

MEMBER STATE QUESTIONNAIRE: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

PURPOSE

- To gather baseline information from Member States to monitor progress on implementing decision [WHA71\(9\)](#). Some additional questions are included to collect useful information for the Secretariat to develop an implementation plan as requested in this decision and for the implementation of other related resolutions, such as [WHA72.8](#).
- The responses to this questionnaire will be compiled in aggregate form and analysed by the Secretariat for inclusion in the 2020 report on progress and will complement the report on progress made by the WHO Secretariat in implementing the decision, notably the recommendations addressed to the Secretariat. Country names will not be attributed to the information provided. Country responses will also be used to guide follow-up actions and provision of assistance and support.

BACKGROUND

- To foster innovation and improve access for people in developing countries, the World Health Assembly (WHA) adopted resolution [WHA61.21](#) and resolution [WHA62.16](#), on a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property ([GSPA](#)).
- [WHA62.16](#) requested the Director-General "to conduct an overall programme review of the global strategy and plan of action in 2014 on its achievements, remaining challenges and recommendations on the way forward to the Health Assembly in 2015 through the Executive Board." In [WHA68.18](#), the WHA decided "to extend the time frames of the plan of action on public health, innovation and intellectual property from 2015 until 2022." [WHA68.18](#) also requested the Director-General "to present the terms of reference of the overall programme review for approval by the Executive Board at its 140th session in January 2017, and to present the composition of the overall programme review panel for consideration by the bureau of the Executive Board in February 2017."
- Eighteen experts were selected from a roster of names proposed by Member States and all WHO Regional Directors and a consolidated report with forward looking recommendations ([document A71/13](#)) was presented at the 71st WHA in May 2018, through the 142nd Executive Board session. In their [report](#), the panel considered that the eight elements of the [GSPA](#) remain broadly valid, noting that the main problem is the lack of impact in its implementation. The report, therefore, prioritized 33 actions directed to the WHO Secretariat and/or Member States, rather than the multiplicity of relevant stakeholders noting that, although the contribution of stakeholders is integral to the success of the GSPA-PHI, it is the role of the WHO Secretariat and Member States to encourage their appropriate involvement. The prioritized address current needs in research and development and access to medicines that are feasible, practical and, as far as possible, can be monitored, along with a governance mechanism for the [GSPA](#), with a focus on implementation and monitoring.
- At its Seventy-first session in May 2018, the WHA approved decision [WHA71\(9\)](#), which urged "Member States to implement, as appropriate and taking into account national contexts, the recommendations of the review panel that are addressed to Member States and consistent with the global strategy and plan of action on public health, innovation and intellectual property." Likewise, the decision requested "the Director-General to implement the recommendations addressed to the Secretariat as prioritized by the review panel, in an implementation plan, consistent with the global strategy and plan of action on public health, innovation and intellectual property" as well as to "submit a report on progress made in implementing this decision to the Seventy-third WHA in 2020, through the Executive Board at its 146th session."
- Recommendation 32 of the review panel (see document [A71/13](#)) requires "the WHO Secretariat to draw up a detailed implementation plan and establish a mechanism to support implementation and monitoring of the global strategy and plan of action."

ABOUT THE QUESTIONNAIRE The questionnaire is organized in the following way:

- **Section A** on Member State information
- **Section B** on statement of policy on data sharing
- **Section C** on GSPA elements
 - Prioritize research and development needs
 - Promote research and development
 - Build and improve research capacity
 - Promote transfer of technology
 - Manage intellectual property to contribute to innovation and public health
 - Improve delivery and access
 - Promote sustainable financing mechanisms
 - Establish a monitoring and accountability mechanism
- **Section D** on other aspects

If you wish to submit any additional information to the Secretariat to be considered for inclusion in the 2020 report on progress, you will have an opportunity to upload documents at the end of the questionnaire. Any sensitive, confidential or unpublished documents should be emailed to gspoa@who.int. We thank you in advance for taking the time to complete this questionnaire.

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SECTION A. GENERAL INFORMATION

To ensure the most accurate data, WHO recommends that the mission focal point coordinate the collection and reporting of your government's intersectoral (from all relevant government authorities relating to public health, innovation, and intellectual property) response to the questionnaire.

* 1 Your country name:

Choose one of the following answers

Please choose...



