were based in the European Region, another three in the Region of the Americas, and one more in the Western Pacific Region. Seven of them indicated that they were at least moderately familiar with the work of the Member State mechanism.

Additional key informant interviews took place**.** A total of 14 informants, including four members of the Steering Committee and the Member State mechanism secretariat, were interviewed. The informants offered additional perspectives on the mechanism.

Findings

The review found that the mechanism continues to be relevant, it plays a critical role in raising awareness of SSFFC medical products and Member States would want it to continue.

With regard to the extent to which the objectives of the mechanism have been achieved, there is a substantial consensus that the mechanism has made reasonable progress in this regard, given the initial challenges and time required to create the enabling environment for the effective functioning of the mechanism. Member States considered that the mechanism is an adequate global platform to promote the prevention, detection and response to SSFFC medical products and associated activities. They also expressed agreement with the objectives and workplan of the mechanism and noted the value of a number of its products

and activities. Overall, stakeholders considered that the mechanism had partially addressed the objectives established in 2012. A key achievement during this period has been the agreement on the definitions of SSFFC medical products (see document A70/23).

Essentially, the formal and informal organizational structures created as a result of the mechanism and the ensuing collaborative climate and trust that emerged are recognized as important and necessary intermediate achievements. The factors that emerged as being supportive were Steering Committee leadership and commitment, the supporting of the mechanism by WHO and the development of good products and the convening of expert and Steering Committee meetings.

However, the main gaps identified are: an unfinished technical agenda; limited coordination processes among the different actors involved in the work of the mechanism; and the inadequate systems of communication and dissemination of information between the mechanism and Member States, as illustrated by the limited reach of the products and activities of the mechanism. Better synergies and improved coordination and sharing of information with Member States, as well as processes linking all three levels of the Organization, could facilitate better strategic planning and coordination of relevant programmes as well as technical support to countries while fostering wider collaboration and engagement, making the mechanism stronger and more successful.

In addition, strengthened communication between Member States and the mechanism, including its secretariat, would facilitate better information flow and sharing of ideas and contribute to the output of the working groups. This would imply more advocacy to inform institutions, manufacturers and other actors about the SSFFC challenges and the achievements of the mechanism.

The review noted that the mechanism was under-resourced, in part as a consequence of not being properly prioritized within WHO and among the actors of the mechanism. The diversity of initial political perspectives and expectations about the mechanism and the evolving operating procedures and governance structure were seen as factors that may have delayed the achievement of the objectives.

When considering options for future action, the mechanism should revisit its current workplan in order to complete outstanding activities. Furthermore, this would also be an opportune moment to consider plans and activities for the next phase and secure sufficient funding to enable the effective delivery of its renewed mandate. Strategically, the mechanism should place greater emphasis on expanding its stakeholder base, involving Member States more actively as well as regulatory agencies and non-state actors, and consolidate its activities, products, processes and outreach to provide sustainable support to Member States.

Recommendations

1. Members of the Steering Committee of the Member State mechanism to revisit the current workplan, ensuring outstanding activities within the workplan are completed, and consider plans and activities for the next phase.

2. Develop appropriate processes for effective coordination, communication, and dissemination of information on main action areas and outputs.

Action points:

a. strengthen coordination and harmonize procedures between the mechanism and relevant technical teams in WHO at headquarters and regional levels, and between the mechanism and Member States
b. establish better systems for regional communication and dissemination of information between the mechanism and Member States, including strengthening use of electronic platforms and focal point networks
c. improve coordination and communication on SSFFC matters across the three levels of the Organization
d. encourage active engagement of more Member States in the work of the mechanism.

3. Build and expand national capacity to address SSFFC medical products.

Action points:

a. provide training to national focal points on the prevention, detection and response to SSFFC medical products
b. develop tools to support implementation of the mechanism's activities
c. expand the number of Member States that are actively engaged in the process.

4. Secure sufficient additional resources for the mechanism to be able to achieve all of its objectives.

Action points**:**

a. the mechanism should support secretariat efforts to secure additional resources from Member States and the international donor community
b. WHO's senior management should consider prioritizing support and funding for the mechanism secretariat.

5. Encourage the engagement of additional actors in the mechanism, including academic institutions, manufacturers, nongovernmental organizations, civil society and related technical institutions at global, regional and country levels.

1. Introduction

The Member State mechanism on substandard/spurious/falsely labelled/falsified/ counterfeit medical products

In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19, in which it decided to establish a Member State mechanism aimed at protecting public health and promoting access to affordable, safe, efficacious, and quality medical products, by promoting the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products and associated activities. This resolution[3] renewed and re-established a mandate for the Secretariat and Member States in addressing SSFFC medical products from a public health perspective in a transparent and inclusive way. The Member State mechanism is supported by WHO and facilitated by the mechanism secretariat.

The goal of the mechanism is to protect public health and promote access to affordable, safe, efficacious and quality medical products, through effective collaboration among Member States and the Secretariat, for the prevention and control of SSFFC medical products and associated activities.

The objectives of the mechanism are:

1) To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of SSFFC medical products in order to strengthen national and regional capacities.

2) To strengthen national and regional capacities in order to ensure the integrity of the supply chain.

3) To exchange experiences, lessons learnt best practices, and information on ongoing activities at national, regional, and global levels.

4) To identify actions, activities and behaviours that result in SSFFC medical products and make recommendations, including for improving the quality, safety and efficacy of medical products.

5) To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.

6) To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of SSFFC medical products.

7) To facilitate consultation, cooperation, and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective.

[3] The resolution further decided to review the Member State mechanism after three years of operation.

8) To promote cooperation and collaboration on surveillance and monitoring of SSFFC medical products.

9) To further develop definitions of SSFFC medical products that focus on the protection of public health.

The review of the Member State mechanism was mandated by resolution WHA65.19 to be conducted in 2016. The Health Assembly subsequently decided to postpone the review by one year to 2017.[4] At the fourth meeting of the Member State mechanism, held on 19 and 20 November 2015, there was agreement that the review process should be led by the WHO Evaluation Office, and that further details on the review, including on the questionnaire, would be provided to the Steering Committee of the Member State mechanism at its meeting in March 2016. Subsequently, the Steering Committee members agreed that, based on decision WHA68(12), the review should cover the period 2012−2016.

Purpose of the review and high level objectives

The overall purpose of the review was to estimate the extent to which the Member State mechanism had progressed in achieving its objectives in the period 2012–2016; to identify gaps and remaining challenges; and to make recommendations on the way forward.

The objectives of the review were to respond to the following four high-level questions:

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Approach

The review sought the informed opinion of the primary stakeholders of the mechanism: all Member States (including health ministries and national/regional regulatory agencies), and WHO offices involved in supporting the implementation of the mechanism by Member States, such as the mechanism's secretariat and essential medicines regional advisers. Furthermore, nongovernmental organizations in official relations with WHO were made aware of this review and requested to express interest to participate in it, at which point, the Evaluation Office provided them access to the online survey.

The survey for the review was managed online through a secure WHO electronic platform.

The scope of the review covered the implementation of the eight strategies and action areas defined in the work plan of the Member State mechanism together with their relationship to the achievement of the objectives of the mechanism. The review estimated the extent of implementation of the work plan and explored its potential to achieve the corresponding objectives. The review also explored the factors that supported or hampered implementation of the work plan, and collected survey respondents' proposed options for improving the effectiveness of the mechanism.

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[4] Decision WHA68(12).

2. Methodology

The review of the Member State mechanism was designed to generate formative information on the operations, experience and achievements of the mechanism, identify gaps and challenges, and demonstrate whether the mechanism's objectives set in 2012 have been achieved. The review generated information on the impact of the mechanism at the completion of the first review period of 2012-2016. The Steering Committee of the Member State mechanism had opportunities to review and comment on the Terms of Reference of the review and the survey questionnaire at its 4th and 5th meetings.

The review process

The review was carried out through a combination of:

1. **An online survey for the primary stakeholders of the Member State mechanism,** namely all Member States (including health ministries and national/regional regulatory agencies).
2. **Interviews** of Steering Committee members who expressed interest in being interviewed and the Member State mechanism secretariat staff (WHO staff at headquarters and regional advisors) involved in supporting the implementation of the mechanism.
3. **An online survey for interested nongovernmental organizations**.
4. **A document review**.

Analysis of data collected

The analyses addressed the extent to which the mechanism's objectives have been achieved, major gaps in achievement of those objectives, the factors that either supported or hampered the achievement of the objectives, and how the mechanism could be more effective. The two analytic parts were: analysis of stakeholder questionnaire results and analysis of interview results.

1. **Review of existing materials** was used to determine the mechanism's objectives and progress in the form of: reports and agreements, work plans, technical documents on the progress of activities A to G of the Working Groups .

2. Analysis of stakeholder questionnaire results: The questionnaire [5] was designed so that information could be gathered from any stakeholder relevant to the mechanism, even if they did not have a working knowledge of the mechanism itself. Survey data were analysed through calculation of frequencies and trends in the survey questions and responses to open-ended questions were also reviewed. The open-ended questions in the questionnaire explored stakeholders' perceptions and helped to gain rich quantitative data.

3. Analysis of interview results: The written guide used to conduct the interviews and record responses was structured to develop information on the informants' perspectives regarding the review questions. Informants' opinions and feedback were analysed to identify common themes and variations in responses.

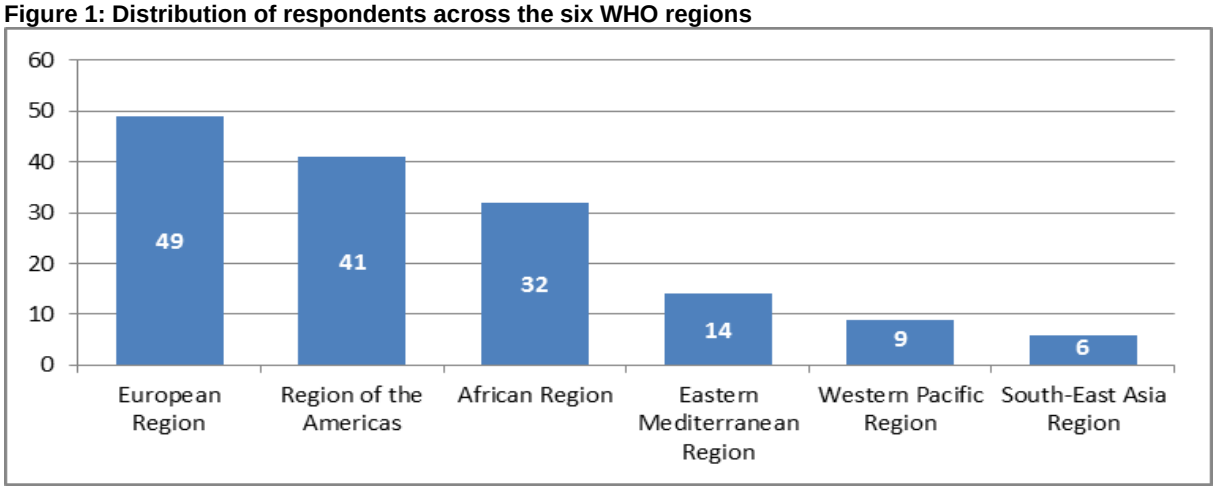
[5] The questionnaire was agreed with the Member State mechanism at its 5th meeting in November 2016.

Participants in the review

Questionnaire respondents

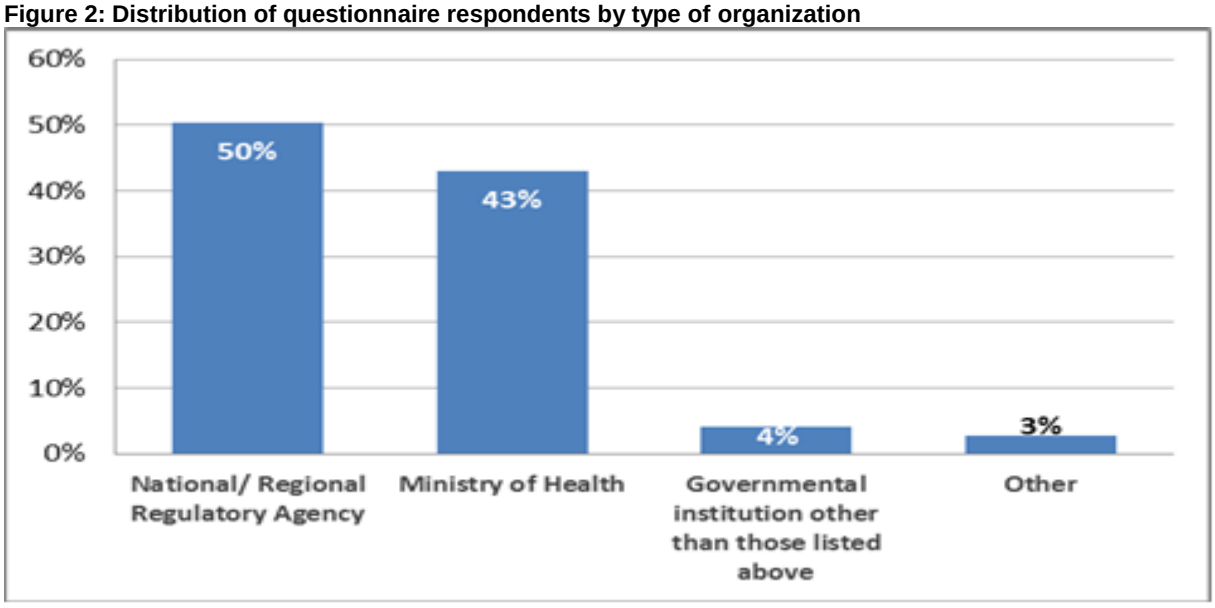
There were 151 Member State representatives who responded to the survey, corresponding to 104 Member States across the six WHO regions. Of these, 36 countries provided two or more complete responses per country, and 68 other countries provided one complete response per country (see Figure 1 for regional distribution and Box 1 for list of participating countries). The sample was adequate to generate useful estimates of stakeholders' views and experiences.

Figure 1: Distribution of respondents across the six WHO regions



The distribution of respondents by the type of organization is shown in Figure 2. National and regional regulatory agencies (77 respondents or 50%) and health ministries (65 respondents or 43%), were well represented. About 4% of respondents were from other governmental institutions. Only four respondents did not state their affiliation.

Figure 2: Distribution of questionnaire respondents by type of organization

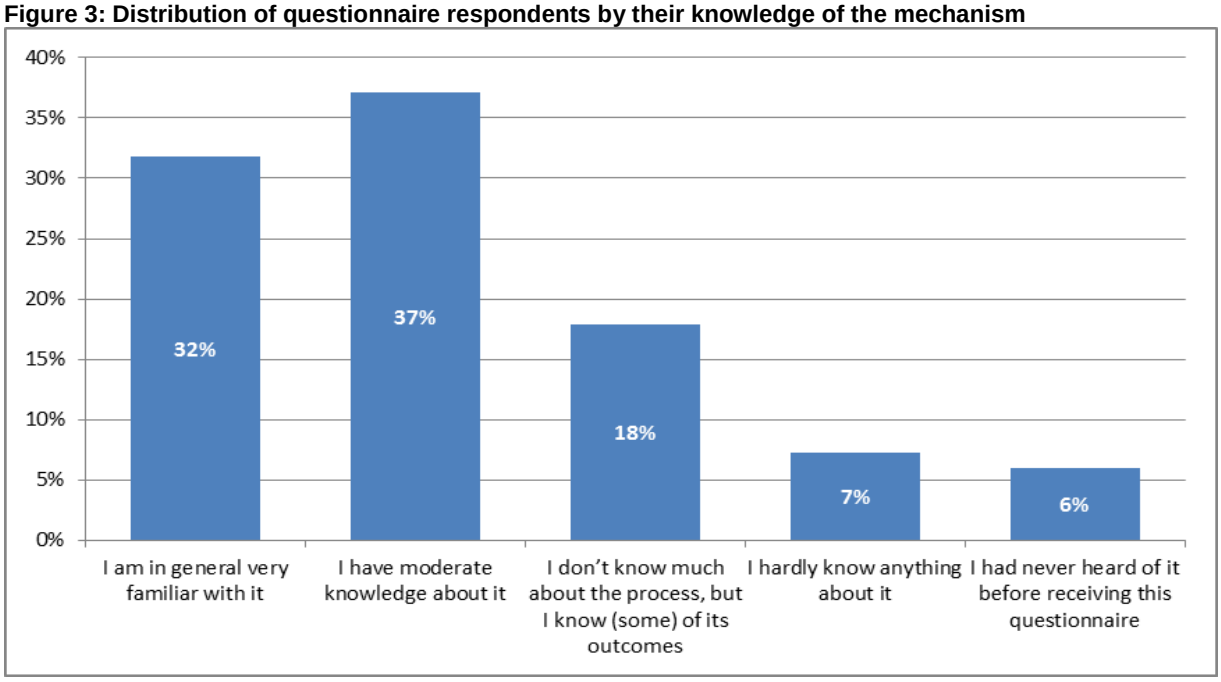


Of the respondents, 91 (60%) were familiar with the work of the mechanism, either by serving on the Steering Committee (7 respondents), participating in one of the Working Groups (21 respondents) or attending some of the mechanism's meetings (46 respondents),

or advising the delegates to the mechanism (17 respondents). Another 37% of respondents had some exposure and were interested in its outcomes.

About 70% of the questionnaire's respondents considered they had 'good' or 'moderate' knowledge of the mechanism to be able to respond to the questions with some degree of informed opinion. Based on the stakeholder's database used as the source to distribute the survey, it is estimated that the remaining 30% of respondents were engaged in the management of medicines, supply chain, quality control, safety of medicines, pharmacovigilence, and SSFFC medical issues. An open-ended question in the questionnaire confirmed the interest of many respondents in SSFFC medical products and what the mechanism had to offer. About 13% said that they knew little about the mechanism or had never heard of the mechanism before. The distribution of respondents by their declared knowledge of the mechanism is shown in Figure 3.

Figure 3: Distribution of questionnaire respondents by their knowledge of the mechanism



Eleven nongovernmental organizations in official relations with WHO responded to the survey. Seven of them were based in the European Region, another three in the Region of the Americas, and one more in the Western Pacific Region. Seven of them indicated that they were at least moderately familiar with the work of the Member State mechanism.

Additional key informant interviews took place**.** A total of 14 informants, including four members of the Steering Committee and the Member State mechanism secretariat, were interviewed. The informants offered additional perspectives on the mechanism.

