INTRODUCTION

The World Health Organization (WHO) is working with Member States to implement the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (GSPA-PHI).

The GSPA-PHI is very broad in scope. It recommends specific actions across multiple sectors and at multiple levels (global, regional and national) to promote innovation in, and access to, essential medical technologies in low- and middle-income countries. While the WHO is working to implement the GSPA-PHI at all levels, the most important effort must be at the national level. This tool has been developed to address that need and specifically to ensure that capacity is developed to generate innovation in medical technologies, sufficient research is conducted to address needs of developing countries in terms of medical technologies and access to new, needed technologies is promoted in these countries.

As part of these efforts, the WHO has developed a National Assessment Tool (NAT) based on country-specific action items in the GSPA-PHI. This tool facilitates a systematic assessment of the conducive environment to innovation for medical technologies, helping Member States to analyse their situation in terms policies, regulations, legislations, infrastructure and funding. Furthermore, countries can benchmark their own strengths and weaknesses in implementing the GSPA-PHI and identify where policy interventions are needed. Specific actions to be undertaken at global and regional levels have been excluded, and specific actions that name the WHO as the key stakeholder have also been excluded unless those actions require information to be collected from countries, in which case a question has been formulated and included in this tool.

The development of this National Assessment Tool has benefitted from several recent complementary initiatives including: Strengthening Pharmaceutical Innovation in Africa,¹ the Innovation Union Scoreboard,² and the Draft HAI Africa Pilot Monitoring

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Information collected through this tool will be retained in a web-based monitoring and evaluation platform\(^3\) developed by PHI as an integral part the WHO's contribution to GSPA-PHI implementation (Element 8). This database will assist in:

- drafting GSPA-PHI country progress reports and reports to WHO governing bodies;
- tailoring WHO technical assistance to meet the needs of Member States; and
- identifying gaps and opportunities to be addressed by development partners.

**STRUCTURE AND USE:**

This National Assessment Tool takes the form of a semi-structured questionnaire. It is designed to guide the collection and assessment of all relevant information. However, low- and middle-income countries are so diverse that a one-size-fits-all approach is unlikely to succeed. This tool should be adapted as needed to fit each national context.

In general, the structure of this assessment tool follows the order of Elements in the GSPA-PHI. Similar questions have been grouped together under topics derived from Elements with one exception: references to traditional medicine in Elements 1, 3 and 5 have been formulated as questions and grouped together in a separate section.

At the end of each question in this assessment tool, relevant specific action items in the GSPA-PHI are noted. When such numbers are not provided, this means that while no specific action item is linked directly to the question the information is still required to complement or clarify other questions and complete the picture.

Responses to questions in this assessment tool are not expected in the form of "yes" or "no." In most cases, explanation and supportive documentation are required. WHO might already have collected some of the information requested by this questionnaire: in such cases, the information is provided and the respondent should either update it or confirm it. Those using this tool should be thoroughly briefed about its use. Regarding this last aspect, the WHO recommends the establishment of a National Task Force on implementation of GSPA-PHI comprised of relevant stakeholders from the public and private sectors including civil society organizations.

**National Task Force:** Members may include, but need not be limited to, representatives from ministries of health, science & technology, trade & industry and finance; national research councils and research institutions; the national regulatory authority; non-profit civil society organizations involved in health care delivery and economic development; trade associations and for-profit firms. Diverse membership will facilitate the collection

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\(^4\) This platform ensures tracking of the implementation phase of the GSPA-PHI. It will provide member states with a tool to map their own efforts and serve as a repository for relevant documentation, a reporting tool to WHO governing bodies, a planning and coordination space for intersectoral policies, and a unique interface for health innovation issues. http://www.healthresearchweb.org/phi_beta
of accurate information needed by policy makers and development partners and to coordinate national effort in implementation of GSPA-PHI.
NOTE ON "INNOVATION": The Global Forum for Health Research has defined “innovation” as “encompassing the entire process from the generation of new knowledge, to the transformation of that knowledge into useful products or services, to the implementation of those services or products.” For the purpose of this tool, “innovation” involves policies and practices that enable and encourage the development, production and delivery of existing and new drugs, vaccines, diagnostics and other medical devices to people who need them.

NOTE ON NATIONAL POLICIES/STRATEGIES: This tool contains questions about national policies or strategies in multiple sections including health research policy, S&T (or innovation) policy, ethical review policy, human resources for health policy, local public-private R&D partnerships policy, North-South technology transfer policy, trade and investment policy, industrial policy, anti-dumping policy, poverty reduction policy, medicines policy, and traditional medicines policy.

PRELIMINARY QUESTIONS

1: Are you aware of any other assessments of your country's health innovation capacity?