* 2 Mission focal point name (i.e. surname, given name):

* 3 Mission focal point title (e.g. Health Attaché):

4 Mission focal point contact information (i.e. email address; phone number):

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SECTION B. STATEMENT OF POLICY ON DATA SHARING

Data are the basis for all sound public health actions and the benefits of data sharing are widely recognized, including scientific and public health benefits. Whenever possible, WHO wishes to promote the sharing of health data, including but not restricted to surveillance and epidemiological data. In this connection, and without prejudice to information sharing and publication pursuant to legally binding instruments, by providing data to WHO, [MISSION FOCAL POINT NAME] of [YOUR COUNTRY NAME]:

- Confirms that all data to be supplied to WHO (including but not limited to the types listed in Table 1) hereunder have been collected in accordance with applicable national laws, including data protection laws aimed at protecting the confidentiality of identifiable persons;
- Agrees that WHO shall be entitled, subject always to measures to ensure the ethical and secure use of the data, and subject always to an appropriate acknowledgement of [YOUR COUNTRY NAME]:
 - to publish the data, stripped of any personal identifiers (such data without personal identifiers being hereinafter referred to as “the Data”) and make the Data available to any interested party on request (to the extent they have not, or not yet, been published by WHO) on terms that allow non-commercial, not-for-profit use of the Data for public health purposes (provided always that publication of the Data shall remain under the control of WHO);
 - to use, compile, aggregate, evaluate and analyse the Data and publish and disseminate the results thereof in conjunction with WHO’s work and in accordance with the Organization’s policies and practices.
- Except where data sharing and publication is required under legally binding instruments (IHR, WHO Nomenclature Regulations 1967, etc.), the [MISSION FOCAL POINT NAME] of [YOUR COUNTRY NAME] may in respect of certain data opt out of (any part of) the above, by notifying WHO thereof in writing at the following email address, provided that any such notification shall clearly identify the data in question and clearly indicate the scope of the opt-out (in reference to the above), and provided that specific reasons shall be given for the opt out.

Except where data sharing and publication is required under legally binding instruments (IHR, WHO Nomenclature Regulations 1967, etc.), of [YOUR COUNTRY NAME] may in respect of certain data opt out of (any part of) the above, by notifying WHO thereof in writing at the following address, provided that any such notification shall clearly identify the data in question and clearly indicate the scope of the opt-out (in reference to the above), and provided that specific reasons shall be given for the opt out.

Director Strategy, Policy and information (SPI)
World Health Organization
20, avenue Appia
1211 Geneva Switzerland

* 5 Do you agree to the [‘statement of policy on data sharing’](#) as outlined above?

☐ Yes

☐ No

* 6 You have indicated that your country does not accept the statement of policy on data sharing. If you wish to proceed with the questionnaire but do not wish to accept the statement of policy on data sharing, please contact the Secretariat at gspoa@who.int. Otherwise, please indicate below why you do not accept the statement of policy on data sharing.

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SECTION C. GSPA ELEMENTS: Promote research and development

7 In the past two years, has your country promoted programmes for collaboration with (and provision of support to) developing countries to strengthen clinical trial capacity and expert networks regionally and, where relevant, nationally?

Check any that apply

- ☐ No promotion within the past two years
- ☐ Developed a platform for exchange of ideas and cross-fertilization
- ☐ Provided seed funding or other financial incentives to stimulate collaboration
- ☐ Provided material resources
- ☐ Provided human resources
- ☐ Expert network participation

Other:

 This question corresponds to recommendation 6 of the actions prioritized by the expert panel for the overall programme review and [WHA72.8](#).


Recommendation 6: Member States to promote programmes for collaboration with (and provision of support to) developing countries to strengthen clinical trial capacity and expert networks regionally and, where relevant, nationally. (Indicator: Report on mapping of programmes for strengthening clinical trial capacity and expert networks regionally and nationally by 2021.)

8 In the past two years, has your country encouraged funders of research and development to make all resulting publications open access immediately or, at the most, within six months after publication?

Check any that apply

- ☐ No encouragement within the past two years
- ☐ Require open-access mandate as a contractual condition for grant recipients in public or public-private collaborations
- ☐ Created new initiatives to facilitate open access
- ☐ Provided incentives to facilitate open access

Other:

 This question corresponds to recommendation 7 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 7: Member States and the WHO Secretariat to encourage funders of research and development to make all resulting publications open access immediately or, at the most, within six months after publication. (Indicator: Report by 2022 on new initiatives by funders of research and development to ensure that the resulting publications in peer-reviewed journals are open access.)

9 You have indicated that your country has created new initiatives to facilitate open access; therefore, please describe the initiative, provide relevant links, and upload any related information.

10 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

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SECTION C. GSPA ELEMENTS: Build and improve research capacity

11 In the past two years, has your country developed and/or supported collaboration programmes between internationally recognized centres for research and development and relevant institutions in developing countries to enable those countries to enhance their capacity across the research and development pipeline?