Box 1. Countries listed as respondents of the survey (and number of responses)

African Region		**Region of the Americas**		**Eastern Mediterranean Region**	
Algeria	**2**	Argentina	**2**	Afghanistan	1
Botswana	**2**	Bahamas	1	Egypt	**2**
Burkina Faso	1	Barbados	1	Iran (Islamic Republic of)	**2**
Burundi	**2**	Belize	**2**	Iraq	**2**
Cabo Verde	**2**	Brazil	**4**	Jordan	1
Comoros	1	Canada	1	Kuwait	1
Democratic Republic of the Congo	1	Chile	1	Oman	**3**
Ethiopia	1	Colombia	**2**	Pakistan	1
Ghana	1	Costa Rica	1	Sudan	1
Kenya	1	Cuba	1		
Madagascar	1	Dominica	1	**South-East Asia Region**	
Malawi	1	Dominican Republic	**2**	Bangladesh	1
Mali	1	Ecuador	**2**	India	1
Mauritius	1	El Salvador	**3**	Maldives	1
Mozambique	1	Guatemala	1	Thailand	1
Rwanda	**3**	Guyana	1	Timor-Leste	**2**
Senegal	1	Haiti	1		
Seychelles	**2**	Jamaica	**2**	**Western Pacific Region**	
South Sudan	1	Mexico	1	Australia	2
Uganda	1	Panama	**2**	China (People's Republic of)	1
United Republic of Tanzania	**2**	Paraguay	**2**	Fiji	1
Zambia	**2**	Peru	1	Japan	1
Zimbabwe	1	Suriname	1	Philippines	**3**
		United States of America	**4**	Singapore	1
		Uruguay	1		

European Region			
Albania	**2**	Monaco	**2**
Andorra	1	Montenegro	**3**
Armenia	1	Norway	**2**
Austria	**2**	Portugal	1
Azerbaijan	1	Republic of Moldova	1
Belarus	1	Romania	1
Belgium	**2**	Russian Federation	1
Bosnia and Herzegovina	1	Slovakia	1
Bulgaria	**3**	Slovenia	1
Croatia	**2**	Spain	1
Czech Republic	1	Sweden	**2**
Estonia	1	Switzerland	1
Finland	1	Turkey	1
Georgia	1	United Kingdom of Great Britain and Northern Ireland	**3**
Germany	1		
Greece	1		
Iceland	1		
Italy	1		
Latvia	1		
Lithuania	1		
Luxembourg	1		
Malta	1		

3. Review findings

The results presented in this section address the feedback received from Member States through the review survey. Additionally, perspectives gained from the informal interviews and input provided by interested NGOs is presented at the end of this section.

The survey responses capture the dynamics of stakeholders' experiences with the Member State mechanism. The extent and quality of stakeholder participation in the questionnaire showed the high level of interest of the Member States (ministries of health and national regulatory authorities) in the mechanism. A vast majority of respondents stressed the relevance of the prevention, detection and response to SSFFC medical products for their area of work.

In the online survey, a set of questions were addressed to all respondents, while another subset of questions were targeted at respondents with some involvement or engagement with the mechanism.

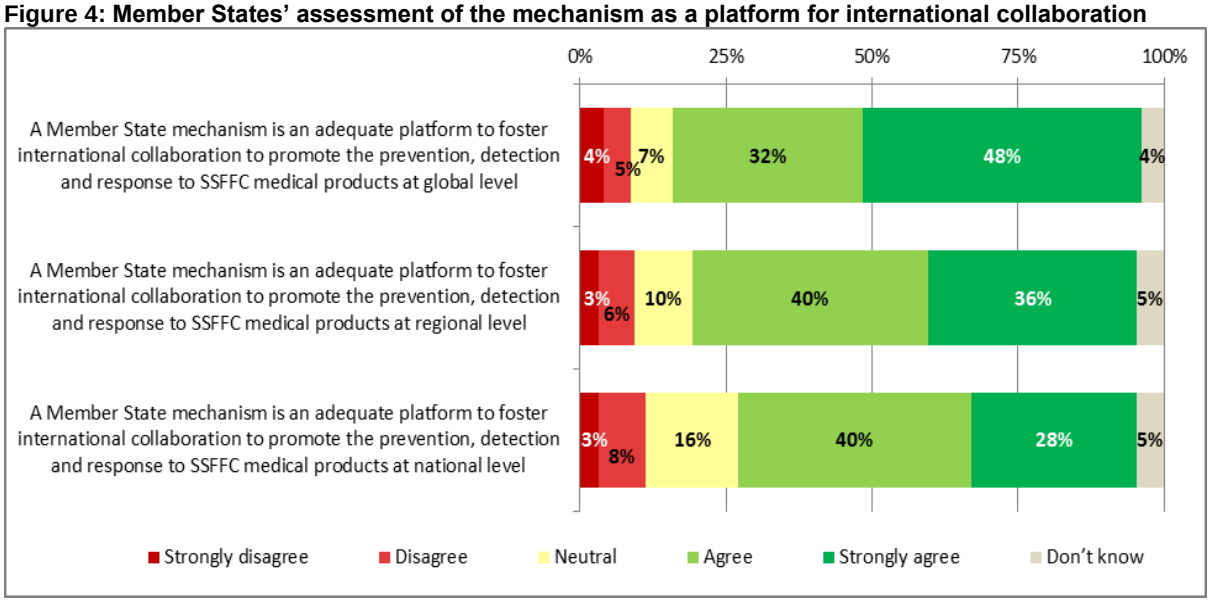
A. Questions addressed to all respondents

(i) Role of the Member State mechanism as a platform for global collaboration on SSFFC medical products

In the survey, Member States were asked to indicate their level of agreement with the statement: ***"****A Member State mechanism is an adequate platform to foster international collaboration to promote the prevention, detection and response to SSFFC medical products at global/regional/national level".*

Figure 4 shows that an overwhelming majority of Member States (80%) either 'agreed' or 'strongly agreed' on the role of the mechanism as a platform to foster international collaboration on SSFFC medical products at the global level. A slightly lower percentage (76%) of respondents also considered that the mechanism played an adequate collaborative role at regional level and 68% of respondents considered that it was also relevant at national level. These differences suggest that respondents felt that the mechanism's goals address SSFFC medical products issues slightly better at global than at national level. Nevertheless, they expressed strong support for the role of the Member State mechanism as a platform for Member State collaboration on SSFFC medical products at multiple levels of concern.

Figure 4: Member States' assessment of the mechanism as a platform for international collaboration



Member States, through responses to an open-ended question, valued the collaborative nature of the mechanism between Member States and international organisations and expressed its importance as an instrument to prevent, detect and respond to SSFFC medical products. They appreciated, among other aspects, the fact that it offers a forum for Member States to discuss the main public health issues related to SSFFC medical products, and it also provides an opportunity to learn about the strengths and weaknesses of regulatory mechanisms. Member States valued the opportunity to share experiences and documentation about public health issues related to SSFFC medical products.

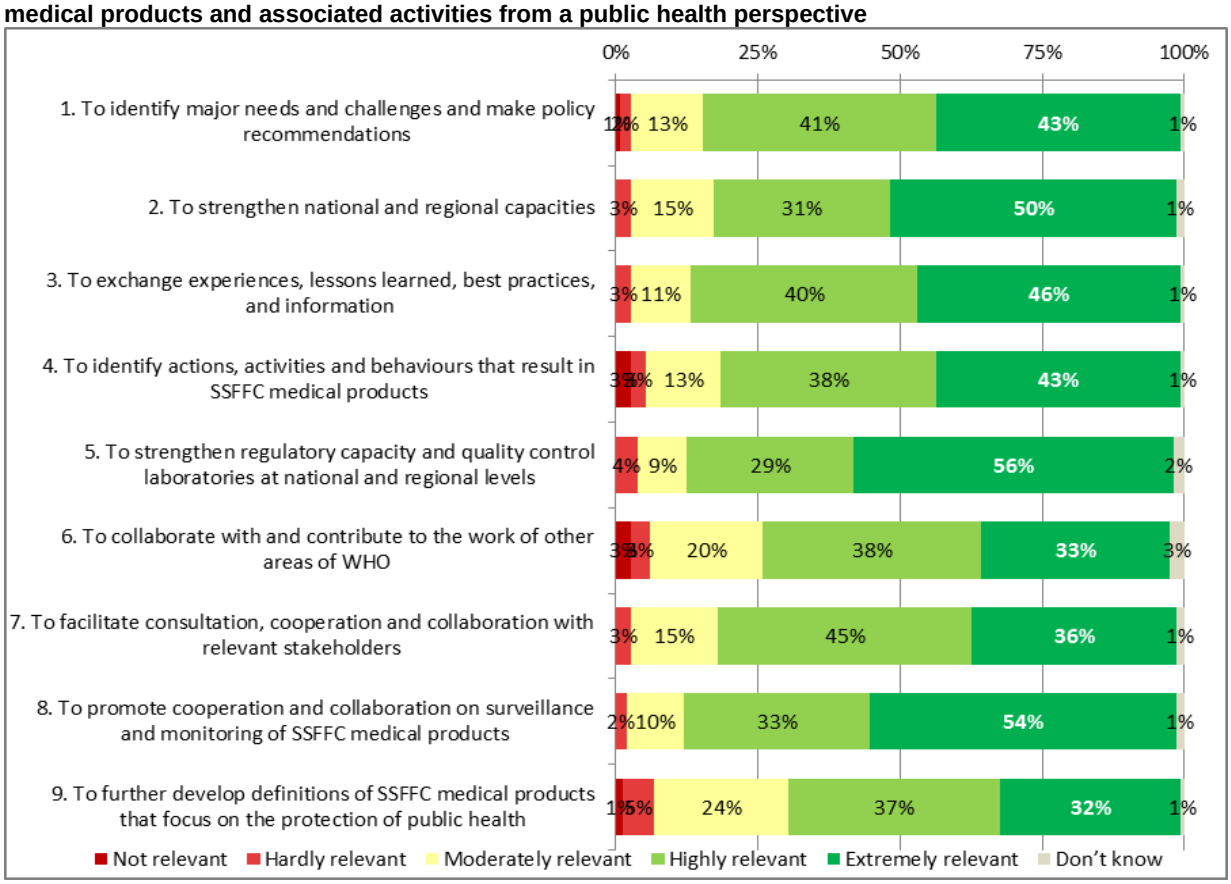
(ii) Relevance of the Member State mechanism objectives to promoting the prevention, detection and response to SSFFC medical products and associated activities from a public health perspective

As shown in Figure 5, most respondents considered that the objectives of the mechanism were extremely or highly relevant from a public health perspective.

Respondents rated quite consistently the relevance of all MSM objectives. Objectives 3, 5, and 8 received the highest scores. At least 85% of the respondents considered that such objectives were extremely or highly relevant:

- Objective 8 "*To promote cooperation and collaboration on surveillance and monitoring of SSFFC medical products":* 87% of the respondents rated it as extremely or highly relevant.
- Objective 3 *"To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional, and global levels*": 86% of the respondents rated it as extremely or highly relevant.
- Objective 5: "*To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries"* with 85% of the respondents rating it as extremely or highly relevant.

Figure 5: Relevance of the nine objectives to promoting the prevention, detection and response to SSFFC medical products and associated activities from a public health perspective

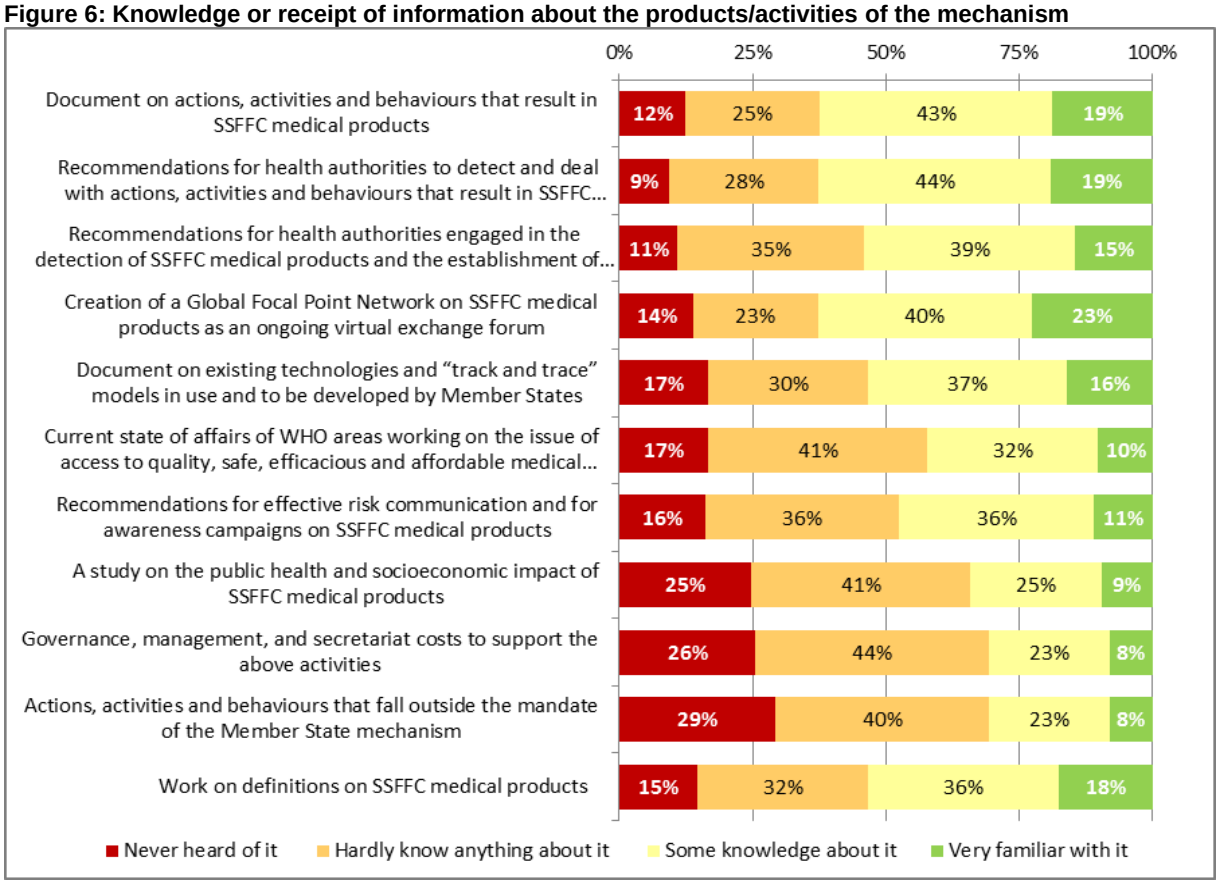


In response to an open-ended question, 17 Member States proposed additional objectives that they also considered relevant, such as: encouraging capacity building at country level, engaging civil society in the prevention, detection and response to SSFFC medical products, and fostering surveillance of SSFFC medical products at the national and regional levels.

(iii) Information made available by the mechanism

The mechanism was tasked with delivering a work-plan along the lines of its original objectives. The survey enquired as to the degree of awareness and information received on the products and activities that were the focus of the work of the mechanism. Figure 6 shows that only a small percentage of respondents (8% to 23%) were very familiar with the mechanism's efforts and actions in addressing SSFFC medical products, whereas the majority of the respondents seemed to be less informed about numerous products and activities.

Figure 6: Knowledge or receipt of information about the products/activities of the mechanism

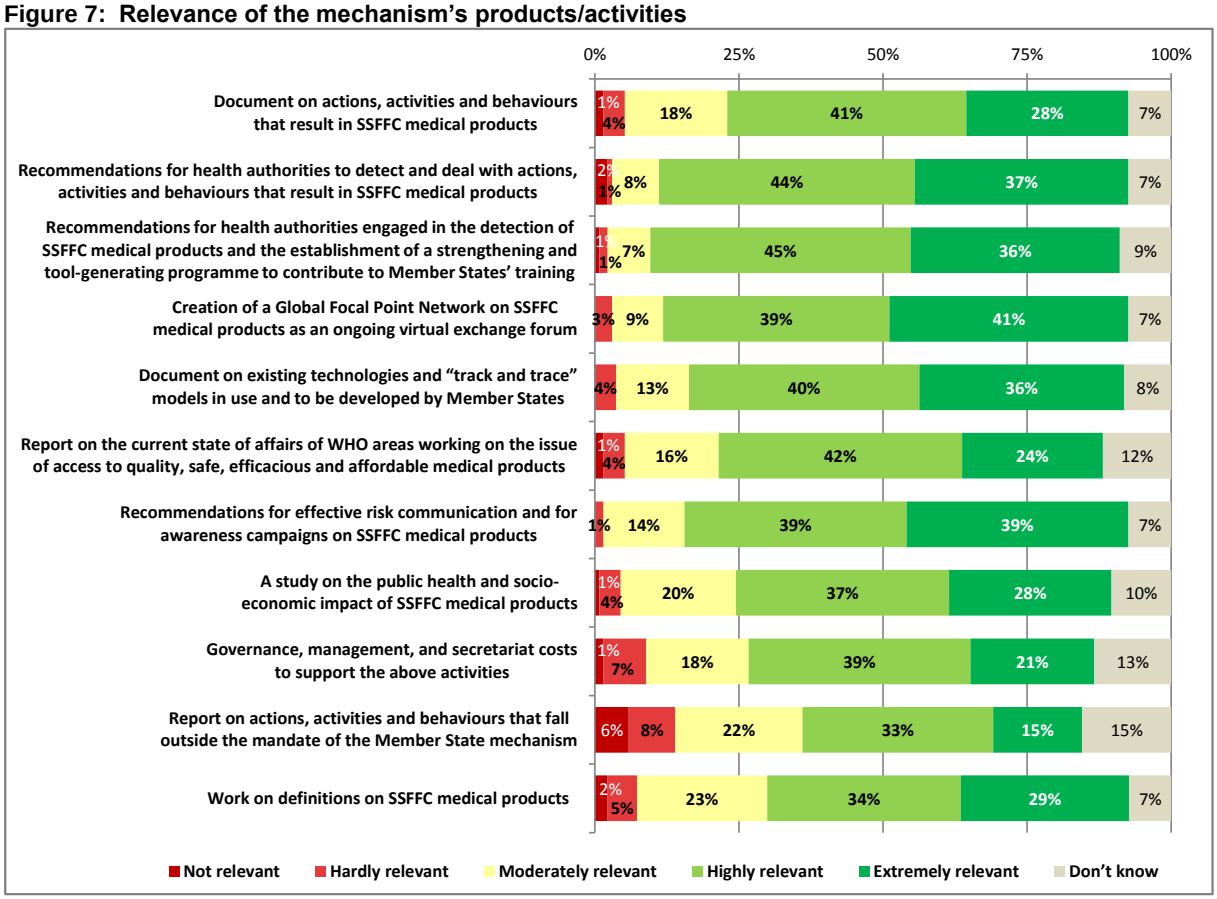


These responses point to weaknesses in communication and dissemination of information in relation to the work of the mechanism.

(iv) Relevance of the products and activities of the Member State mechanism to promote the prevention, detection and response to SSFFC medical products from a public health perspective

Respondents considered that most products and activities of the mechanism were 'extremely relevant' or 'highly relevant' from a public health perspective, as shown in Figure 7. The products and activities considered most relevant were "*recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training*" and the "recommendations for *health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products*". Both categories of products and activities were rated by over 80% of respondents as extremely or highly relevant. The "*creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum*" was also rated by 80% of the respondents as extremely or highly relevant. Furthermore, the "*recommendations for effective risk communication and for awareness campaigns on SSFFC medical products"* were considered extremely or highly or relevant by 78% of the respondents.

