WHO standards for quality, safety and efficacy of health products
Stakeholder feedback report
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Stakeholder feedback report
## Contents

Acknowledgements........................................................................................................................................ iv  
List of abbreviations...................................................................................................................................... v  
Executive Summary......................................................................................................................................... vi  
Introduction .................................................................................................................................................. 1  
Approach...................................................................................................................................................... 2  
Results.......................................................................................................................................................... 3  
  Respondents ................................................................................................................................................ 3  
  Adoption of WHO guidelines ........................................................................................................................ 3  
  Use of other Guidelines ............................................................................................................................... 6  
  Benefits and disadvantages of adopting WHO guidelines ............................................................................ 7  
  Factors that support or impede adoption and implementation of WHO guidelines ............................. 8  
  Features that strengthen adoption .............................................................................................................. 9  
  Future Development of WHO Guidelines ................................................................................................... 12  
Discussion.................................................................................................................................................... 15  
Conclusions.................................................................................................................................................. 17
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### List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BSI</td>
<td>British Standards Institution</td>
</tr>
<tr>
<td>GL</td>
<td>Guideline</td>
</tr>
<tr>
<td>GL Blood GMP</td>
<td>WHO guidelines on good manufacturing practices for blood establishments</td>
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<tr>
<td>GL Procurement</td>
<td>Model quality assurance system for procurement agencies</td>
</tr>
<tr>
<td>GL Influenza vaccine</td>
<td>Recommendations for the production and control of influenza vaccine (inactivated)</td>
</tr>
<tr>
<td>GL Stability</td>
<td>Stability testing of active pharmaceutical ingredients and finished pharmaceutical products</td>
</tr>
<tr>
<td>GL HVAC</td>
<td>Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products</td>
</tr>
<tr>
<td>GL Vaccine lot approval</td>
<td>Guidelines for independent lot release of vaccines by regulatory authorities</td>
</tr>
<tr>
<td>GL Biologics change approval</td>
<td>Guidelines on procedures and data requirements for changes to approved biotherapeutic products</td>
</tr>
<tr>
<td>GL Biologics GMP</td>
<td>WHO good manufacturing practices for biological products</td>
</tr>
<tr>
<td>HVAC</td>
<td>Heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products</td>
</tr>
<tr>
<td>ICH</td>
<td>International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<tr>
<td>ISPE</td>
<td>International Society for Pharmaceutical Engineering</td>
</tr>
<tr>
<td>NRA</td>
<td>A National Regulatory Authority for the quality, safety and efficacy of health products</td>
</tr>
<tr>
<td>PIC/S</td>
<td>Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme</td>
</tr>
<tr>
<td>QMS</td>
<td>Quality Management System</td>
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<td>WHO</td>
<td>World Health Organization</td>
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</table>
Executive Summary

Universal health coverage includes appropriate access to affordable and quality-assured medicines, vaccines and health products. The Secretariat is charged with the tasks of developing and maintaining global norms, international standards and guidelines for the quality, safety and efficacy of health products, as well as providing guidance on harmonized implementation efforts.

To better understand Member State needs for WHO standards and guidelines for the quality, safety and efficacy of health products, a stakeholder feedback survey was conducted on 8 WHO guidelines. 83 stakeholders participated from 13 Member States. This report presents the approach, results, and results analysis regarding the levels of adoption and factors that impede or support adoption of the selected WHO guidelines for health products.

Overall, the results provide useful information on the approach for obtaining feedback on guideline adoption and implementation. With some modifications the approach could be repeated to monitor the adoption of the same WHO guidelines as reviewed in this survey. However, alternative approaches to surveys are needed for more efficient monitoring of the adoption and implementation of WHO guidelines.

The findings show that WHO guidelines on quality, safety and efficacy of health products are generally partially or fully adopted although more work is needed to understand how adoption could be enhanced. The results of this survey indicate that other non-WHO guidelines are frequently in use alone or in conjunction with WHO guidelines. A better understanding is needed for why one guideline may be used over another or how one guideline may inform the other. There may also be opportunities for enhanced collaboration between WHO and other standard setting organizations to harmonize similar guidelines.