- ☐ Yes
- ☐ No
- ☒ No answer

 This question corresponds to recommendation 8 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 8: The WHO Secretariat and Member States to develop and support collaboration programmes between internationally recognized centres for research and development and relevant institutions in developing countries to enable those countries to enhance their capacity across the research and development pipeline. (Indicator: Report on new collaboration programmes developed and supported by 2021.)

12 You have indicated that, in the past two years, your country developed and/or supported collaboration programmes between internationally recognized centres for research and development and relevant institutions in developing countries to enable those countries to enhance their capacity across the research and development pipeline; therefore, check any that apply.

Check any that apply


- ☐ Developed and supported a new collaboration programme (North:South collaboration)
- ☐ Developed and supported a new collaboration programme (South:South collaboration)
- ☐ Supported an existing collaboration programme (North:South collaboration)
- ☐ Supported an existing collaboration programme (South:South collaboration)

13 Please describe the new North-South collaboration programme(s) which your country developed and supported in the past two years.

14 Please describe the new South-South collaboration programme(s) which your country developed and supported in the past two years.

15 Are certified quality training courses on research and development, including online courses, available for personnel involved in research and development in your country?

- ☐ Yes
- ☐ No
- ☒ No answer

 This question corresponds to recommendation 11 of the actions prioritized by the expert panel for the overall programme review.


Recommendation 11: Member States to promote the availability of training courses of certified quality, including online courses, for personnel involved in research and development. (Indicator: Monitoring the availability of certified quality training courses on research and development.)

16 You have indicated that certified quality training courses on research and development are available for personnel involved in research and development in your country; therefore, please provide a bulleted list of available, certified quality training courses on research and development, including links to online courses where available.

17 In the past two years, to what extent has your country promoted the availability of training courses of certified quality, including online courses, for personnel involved in research and development?

Choose one of the following answers

- ☐ Not at all
- ☐ To some extent
- ☐ To a fair extent
- ☐ To a great extent
- ☒ No answer

 This question corresponds to recommendation 11 of the actions prioritized by the expert panel for the overall programme review.


Recommendation 11: Member States to promote the availability of training courses of certified quality, including online courses, for personnel involved in research and development. (Indicator: Monitoring the availability of certified quality training courses on research and development.)

18 You have indicated that your country, in the past two years, has promoted the availability of training courses of certified quality, including online courses, for personnel involved in research and development; therefore, please describe how your country has promoted the availability of the training courses.

19 Does your country have any national programmes or participate in any regional programmes for developing strategies and strengthening capacity in research and development for traditional medicine by 2022?

Check any that apply

- ☐ Not at all
- ☐ Yes, a national programme is currently being developed
- ☐ Yes, a national programme is fully functional
- ☐ Yes, regional programme participation


 This question corresponds to recommendation 12 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 12: Member States, with the support of the WHO Secretariat, to develop strategies and strengthen their capacity for policy formulation, regulation, research methodology and ethics, and resource preservation in traditional medicine in line with the [WHO traditional medicine strategy: 2014–2023](#). (Indicator: Report on national and regional programmes for developing strategies and strengthening capacity in research and development for traditional medicine by 2022.)

20 You have indicated that a national programme is fully functional; therefore, in the past two years, to what extent has your national programme:

	Not at all	To some extent	To a fair extent	To a great extent	No answer
Developed strategies for <u>policy formulation</u> in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Developed strategies for <u>regulation</u> in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Developed strategies for <u>research methodology and ethics</u> in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Developed strategies for <u>resource preservation</u> in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Strengthened capacity for <u>policy formulation</u> in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Strengthened capacity for <u>regulation</u> in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

	Not at all	To some extent	To a fair extent	To a great extent	No answer
Strengthened capacity for research methodology and ethics in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Strengthened capacity for resource preservation in traditional medicine in line with the WHO traditional medicine strategy: 2014–2023	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

 This question corresponds to recommendation 12 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 12: Member States, with the support of the WHO Secretariat, to develop strategies and strengthen their capacity for policy formulation, regulation, research methodology and ethics, and resource preservation in traditional medicine in line with the [WHO traditional medicine strategy: 2014–2023](#). (Indicator: Report on national and regional programmes for developing strategies and strengthening capacity in research and development for traditional medicine by 2022.)

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SECTION C. GSPA ELEMENTS: Promote transfer of technology

21 Does your country have a national technology transfer programme(s) related to local health technology production?

☐ Yes

☐ No

☒ No answer

 This question corresponds to recommendation 15 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 15: The WHO Secretariat to identify new opportunities for collaboration with other United Nations organizations (e.g. UNIDO, UNCTAD) to promote technology transfer as part of local health technology production programmes in developing countries in line with country needs. (Indicator: Inter-organizational report on national technology transfer programmes developed and disseminated by 2022.)