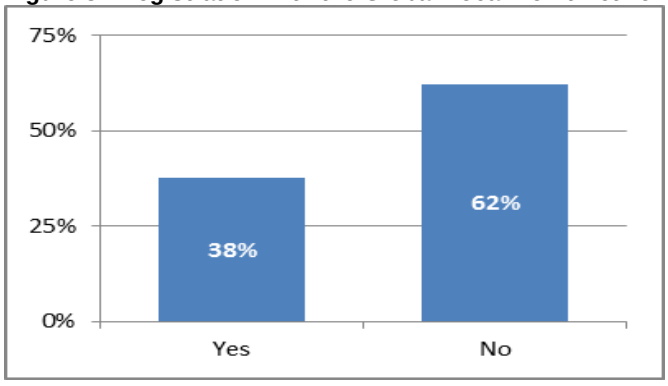
Figure 7: Relevance of the mechanism's products/activities



In response to an open-ended question seeking suggestions for additional useful products to address SSFFC medical products offered several proposals including additional activities in support of the training and capacity building of regulatory officers on areas related to the detection, prevention and response to SSFFC medical products. They also suggested the inclusion of additional activities to address internet advertising and sales of SSFFC medical products; and recommended customizing the mechanism's products and activities for small regulatory agencies.

(v) Registration with the Global Focal Point Network on SSFFC medical products

Figure 8: Registration with the Global Focal Point Network on SSFFC medical products



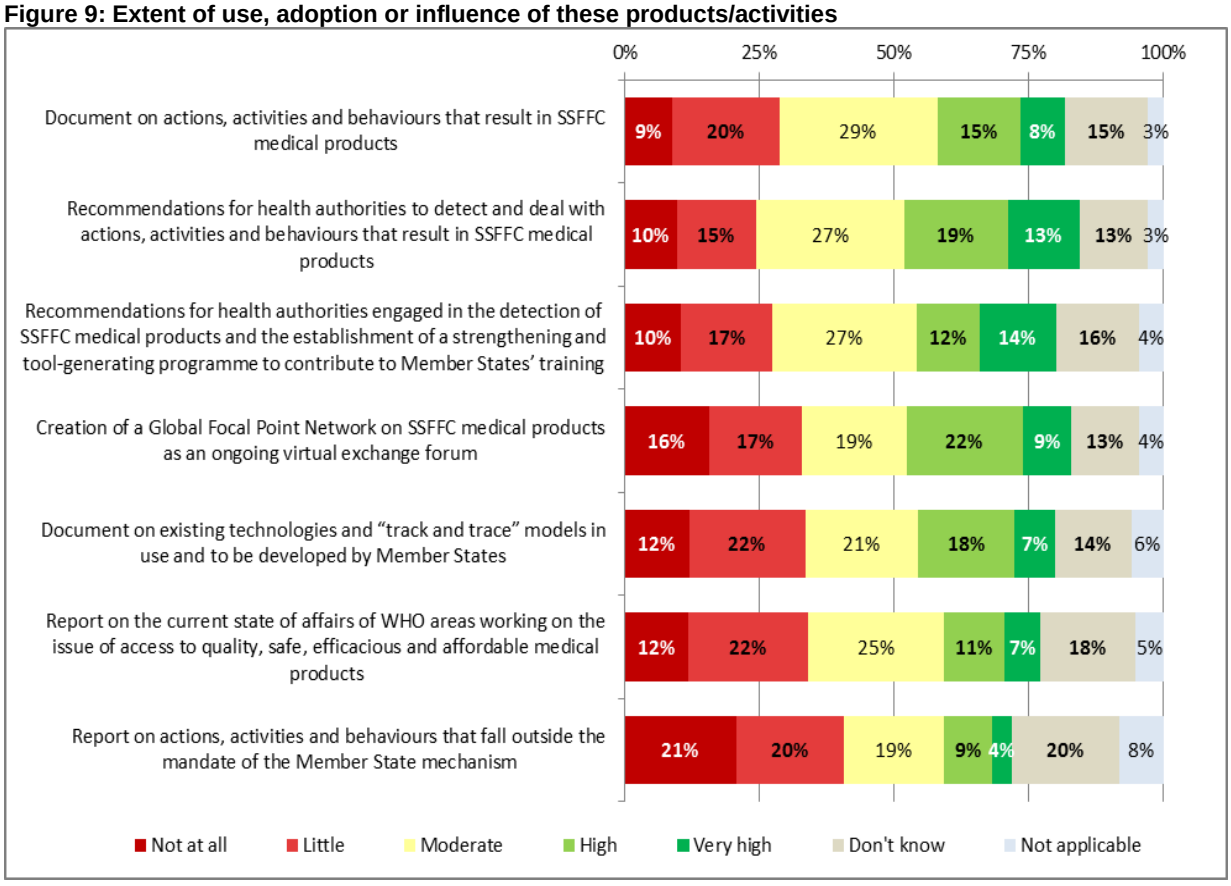
Despite the Global Focal Point network being one of the better known products and activities of the mechanism, only 38% of the respondents declared having registered with the network, suggesting a potential gap in the outreach of the mechanism.

(vi) Use, adoption or policy and practice influence of the products and activities of the mechanism

With regard to the question on the extent of use, adoption or influence of the products/activities being developed by the mechanism, a small percentage of respondents (13% to 32%) reported a high or very high level of influence, adoption or use of the products and activities (Figure 9).

The *"recommendations for health authorities to detect and deal with actions, activities and behaviours that results in SSFFC medical products"* and *the "Global Focal Point Network on SSFFC medical products"* were the products rated most highly. However, the share of respondents that expressed no or very little use, adoption or influence of the products and activities of the mechanism was equally significant. A significant percentage (between 33% and 41%in certain cases) expressed lack of or very little use , adoption or influence of the products and activities of the mechanism.

Figure 9: Extent of use, adoption or influence of these products/activities

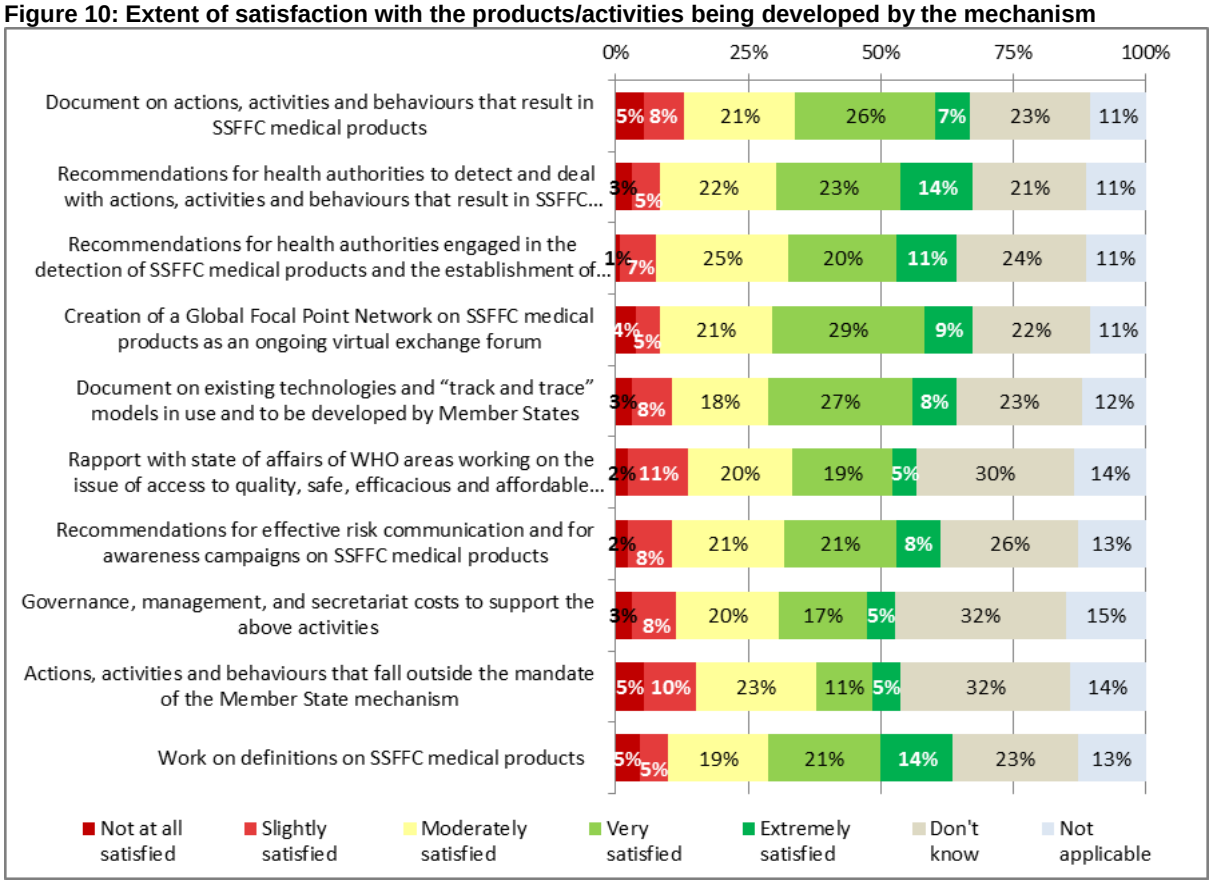


Despite the low recorded uptake of the products/activities of the Member State mechanism, respondents nevertheless reported some degree of familiarity with, and influence of, the products at national level, as mentioned in the linked open-ended question. There were 35 responses from Member States outlining how the mechanism's products have influenced national actions. These included the launching of awareness campaigns about SSFFC medical products, the exchange of information with national authorities and the drafting of norms and procedures.

(vii) Satisfaction with the products/activities being developed by the mechanism

When asked about their extent of satisfaction with the products and activities of the mechanism, the respondents illustrated once again their varying levels of exposure to them and varying degrees of satisfaction with them (Figure 10). Between 16% and 38% of respondents indicated that they were extremely or very satisfied with the products and activities of the mechanism. However, between 8% and 15% of respondents also expressed a lower level of satisfaction with the products and activities.

Figure 10: Extent of satisfaction with the products/activities being developed by the mechanism



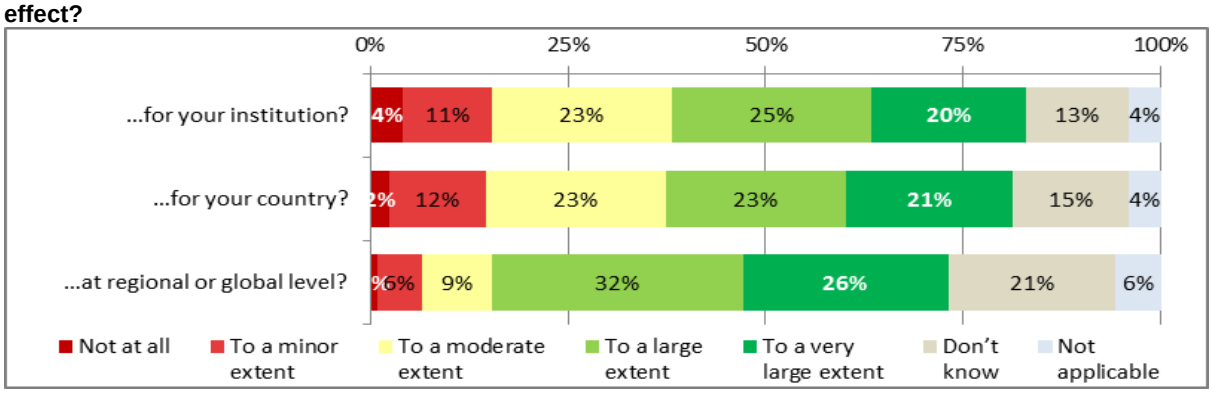
The ratings suggest that the mechanism has not yet fulfilled all expectations of Member States, either because of the quality of the products, the lack of or limited awareness about them, or because of unaccomplished objectives of the mechanism.

On the open-ended question regarding the level of satisfaction with these products/ activities, some respondents highlighted the limited knowledge that persists in national agencies about the mechanism's products and activities. It was also mentioned that information about the mechanism is not disseminated in a timely manner or, in some cases, although some individuals at country level may be aware of the Member State mechanism recommendations, actions and activities, these are not properly disseminated to those responsible for dealing with SSFFC medical products in national institutions.

(viii) Degree to which the work of the mechanism has a positive or beneficial effect

Overall, the work of the mechanism appeared to be well accepted by most survey respondents. They considered that the work of the mechanism exerted a positive effect, particularly at the global level, but also in Member States (Figure 11).

Figure 11: To what degree does the work of the Member State mechanism have a positive or beneficial effect?



With regard to the open-ended question on the main issues in effectively promoting the prevention, detection and response to SSFFC medical products, respondents highlighted: the lack of awareness among critical actors at national level, including relevant institutions and the general public; limited systems of market surveillance to prevent and detect SSFFC medical products; inadequate technical capacity and expertise to articulate an effective response; and overall limited resources to establish the required mechanisms for the prevention, detection and response to SSFFC medical products.

In addressing the open-ended question on the priorities that WHO and the international community should undertake to address the prevention, detection and response to SSFFC medical products, respondents gave priority to areas that foster awareness about the public health issues surrounding SSFFC medical products and contribute to strengthening capacity at national level, including support for a legislative framework to promote the prevention, detection and response to SSFFC medical products. They encouraged support for: collaborative work at national and international levels; developing tools to facilitate global surveillance and response actions; and fostering a global network of national focal points for the prevention, detection and response to SSFFC medical products; broadly disseminating the work of the mechanism; and strengthening its engagement with national regulatory agencies..

Finally, the respondents highlighted the importance of the public health issues related to SSFFC medical products and their relation to other public health priorities such as antimicrobial resistance, advocating for the adoption of an urgent and coordinated approach in the response to them. Respondents encouraged the continuation of the mechanism and suggested renewed efforts, including strengthening global awareness and building regulatory and technical capacity in Member States to address this critical issue at global and national level. They also encouraged the expansion of the reach of the work of the mechanism to ensure effective engagement from, and support to, low-income countries.

B. Questions addressed to respondents involved in the work of the mechanism

The survey also examined the adequacy of the inputs and processes that served the mechanism during the past four years. The following questions were specifically addressed to those respondents who were familiar with the operations of the mechanism, either by having served on the Steering Committee or on any of its working groups, or by having attended some of the meetings of the mechanism or having provided technical advice to it. Fifty one respondents met such conditions and provided answers to these questions.

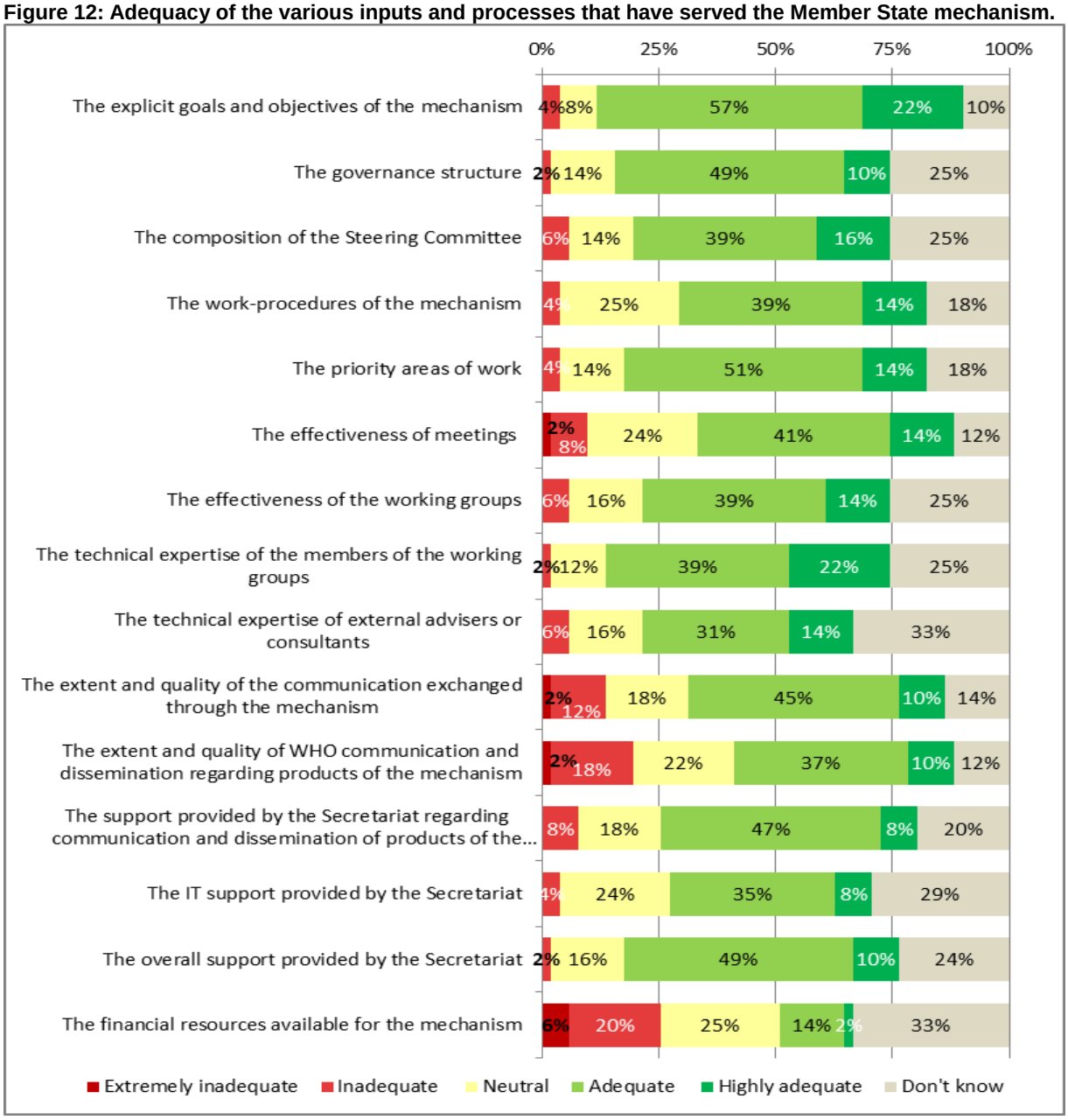
(i) Adequacy of the inputs and processes that have served the Member State mechanism

Overall, the majority of respondents considered that most of the key inputs and processes of the mechanism were adequate to meet the mechanism's objectives, as can be seen in Figure 12.

As presented in Figure 12, the explicit goals and objectives of the mechanism, as well as its priority areas of work and its governance structure, including the Steering Committee composition, were seen as positive elements. Almost 80% of the respondents thought that the explicit goals and objectives of the mechanism were among the most adequate aspects of the mechanism. About 65% of respondents also rated positively the adequacy of the priority areas of work. The governance structure and the composition of the steering committee were considered highly adequate or adequate by 59% and 55% of the respondents respectively. The positive influence of these factors was reinforced by respondents in their responses to open-ended questions (see below).