2: Does your country have a National Task Force on the GSPA-PHI?
## Health R&D policies and infrastructure

1. **National strategy(ies) and priority setting:** Has your country established needs-based priorities for health R&D? What was the process for their definition (e.g., did it include relevant stakeholders)? How often are these priorities reassessed? (Element 1.2.a) Are these priorities contained in a national health research policy/strategy or any other equivalent document? If yes, please list the strategy’s goals and describe the mechanisms for intra-ministerial coordination. Has your country included *health systems research* in the national health research policy/strategy or in any other equivalent document? (Element 1.2.c). Provide links to sources of information.

2. **Domestic support and leadership:** Does your country have a national health research council or equivalent domestic funding body/agency? What is its structure? Which mechanisms exist for intra-ministerial coordination? Please provide links to sources of information. (Element 2.5.a)

3. **Research institutions, capacity and accreditation:** What are the key publicly-funded R&D centres/institutes in your country? (Element 3.1.b) What is the balance of publicly-funded research taking place in universities, government research institutions, hospitals, field sites and non-governmental organizations? Does your country have systems to accredit universities, courses and other training, including research training? Please list WHO collaborating centres in your country.

4. **Research networks:** Do researchers and/or research institutions in your country participate in national, regional and/or global health research networks or groups? (Element 3.1b) Please, provide links to sources of information.

## Funding for health R&D

5. **Public spending:** What is the national health budget? What is the public budget for health R&D? How much does the private sector spend on health R&D? (Element 1.2e). If possible, provide trends in such funding over the past 5-10 years. (Element 1.2e)

[POSSIBLE SOURCE: National Health Accounts](http://www.who.int/nha/en/index.html)

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5 e.g., (i) permanent/semi-permanent network such as academic societies/associations or ad hoc/time-limited joint venture for a specific research project; (ii) network/group to be composed only of public sector institutes, only private sector institutes, or both public and private sector institutes. etc.

6 Total government health expenditure, total health expenditures as % of nominal GDP, government health expenditure as % of total government expenditure

6. **External support**: Provide information related to donor funding for public sector health research programs including health-related innovation. (Element 2.1.b,c)

7. **Tracking and transparency**: Does your country have publicly accessible information on sources of financing for health R&D? If yes, please provide details.

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### Discovery science and clinical research

8. **Research exemption**: Does legislation in your country provide a research exemption to ensure that research involving patented inventions is not considered infringement? (Element 2.4.e)

9. **Clinical trials capacity**: Are there any public and/or private efforts in your country to build capacity to conduct clinical trials? Does your country maintain a publically available clinical trials registry? Please provide a brief description of clinical trials capacity in your country, both public and private (e.g., contract research organizations).

10. **Ethical review**: Is there a national ethical review policy for clinical trials? Does it cover the composition and functions of institutional ethical review committees? Where have such committees been established, and are they linked to other similar committees through national, regional and/or global networks? (Elements 2.2.f, 3.3.b, 3.3.c)

11. **International collaboration**: Does your country participate in international efforts to build capacity and improve information in this area, e.g., International Clinical Trials Registry Platform (ICTRP) or European and Developing Countries Clinical Trials Partnership (EDCTP)? (Elements 2.2.f, 3.3.b, 3.3.c, 6.2.f)

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### Access to knowledge

12. **Scientific literature**: Do health professionals and researchers in your country have ready access to global public health literature? Are relevant publications available in national academic and government research institutions? (Element 2.4.a)

13. **Compound libraries**: Does your country maintain compound libraries? If yes, please provide a list, description, and note whether your country provides open access to these. (Element 2.2.a,b) Do researchers in your country have access to [Definition of compound libraries from Nature.com](http://www.nature.com/nrg/journal/v5/n4/glossary/nrg1317_glossary.html)
compound libraries established abroad? Please provide details and reasons. (Element 2.2.a,b)

14. **Relevance to product development**: If such open-access is available (as explained above), has it led to any new medical products? (Element 2.2.a)

**BUILDING AND IMPROVING INNOVATIVE CAPACITY**

**Human resource needs**

15. **National policy**: Does your country have a national policy or strategy focusing on human resources for health? If yes, does this policy include health researchers? Does it include incentives to retain health professionals including researchers? Please, provide details (Element 3.2.b,c)

16. **Public investment**: How much does your country invest in education and training of researchers and public health workers? (Element 3.1.a)

17. **Future workforce, general**: What disciplines are taught at university level related to public health, health research and health innovation? How many doctoral students per discipline does your country have? What has been the trend over the last 5-10 years? (Element 3.1a) [POSSIBLE SOURCE: UNESCO]

18. **Local production**: Do universities in your country provide education in industrial pharmacy, technology assessment, technology management, business management and entrepreneurship, project management and accounting? Do they have basic and applied tertiary science education and research training relevant to drug manufacture (e.g., medicinal chemistry, pharmacology, biostatistics, target identification, etc.) and vaccine manufacture (e.g., antigen development, vaccine formulation and industrial engineering education covering biologics manufacturing)?