22 You have indicated that your country has a national technology transfer programme(s) related to local health technology production; therefore, please provide additional information on your national technology transfer programme(s), including any relevant links.

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SECTION C. GSPA ELEMENTS: Manage intellectual property to contribute to innovation and public health

23 Does your national and/or regional intellectual property legislation fully reflect the flexibilities provided in the [TRIPS Agreement](#), including those recognized in the [Doha Declaration on the TRIPS Agreement and Public Health](#) and in Articles 27, 30 (including the research exception ("Bolar" provision)), 31 and 31bis of the TRIPS Agreement?

Check any that apply

- ☐ Article 6 (Exhaustion) of the TRIPS Agreement
- ☐ Articles 7 (Objectives) and 8 (Principles) of the TRIPS Agreement
- ☐ Article 27 (Patentable Subject Matter) of the TRIPS Agreement
- ☐ Article 30 (Exceptions to Rights Conferred) of the TRIPS Agreement
- ☐ Article 31 (Other Use Without Authorization of the Right Holder) of the TRIPS Agreement
- ☐ Article 31 bis (Special Compulsory Licensing System) of the TRIPS Agreement
- ☐ Article 66.1 (Least-Developed Country Members) of the TRIPS Agreement
- ☐ Other relevant provisions related to public health safeguards

 This question corresponds to recommendation 16 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 16: The WHO Secretariat, in collaboration with other international organizations working in intellectual property, to advocate for the development of national legislation to fully reflect the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreement. (Indicator: Inter-organizational report on national legislation and patenting guidelines that include the flexibilities provided in the TRIPS Agreement prepared by 2021.)

24 You have indicated that your national and/or regional intellectual property legislation reflects [Article 6 \(Exhaustion\)](#) of the TRIPS Agreement. Does the legislation provide [national](#), [regional](#), or [international](#) exhaustion? Please upload the relevant provisions from your legislation below.

Choose one of the following answers

- ☐ National exhaustion
- ☐ Regional exhaustion
- ☐ International exhaustion
- ☒ No answer

25 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

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26 You have indicated that your national and/or regional intellectual property legislation reflects [Articles 7 \(Objectives\) and 8 \(Principles\)](#) of the TRIPS Agreement. How does your national and/or regional intellectual property legislation include this Article? Please upload the relevant provisions from your legislation below.

27 You can upload png, gif, doc, odt, pdf under 10240 KB each.

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28 You have indicated that your national and/or regional intellectual property legislation reflects [Article 27 \(Patentable Subject Matter\)](#) of the TRIPS Agreement. How does your country implement this Article? In particular, how does your legislation implement 27.3 (a) and (b) of the TRIPS Agreement? Please upload the relevant provisions from your legislation below.

29 You can upload png, gif, doc, odt, pdf under 10240 KB each.

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30 You have indicated that your national and/or regional intellectual property legislation reflects [Article 30 \(Exceptions to Rights Conferred\)](#) of the TRIPS Agreement. How does your country implement this Article, including the research exception ("Bolar" provision)? Please upload the relevant provisions from your legislation below.

31 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

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32 You have indicated that your national and/or regional intellectual property legislation reflects [Article 31 \(Other Use Without Authorization of the Right Holder\)](#) of the TRIPS Agreement. What are the grounds upon which your country grants compulsory licences and public non-commercial use licenses (government use licences)? Please upload the relevant provisions from your legislation below.

How does your country determine what constitutes a national emergency or other circumstances of extreme urgency? Please upload the relevant provisions from your legislation below.

33 You can upload png, gif, doc, odt, pdf under 10240 KB each.

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34 You have indicated that your national and/or regional intellectual property legislation reflects [Article 31bis \(Special Compulsory Licensing System\)](#) of the TRIPS Agreement. How does your national and/or regional intellectual property legislation implement this Article? Please upload the relevant provisions from your legislation below.

35 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

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36 If your country is a Least-Developed Country Member of WTO and your national and/or regional intellectual property legislation reflects [Article 66.1 \(Least-Developed Country Members\)](#), taking into account the extension for LDCs until January 2023) of the TRIPS Agreement, how does your country implement the transition period? Please upload the relevant provisions from your legislation below.

37 You can upload png, gif, doc, odt, pdf under 10240 KB each.

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38 You have indicated that your national and/or regional intellectual property legislation reflects other relevant provisions related to public health safeguards; therefore, please upload the relevant provisions from your legislation below. You can upload png, gif, doc, odt, pdf under 10240 KB each.


Please upload at most one file

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39 Does your national and/or regional patent office use patenting guidelines for the examination of pharmaceutical products?