The survey results provide important feedback on the future development of WHO guidelines such as better access to WHO guidelines through fast internet search results, for searchable formats, and for translations to national languages where necessary. The results also indicate areas for further work such as to understand the specificities around the national legislation and mandatory requirements so that guidelines can be adapted to these requirements.

The results of this survey demonstrate the need for the continued role of WHO in promoting and facilitating harmonization of norms and standards on quality, safety and efficacy of health products.
Introduction

The World Health Organization (WHO) Constitution mandates that the organization develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products. WHO has been implementing this mandate since the establishment of the Constitution and in line with the universal health coverage goals of the 13th WHO General Programme of Work.

Universal health coverage includes appropriate access to affordable and quality-assured medicines, vaccines and health products (including medical devices, as well as blood and blood products). The Secretariat is charged with the tasks of developing and maintaining global norms, international standards and guidelines for the quality, safety and efficacy of health products, as well as providing guidance on harmonized implementation efforts.

To better understand Member State needs for WHO guidelines for the quality, safety and efficacy of health products, a stakeholder feedback survey was conducted. The main objective of the survey was to assess whether selected WHO guidelines covering pharmaceuticals, vaccines, biological therapeutics, blood and blood products are relevant, used and meet the needs of Member States. Specific objectives included to:

1. Develop an approach to monitor and evaluate the adoption and implementation of guidelines.
2. Determine the levels of adoption of the selected guidelines.
3. Understand the factors that support or impede adoption and implementation of the selected guidelines.
4. Assess opportunities for collaboration with other standard setting organizations to facilitate the adoption and implementation of WHO guidelines.
5. Determine applicability of the approach to other WHO guidelines and physical reference standards.

This report presents the approach, results, results analysis and conclusions regarding these specific objectives.
Approach

Criteria for choosing which WHO guidelines to include in the feedback survey were developed. It was decided to select a range of guidelines covering biotherapeutic, blood, pharmaceutical, and vaccine guidelines; recent (2015-2020), relatively recent (2000 to 2015) and older guidelines (before 200); and those having either a wide or a narrow, scope. Using these criteria, the following WHO guidelines were selected for obtaining feedback:

1. WHO guidelines on good manufacturing practices for blood establishments (GL Blood GMP)
2. Model quality assurance system for procurement agencies (GL Procurement)
3. Recommendations for the production and control of influenza vaccine (inactivated) (GL Influenza vaccine)
4. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (GL Stability)
5. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (GL HVAC)
6. Guidelines for independent lot release of vaccines by regulatory authorities (GL Vaccine lot approval)
7. Guidelines on procedures and data requirements for changes to approved biotherapeutic products (GL Biologics change approval)
8. WHO good manufacturing practices for biological products (GL Biologics GMP)

A questionnaire was developed in English by the British Standards Institution (BSI) with inputs from WHO, and translated into French, Spanish and Russian. The questionnaire was structured to obtain feedback on general benefits of adopting guidelines; level of usefulness and benefits of selected WHO guidelines; opinions on which factors are useful for WHO guidelines; and opinions on future development of WHO guidelines.

BSI developed criteria for selection of countries and worked with WHO Regional Offices to arrive at a subsample of countries across WHO regions and income levels and with representation of different UN languages. BSI consulted with WHO Regional and Country Offices to identify potential participants with expertise in working with or implementing the different areas covered by the selected guidelines in the countries. Invitations to respond to the survey were sent to over 2000 potential participants by BSI in most cases and in some cases by the WHO Country Office and the National Regulatory Authority (NRA). The invitations were sent by mass e-mail distribution, with blind copies to ensure anonymity. 2 email reminders to respond to the survey were sent to the invited participants and the deadline to respond was extended twice.