On the other hand, some aspects of the mechanism received less positive ratings. Some 26% of the respondents considered that the financial resources allocated to the mechanism were inadequate. The extent and quality of the communication and dissemination processes for products and activities of the mechanism was negatively rated by 20% of the respondents. Communication issues seemed to encompass both the communication within the mechanism as well as the Secretariat support towards communication and dissemination of its products and activities.

Figure 12: Adequacy of the various inputs and processes that have served the Member State mechanism.



(ii) Success factors behind the achievements of the mechanism

In responses to an open-ended question, the strong support of most Member States and the WHO Secretariat, combined with the more recent evolution of the mechanism to concentrate more on technical work, have favoured the latest accomplishments of the mechanism. In particular, the recent agreement on definitions, to be submitted to the Seventieth World Health Assembly, was viewed by many as a key achievement to enable the progress of the mechanism by more clearly sorting out public health issues from intellectual property right concerns.

(iii) Barriers that hindered the progress of the mechanism

Concerns with the limited resources available to the mechanism and to Member States for actions related to the prevention, detection and response to SSFFC medical products, and with the inadequate access to, or exchange of, information were emphasized by respondents

in responses to an open-ended question. Some respondents considered the inadequate communication and limited information flow were among the major challenges of the mechanism, along with the limited resources. Additionally, respondents highlighted that political rather than technical perspectives around the focus of the mechanism, particularly at its early stages, limited its progress. This was compounded by different levels of commitment of Member States, in part due to limited national regulatory capacity.

(iv) Communication with national or regional authorities and other stakeholders

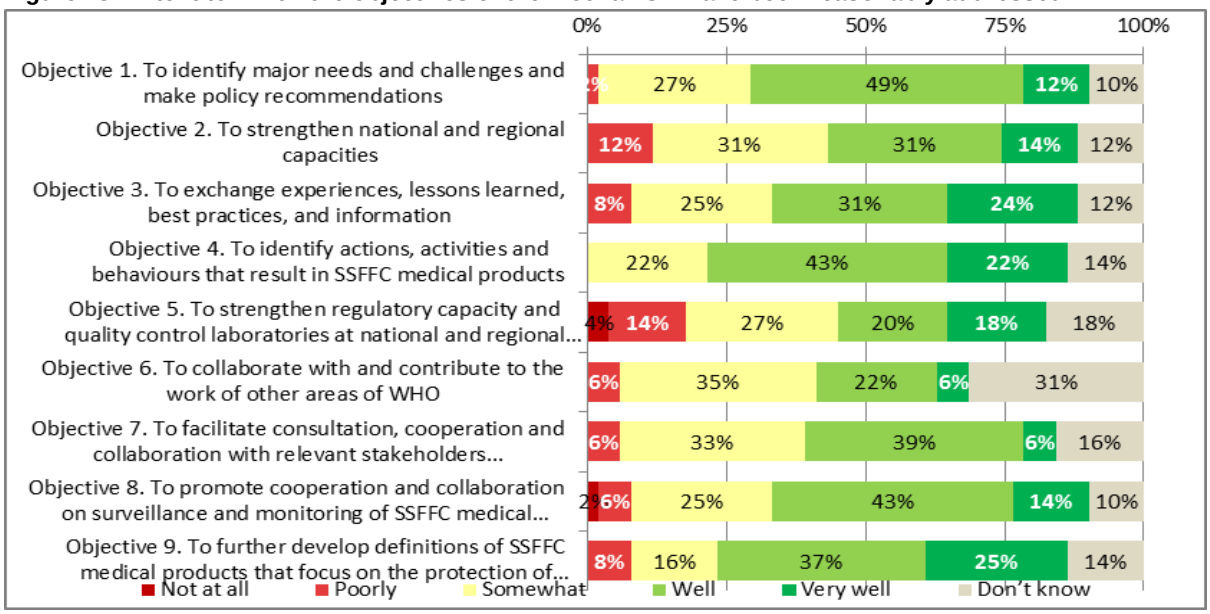
In responses to an open-ended question, weaknesses of communication and dissemination of information on the mechanism were identified as important issues to be addressed. Respondents identified challenges related to inadequate coordination systems between the mechanism and concerned technical units in WHO, and also between the mechanism and Member State focal points for SSFFC medical products. Respondents also felt that the dissemination of information at various levels needed improvement, such as from the Steering Committee meetings to the overall mechanism in relation to the meeting outcomes and to the dissemination of the mechanism products and activities.

Respondents recommended the strengthening of the mechanism's communication and dissemination processes through various means, including increasing the coordination within WHO on SSFFC medical products issues; establishing or enhancing virtual fora and communication tools, including the production of regular online meetings, webinars, newsletters and reports; fostering focal point networks at regional and national levels; and embedding communication activities within related capacity building initiatives. They also highlighted the importance of reaching the national and subnational regulatory structure.

(v) Addressing the objectives of the mechanism

Overall, respondents considered that the original objectives of the mechanism had been reasonably well addressed, with objectives 1 "*To identify major needs and challenges and make policy recommendations*", 4 "*To identify actions, activities and behaviours that result in SSFFC medical products*" and 9 "*To further develop definitions of SSFFC medical products that focus on the protection of public health*" being highly rated ('very well' or 'well' addressed), as shown in Figure 13.

Figure 13: Extent to which the objectives of the mechanism have been reasonably addressed

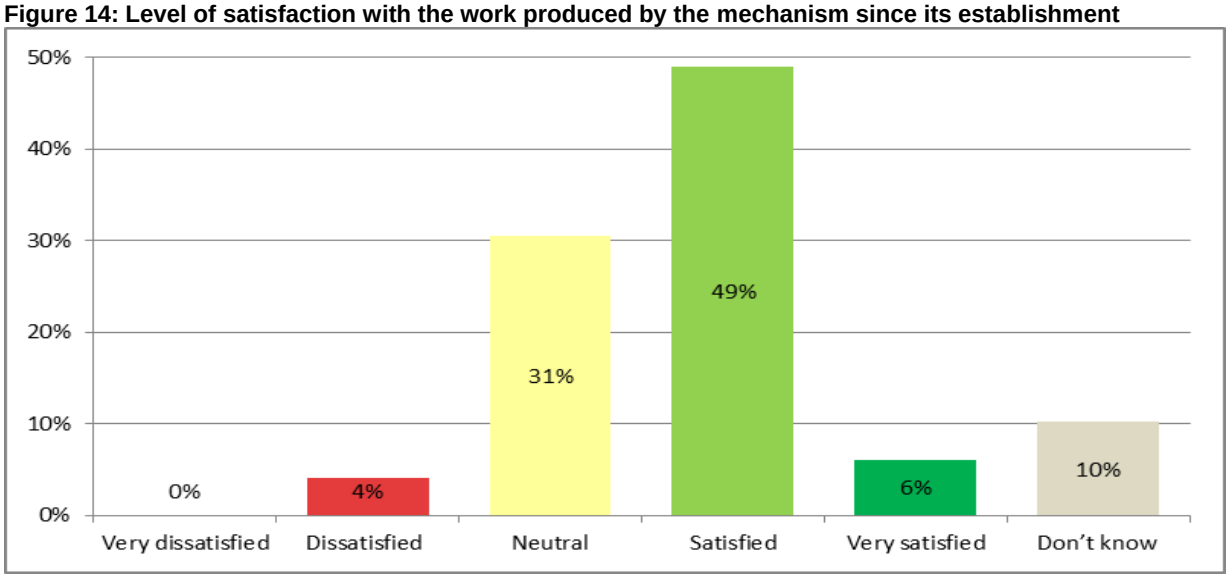


Taken collectively with the responses to earlier questions, these responses reiterate the perception that the mechanism still has an unfinished agenda in terms of achieving its original objectives. They may also point to an evolution in the priorities of the mechanism and its workplan over time, resulting in some objectives having received greater attention than others. In light of the new phase of the mechanism, it may be an opportune time to revisit the mechanism's objectives and workplan.

(vi) Level of satisfaction with the work produced by the mechanism since its establishment

The majority of respondents in this group expressed satisfaction with the work produced by the mechanism since its establishment. Only 4% expressed dissatisfaction with its outputs (Figure 14).

Figure 14: Level of satisfaction with the work produced by the mechanism since its establishment



Interviews

A total of 14 informants, including 4 Steering Committee members and the mechanism secretariat, offered perspectives and informed opinions about the mechanism with regard to achievement of its products and activities. Their views confirmed the findings obtained through the Member State survey.

Interviewees highlighted the evolution of the mechanism over time, recognizing the importance of having built a trusting and collaborative environment which enabled Member States to share their perspectives with regard to prioritizing issues and working collaboratively to address the objectives of the mechanism.

Perspectives of NGOs

Eleven nongovernmental organizations in official relations with WHO responded to the survey. They expressed interest in the goals of the mechanism and in collaborating with global health actors in order to address this critical issue, and shared their satisfaction with the relevance of the objectives of the mechanism. Their extent of knowledge about the specific products and activities was more limited. Only a few have had exposure to some of the products and activities of the mechanism. Those who acknowledged some familiarity with such products also recognized their positive influence in their environment. The agreement on definitions for SSFFC medical products and the creation of a Global Focal Point Network for SSFFC medical products were the activities most valued by the nongovernmental organizations that responded to the survey. Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a programme to contribute to Member State training, were also mentioned as important issues. On the other hand, the actions, activities and behaviours that fall outside the mandate of the mechanism was the least valued area of activity.

In general, nongovernmental organizations showed limited knowledge about the work of the mechanism, and mentioned the need for a dedicated strategy to engage Non-State actors in this undertaking. They encouraged further involvement of Non-State actors in order to improve the effectiveness of the mechanism.

Nongovernmental organizations also recognized the positive effect of the mechanism as a global collaborative platform, and recommended that it should continue, focusing on global surveillance of SSFFC medical products and increased transparency in actions to address the public health issues related to SSFFC medical products.

4. Conclusions

The review found that the mechanism continues to be relevant, it plays a critical role in raising awareness of SSFFC medical products and Member States would want it to continue.

With regard to the extent to which the objectives of the mechanism have been achieved, there is a substantial consensus that the mechanism has made reasonable progress in this regard, given the initial challenges and time required to create the enabling environment for the effective functioning of the mechanism. Member States considered that the mechanism is an adequate global platform to promote the prevention, detection and response to SSFFC medical products and associated activities. They also expressed agreement with the objectives and workplan of the mechanism and noted the value of a number of its products and activities. Overall, stakeholders considered that the mechanism had partially addressed the objectives established in 2012. A key achievement during this period has been the agreement on the definitions of SSFFC medical products (see document A70/23).

Essentially, the formal and informal organizational structures created as a result of the mechanism and the ensuing collaborative climate and trust that emerged are recognized as important and necessary intermediate achievements. The factors that emerged as being supportive were Steering Committee leadership and commitment, the supporting of the mechanism by WHO and the development of good products and the convening of expert and Steering Committee meetings.

However, the main gaps identified are: an unfinished technical agenda; limited coordination processes among the different actors involved in the work of the mechanism; and the inadequate systems of communication and dissemination of information between the mechanism and Member States, as illustrated by the limited reach of the products and activities of the mechanism. Better synergies and improved coordination and sharing of information with Member States, as well as processes linking all three levels of the Organization, could facilitate better strategic planning and coordination of relevant programmes as well as technical support to countries while fostering wider collaboration and engagement, making the mechanism stronger and more successful.

In addition, strengthened communication between Member States and the mechanism, including its secretariat, would facilitate better information flow and sharing of ideas and contribute to the output of the working groups. This would imply more advocacy to inform institutions, manufacturers and other actors about the SSFFC challenges and the achievements of the mechanism.

The review noted that the mechanism was under-resourced, in part as a consequence of not being properly prioritized within WHO and among the actors of the mechanism. The diversity of initial political perspectives and expectations about the mechanism and the evolving operating procedures and governance structure were seen as factors that may have delayed the achievement of the objectives.

When considering options for future action, the mechanism should revisit its current workplan in order to complete outstanding activities. Furthermore, this would also be an opportune moment to consider plans and activities for the next phase and secure sufficient funding to enable the effective delivery of its renewed mandate. Strategically, the mechanism should place greater emphasis on expanding its stakeholder base, involving Member States more

actively as well as regulatory agencies and non-state actors, and consolidate its activities, products, processes and outreach to provide sustainable support to Member States.

5. Recommendations and key actions

1. Members of the Steering Committee of the Member State mechanism to revisit the current workplan, ensuring outstanding activities within the workplan are completed, and consider plans and activities for the next phase.

2. Develop appropriate processes for effective coordination, communication, and dissemination of information on main action areas and outputs.

Action points:

a. strengthen coordination and harmonize procedures between the mechanism and relevant technical teams in WHO at headquarters and regional levels, and between the mechanism and Member States
b. establish better systems for regional communication and dissemination of information between the mechanism and Member States, including strengthening use of electronic platforms and focal point networks
c. improve coordination and communication on SSFFC matters across the three levels of the Organization
d. encourage active engagement of more Member States in the work of the mechanism.

3. Build and expand national capacity to address SSFFC medical products.

Action points:

a. provide training to national focal points on the prevention, detection and response to SSFFC medical products
b. develop tools to support implementation of the mechanism's activities
c. expand the number of Member States that are actively engaged in the process.

4. Secure sufficient additional resources for the mechanism to be able to achieve all of its objectives.

Action points**:**

d. the mechanism should support secretariat efforts to secure additional resources from Member States and the international donor community
e. WHO's senior management should consider prioritising support and funding for the mechanism secretariat.

5. Encourage the engagement of additional actors in the mechanism, including academic institutions, manufacturers, nongovernmental organizations, civil society and related technical institutions at global, regional and country levels.

Annex 1: Review Terms of Reference[1]

1. Following resolution WHA65.19 (2012) and decision WHA68(12) (2015), and the decision of the Steering Committee of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products at its meeting of September 2015, these terms of reference describe the approach to conducting the review of the mechanism. The aim of the review is to estimate the extent to which the mechanism has progressed in achieving its objectives; to identify gaps and remaining challenges; and to make recommendations on the way forward.

Background

2. In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19, in which it decided to establish a Member State mechanism with the general goal of promoting, through effective collaboration among Member States and the Secretariat, the prevention and control of SSFFC medical products and associated activities in order to protect public health and promote access to affordable, safe, efficacious and quality medical products. The mechanism's terms of reference further set out that its functioning would be reviewed after three years of operation. In 2015, the Sixty-eighth World Health Assembly adopted decision WHA68(12), in which it decided to postpone the review of the mechanism by one year.

3. The Steering Committee of the Member State mechanism, at its meeting in September 2015, decided that the review of the mechanism, which will be conducted through an online survey,[2] will examine the success of the mechanism in achieving the objectives set forth in resolution WHA65.19, documenting achievements, gaps and remaining challenges, and that it will make recommendations on the way forward.

4. At the fourth meeting of the Member State mechanism, held on 19 and 20 November 2015, there was agreement that the review process should be led by the WHO Evaluation Office, and that further details on the review, including on the questionnaire, would be provided to the Steering Committee at its meeting in March 2016. Subsequently, the Steering Committee members agreed that, based on decision WHA68(12), the review should cover the period 2012−2016. In this regard, the review will be conducted after the fifth meeting of the Member State mechanism in 2016, following which it will be submitted to the Seventieth World Health Assembly in May 2017. In addition, the review will be uploaded on the Mednet collaborative platform, providing Steering Committee members with an opportunity to view it before it is considered by the Health Assembly.

Objectives of the mechanism

5. The Member State mechanism on SSFFC has the following objectives:[3]

(a) to identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of "substandard/ spurious/falsely-labelled/falsified/counterfeit medical products" in order to strengthen national and regional capacities;

(b) to strengthen national and regional capacities in order to ensure the integrity of the supply chain;

(c) to exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels;

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1 See document A/MSM/5/4.
2 See document A/MSM/5/4 Add.1 for the survey questionnaire.
3 See document WHA65/2012/REC/1, resolution WHA65.19, Annex.

(d) to identify actions, activities and behaviours that result in substandard/spurious/falsely labelled/falsified/counterfeit medical products" and make recommendations, including for improving the quality, safety and efficacy of medical products;

(e) to strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries;

(f) to collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products";

(g) to facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective;

(h) to promote cooperation and collaboration on surveillance and monitoring of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products"; and

(i) to further develop definitions of "substandard/spurious/falsely-labelled/falsified/ counterfeit medical products" that focus on the protection of public health.

Purpose of the review and high level objectives

6. The overall purpose of the review is as follows: to estimate the extent to which the Member State mechanism has progressed in achieving its objectives in the period 2012–2016; to identify gaps and remaining challenges; and to make recommendations on the way forward.

7. The objective of the review is to respond to the following high-level questions:

- To what extent have the objectives of the mechanism been achieved?
- Which are the major gaps in the achievement of those objectives?
- Which are the principal factors that have either supported or hampered the achievement of the mechanism objectives?
- How could the mechanism be more effective in achieving its objectives?

Approach

8. The review will seek the informed opinion of the primary stakeholders of the mechanism, namely, all Member States (including health ministries and national/regional regulatory agencies), together with Secretariat staff involved in supporting the implementation of the mechanism by Member States, such as the mechanism's secretariat and Regional Advisors for essential medicines and health products. It is also proposed that nongovernmental organizations in official relations with WHO[4] are made aware of the review, and that they may express the wish to participate in it, at which point, the Evaluation Office would provide them access to the online survey.

9. The survey will be managed through secure WHO electronic platforms.

[4] Following the adoption by the Sixty-ninth World Health Assembly of the Framework of Engagement with Non-State Actors (resolution WHA69.10), the nongovernmental organizations concerned would fall within the group of non-State actors in official relations with WHO.

10. The scope of the review would cover the implementation of the eight strategies and action areas defined in the work plan of Member State mechanism,[5] together with their relationship with the achievement of the objectives of the mechanism. The review will estimate the extent of implementation of the work plan and will explore its suitability to achieve the corresponding objectives. The review will also explore the factors that may have favoured or hampered implementation of the work plan; and will collect survey respondents' proposed options for improving the effectiveness of the mechanism.

Steering and oversight

11. The review will be managed by the WHO Evaluation Office.

Timeline

12. The review will be conducted during the last quarter of 2016 and the first quarter of 2017, with the intention of finalizing it in time for consideration by the Seventieth World Health Assembly in May 2017. The figure below sets out a high-level timeline.

Figure: Timeline for the review of the Member State mechanism on SSFFC medical products

October 2016: Finalization of questionnaire in collaboration with Steering Committee of the mechanism
November 2016: Presentation of terms of reference and questionnaire to the mechanism
December 2016: Launch of survey to canvass views of stakeholders in the mechanism

February 2017: Finalization of data collection and analysis
March 2017: Presentation of preliminary results to Steering Committee
April 2017: Preliminary results posted in MedNet for review by the mechanism
May 2017: Presentation of review report to Seventieth World Health Assembly

[5] See document A/MSM/2/6, Annex 2.

Annex 2: Methodology

The review was carried out by staff from the WHO Evaluation Office (Itziar Larizgoitia and Simon Bettighofer) supported by an external consultant (Agnes Leotsakos). It was conducted within a timeframe of 4 months, commencing December 2016.