Check any that apply

- ☐ No, national patent office does not use patenting guidelines for the examination of pharmaceutical products
- ☐ No, regional patent office does not use patenting guidelines for the examination of pharmaceutical products
- ☐ Yes, national patent office uses patenting guidelines for the examination of pharmaceutical products
- ☐ Yes, regional patent office uses patenting guidelines for the examination of pharmaceutical products

 This question corresponds to recommendation 16 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 16: The WHO Secretariat, in collaboration with other international organizations working in intellectual property, to advocate for the development of national legislation to fully reflect the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health and in Articles 27, 30 (including the research exception and “Bolar” provision), 31 and 31bis of the TRIPS Agreement. (Indicator: Inter-organizational report on national legislation and patenting guidelines that include the flexibilities provided in the TRIPS Agreement prepared by 2021.)

40 You have indicated that your national patent office uses patenting guidelines for the examination of pharmaceutical products. Therefore, please provide a link to or upload below a copy of the patenting guidelines used by the national patent office for the examination of pharmaceutical products.

41 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

[Upload files](#)

42 You have indicated that your regional patent office uses patenting guidelines for the examination of pharmaceutical products. Therefore, please provide a link to or upload below a copy of the patenting guidelines used by the regional patent office for the examination of pharmaceutical products.

43 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

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44 Action 5.1 (c) of the [GSPA](#) recommends that stakeholders “facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases that contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.”

Do your national procurement agencies know about and/or use existing databases like [MedsPaL](#) or any other user-friendly global database that contains public information on the administrative status of health-related patents and licences to facilitate procurement of medicines and health products?

Check any that apply

- ☐ No, do not know about or use MedsPaL
- ☐ Yes, know about but do not use MedsPaL
- ☐ Yes, know about and use MedsPaL

Other:

 This question corresponds to recommendation 17 of the actions prioritized by the expert panel for the overall programme review and [WHA72.8](#).

Recommendation 17: The WHO Secretariat, in collaboration with partners, to promote the further development of databases of patents and non-confidential licence agreements for health products and facilitate greater access to such databases. (Indicator: Monitor coverage and use of existing and new databases of patent and licence information.)

45 Has your national and/or regional patent office signed or considered signing a collaborative agreement with the [Medicines Patent Pool](#) to provide regular updates to patent data for key health products to [MedsPaL](#)?

Check any that apply

☐ No, neither national nor regional patent office, where applicable, have signed or have considered signing a collaborative agreement with the Medicines Patent Pool

☐ Yes, national patent office has signed or has considered signing a collaborative agreement with the Medicines Patent Pool

☐ Yes, regional patent office has signed or has considered signing a collaborative agreement with the Medicines Patent Pool

Other:

46 Does your national and/or regional patent office or other government agencies have publicly-available health-related patent and licensing status information databases online?

Check any that apply

☐ Granted patents

☐ Published patent applications

☐ Published patent application legal status


☐ Patents granted and/or rejected under appeal

☐ Patent licenses

☐ Patent term extensions or supplementary protection certificates, where applicable

☐ Test data exclusivity protection database, where applicable

Other:

 This question corresponds to recommendation 17 of the actions prioritized by the expert panel for the overall programme review and WHA72.8.

Recommendation 17: The WHO Secretariat, in collaboration with partners, to promote the further development of databases of patents and non-confidential licence agreements for health products and facilitate greater access to such databases. (Indicator: Monitor coverage and use of existing and new databases of patent and licence information.)


47 You have indicated that your national and/or regional patent office or other government agencies have publicly-available health-related patent and licensing status information databases online; therefore, please provide any related links below.

48 In the past two years, how has your country, when negotiating trade agreements, taken into account the impact on public health of adopting provisions that go beyond the standards of the [TRIPS Agreement](#)?

Check any that apply

- ☐ No consideration of the impact on public health when negotiating trade agreements
- ☐ Use of health impact assessment tools or other independent and comprehensive measures to assess public health impact
- ☐ Participation of national public health actors in trade agreement negotiations
- ☐ Promoting access to negotiating texts and meaningful opportunities for health negotiators' engagement and feedback

Other:

 This question corresponds to recommendation 19 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 19: Member States, when negotiating trade agreements, to take into account the impact on public health of adopting provisions that go beyond the requirements of the TRIPS Agreement. (Indicator: Assessment by 2022 of evidence that negotiators of new trade agreements have taken account of the public health impact of the adoption of such agreements.)

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SECTION C. GSPA ELEMENTS: Improve delivery and access

49 Has your country developed or used good practices on evidence-based selection and health technology assessment for health products for national use to support creation or updating of national lists of essential health products for reimbursement, insurance and/or procurement purposes?