Microsoft Forms was used as the survey platform, with the option to use a printed form. Feedback was collected and analyzed between September 2021 and December 2022. The survey was confidential and anonymous with contact information used for primary data validation and deleted at the end of the analysis. BSI performed a data cleaning and conducted the analysis.
Results

Respondents
The list of countries participating included Armenia, Bangladesh, Croatia, Democratic Republic of Congo, Republic of Korea, Ghana, Indonesia, Nigeria, Pakistan, Philippines, Saudi Arabia, Syrian Arab Republic, and Timor-Leste. The majority of respondents, 81% came from low- and low-middle-income countries. The countries were distributed across the WHO regions with 3 countries from the African Region, 3 from the Southeast Asia Region, 3 from Eastern Mediterranean Region, 2 from European Region, and 2 from the Western Pacific Region.

Over 2000 invitations to participate were sent and there were 83 respondents, a response rate of 4%. Of the total respondents, 46% were from National Regulatory Authorities (NRAs), 34% manufacturers, 18% purchasers/distributors (importers, wholesalers, donors, local or regional purchasing entity and 2% surveillance organizations.

Adoption of WHO guidelines
Respondents were requested to specify their level of adoption for each guideline by indicating a numeric value of 0 to 13 with 0 being no adoption and 13 being full adoption. Each numeric value corresponded to a description for the level of adoption providing additional information on why a guideline may not have been adopted or only partially adopted and the extent to which it had been adopted (Table 1). For analysis and expression of the results the level of adoption can be aggregated with shades of blue indicating full adoption, shades of green, partial adoption and shades of red, no adoption.

Table 1 Survey options for level of adoption and color codes for analysis

<table>
<thead>
<tr>
<th>Numeric level of adoption</th>
<th>Aggregate level of adoption</th>
<th>Descriptive level of adoption</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Full adoption</td>
<td>Full adoption (word by word application with translation, if required)</td>
</tr>
<tr>
<td>12</td>
<td>Full adoption</td>
<td>Full adoption with officially endorsed additional explanation/interpretation texts</td>
</tr>
<tr>
<td>11</td>
<td>Full adoption</td>
<td>Assumed full adoption. Assumes that the relevant authority has incorporated the requirements in the legislation and/or product specifications, and these are followed</td>
</tr>
<tr>
<td>10</td>
<td>Partial</td>
<td>Partial adoption. In the process of fully adopting the guideline.</td>
</tr>
<tr>
<td>11</td>
<td>Partial</td>
<td>Partial adoption with added or omitted sections, endorsed by the relevant authority</td>
</tr>
<tr>
<td>12</td>
<td>Partial</td>
<td>Adoption of parts of the guideline, based on a documented gap analysis</td>
</tr>
<tr>
<td>13</td>
<td>Partial</td>
<td>Partial adoption, based on a gap analysis that is not official/documentated</td>
</tr>
<tr>
<td>14</td>
<td>Partial</td>
<td>Full implementation of the guideline with no regular assessment of adherence</td>
</tr>
<tr>
<td>5</td>
<td>No adoption</td>
<td>No adoption, however the standard is used, if required for a specific purpose</td>
</tr>
<tr>
<td>4</td>
<td>No adoption</td>
<td>No adoption, however planning to adopt in the near future</td>
</tr>
<tr>
<td>3</td>
<td>No adoption</td>
<td>No adoption, as other guidelines or legislation is followed</td>
</tr>
<tr>
<td>2</td>
<td>No adoption</td>
<td>No adoption as we are not aware of this guideline</td>
</tr>
<tr>
<td>1</td>
<td>No adoption</td>
<td>No adoption as support is needed to implement</td>
</tr>
<tr>
<td>0</td>
<td>No adoption</td>
<td>No adoption for other reasons</td>
</tr>
</tbody>
</table>
The level of adoption was found to be generally high for all guidelines, with more than 40% of the respondents stating an aggregate level of full adoption for each of the guidelines. Fig. 1a and Fig. 1b show the % of respondents reporting an aggregate level of adoption (no, partial or full) and detailed adoption level for each of 8 guidelines.