19. **IP management**: Has there been any assessment of education and training needs for IP management, drafting and negotiating licenses, drafting patent applications, patent management, claims interpretation, how to manage IP "creatively" to promote both innovation and access, how to use TRIPS flexibilities and how to draft IP-related legislation that is sensitive to public health needs? (Element 5.1.a,e)

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9 Medicine, pharmaceutical science, health economics, traditional medicine, nursing schools etc
10 Life sciences, pharmaceutical sciences, chemistry, biology, traditional medicine, biotechnology, genomics etc. Please, refer to doctorate candidates with the nationality of your country that graduate from local universities.
20. **Dialogue with industry:** Do educational institutions and the education ministry in your country have mechanisms for continuing dialogue with representatives from industry to match curricula with industry needs? If yes, please provide details.

### Incentives for health innovation

21. **“Putting fuel in the tank” (rewarding academics):** Is there a policy or mechanism in your country to encourage health researchers to contribute to technological innovation (e.g., career advancement linked to patenting and/or industry collaboration)?  

22. **“Engaging the gears” (local public-private R&D partnerships):** Does your country have national policies to encourage R&D partnerships between publicly funded research institutions and local industry (e.g., Bayh-Dole-like legislation)? Please list examples of such partnerships, if any, and describe outcomes. Do academic and government research institutions in your country have Technology Transfer Offices (TTOs) to facilitate such partnerships to translate publicly funded research knowledge into products? If so, have they developed institutional policies to encourage access to inventions that arise from public investments?

23. **“Driving innovation” (with push and pull incentives):** What incentives exist in your country to encourage and reward local entrepreneurs and manufacturers in order to strengthen local innovation and production of health products (Element 3.5.a)? Examples may include R&D grants, tax breaks for R&D, business incubators, recognition and/or monetary prizes, soft-loans, preferential pricing for procurement from local manufacturers, restrictions on importation, grants to local public-private R&D partnerships and for Small Business Innovation Research (SBIR) to help local industry attract private capital and encourage the creation of spin-off companies from academic and government research institutions. Please distinguish between domestic incentives and those (if any) from external development partners. Please provide sources and examples.

24. **“Steering” innovation toward affordability and access:** Are any such incentives specifically designed to promote affordability and access for medicines that are a high priority to the national health system? Please provide sources and examples.

25. **Understanding national health information system:** Provide details about national health surveillance and information systems (Element 3.1c). Are there any assessment reports on the national health information system of your country?

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11 In public or private academic institutions or government laboratories.
12 For example, have they signed the AUTM Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies?
North-south and south-south cooperation for building innovation capacity

26. **Partnering:** Are there any North–South and/or South–South partnerships and programs for capacity building in the area of health innovation? (Elements 3.3.b, 2.2.f, 4.2.a)

MANUFACTURING OF PHARMACEUTICALS

**NOTE:** Questions 26-30 are drawn primarily from GSPA-PHI Element 4. Questions 31-50 are based on legislative and industry sections of "Strengthening Pharmaceutical Innovation in Africa," a project of the New Partnership for Africa’s Development (NEPAD) and the Council on Health Research for Development (COHRED).

International transfer of technology

27. **National strategy:** Is there a national strategy or policy to encourage and assist local manufacturers to acquire technologies from other countries for local production of health care products ("North-South technology transfer")? Please provide a link to sources of information.

28. **Technology assessment:** Is there a capacity for technology assessment in your country? Is there any recent assessment of technologies needed for health R&D and for local production of health products? (Element 4.3.b) Please provide links to sources of information. (See Q: 20, 43)

29. **Tracking collaboration and outcomes:** Does your country have a system for recording initiatives to facilitate technology transfer for local production of health products including: national, South-South and North-South cooperation? (Element 4.2.b) Does your country measure the contribution of local production to access to health products? If yes, please provide links to sources of information.

30. **Case studies:** Does your country have examples of success stories or failures in North–South and South–South technology transfer for local production of health products? If yes, please provide details and sources. (Elements 4.2.a, 3.3.b, 2.2.f)

31. **External private investment:** What is the level of foreign private investment (FDI and other financial flows) in pharmaceutical and other essential health technologies in your country? Please provide links to sources of information.