Check any that apply

- ☐ No, neither developed nor used good practices on evidence-based selection and health technology assessment for health products for national use
- ☐ Yes, developed good practices on evidence-based selection and health technology assessment for health products for national use
- ☐ Yes, used good practices on evidence-based selection and health technology assessment for health products for national use

 This question corresponds to recommendation 20 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 20: The WHO Secretariat to develop and share good practices on evidence-based selection and health technology assessment for health products for national use, and support bilateral and regional collaboration between countries. (Indicator: Good practices on evidence-based selection and health technology assessment developed and disseminated by 2019. Report on bilateral and regional collaboration programmes prepared by WHO by 2022.)

50 If yes, please describe and upload below any good practices that your country has developed on evidence-based selection and health technology assessment for health products for national use.

51 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

[Upload files](#)

52 If yes, please describe and upload below any good practices that your country has used on evidence-based selection and health technology assessment for health products for national use.

53 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

[Upload files](#)


54 Does your country participate in any bilateral and/or regional collaboration programme(s) on evidence-based selection and/or health technology assessment for health products for national use?

Check any that apply

☐ No participation in bilateral and/or regional collaboration programme(s)

☐ Yes, participation in bilateral collaboration programme(s)

☐ Yes, participation in regional collaboration programme(s)

 *This question corresponds to recommendation 20 of the actions prioritized by the expert panel for the overall programme review.*

Recommendation 20: The WHO Secretariat to develop and share good practices on evidence-based selection and health technology assessment for health products for national use, and support bilateral and regional collaboration between countries. (Indicator: Good practices on evidence-based selection and health technology assessment developed and disseminated by 2019. Report on bilateral and regional collaboration programmes prepared by WHO by 2022.)

55 If yes, please describe the bilateral collaboration programme(s) in which your country participates, provide any relevant links, and upload related information below.

56 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

[Upload files](#)

57 If yes, please describe the regional collaboration programme(s) in which your country participates, provide any relevant links, and upload below any related information.


58 You can upload png, gif, doc, odt, pdf under 10240 KB each.

Please upload at most one file

[Upload files](#)

59 Does your country present price information of pharmaceutical products in the public domain as part of a regular procedure?

- ☐ Yes
- ☐ No
- ☒ No answer

 This question corresponds to recommendation 21 of the actions prioritized by the expert panel for the overall programme review and [WHA72.8](#).

Recommendation 21: The WHO Secretariat to provide guidance to Member States on promoting and monitoring transparency in medicine prices and on implementation of pricing and reimbursement policies. (Indicator: Guidance developed and disseminated in countries by 2020.)

60 If yes, what type of price information is presented?

Check any that apply

- ☐ Prices at which manufacturers sell the product
- ☐ Prices at which wholesalers or distributors sell the product
- ☐ Prices at which pharmacies or retailers sell the product
- ☐ Prices at which government authorities procure the product
- ☐ Prices at which government authorities set as the benchmarks
- ☐ Prices at which government authorities or insurers reimburse the providers or consumers

Other:


61 You have indicated that price information of pharmaceutical products is presented in the public domain as part of a regular procedure; therefore, please provide any related links below regarding what type of price information is presented.

62 What potential factors might result in a difference between the published price and the actual market price for a particular product? (please include relevant links in comment box)

Choose one of the following answers

- ☐ None because published prices are the actual prices
- ☐ Confidential rebates and discounts to governments
- ☐ Confidential rebates and discounts to service providers or intermediaries
- ☐ Non-confidential rebates and discounts to governments
- ☐ Non-confidential rebates and discounts to service providers or intermediaries
- ☐ Published prices are maximum regulated prices; actual market prices are lower but varied
- ☐ Published prices are not updated in a timely manner to reflect actual prices
- ☐ Other or comments, please describe
- ☒ No answer

Please enter your comment here:


 This question corresponds to recommendation 21 of the actions prioritized by the expert panel for the overall programme review and [WHA72.8](#).

Recommendation 21: The WHO Secretariat to provide guidance to Member States on promoting and monitoring transparency in medicine prices and on implementation of pricing and reimbursement policies. (Indicator: Guidance developed and disseminated in countries by 2020.)

63 Please select the responses that best describe the collection and disclosure of price information of pharmaceutical products in your country.

Choose one of the following answers

- ☐ Price information is not collected as part of a regular procedure and known only to individual sellers (e.g. manufacturers, service providers) and payers/buyers (e.g. governments, service providers, and consumers)
- ☐ Price information is collected as part of a regular procedure and shared confidentially only with relevant authorities within the country
- ☐ Price information is collected as part of a regular procedure and shared only upon request confidentially with authorities or interested parties that are deemed appropriate
- ☐ Price information is infrequently collected only for specific purposes and circumstances (e.g. government audits)
- ☐ Other:
- ☒ No answer

 This question corresponds to recommendation 21 of the actions prioritized by the expert panel for the overall programme review and [WHA72.8](#).