The WHO guidelines on good manufacturing practices for blood establishments had the highest level of adoption of all the guidelines surveyed with more than 60% of survey participants indicating full adoption of the guideline. 5 of the 8 guidelines surveyed were reported by more than 80% of participants to have partial or full adoption of those guidelines.

For those respondents indicating an aggregate level of full adoption, the most common description provided was level of adoption number 11, where the respondent assumes that the corresponding authority has incorporated the requirements of the guideline in the legislation.

The guidelines with up to 30% participants indicating no adoption included: Recommendations for the production and control of influenza vaccine (inactivated); Stability testing of active pharmaceutical ingredients and finished pharmaceutical products; and Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products.

For those respondents indicating no adoption of a guideline, the most common description provided was either adoption level 3, other guidelines being followed or adoption level 5, that the guideline is only used if there is a specific need.

**Fig. 1a** Aggregate and detailed level of adoption for the WHO guidelines surveyed (for legend see also Table 1)
The aggregate level of full adoption is higher for manufacturers and purchasing organizations than for NRAs and surveillance organizations (Fig. 2a and Fig. 2b) for all guidelines except procurement. For those not adopting WHO guidelines, the rate was highest for NRA respondents not adopting the WHO guidelines for influenza vaccine, stability, and heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (HVAC) compared to the other guidelines.

**Fig. 2a** Aggregate level of adoption by type of respondent (company includes manufacturers and purchasing organizations and NRA includes NRA’s and surveillance organizations)
*Fig. 2b* Aggregate level of adoption by type of respondent (company includes manufacturers and purchasing organizations and NRA includes NRA’s and surveillance organizations)

Guideline adoption by income level shows a lower level of adoption for respondents from high-income countries (Fig. 3).

*Fig. 3* Median value of adoption in relation to income level (0 no adoption to 13 full adoption)

Use of other Guidelines

Overall, about 60% of respondents indicated use of other similar guidelines either alone or in combination with the corresponding WHO guideline. Table 2 shows other guidelines referred to by respondents including national, regional or other WHO guidelines; or guidelines from the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH); the International Society for Pharmaceutical Engineering (ISPE), International Standards Organization (ISO); Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S); or other non-specified guideline. Other guidelines most frequently mentioned included non-specified, national or regional guidelines. Of the 8 WHO guidelines, the Stability testing of active pharmaceutical ingredients and finished pharmaceutical products had the most reports of use of other guidelines, with the one from ICH being reported the most.
Table 2 Number of respondents indicating use of other guidelines

<table>
<thead>
<tr>
<th></th>
<th>GL Blood GMP</th>
<th>GL Procurement</th>
<th>GL Influenza Vaccine</th>
<th>GL Stability</th>
<th>GL HVAC</th>
<th>GL Vaccine Lot Release</th>
<th>GL Biologics Change Approval</th>
<th>GL Biologics GMP</th>
<th>General</th>
<th>Total</th>
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<tr>
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<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>11</td>
<td>24</td>
</tr>
<tr>
<td>Regional</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>International</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Other WHO</td>
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<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>18</td>
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<td>ICH</td>
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<td>ISO</td>
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<td>1</td>
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<td>4</td>
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<tr>
<td>ISPE</td>
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<td></td>
<td>4</td>
<td></td>
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<tr>
<td>PIC/S</td>
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<td></td>
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<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
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<td>5</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>28</td>
</tr>
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<td>9</td>
<td>25</td>
<td>17</td>
<td>7</td>
<td>5</td>
<td>11</td>
<td>33</td>
<td>134</td>
</tr>
</tbody>
</table>

Benefits and disadvantages of adopting WHO guidelines
The majority of respondents indicated that adoption of WHO guidelines, in general is of great or significant advantage for reasons provided in a pre-set list of answers that included: health product quality and safety, market authorization or approval, effective relevant organization Quality Management System (QMS), organizational benefits, organizational recognition, and branding and trustworthiness (Fig. 4).