Document review

The document review comprised mainly relevant WHO documents related to MSM activities and progress. The materials that documented and described the work of the Member State mechanism and Steering Committee activities were obtained from WHO websites.[1]

Online survey

The WHO Evaluation Office engaged with members of the Steering Committee during the period March to September 2016 for the development of the Terms of Reference (Annex 1) and the preparation of an online questionnaire for the primary stakeholders of the mechanism, namely all Member States. The questionnaire was submitted to the fifth meeting of the mechanism in November 2016 and was further revised based on feedback received at that meeting.

The online survey was launched on 28 December 2016 in English, French and Spanish (Annex 3). Member States were informed of the survey through a Note Verbale sent to all Member States requesting that they identify appropriate technical focal points to complete the survey. In addition, the WHO Evaluation Office sent electronic communications to individuals on the WHO essential medicines stakeholder databases, comprising national and regional regulatory focal points, inviting them to complete the survey. These databases included over 550 individuals, primarily from health ministries and national and regional drug regulatory authorities. A reminder was sent to stakeholders early in January 2017 and the survey was closed on 31 January 2017.

Nongovernmental organizations in official relations with WHO were made aware of the survey on 9 January 2017 through an electronic communication from the WHO Evaluation Office. A separate survey link was made available to those nongovernmental organizations in official relations with WHO that expressed interest to participate in the survey. Their responses were analysed separately.

Face-to-face/telephone interviews

On 16 December 2016, the WHO Evaluation Office invited all members of the outgoing Steering Committee to participate in a semi-structured interview to complement the survey data and provide insights into the activities of the mechanism. Four members of the outgoing Steering Committee and ten members of the mechanism secretariat, including regional advisors, were interviewed. The interviews lasted for 30-45 minutes and were conducted by members of the evaluation team, either face-to face, where possible, or by telephone, with the exception of two that were received as written comments from the interviewees, due to limited time availability of respondents.

Data analysis and preparation of report

Qualitative data collected through the survey and interviews were analysed by identifying emerging themes and subthemes. Quantitative survey data was analysed through calculation of frequencies and trends in the survey questions. Finally, the data were triangulated to identify common response patterns and draw conclusions. The draft review report was shared with the Steering Committee for review and comments and the findings were presented and discussed during the Steering Committee meeting, 29-30 March 2017. Based on input received from the Steering Committee, the report was finalized and submitted to the Seventieth World Health Assembly.

[1] http://www.who.int/medicines/regulation/ssffc/mechanism/en/
http://www.who.int/medicines/regulation/ssffc/en/
http://apps.who.int/gb/ssffc/

Annex 3: Survey questionnaire (English version)

World Health Organization

Review of the Member State mechanism on substandard/ spurious/ falsely-labelled/ falsified/ counterfeit medical products

Welcome to the online survey.

In order to protect public health and promote access to affordable, safe, efficacious and quality medical products, the Sixty-fifth World Health Assembly adopted resolution WHA65.19 (2012), in which it decided to establish a mechanism whose general goal is to promote effective collaboration among Member States and the Secretariat, for the prevention, detection and response to substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products and associated activities.

In line with the terms of reference of the Member State mechanism, the WHO Evaluation Office is conducting a review of the mechanism in order to gather evidence on its progress. The review, which makes use of this questionnaire, includes the functioning and work of the mechanism during its first four years, namely, for the period 2012−2016. The findings of the review will be presented to the Seventieth World Health Assembly in May 2017. It is expected that this questionnaire will document achievements, gaps and remaining challenges that will enable recommendations on the way forward.

The review will focus on the following high-level criteria :

- The perceived **relevance of the mechanism, its objectives and actions** undertaken
- The **benefits gained by the actions** undertaken under the mechanism
- The **gaps and challenges** that have hindered the achievement of objectives and the **success factors** that have contributed to the achievements of the mechanism
- The **overall appraisal** of the mechanism

Thank you for responding to this questionnaire.

Affiliation of respondent

2) In which country do you work?

[DROPDOWN]: List of WHO Member States and Associate Members

3) What type of institution do you work for?

Choose one of the following answers

- ○ Ministry of Health
- ○ National/Regional Regulatory Agency
- ○ Governmental institution other than those listed above
- ○ Academia/research Institution/other public health-related agency
- ○ Nongovernmental organizations in official relations with WHO active in the pharmaceutical field
- ○ Other (please specify): _____

4) How relevant is the prevention, detection and response to substandard/ spurious/ falsely-labelled/ falsified/ counterfeit (SSFFC) medical products to you and your work?

5) How would you describe your knowledge about the Member State mechanism on SSFFC medical products?

Choose one of the following answers

- ○ I am in general very familiar with it
- ○ I have moderate knowledge about it
- ○ I don't know much about the process, but I know (some) of its outcomes
- ○ I hardly know anything about it
- ○ I had never heard of it before receiving this questionnaire

6) Have you received information about the Member State mechanism on SSFFC medical products?

Check any that apply

- ○ No, I have not received information
- ○ Yes, from WHO headquarters
- ○ Yes, from WHO regional offices
- ○ Yes, from WHO country offices
- ○ Yes, from other sources (please specify): _____

⌧ *FILTER ON: Next question only appears if respondent did not answer "I had never heard of it before receiving this questionnaire" in Question 5*

7) What is your relationship with the mechanism?

Check any that apply

- ○ I am, or have been, a member of the Steering Committee
- ○ I am, or have been, a member of a working group of the mechanism
- ○ I have attended some of the meetings of the mechanism
- ○ I have provided direct advice to the mechanism or to delegates participating in the mechanism
- ○ I have used some of the outputs of the mechanism in my country or work environment
- ○ I am interested at the outcomes of the mechanism
- ○ None of the above /other (please specify): _____

Relevance of the mechanism and its actions

8) The World Health Assembly established a mechanism for international collaboration among Member States to address global issues of relevance from a public health perspective related to substandard/ spurious/ falsely-labelled/ falsified/ counterfeit (SSFFC) medical products.

Please indicate your level of agreement with the following statements:

	(1) Strongly disagree	(2) Disagree	(3) Neutral	(4) Agree	(5) Strongly agree	(-) Don't know
A Member State mechanism is an adequate platform to foster international collaboration to promote the prevention, detection and response to SSFFC medical products **at global level**	○	○	○	○	○	○
A Member State mechanism is an adequate platform to foster international collaboration to promote the prevention, detection and response to SSFFC medical products **at regional level**	○	○	○	○	○	○
A Member State mechanism is an adequate platform to foster international collaboration to promote the prevention, detection and response to SSFFC medical products **at national level**	○	○	○	○	○	○

9) If you want to further elaborate on your opinion regarding these statements, please use the text field below:

10) To what extent do you consider the following objectives are relevant to promoting the prevention, detection and response to substandard/ spurious/ falsely-labelled/ falsified/ counterfeit (SSFFC) medical products and associated activities from a public health perspective?

	(1) Not relevant	(2) Hardly relevant	(3) Moderately relevant	(4) Highly relevant	(5) Extremely relevant	(–) Don't know
Objective 1. To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of SSFFC medical products in order to strengthen national and regional capacities	○	○	○	○	○	○
Objective 2. To strengthen national and regional capacities in order to ensure the integrity of the supply chain	○	○	○	○	○	○

	(1) Not relevant	(2) Hardly relevant	(3) Moderately relevant	(4) Highly relevant	(5) Extremely relevant	(–) Don't know
Objective 3. To exchange experiences, lessons learned, best practices, and information on ongoing activities at national, regional and global levels	○	○	○	○	○	○
Objective 4. To identify actions, activities and behaviours that result in SSFFC medical products and make recommendations, including for improving the quality, safety and efficacy of medical products	○	○	○	○	○	○
Objective 5. To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries	○	○	○	○	○	○
Objective 6. To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of SSFFC medical products	○	○	○	○	○	○
Objective 7. To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective	○	○	○	○	○	○
Objective 8. To promote cooperation and collaboration on surveillance and monitoring of SSFFC medical products	○	○	○	○	○	○
Objective 9. To further develop definitions of SSFFC medical products that focus on the protection of public health	○	○	○	○	○	○

11) Is there any additional objective that you consider important to add?

- ○ Yes
- ○ No

⌧ *FILTER ON: Next question only appears if respondent answered "Yes" in Question 11*

12) If yes, please specify which objective(s) you consider important to add:

Activities undertaken by the mechanism

13) Since 2012, the Member State mechanism has been working on various products/activities in order to achieve its objectives. Do you know or have you received any information about the following products/activities?

	(1) I have never heard of this product or activity	(2) I hardly know anything about this product or activity	(3) I have some knowledge about this product or activity	(4) I am very familiar with this product or activity
Document on actions, activities and behaviours that result in SSFFC medical products	○	○	○	○
Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products	○	○	○	○
Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training	○	○	○	○
Creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum	○	○	○	○
Document on existing technologies and "track and trace" models in use and to be developed by Member States	○	○	○	○

	(1) I have never heard of this product or activity	(2) I hardly know anything about this product or activity	(3) I have some knowledge about this product or activity	(4) I am very familiar with this product or activity
Report on the current state of affairs of WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products	○	○	○	○
Recommendations for effective risk communication and for awareness campaigns on SSFFC medical products	○	○	○	○
A study on the public health and socioeconomic impact of SSFFC medical products	○	○	○	○
Governance, management, and secretariat costs to support the above activities	○	○	○	○
Report on actions, activities and behaviours that fall outside the mandate of the Member State mechanism	○	○	○	○
Work on definitions on SSFFC medical products	○	○	○	○

14) Regarding these products/activities, how would you rate their relevance to promote the prevention, detection and response to substandard/ spurious/ falsely-labelled/ falsified/ counterfeit medical products from a public health perspective?

	(1) Not relevant	(2) Hardly relevant	(3) Moderately relevant	(4) Highly relevant	(5) Extremely relevant	(–) Don't know
Document on actions, activities and behaviours that result in SSFFC medical products	○	○	○	○	○	○
Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products	○	○	○	○	○	○
Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training	○	○	○	○	○	○
Creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum	○	○	○	○	○	○
Document on existing technologies and "track and trace" models in use and to be developed by Member States	○	○	○	○	○	○
Report on the current state of affairs of WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products	○	○	○	○	○	○
Recommendations for effective risk communication and for awareness campaigns on SSFFC medical products	○	○	○	○	○	○
A study on the public health and socioeconomic impact of SSFFC medical products	○	○	○	○	○	○
Governance, management, and secretariat costs to support the above activities	○	○	○	○	○	○
Report on actions, activities and behaviours that fall outside the mandate of the Member State mechanism	○	○	○	○	○	○
Work on definitions on SSFFC medical products	○	○	○	○	○	○

15) Is there any additional product/activity that you consider important to add?

○ Yes
○ No

⌦ *FILTER ON: Next question only appears if respondent answered "Yes" in Question 15*

16) If yes, please specify which additional product/activity you consider important to add:

17) Have you registered with the Global Focal Point Network on SSFFC medical products?

- ○ Yes
- ○ No

18) To what extent have the products/activities listed in the following table been used, adopted or influenced policy and practice in your country or work environment? Please rate the extent of use, adoption or influence of these products/activities based on your knowledge.

	(1) Not at all	(2) Little	(3) Moderate	(4) High	(5) Very high	(–) Don't know	(x) N/A
Document on actions, activities and behaviours that result in SSFFC medical products	○	○	○	○	○	○	○
Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products	○	○	○	○	○	○	○
Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training	○	○	○	○	○	○	○
Creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum	○	○	○	○	○	○	○
Document on existing technologies and "track and trace" models in use and to be developed by Member States	○	○	○	○	○	○	○
Report on the current state of affairs of WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products	○	○	○	○	○	○	○
Report on actions, activities and behaviours that fall outside the mandate of the Member State mechanism	○	○	○	○	○	○	○

19) If possible, please provide examples regarding the products/activities that have been used, adopted or influenced policy and practice in your country or work environment:

20) What is your extent of satisfaction with the products/activities being developed by the mechanism?

	(1) Not at all satisfied	(2) Slightly satisfied	(3) Moderately satisfied	(4) Very satisfied	(5) Extremely satisfied	(–) Don't know	(x) N/A
Document on actions, activities and behaviours that result in SSFFC medical products	○	○	○	○	○	○	○
Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products	○	○	○	○	○	○	○
Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training	○	○	○	○	○	○	○
Creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum	○	○	○	○	○	○	○
Document on existing technologies and "track and trace" models in use and to be developed by Member States	○	○	○	○	○	○	○

	(1) Not at all satisfied	(2) Slightly satisfied	(3) Moderately satisfied	(4) Very satisfied	(5) Extremely satisfied	(–) Don't know	(x) N/A
Report on the current state of affairs of WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products	○	○	○	○	○	○	○
Recommendations for effective risk communication and for awareness campaigns on SSFFC medical products	○	○	○	○	○	○	○
Governance, management, and secretariat costs to support the above activities	○	○	○	○	○	○	○
Report on actions, activities and behaviours that fall outside the mandate of the Member State mechanism	○	○	○	○	○	○	○
Work on definitions on SSFFC medical products	○	○	○	○	○	○	○

21) If you want to further elaborate your opinion regarding your extent of satisfaction with the products/activities, please use the text field below:

Gaps and challenges; success factors and barriers

⌧ *FILTER ON: Next questions only appear if respondent answered one of the following in Question 7*

- ○ I am, or have been, a member of the Steering Committee
- ○ I am, or have been, a member of a working group of the mechanism
- ○ I have attended some of the meetings of the mechanism
- ○ I have provided direct advice to the mechanism or to delegates participating in the mechanism

22) Please, rate your opinion about the adequacy of the various inputs and processes that have served the Member State mechanism.

	(1) Extremely inadequate	(2) Inadequate	(3) Neutral	(4) Adequate	(5) Highly adequate	(–) Don't know
The explicit goals and objectives of the mechanism	○	○	○	○	○	○
The governance structure	○	○	○	○	○	○
The composition of the Steering Committee	○	○	○	○	○	○
The work-procedures of the mechanism	○	○	○	○	○	○
The priority areas of work	○	○	○	○	○	○
The effectiveness of meetings	○	○	○	○	○	○
The effectiveness of the working groups	○	○	○	○	○	○
The technical expertise of the members of the working groups	○	○	○	○	○	○
The technical expertise of external advisers or consultants	○	○	○	○	○	○
The extent and quality of the communication exchanged through the mechanism	○	○	○	○	○	○
The extent and quality of WHO communication and dissemination regarding products of the mechanism	○	○	○	○	○	○
The support provided by the Secretariat regarding communication and dissemination of products of the mechanism	○	○	○	○	○	○
The IT support provided by the Secretariat	○	○	○	○	○	○
The overall support provided by the Secretariat	○	○	○	○	○	○
The financial resources available for the mechanism	○	○	○	○	○	○

23) Which would you consider are the main success factors behind the achievements of the mechanism?

Please use the text field to type your answer.

24) Which would you consider are the main barriers that hindered the progress of the mechanism?

Please use the text field to type your answer.

25) Which would you consider are the best ways to communicate to national or regional regulatory authorities and other stakeholders about the Member State mechanism with a view to generate awareness and promote the use of its products?

Please use the text field to type your answer.

26) To what extent would you consider the objectives of the mechanism have been reasonably addressed?

	(1) Not at all	(2) Poorly	(3) Some-what	(4) Well	(5) Very well	(–) Don't know
Objective 1. To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of SSFFC medical products in order to strengthen national and regional capacities	○	○	○	○	○	○
Objective 2. To strengthen national and regional capacities in order to ensure the integrity of the supply chain	○	○	○	○	○	○
Objective 3. To exchange experiences, lessons learned, best practices, and information on ongoing activities at national, regional and global levels	○	○	○	○	○	○
Objective 4. To identify actions, activities and behaviours that result in SSFFC medical products and make recommendations, including for improving the quality, safety and efficacy of medical products	○	○	○	○	○	○
Objective 5. To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries	○	○	○	○	○	○
Objective 6. To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of SSFFC medical products	○	○	○	○	○	○
Objective 7. To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective	○	○	○	○	○	○
Objective 8. To promote cooperation and collaboration on surveillance and monitoring of SSFFC medical products	○	○	○	○	○	○
Objective 9. To further develop definitions of SSFFC medical products that focus on the protection of public health	○	○	○	○	○	○

Overall appraisal

27) What is your level of satisfaction with the work produced by the mechanism since its establishment in 2012?

(1) Very dissatisfied	(2) Dissatisfied	(3) Neutral	(4) Satisfied	(5) Very satisfied	(-) Don't know
○	○	○	○	○	○

28) If you want to further elaborate regarding this question, please use the text field below:

29) Would you consider any adjustments necessary to the Member State mechanism on SSFFC medical products?

Please use the text field to type your answer.

FILTER OFF: From here including again all respondents that were filtered out before question 22

30) To what degree does the work of the Member State mechanism have a positive or beneficial effect?

	(1) Not at all	(2) To a minor extent	(3) To a moderate extent	(4) To a large extent	(5) To a very large extent	(–) Don't know	(x) N/A
…for your institution?	○	○	○	○	○	○	○
…for your country?	○	○	○	○	○	○	○
…at regional or global level?	○	○	○	○	○	○	○

31) In your opinion, which are the main issues facing your country in effectively promoting the prevention, detection and response to SSFFC medical products from a public health perspective?

Please use the text field to type your answer.

32) In your opinion, which should be the priorities that WHO and the international community should undertake to address the prevention, detection and response to SSFFC medical products?

Please use the text field to type your answer.

33) Is there anything else that you would like to add?

Please use the text field to type your answer.

END OF QUESTIONNAIRE

Thank you for responding to this survey.

If you are willing to be contacted to provide further feedback to the evaluation team, please indicate your name, affiliation and email address below. Your responses will remain private and confidential. If you do not wish to share your contact details, just leave the fields blank.

Name:

Institution:

Mail address:

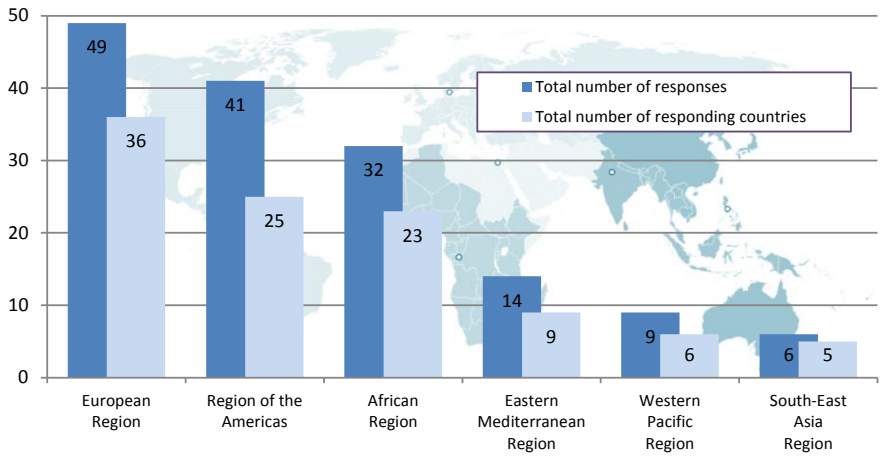
Please click the < Submit > button below to finalize the questionnaire.