Recommendation 21: The WHO Secretariat to provide guidance to Member States on promoting and monitoring transparency in medicine prices and on implementation of pricing and reimbursement policies. (Indicator: Guidance developed and disseminated in countries by 2020.)

64 In general, what are the overall effects of disclosure or sharing of price information on subsequent patient access to medicines in your country?

Check any that apply

- ☐ Not applicable because price information is not collected or shared
- ☐ Not sure because an assessment has not been conducted
- ☐ Assessment has been conducted but the findings were inconclusive
- ☐ Assessment found that information disclosure or sharing has resulted in lower prices
- ☐ Assessment found that information disclosure or sharing has resulted in higher prices
- ☐ Assessment found that information disclosure or sharing has resulted in better governance
- ☐ Assessment found that information disclosure or sharing has resulted in less efficient processes
- ☐ Assessment found that information disclosure or sharing has resulted in more efficient processes

Other:

 This question corresponds to recommendation 21 of the actions prioritized by the expert panel for the overall programme review and [WHA72.8](#).


Recommendation 21: The WHO Secretariat to provide guidance to Member States on promoting and monitoring transparency in medicine prices and on implementation of pricing and reimbursement policies. (Indicator: Guidance developed and disseminated in countries by 2020.)

65 How has your country monitored patient out-of-pocket expenditure on health products?

Check any that apply

- ☐ Not monitored
- ☐ Patient out-of-pocket costs on health products is fully regulated and known
- ☐ Routinely monitored through health claims data
- ☐ Selectively assessed by academics in research projects
- ☐ Selectively assessed through commissioned surveys


Other:

 This question corresponds to recommendation 22 of the actions prioritized by the expert panel for the overall programme review and [WHA72.8](#).

Recommendation 22: The WHO Secretariat, in cooperation with Member States and other partners, to establish mechanisms to monitor patient out-of-pocket expenditure on health products. (Indicator: Monitoring patient out-of-pocket expenditure on health products.)


66 In the past two years, has your country assessed national procurement and supply chain capacity and/or practices, including self-assessments or external assessments?

- ☐ Yes
- ☐ No
- ☒ No answer

 This question corresponds to recommendation 26 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 26: The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)

67 You have indicated that, in the past two years, your country has assessed national procurement and supply chain capacity and/or practices, including self-assessments or external assessments; therefore, please indicate the entity that performed the assessment and upload below any relevant reports (excluding confidential materials).

 This question corresponds to recommendation 26 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 26: The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)

68 You can upload png, gif, doc, odt, pdf under 10240 KB each.

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69 You have indicated that, in the past two years, your country has not assessed national procurement and supply chain capacity and/or practices, including self-assessments or external assessments. Therefore, please indicate if there are existing plans to perform an assessment prior to the end of 2022.

Check any that apply

☐ Not planned

☐ Date of planned assessment

 This question corresponds to recommendation 26 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 26: The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)

70 You have indicated that there are existing plans to perform an assessment prior to the end of 2022; therefore, please provide the date of the planned assessment.

Format: dd-mm-yyyy

71 To what extent do the above assessments (completed and/or planned) address participation, benefits or other aspects of regional collaboration in procurement and supply chain management?

Choose one of the following answers


☐ Not at all

☐ To some extent (e.g. consideration of potential collaboration)

☐ To a fair extent (e.g. feasibility or planning exercises)

☐ To a great extent (e.g. assessment of active participation in regional initiatives)

☒ No answer

 This question corresponds to recommendation 26 of the actions prioritized by the expert panel for the overall programme review.


Recommendation 26: The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)

72 You have indicated that the above assessments (completed and/or planned) address participation, benefits or other aspects of regional collaboration in procurement and supply chain management; therefore, please describe.

73 To what extent does your country participate in collective negotiation for procurement of medicines and health products?

Check any that apply


- ☐ Not at all (e.g. all decentralized procurement, without a national central medical stores procurement and without demand consolidation with other countries)
- ☐ Consolidation of sub-national demand for at least some medicines and health products (e.g. use of a central medical stores at national level)
- ☐ Information sharing across countries within an established group
- ☐ Participation in external, collective negotiation (e.g. Global Drug Facility)
- ☐ Pooled procurement across countries, including use of joint contracting mechanisms
- ☐ Pooled procurement across countries, including joint contracting mechanisms and financing mechanisms

 This question corresponds to recommendation 26 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 26: The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)

74 Are there additional plans to participate in collective negotiation prior to the end of 2022?

- ☐ Yes
- ☐ No
- ☒ No answer


 This question corresponds to recommendation 26 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 26: The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)

75 You have indicated that there are additional plans to participate in collective negotiation prior to the end of 2022; therefore, please indicate which ones are planned.