Fig. 4 Advantage of adoption of WHO guidelines (% of respondents)

Advantages of adoption were explored for guidelines in general and for each of the guidelines specifically (Fig. 5). The most important benefit in general was reported as quality and safety followed by authorization. There are no significant differences seen between the different guidelines with the exception of the Guidelines for independent lot release of vaccines by regulatory authorities which shows that more respondents considered the advantages to be greater for quality and safety, authorization and the organization than for the other guidelines.
Other advantages of adoption of WHO guidelines mentioned by respondents, apart from the pre-set list of answers, included: increase in market access (7 respondents); reinforces quality reputation (5 respondents); increased efficiency and effectiveness (4 respondents); supports use of common standards/harmonization (3 respondents); and adoption saves time, resources and money (2 respondents). Disadvantages of adoption included: the cost of implementation (3 respondents) and lack of language versions (1 respondent).

Factors that support or impede adoption and implementation of WHO guidelines
Survey participants were requested to indicate which factors they considered that support or impede the adoption and implementation of WHO guidelines according to a preset list of factors including, legislation and requirements; other mandatory guidelines; professional network expectations, organizational strength; and the stakeholder influence in WHO guideline development. Generally, all of the preset factors were reported as supporting adoption (Fig. 6). The factor most frequently considered as an impediment to adoption was involvement in the WHO guideline development and revision process.
Fig. 6 Factors that impede or support adoption of WHO guidelines

![Bar chart showing factors that impede or support adoption of WHO guidelines.](image)

Features that strengthen adoption

Technical factors

Survey participants were requested to give their opinion on how each guideline could be strengthened with regards to technical quality by selecting preset options which included scientific, valid, present day, state of the art technical information and guidance; inclusion of more technical options (e.g. automation); or more explanations and/or references in the guidelines to ease understanding of the complex parts of the technologies.

The most important feature for improving WHO guidelines was reported as the scientific valid, present-day technology followed by more explanation of technically complex subjects (Fig. 7). These features were most reported for the guideline on Stability testing of active pharmaceutical ingredients and finished pharmaceutical products and the Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products.

Some differences in the technical factors deemed important for improving WHO guidelines can be seen by type of respondent. Fig. 8 shows that manufacturers and distributors (companies) considered the scientific validity option as the most important for a number of the guidelines as compared to NRAs and surveillance organizations with more than 50% of respondents indicating this option.
**Fig. 7** Technical factors deemed important for strengthening WHO guidelines by specific guideline (number of respondents)

**Fig. 8** Technical factors deemed important for strengthening WHO guidelines by type of respondent (%)

**Readability**
Survey participants were requested to give their opinion on how each guideline could be strengthened for readability by selecting from preset options including structure; clarity of purpose; clarity of aim and scope; specification of the target group; information included in the introduction/forward; information included in the conclusions; formulations and sentence complexity; formatting; and figures, tables and illustrations.
Overall, clarity of the purpose and scope of the guideline was the most commonly mentioned option for improving WHO guidelines followed by formulations and sentence complexity; and figures, tables and illustrations. There is some variation between the guidelines regarding which factors could be strengthened to ensure readability (Fig. 9).

**Fig. 9** Readability features that strengthen adoption of WHO guidelines (number of respondents)

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**Other features**

Survey participants were requested to give their opinion on how each guideline could be strengthened regarding other features by selecting from preset options which included: availability (internet access within minutes); availability in national languages; searchable version; the adequacy of the document origin specifications such as date, version, authors, source, quality control, approval, version and document identity; document safety and traceability secured; guideline recognition value (recognized authors, standard setting body, peer reviewers, funding organizations, etc.); or the cost.