Submit the form

Annex 4: Results from the Member State survey (quantitative)

Survey participation

In which country do you work?



Total number of responses

European Region	49
Region of the Americas	41
African Region	32
Eastern Mediterranean Region	14
Western Pacific Region	9
South-East Asia Region	6
Total	**151**

Total number of responding countries

European Region	36
Region of the Americas	25
African Region	23
Eastern Mediterranean Region	9
Western Pacific Region	6
South-East Asia Region	5
Total	**104**

List of responding countries (incl. number of responses, sorted by WHO region)

European Region	
Albania	2
Andorra	1
Armenia	1
Austria	2
Azerbaijan	1
Belarus	1
Belgium	2
Bosnia and Herzegovina	1
Bulgaria	3
Croatia	2
Czechia	1
Estonia	1
Finland	1
Georgia	1
Germany	1
Greece	1
Iceland	1
Italy	1
Latvia	1
Lithuania	1
Luxembourg	1
Malta	1
Monaco	2
Montenegro	3
Norway	2
Portugal	1
Republic of Moldova	1
Romania	1
Russian Federation	1
Slovakia	1
Slovenia	1
Spain	1
Sweden	2
Switzerland	1
Turkey	1
United Kingdom of Great Britain and Northern Ireland	3
Total	**49**

Region of the Americas	
Argentina	2
Bahamas	1
Barbados	1
Belize	2
Brazil	4
Canada	1
Chile	1
Colombia	2
Costa Rica	1
Cuba	1
Dominica	1
Dominican Republic	2
Ecuador	2
El Salvador	3
Guatemala	1
Guyana	1
Haiti	1
Jamaica	2
Mexico	1
Panama	2
Paraguay	2
Peru	1
Suriname	1
United States of America	4
Uruguay	1
Total	**41**

Eastern Mediterranean Region	
Afghanistan	1
Egypt	2
Iran (Islamic Republic of)	2
Iraq	2
Jordan	1
Kuwait	1
Oman	3
Pakistan	1
Sudan	1
Total	**14**

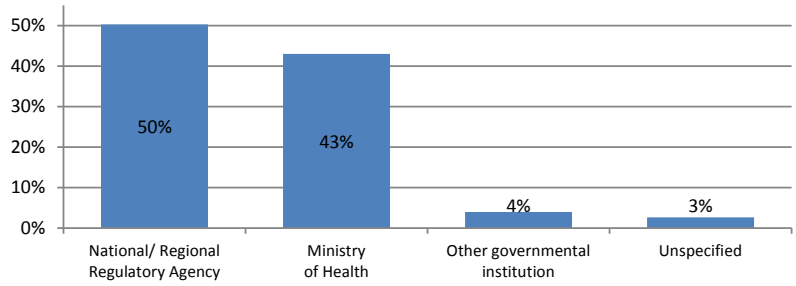
African Region	
Algeria	2
Botswana	2
Burkina Faso	1
Burundi	2
Cabo Verde	2
Comoros	1
Democratic Republic of the Congo	1
Ethiopia	1
Ghana	1
Kenya	1
Madagascar	1
Malawi	1
Mali	1
Mauritius	1
Mozambique	1
Rwanda	3
Senegal	1
Seychelles	2
South Sudan	1
Uganda	1
United Republic of Tanzania	2
Zambia	2
Zimbabwe	1
Total	**32**

Western Pacific Region	
Australia	2
China	1
Fiji	1
Japan	1
Philippines	3
Singapore	1
Total	**9**

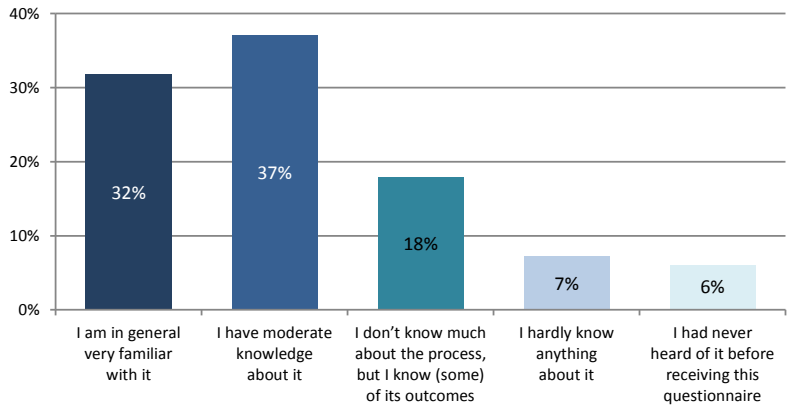
South-East Asia Region	
Bangladesh	1
India	1
Maldives	1
Thailand	1
Timor-Leste	2
Total	**6**

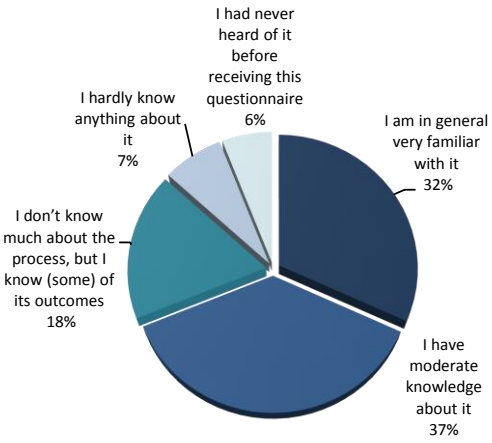
Affiliation of respondent

What type of institution do you work for?

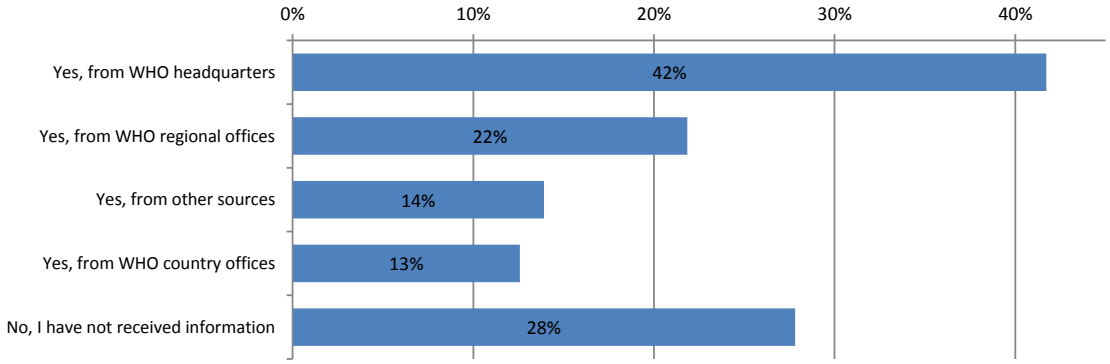


How would you describe your knowledge about the Member State mechanism on SSFFC medical products?

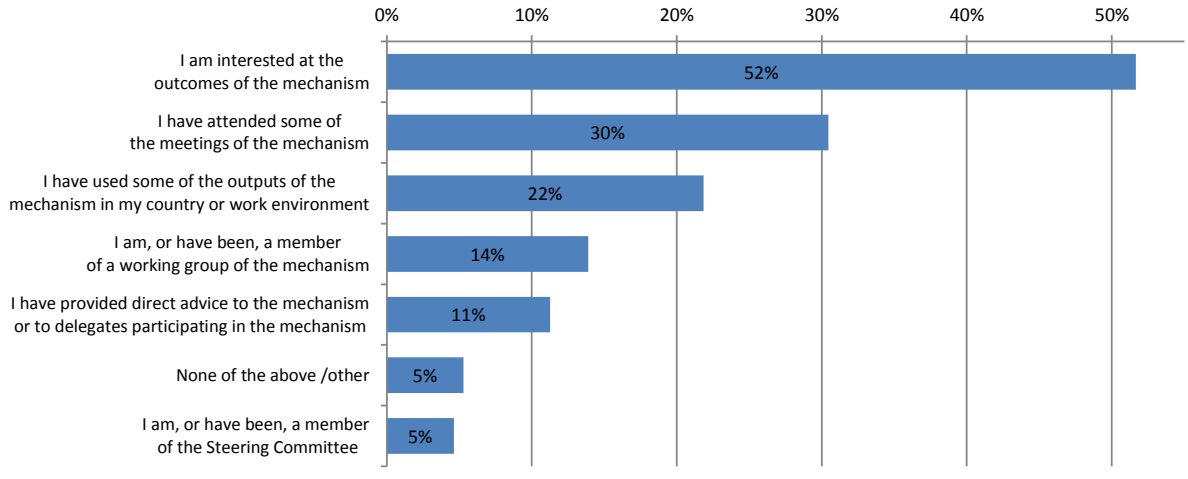




Have you received information about the Member State mechanism on SSFFC medical products? [multiple answers possible]

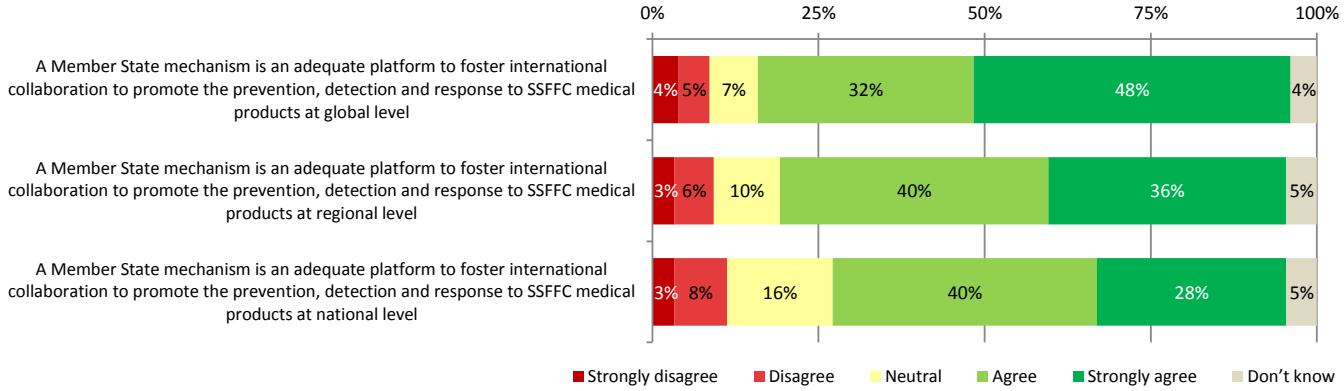


What is your relationship with the mechanism? [multiple answers possible]

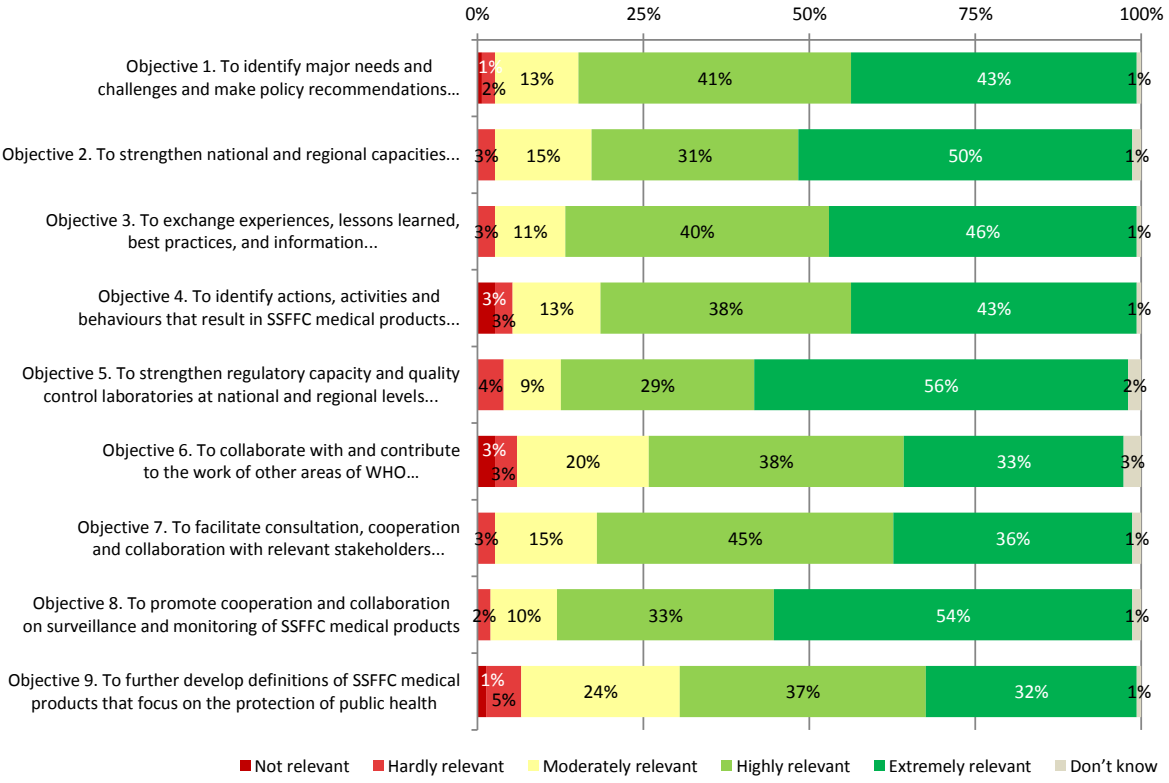


Relevance of the mechanism and its actions

Please indicate your level of agreement with the following statements:

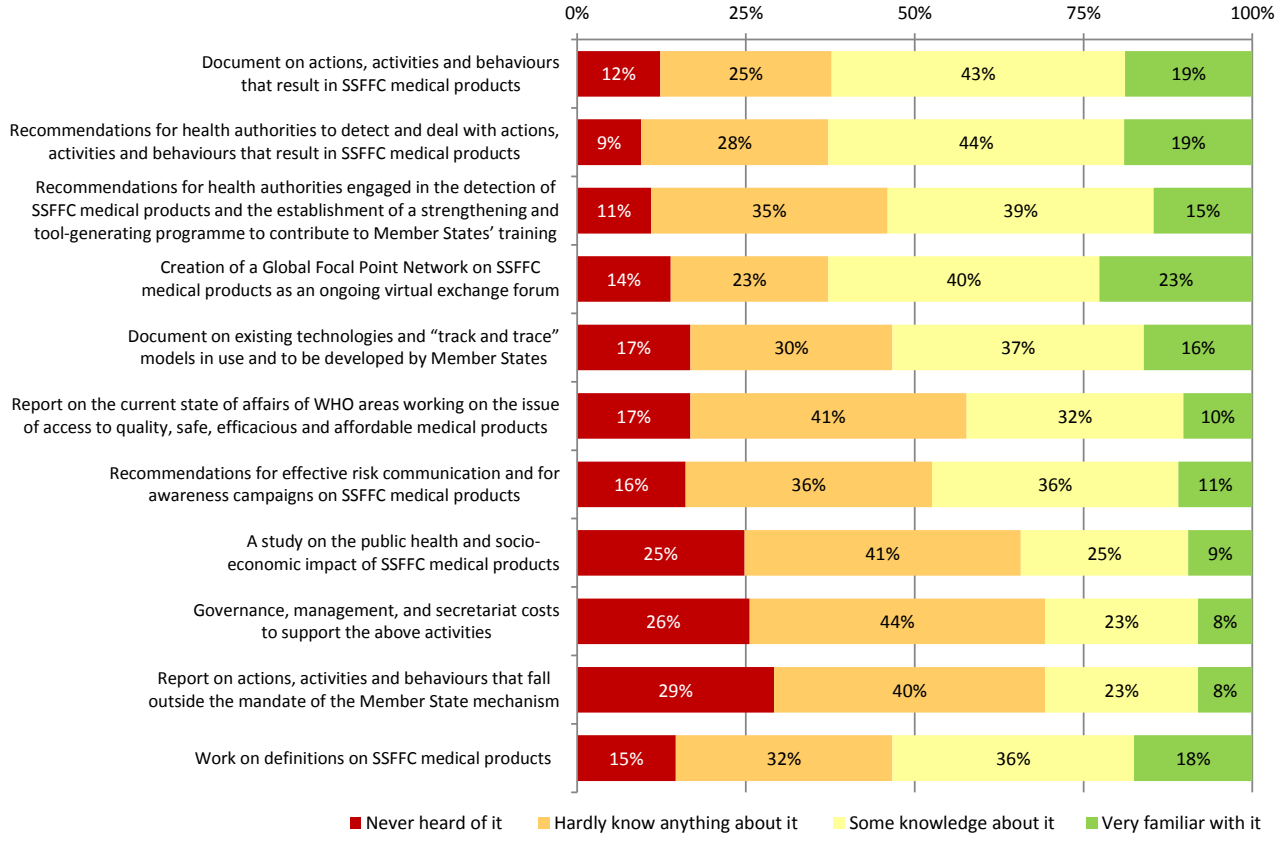


To what extent do you consider the following objectives are relevant to promoting the prevention, detection and response to substandard/ spurious/ falsely-labelled/ falsified/ counterfeit (SSFFC) medical products and associated activities from a public health perspective?