Check any that apply

- ☐ No additional plans
- ☐ Consolidation of sub-national demand for at least some medicines and health products (e.g., use of a central medical stores at national level)
- ☐ Information sharing across countries within an established group
- ☐ Participation in external, collective negotiation e.g., Global Drug Facility
- ☐ Pooled procurement across countries, including use of joint contracting mechanisms
- ☐ Pooled procurement across countries, including joint contracting mechanisms and financing mechanisms.

 *This question corresponds to recommendation 26 of the actions prioritized by the expert panel for the overall programme review.*

Recommendation 26: The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)

76 Please describe what kind of best practices, based on assessments or available guidance, your country uses for procurement of medicines and other health products. Please also upload below any relevant information.

 *This question corresponds to recommendation 26 of the actions prioritized by the expert panel for the overall programme review.*

Recommendation 26: The WHO Secretariat to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency, including for joint procurement. (Indicator: Assessment of national and regional initiatives for promoting good practices to improve procurement and supply chain efficiency by 2022.)

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SECTION C. GSPA ELEMENTS: Promote sustainable financing mechanisms

78 In the past two years, has your country committed to increasing domestic resource mobilization and supporting the [Addis Tax Initiative](#) in order to, inter alia, implement the health-related [Sustainable Development Goals](#)?

Check any that apply

- ☐ No commitment to increasing domestic resource mobilization and supporting the Addis Tax Initiative
- ☐ Yes, commitment to increasing domestic resource mobilization
- ☐ Yes, commitment to supporting the Addis Tax Initiative

 *This question corresponds to recommendation 29 of the actions prioritized by the expert panel for the overall programme review.*


Recommendation 29: Member States to commit to increasing domestic resource mobilization and supporting the Addis Tax Initiative in order to, inter alia, implement the health-related Sustainable Development Goals. (Indicator: Data from Member States on domestic resource mobilization gathered by 2021.)

79 You have indicated that your country, in the past two years, has committed to increasing domestic resource mobilization; therefore, please provide data on domestic resource mobilization.

80 In the past two years, to what extent has your country encouraged the implementation of schemes which partially or wholly delink product prices from research and development costs, including actions recommended by the [Consultative Expert Working Group on Research and Development: Financing and Coordination](#)?

Choose one of the following answers

- ☐ Not at all
- ☐ To some extent
- ☐ To a fair extent
- ☐ To a great extent
- ☒ No answer

 This question corresponds to recommendation 30 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 30: Member States to encourage the implementation of schemes which partially or wholly delink product prices from research and development costs, including actions recommended by the Consultative Expert Working Group on Research and Development: Financing and Coordination. (Indicator: New schemes to partially or wholly delink product prices from research and development costs developed, approved and implemented by 2022.)

81 You have indicated that, in the past two years, your country has encouraged the implementation of schemes which partially or wholly delink product prices from research and development costs; therefore, has your country been involved in the creation of new schemes to partially or wholly delink product prices from research and development costs? If yes, please upload below additional information that describes your involvement.

- ☐ Yes
- ☐ No
- ☒ No answer

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83 In the past two years, to what extent has your country encouraged an increase and diversification of funding for product development partnerships?

Choose one of the following answers

- ☐ Not at all
- ☐ To some extent
- ☐ To a fair extent
- ☐ To a great extent
- ☒ No answer

 This question corresponds to recommendation 31 of the actions prioritized by the expert panel for the overall programme review.

Recommendation 31: Member States, with the WHO Secretariat's support, to encourage an increase and diversification of funding for product development partnerships. (Indicator: increased and diversified funding for product development partnerships and progress as reported by G-Finder by 2022.)

84 You have indicated that, in the past two years, your country has encouraged an increase and diversification of funding for product development partnerships; therefore, please elaborate on how your country has encouraged an increase and diversification of funding for product development partnerships.

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SECTION D. OTHER ASPECTS

85 If you have any other information you wish to contribute or related documents that you wish to upload, please do so below. Any sensitive, confidential or unpublished documents should be emailed to gspoa@who.int. We thank you again for taking the time to complete this questionnaire.

Element 1: Prioritize research and development needs

Element 2: Promote research and development

Element 3: Build and improve research capacity

Element 4: Promote transfer of technology

Element 5: Manage intellectual property to contribute to innovation and public health

Element 6: Improve delivery and access

Element 7: Promote sustainable financing mechanisms

Element 8: Establish a monitoring and accountability mechanism

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