Overall, the most common feature reported by respondents for strengthening WHO guidelines was quick internet access followed by text searchability and national language versions (Fig. 9).
Future Development of WHO Guidelines

Survey respondents ranked their opinions on what they considered as most important for adoption of future WHO guidelines. Fig. 10 shows responses to general considerations including: health product quality legislation and mandatory requirements from authorities and/or purchasing organizations; availability of other non-mandatory guidelines for health product quality; expectations of the organizations professional network; a strong organization (management, staff capacity, facilities, procedures, quality management system, finance); involvement of the organization in the development and revision process of WHO guidelines. The most important consideration for supporting adoption was reported as quality legislation and mandatory requirements from authorities and/or purchasing organizations followed by the strength of the organization.

Fig. 10 Features considered important for adoption of future WHO guidelines (weighted ranking)
Fig. 11 shows a weighed ranking of responses to what were the most important considerations for the development of future WHO guidelines. Technical content was the most important consideration followed by readability.

**Fig. 11** Considerations for future development of WHO guidelines (weighted ranking)

![Diagram of weighted ranking]

Fig. 12 shows what specific technical considerations were deemed important for future development of WHO guidelines including: scientific valid, present day, state-of-the-art technical information and guidance; inclusion of technical options; or more explanations and/or references in the guideline to ease understanding of the complex part of the technology. The answers to these ranked questions indicate that the most important factor is the technical quality of the guideline, with the scientific valid, present-day technology being the most important.

**Fig. 12** Technical considerations for future development of WHO guidelines (weighed ranking)

![Diagram of technical considerations]

Fig. 13 shows a weighed ranking of responses to what specific readability features are important for strengthening future adoption of guidelines including: structure; clarity of purpose; clarity of aim and scope; specification of the target group; information included in the introduction/forward; information included in the conclusions; formulations and sentence complexity; formatting; and figures, tables and illustrations. The most important features were reported as structure, clarity of purpose and clarity of aim and scope.
Readability considerations for future development of WHO guidelines (weighed ranking)

Survey participants were requested to give their opinion on how future guidelines could be strengthened regarding other features by ticking a list with preset options which included: availability (internet access within minutes); availability in national languages; searchable version; the adequacy of the document origin specifications such as date, version, authors, source, quality control, approval, version and document identity; document safety and traceability secured; guideline recognition value (recognized authors, standard setting body, peer reviewers, funding organizations, etc.); or the cost. Figure 14 shows a weighed ranking of the features considered important for future development of guidelines.

Other considerations for future development of WHO guidelines (weighed ranking)
Discussion

Recruiting participants to the survey proved to be a challenge in some countries resulting in a low response rate. The challenges to obtain responses were observed mainly in countries where WHO did not have active prior engagements with identified potential participants. It was observed that some contact details were incorrect and a step to validate addresses or to find the correct address was not accounted for in the approach. Follow up and even invitations from WHO or the NRA were not sufficient to encourage more stakeholders to respond to the survey. Including 8 guidelines in the same survey may have contributed to the low response rate as some stakeholders were only interested in responding to questions on the specific guidelines of their interest. Undertaking the survey during the Covid-19 pandemic likely had an impact due to competing priorities. The length of the survey and general survey fatigue may have also contributed to the challenge of obtaining responses.

The results of this survey indicate that WHO guidelines are generally partially or fully adopted and implemented with or without other guidelines. The results suggest that the list of factors provided in the survey (technical, readability and other factors) all support rather than impede the adoption of WHO guidelines.

Nevertheless, respondents indicated some level of no adoption for each of the 8 guidelines. While some factors for not adopting WHO guidelines were identified from the pre-set list of factors it is not possible to understand the specific challenges for the adoption of each guideline from this survey due to the limitations in the number and type of questions asked. It is possible to deduce that the proposed areas to consider for enhanced adoption of guidelines can be factors that may impede adoption if not addressed. Furthermore, the factors that impede adoption would be expected to vary between guidelines due to aspects relating to the life cycle of each guideline and the specific context such as efforts to facilitate and promote adoption.

One explanation for high no adoption rates such as reported for the stability guideline is the corresponding use of another guideline. A high number of respondents reported using other guidelines either alone or in combination with WHO guidelines and this is to be expected when a non-WHO guideline meets or exceeds the recommended acceptable requirements of the country. It was not in the scope of the survey to determine whether non-WHO guidelines are comparable to the WHO recommended guideline.