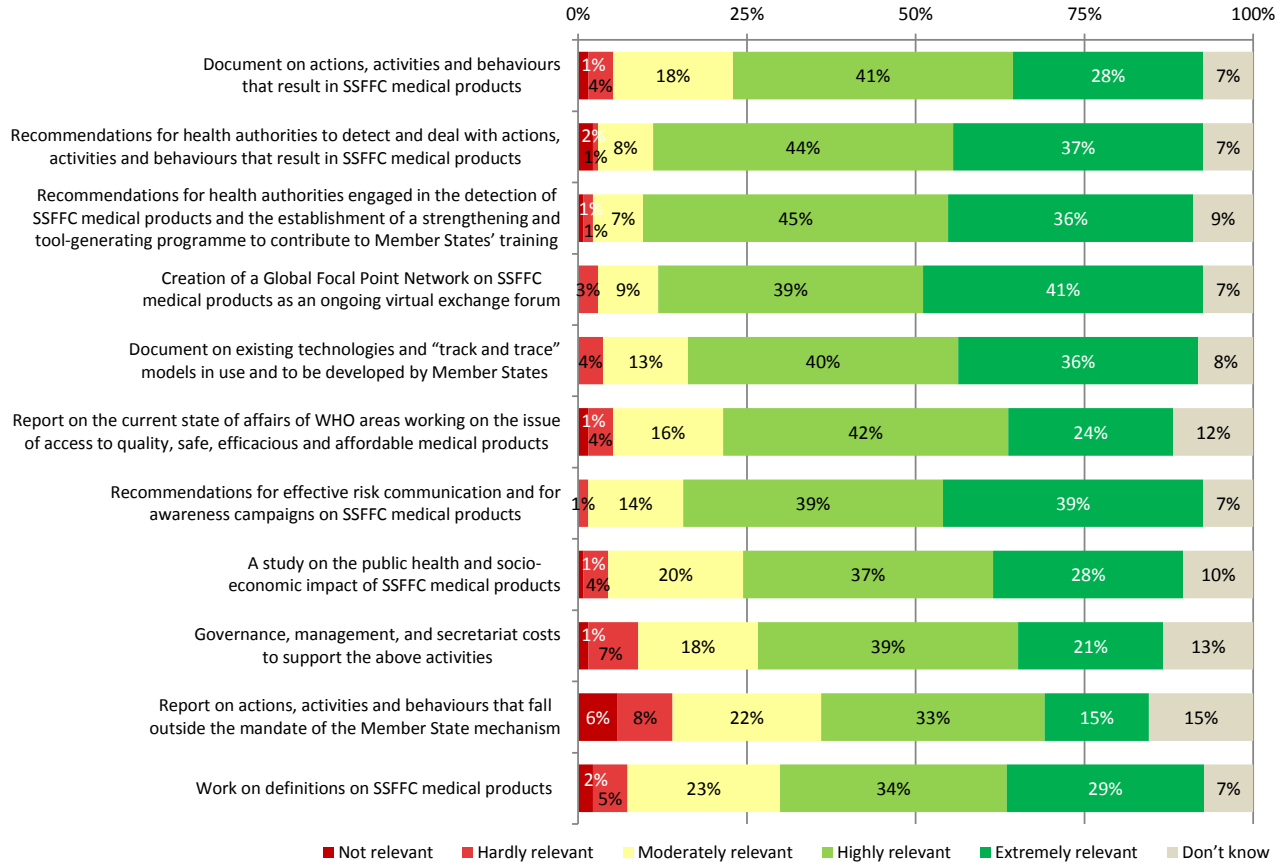


Activities undertaken by the mechanism

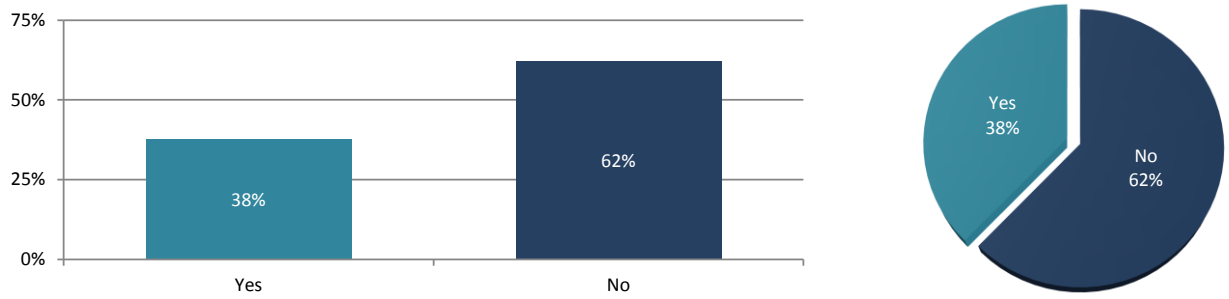
Since 2012, the Member State mechanism has been working on various products/activities in order to achieve its objectives.
Do you know or have you received any information about the following products/activities?



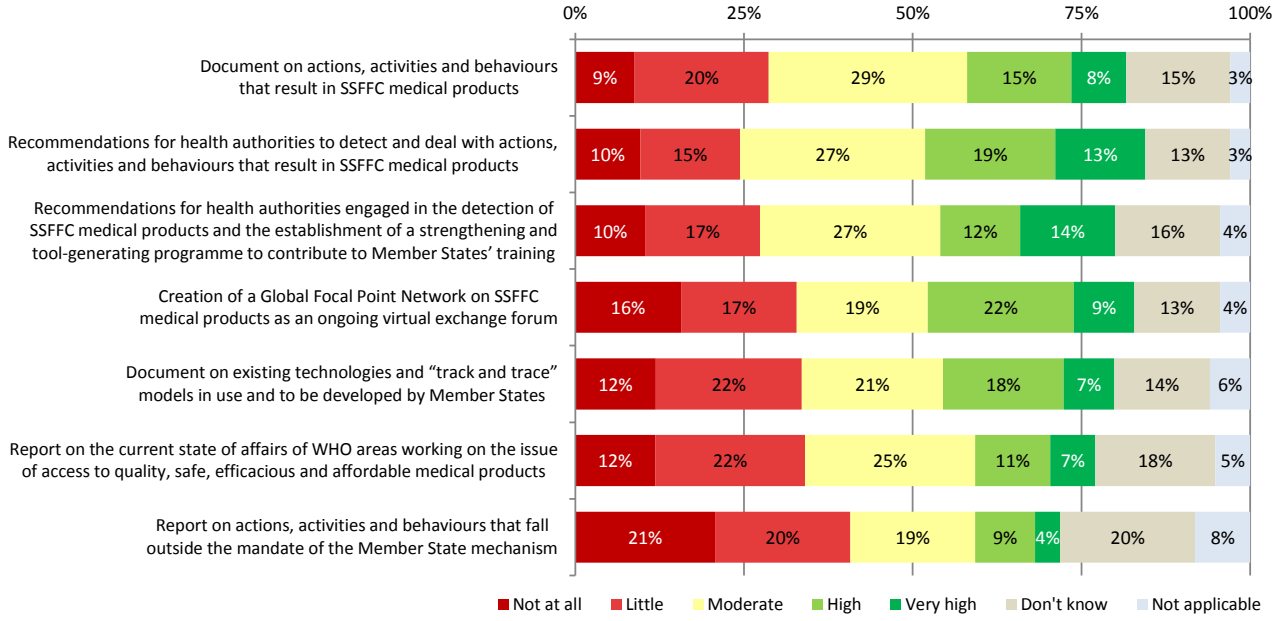
Regarding these products/activities, how would you rate their relevance to promote the prevention, detection and response to substandard/ spurious/ falsely-labelled/ falsified/ counterfeit medical products from a public health perspective?



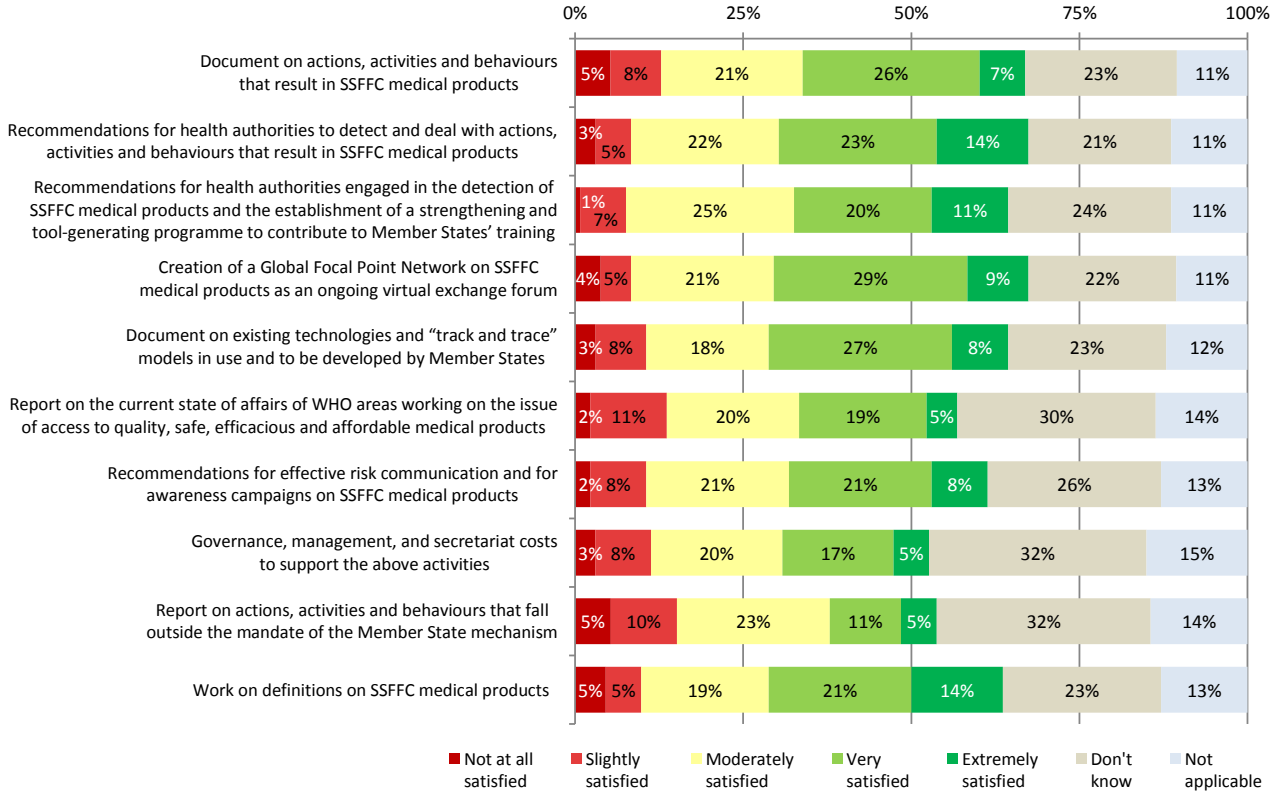
Have you registered with the Global Focal Point Network on SSFFC medical products?



To what extent have the products/activities listed in the following table been used, adopted or influenced policy and practice in your country or work environment? Please rate the extent of use, adoption or influence of these products/activities based on your knowledge.

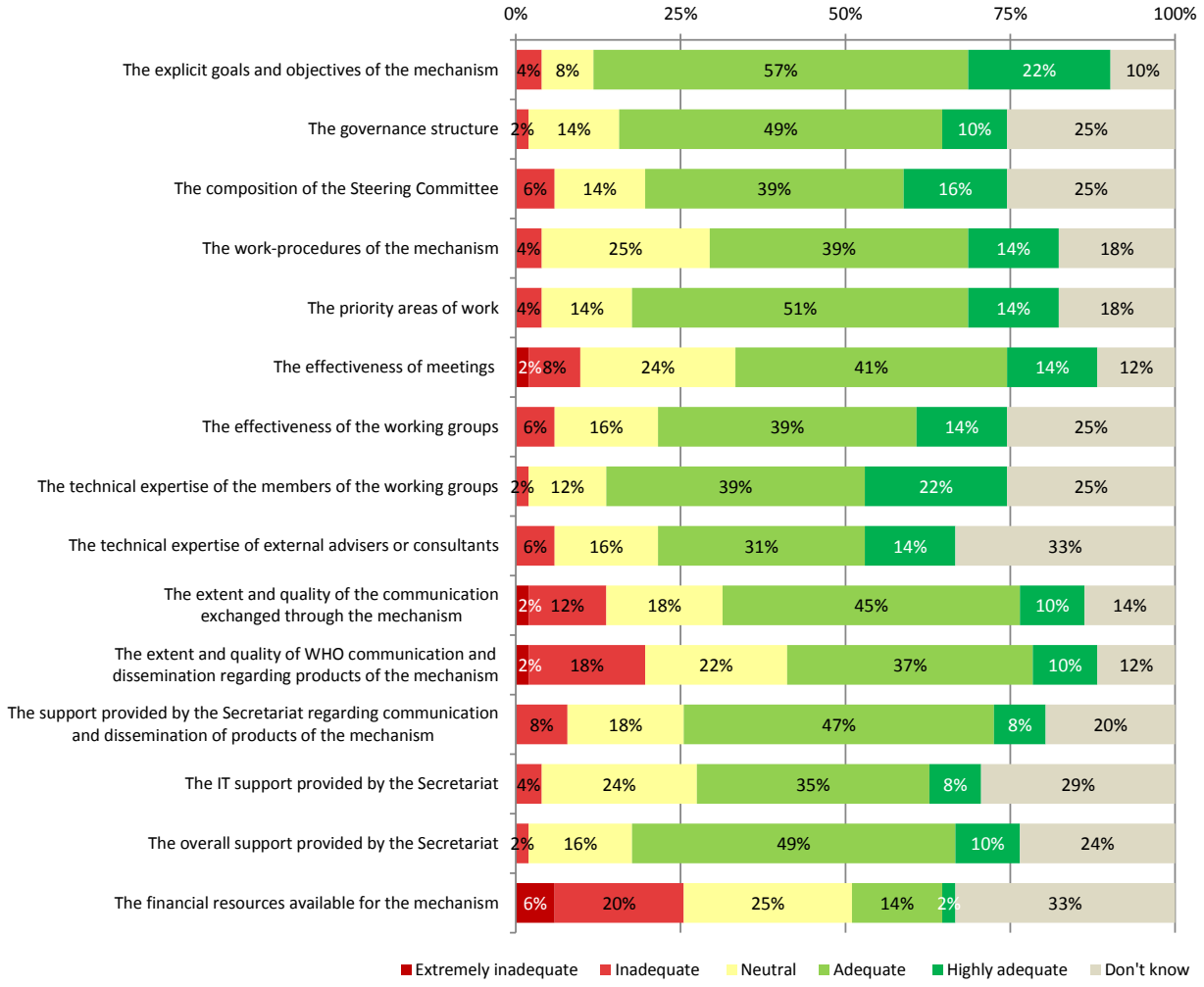


What is your extent of satisfaction with the products/activities being developed by the mechanism?

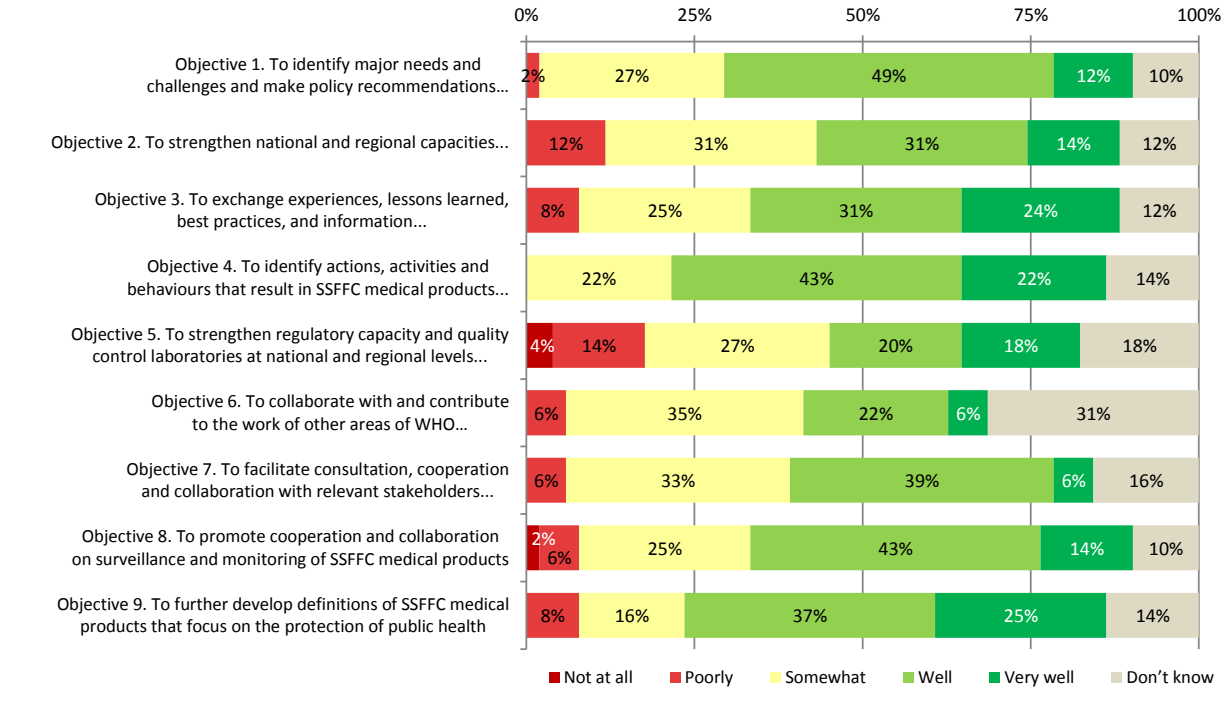


Gaps and challenges; success factors and barriers

Please, rate your opinion about the adequacy of the various inputs and processes that have served the Member State mechanism.

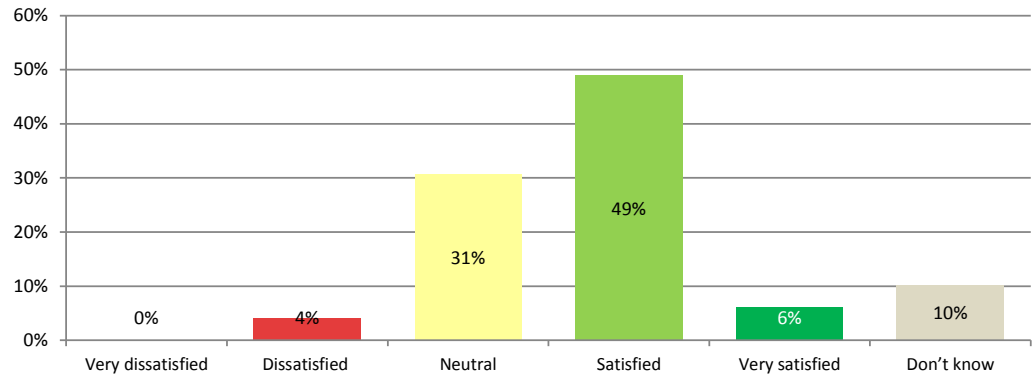


To what extent would you consider the objectives of the mechanism have been reasonably addressed?

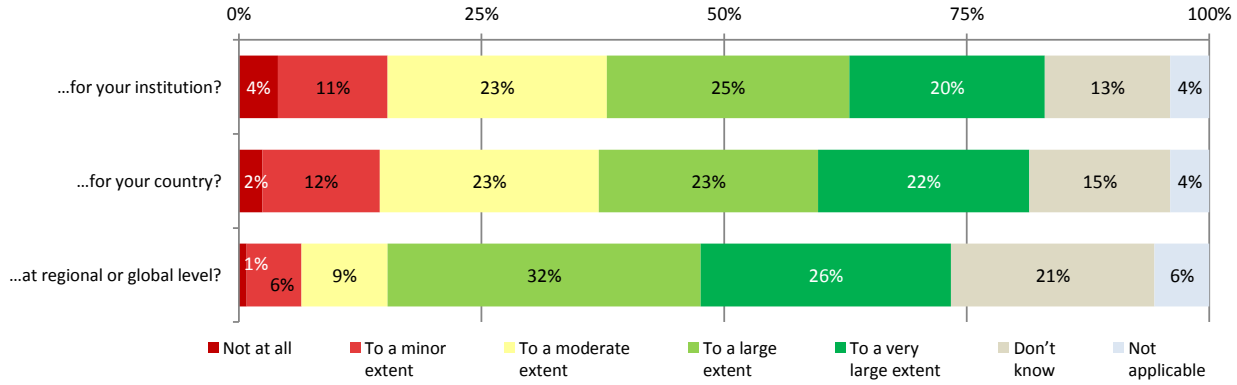


Overall appraisal

What is your level of satisfaction with the work produced by the mechanism since its establishment in 2012?