The higher rate of low adoption for the WHO guidelines for influenza vaccine may be explained by the fact that this guideline was only relevant for a small subset of respondents and thus the majority of respondents indicated that it was not adopted. The higher rate of low adoption for the guideline on stability, and the guideline on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products compared to the other guidelines may be explained by the fact that these guidelines are implemented in manufacturing related activities for vaccines and pharmaceutical products and both industry and NRAs are using ICH and ISPE for stability and HVAC respectively.

Not surprisingly, respondents generally agree that adoption of guidelines was a benefit for health product quality, authorization, organization quality management, branding and, also to some extent for softer benefits such as animal safety and environmental protection. Likewise, respondents consider it important to have a scientific, valid, present-day, state-of-the-art, technical-information standards. Having more
explanations and references to ease the understanding of the guideline was considered important to enhance adoption of each guideline. Regarding readability, the most important factors supporting adoption were the clarity of purpose, aim and scope, the figures, tables, and illustrations. Many respondents specified ease of access to the guideline quickly through the internet as important as well as having a searchable and copiable format and national language versions.

The similar responses for all guidelines with regards to features deemed important for enhanced adoption indicates that these features may be important for other WHO guidelines not included in the survey. A more standardized approach could thus be considered for future development of guidelines. The need for searchability and copiable formats of guidelines indicate that adoption of specific parts of a guideline rather than the whole guideline may be important. It may also indicate the need for adaptation to the local context.
Conclusions

Overall, the results provide useful information on the approach for obtaining feedback on guideline adoption and implementation. With some modifications the approach could be repeated to monitor the adoption of the same WHO guidelines as reviewed in this survey. However, the approach would not be suitable for assessing adoption and implementation of WHO guidelines for other health products or physical standards due to: the complexities of identifying and reaching stakeholders; the long length of the survey; and the need to consider additional technical specificities for each new area addressed by the additional guidelines.

A more targeted approach to obtain feedback from stakeholders, both in identifying them and in obtaining responses would be needed to improve the response rate. Periodic, shorter surveys combined with an information technology-based solution for regular data collection would improve efficiency. Survey questions should avoid leading questions to improve clarity and to help fully understand reasons for not adopting a guideline. These modifications should address survey fatigue while ensuring that data is collected and secured in the most effective, efficient and transparent way.

The approach used also provides some useful information on the level of adoption of WHO guidelines on quality, safety and efficacy of health products and selected features that promote adoption. The findings show that WHO guidelines on quality, safety and efficacy of health products are generally partially or fully adopted although more work is needed to understand how adoption could be enhanced. Methodologies that identify factors attributable and traceable to each guideline along the guideline’s life cycle will contribute to the knowledge. Further work may be needed to understand the specificities around the national legislation and mandatory requirements so that guidelines can be adapted to these requirements. A better understanding is also needed on the comparability of WHO guidelines with non-WHO guidelines.

Continued collaboration between WHO and other standard setting organizations to harmonize and align similar guidelines will be important to support Member States to develop, adapt and implement guidelines in line with WHO recommendations. Collaboration would also strengthen the understanding of which guidelines are in line with WHO recommendations so that stakeholders can be assured that non-WHO guidelines are in line with the acceptable WHO recommendations, standards and/or practice.

Adoption of current WHO guidelines could be enhanced by improving internet searchability and the guideline’s technical and readability features and increasing the involvement of stakeholders in the entire lifecycle of the guideline. Publishing formats should be adapted so that they can be searchable and copiable, and the translation into additional language versions should be considered. For future development of guidelines, careful attention should be paid to structure, clarity of purpose and clarity of aim and scope in addition to the features of internet searchability, searchable formats and language versions.

Finally, and most importantly, the results of this survey demonstrate the need for the continued role of WHO in promoting and facilitating harmonization of norms and standards on quality, safety and efficacy of health products.