To what degree does the work of the Member State mechanism have a positive or beneficial effect?



Annex 5: Results from the Member State survey (qualitative)

- **Q4. How relevant is the prevention, detection and response to substandard/ spurious/ falsely-labelled/ falsified/ counterfeit (SSFFC) medical products to you and your work?**

Nearly 120 responses reported that this area is highly relevant and important. Some answered the question by stating that the prevention, detection, and response to SSFFC are '*Important issues or activities of the agency/authority in which they work', 'In line with the mandate of the agency/authority*', '*Within the responsibilities of the agency/authority*' and '*Interesting issues of work*'.

- **Q9. Elaboration on the statement "A Member State mechanism is an adequate platform to foster international collaboration to promote the prevention, detection and response to SSFFC medical products at global level"**

Forty-two respondents reported that the mechanism is in a position to offer better collaboration, sharing of information and experiences between Member States and international organizations, which is a good approach to preventing and detecting SSFFC medical products. A summary of the responses is as follows:

- The Member State mechanism was considered an adequate option for Member States to discuss the main SSFFC subjects, giving the opportunity to countries to acquire more knowledge about the weaknesses and strengths of each regulatory authority in the combat of these illegal practices.
- It is especially an opportunity to share experiences and develop reference documents and broader guidelines contributing to a global scenario of, as safe as possible, medical products.
- International cooperation through such mechanisms is crucial both at global and regional level.
- The mechanism can strengthen and improve Member State cooperation to overcome issues related to SSFFC medical products.
- Through the mechanism, cooperation to address SSFFC medical products has improved, especially for developing countries.
- The Member State mechanism allows information sharing and learning at many levels. It also helps securing accountability. It requires country support and support to implementation of strategies.
- It is important that the mechanism be responsive to local needs in order to have global impact. Local buying in is essential.
- It is also important to promote & ensure access to affordable and quality generic medicines.
- Local actions should also be in synergy with regional initiatives.
- The major benefit is to foster global collaboration, rather than at the national or regional levels.
- International collaboration is the best approach to prevent and detect SSFFC medical products.
- Each country has its own legislation and systems. The undertake required towards a harmonized strategy is enormous. A more cost-effective strategy could envisage fostering strong national policy and legislative frameworks along inspection and enforcing systems.
- The mechanism fosters international collaboration at the global level; it also becomes a national standard adapted to the local context.
- It favours information exchange between like organizations, while allowing for the contribution of intergovernmental organizations in the promotion of best practices and technologies.
- The mechanism facilitates the identification of needs and bottle-necks and issues recommendations; It develops relevant tools and issues recommendations.
- Other tools and systems are being developed by other intergovernmental/regional institutions.
- Tools and indicators should be prepared and disseminated to regional and then to national level and to country office. Every country should prepare their own tools and indicators according to local frameworks.
- It is very important at the global level and for regions lacking regional cooperation. It will be beneficial to some countries.
- Important to strengthen national representation in the mechanism.
- Important that Ministry of Health institutions, other than regulatory agencies, are involved in the mechanism; as well as private institutions and industry.
- The mechanism is important at national level for capacity strengthening; at regional level to facilitate support and at global level to enhance communication.
- Important to enhance global collaboration and promoting national implementation of recommendations.
- Particularly important for developing countries with scarce resources as it facilitates information and knowledge exchange.

- The work of the Member State mechanism has until now produced a comprehensive agenda with good objectives and produced some useful documents. However, the Secretariat has been underfunded and this has to some degree hampered the development of practical support to countries in need of assistance.

- **Q11. Is there any additional objective that you would like to add to the mechanism?**

Twenty respondents provided suggestions as summarized here below:
- Create and maintain a focal point network for the exchange of information and consultation at large, and establish an ongoing virtual exchange forum.
- Develop educational campaigns to promote change of attitudes within population.
- Improve access by reinforcing studies, policies and regulations that promote access to medical products (stock, pricing and reimbursement).
- Establish the extent of the problem of substandard and falsified medical products.
- Capacity building for regulators to detect falsified and substandard medical products at national level together with promoting research into the issue, especially in developing countries.
- Develop and ensure an enabling legal framework to support the control of entry of falsified and substandard medical products into the legitimate supply chain.
- Develop accessible and friendly IT tools aiming to strengthen pharmacovigilance.
- Include SSFFC medical products in pharmacovigilance systems.
- Engage civil society in the combat against SSFFC medical products.
- Engage political support to prevent, detect and respond to SSFFC medical products.
- Address the sales and distribution of SSFFC medical products through internet.
- Strengthen and develop national capacities for manufacture and quality control of medical products.
- Establish synergies with other initiatives and actors.
- Develop a regional observatory on SSFFC medical products to facilitate access to information and guidance to countries with limited capacity.
- Assess the relationship between SSFFC medical products and access to quality and safer care.

- **Q15. Is there any additional product/activity that you consider important to add?**

Fourteen respondents provided suggestions, as summarized:

- Better cooperation with customs, health regulators, national police and the private sector from countries around the world.
- Assess the relationship between SSFFC medical products and access to quality and safer care.
- Foster training and capacity building, including of national regulators.
- Set up a task force to investigate the most hazardous SSFFC medical products and issue recommendations for their prevention, detection and response.
- Convene regular meetings of regulators to facilitate adoption of global strategies and actions.
- Fight the marketing and sales of SSFFC medical products through social media and internet.
- Engage with civil society and consumer organizations.
- Create a global focal point network on SSFFC medical products as an ongoing virtual exchange forum.
- Foster collaboration between national regulatory agencies and national medical products technical units.
- Develop tools for small regulatory agencies.
- Foster Member States' development of national plans against SSFFC medical products.
- Foster the engagement of a broader range of stakeholders at national and global levels; and develop partnerships as appropriate.
- Increase control of manufacturing and international trade, export and transit of SSFFC medical products.

- **Q19. Examples regarding the products/activities that have been used, adopted or influenced policy and practice in your country or work environment.**

There were 35 responses outlining how the mechanism's products have influenced national actions, including:

- Awareness-raising campaigns for SSFFC medical products, including conferences, and development of information materials for healthcare personnel and the public.
- Training of healthcare personnel, students, vendors and the public.
- Setting up national task forces.
- Setting national guidelines.
- Development of standard operating procedures for the registration of medical products.

- Legal developments to combat SSFFC medical products, including strengthening of border control, and improved collaboration and exchange of information with other national authorities and international institutions.
- Quality drug alerts and exchange of alert; and adoption of the WHO Rapid Alert system.
- Strengthening monitoring of the quality of medicines.
- Strengthening inspection of imports of medical products, border control and collaboration across national relevant authorities.
- Incorporation of safety devices.
- National adaptation of Member State mechanism documents.
- Development of national policy and regulation and of programmes (i.e. track and trace programmes) for the prevention, detection and response to SSFFC medical products, based on guidance produced by the mechanism.
- Adoption of new Member State mechanism definitions.
- Involvement in the Global Focal Point Network on SSFFC medical products, and establishment of national focal points.
- Risk factors identification.
- Preparation of national action plans against antimicrobial resistance in relation to the combat against SSFFC medical products.

- **Q21. Further elaboration on extent of satisfaction with the products/activities of the mechanism.**

Twenty-one responses were provided. Some respondents addressed the fact that there is not enough knowledge of the developed products/activities in national agencies, or that information is not shared in a timely manner, or even that, although some nationals are aware of the Member State mechanism recommendations, actions and activities, they are not properly disseminated among the responsible persons dealing with SSFFC medical products. However, two out of 21 responses expressed interest and satisfaction with specific products developed by the mechanism, such as the document on 'Available authentication technologies for the prevention and detection of SSFFC medical products. A summary of the responses is as follows:

- Distribution of information is improving, though it has been less fluid.
- Many respondents highlighted the limited access to the documents.
- Distribution of information within countries is also challenged. It was noted that key national stakeholders, notably from regulatory agencies, and those responsible for the implementation of the mechanism recommendations, do not participate in the mechanism.
- Some respondents encouraged strengthening the dissemination of documents throughout WHO country offices.
- Some respondents noted the lack of relevance of the products and activities for countries with advanced development in the area of prevention, detection and response to SSFFC medical products.
- Some respondent cautioned against the possible confusion that may be generated by the removal of the term "counterfeit" from the SSFFC designation; and highlighted that such removal would require adequate national legislation and scientific determinations that many countries may be unable to address.

- **Q23. Which would you consider are the main success factors behind the achievements of the mechanism?**

Thirty-five respondents identified success factors. A summary of their responses is as follows:

- Commitment of Member States and their interest to focus more on technical rather than political aspects.
- Leadership and collaboration between Member States.
- Close cooperation between Member States and WHO and the contribution of technical experts.
- Technical expertise of the members of the working groups and of regulators participating in the development of the products.
- Exchange of experience and information.
- Consensus that SSFFC medical products are a threat to public health and safety globally and the need for global collaboration to control the menace posed by SSFFC.
- International encounters and the creation of a forum to share and exchange information between Member States.
- Build-up of trust among representatives in the Steering Committee and plenary.
- The fact that the issue of SSFFC has been put on the agenda of WHO Member States is in itself a success.
- Implementation at national level of products of the mechanism.
- Goals and priority areas of the mechanism.
- WHO-developed Website that enables access for all Member States to the products of the mechanism.
- Support provided by the Secretariat.
- Support provided by the WHO Rapid Alert Project.

- **Q24. Which would you consider are the main barriers that hindered the progress of the mechanism?**

Thirty-five respondents also provided insights into the main barriers hindering progress of the mechanism, as follows:

- An overwhelming majority addressed the issue of limited resources for the mechanism, and within Member States.
- Limited engagement of many Member States leading to geographical imbalances in plenary meetings of the mechanism.
- Poor communication and collaboration amongst partners, the international community regional groups, and Member States' focal points was highlighted as another challenge.
- Inadequate access to or exchange of information, particularly for the regulatory agencies, was of major importance in hindering progress of the mechanism.
- Lack of more tangible results and specific added value compared to other existing platforms.
- Political differences in understanding regarding goals and objectives, particularly at the start.
- Need for more expert input from national medicines regulatory agencies and external experts.
- Lack of harmonisation of regulatory frameworks.
- Inadequate legal and supporting infrastructures to support prevention, detection and response to SSFFC medical products in some Member States.
- Excessive rotation of representatives of some countries.
- Lack of consensus on the definitions in the early stages.
- Need to develop the mechanism at the country level.
- Limited IT communication platforms and tools. Difficulty to liaise remotely with Member State representatives.
- Limited awareness of all Member States about the mechanism.
- Effectiveness of the working groups.
- Extent and quality of WHO communication and dissemination regarding products of the mechanism.

- **Q25. Which are the best ways to communicate to national or regional regulatory authorities and other stakeholders about the Member State mechanism with a view to generate awareness and promote the use of its products?**

Thirty-three respondents suggested the following ways to strengthening communication with stakeholders of the mechanism:

- Strengthen collaboration with WHO country and regional offices to disseminate information about SSFFC medical products.
- Strengthen network and engagement of national regulatory focal points.
- Increase translation of the reports and outputs of the mechanism.
- Strengthen capacity building along dissemination of information.
- Leverage visibility of the mechanism at WHO governing bodies and WHO leadership.
- More active role of the secretariat and WHO in disseminating information through official and non-official channels.
- Engage other non-health actors in the mechanism.
- Strengthen communication tools, including discussion forums for national focal points, newsletters, push-emails; workshops; periodic reports showing the outputs of the mechanism, articles, etc.
- Revamp the WHO website for the MSM mechanism, increasing its accessibility and visibility (linking it with related technical areas) and keeping it up to date.

- **Q28. Further elaboration on the satisfaction with the work produced by the mechanism since its establishment in 2012?**

Fourteen respondents contributed to this question, as summarized below:

- The mechanism could still be more effective. The secretariat should be strengthened with additional resources.
- The level of engagement and technical support provided by Member States have led to its good outputs.
- The mechanism has made important achievements.
- The mechanism should aim to produce more documents.
- Some of the achievements, such as arriving at definition and related guidance and other documents. are excellent work.
- The mechanism must continue its endeavour till its objectives are met.
- More dissemination is necessary.

- **Q29. Would you consider any adjustments necessary to the Member State mechanism on SSFFC medical products?**

Some specific comments are described below:

- The mechanism must develop a means of identifying the needs of each Member States and ways to help that Member State to achieve the objectives
- The mechanism must also work in support of relevant legislation reform.
- Improve the communication and information sharing mechanisms, including with the national regulatory agencies.
- Facilitate developing countries to participate in the mechanism.
- Finalize pending priority activities.
- Expand engagement of other non-health relevant actors, such as representatives of the enforcement and judiciary system and of border control.
- Focus and build on regional recommendations rather that only top-down.
- Increase funding support from WHO assessed contributions.
- Consider financing Member States requiring long distance travel to attend meetings.
- Revise criteria for priority setting.
- Strengthen national capacity building and support implementation.

- **Q31. In your opinion, which are the main issues facing your country in effectively promoting the prevention, detection and response to SSFFC medical products from a public health perspective?**

Ninety respondents provided their opinion on the main issues in the area of SSFFC medical products from a public health perspective. A summary of these is as follows:

- Limited awareness by leadership.
- Lack of understanding among relevant stakeholders of the consequences of SSFFC medical products.
- Lack of awareness and knowledge on the part of the public and civil society; and health care personnel.
- Lack of access by the public to quality and safe essential medicines.
- Lack of knowledge about the extent of the problem at country level; and insufficient understanding of the global picture.
- Limited coordination across relevant institutions and stakeholders at country level.
- Limited capacity, including technical expertise, and skilled human resources, institutional development, national quality control laboratories and portable laboratories.
- Difficulty of border controls.
- Lack of access to required laboratory supplies.
- Limited funding to enable implementation of activities, including awareness raising and training.
- Need for technical and financial assistance.
- Insufficient legislative and normative frameworks, including insufficient enforcing mechanisms, and difficulties to strengthen the legislative framework.
- Insufficient implementation of legislation and quality control procedures.
- Lack of dedicated policies for addressing SSFFC medical products.
- Inadequate regulatory capacity.
- Need to improve market surveillance.
- Limited track and trace systems; and testing capacity.
- Lack of systems to control, prevent and respond to the entrance of SSFFC medical products through internet.
- Challenge of creating strategies that respond to supply chain diversification and growing online distribution.

- **Q32. In your opinion, which should be the priorities that WHO and the international community should undertake to address the prevention, detection and response to SSFFC medical products?**

Some feedback is presented below:

- Make access to quality and affordable medicines a focus of the mechanism.
- Foster Member State engagement in the activities of the mechanism, facilitating engagement of developing countries.
- Foster collaboration among Member States for the prevention, detection and response to SSFFC medical products; including development of secure communication platform for the exchange of information, alerts and pre-alerts.
- Facilitate the establishment of regional collaboration among Member States for the identification of common needs and issues, promotion of activities and implementation of recommendations.
- Foster engagement of engagement of civil society, non-health sector stakeholders, health professionals, regulators and administrators at national, regional and global levels; as well the industry and private sectors.
- Strengthen the global network of regulatory focal points, and support their capacity and access to relevant information.
- Strengthen communications and dissemination of the work and outcomes of the mechanism to Member States, including through the use of secure electronic platforms, and foster more active dissemination throughout relevant national technical units.
- Foster awareness raising campaigns about the risk of SSFFC medical products Develop global policies, strategies and global and regional plans of action to coordinate relevant stakeholders in the combat against SSFFC medical products, including the combat of illegal transactions of medical products through the internet; and the effective supply of quality and safe medical products and essential medicines.
- Develop guidelines and standards for the prevention, detection and response to SSFFC medical products and enable the tracing of the supply chain.
- Develop tools to identify SSFFC medical products; including fostering of technological innovations, and support Member States with instruments so that they can identify SSFFC medical products; including support for the establishment of regional and national quality control laboratories.
- Strengthen market and post-market surveillance and pharmacovigilance systems; as well as relevant information exchange.
- Strengthen capacity of national and regional regulatory agencies and quality control laboratories, with special attention to developing countries.
- Strengthen country capacity for the development and adoption of legislative frameworks and strategies and activities for the prevention, detection and response to SSFFC medical products, including risk communication and awareness campaign training.
- Enhance country technical support in the implementation of strategies for the prevention, detection and response to SSFFC medical products, including development of national plans, implementation of the global track and trace systems, and integrity of the supply chain.
- Allocate resources for the effective coordination of actions against SSFFC medical products.
- Clarify definitions for SSFFC medical products, including the role of authorities with regard to counterfeit products in the light of the revised definitions proposed by the mechanism.
- Consider fostering harmonization of national regulatory systems in relation to SSFFC medical products.
- Reflect on lessons learned during its first phase 2012-2016. It must continue and redefine its objective as time requires.

Annex 6: Documents reviewed

Resolution WHA65.19, Substandard/spurious/falsely-labelled/falsified/counterfeit medical products http://www.who.int/medicines/services/counterfeit/mechanism/WHA65.19_extract.pdf?ua=1, http://www.who.int/medicines/regulation/ssffc/mechanism/en/ , accessed January 2017.

Decision WHA68(12), Substandard/spurious/falsely-labelled/falsified/counterfeit medical products http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_DIV3-en.pdf, accessed January 2017.

The economic cost of IPR infringement, EUIPO, September 2016 https://euipo.europa.eu/ohimportal/en/web/observatory/ipr-infringement-pharmaceutical-sector, accessed March 2017.

Report of the Steering Committee of the Member State mechanism on substandard/spurious/ falsely-labelled/falsified/counterfeit medical products, including the draft work plan as proposed by the Steering Committee, 12 September 2013 http://apps.who.int/gb/ssffc/pdf_files/A_MSM2_2-en.pdf, accessed January 2017.

Report of the third meeting of the Member State mechanism on substandard/spurious/ falsely-labelled falsified/counterfeit medical products, 31 October 2014 http://apps.who.int/gb/ssffc/pdf_files/MSM3/A_MSM3_3-en.pdf, accessed February 2017.

European Commission: Medicinal products for human use https://ec.europa.eu/health/human-use/falsified_medicines_en, accessed January 2017.

European Medicines Agency, Human medicines: regulatory information http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/human_medicines_regulatory.jsp&mid=, accessed January 2017.

Review of the Member State mechanism by the Health Assembly in 2017 - Proposed approach and modalities, 13 November 2015 http://apps.who.int/gb/ssffc/pdf_files/MSM4/A_MSM4_9-en.pdf, accessed January 2017.

Report of the fourth meeting of the Member State mechanism on substandard/spurious/ falsely-labelled/falsified/counterfeit medical products, 15 December 2015 http://apps.who.int/gb/ssffc/pdf_files/MSM4/A_MSM4_10-en.pdf, accessed January 2017.

Review of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products - survey questionnaire, 4 November 2016 http://apps.who.int/gb/ssffc/pdf_files/MSM5/A_MSM5_4Add1-en.pdf,accessed January 2017.

Document A69/41, Substandard/spurious/falsely-labelled/falsified/counterfeit medical products - Report by the Director-General http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_41-en.pdf, accessed February 2017.