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13 This covers medicines, diagnostics, vaccines medical equipment and other medical devices...
### Local production: policies, capacity and legislation

32. **National policies:** Does your country have a national trade and investment policy? Does that policy cover active pharmaceutical ingredients (APIs) and biologics? Does your country have a national industrial policy? Does it cover the biotechnology and pharmaceuticals sectors? Does your country have a national science and technology (or innovation) policy or strategy? Does it include the health sector, and how does it balance economic aspirations with improvements in well-being including public health. What mechanisms are in place for intra-ministerial coordination of the S&T/innovation) policy? Provide links to sources of information.

33. **Publicly funded research institution capacities:** Are academic and government research institutions in your country able to act as sponsors for clinical trials? Do they have facilities (e.g., animal facilities) and the technical capacity to meet international licensure standards (Good Laboratory Practice) for drug discovery and for preclinical studies including preclinical vaccine studies (e.g., toxicity)? Do they have access to vaccine delivery systems and adjuvants?

34. **Biosafety:** What level of biosafety facilities exists in your country?

35. **Border controls:** Does your country minimize tariffs and duties on imported APIs? Describe. Can customs controls distinguish genuine from counterfeit API imports and exports? Does your country have anti-dumping policies (e.g., punitive tariffs)?

### Industry capacity for local production of existing products

36. **Good Manufacturing Practice:** Are pharmaceutical firms able to comply with Good Manufacturing Practice (GMP) in the manufacture of health products? Please provide links to sources of information.

37. **Importing Active Pharmaceutical Ingredients (APIs):** Are pharmaceutical firms able to identify API certified suppliers and test identity, quality and safety of procured APIs? Are they able to specify and test API requirements, e.g., formulation design, which can affect stability and bioavailability of finished drugs? Are they able to conduct bioequivalence studies of generic formulations? Please provide links to sources of information.

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14 “Dumping” happens when a manufacturer offers its product(s) at a price or quantity that cannot be explained through normal market competition. This may force other manufacturers out of a market, or completely out of business, leaving the “dumper” with a monopoly position. ([http://en.wikipedia.org/wiki/Dumping_(pricing_policy](http://en.wikipedia.org/wiki/Dumping_(pricing_policy)]]
38. **Manufacturing and distributing generic drugs:** Are pharmaceutical firms able to undertake formulation, process and scale-up of generic drugs? Are they able to produce APIs to GMP standards and pharmacopoeia requirements? Are they able to undertake small to large-scale manufacturing, commercialize appropriately for local markets and link to local distribution networks? Please provide links to sources of information.

39. **Meeting regulatory requirements:** Are pharmaceutical firms able to prepare drug master files for registration with the National Regulatory Authority? Are they able to prepare regulatory dossiers for generic drug registration, using both data from their own studies and referencing quality, safety and efficacy data from original drug regulatory files?

40. **Vaccine production:** Do firms have facilities specifically tailored to undertake large scale GMP-standard vaccine production (e.g., sealed fermentation, aseptic production and purification, and large-scale harvesting)?
41. **Vaccine quality control and assurance**: Are vaccine producers able to maintain and demonstrate a completely controlled production process (i.e., carry out stability and potency studies; maintain potency and yield during sterile filtration of particle-containing solutions; carry out full tracking of manufacturing batches and lot-by-lot release of vaccines)? Do firms have dedicated in-house quality control laboratories for assay development and processing?

Industry capacity to develop new products

42. **Improving known products**: Are public and/or private sector manufacturers able to access rights to original drugs and registration data for further development (e.g., combination therapies and new formulations)?

43. **Preclinical testing**: Are public and/or private sector manufacturers able to conduct drug and/or vaccine discovery and preclinical studies, bioequivalence studies and complex drug and vaccine clinical trials to international licensure standards? Are they able to access compound libraries and screening facilities? Are they able to access adjuvants and vaccine delivery technologies, and to conduct feasibility studies for large scale vaccine manufacturing?

44. **Meeting regulatory requirements**: Are public and/or private sector manufacturers able to prepare regulatory dossiers for clinical trial authorization and drug and biologics (vaccine) registration using data from their own clinical studies and referencing quality, safety and efficacy data from original drug regulatory files?

45. **Clinical trials**: Are public and/or private sector manufacturers able to design and implement clinical development plans for drugs and biologics (vaccines), and to sponsor drug and vaccine trials?

APPLICATION AND MANAGEMENT OF INTELLECTUAL PROPERTY

Trade agreements and intellectual property (IP)

46. **WTO and TRIPS**: Is your country a member of the World Trade Organization (WTO)? Has it entered into bilateral or regional trade agreements which have resulted in IP protection going beyond what is required by the TRIPS agreement? Has there been any public health impact assessment of such commitments? (Element 5.2.b) Do health representatives in your country participate in bilateral and multilateral trade and IP negotiations? (Element 5.1.g)
47. **National legislation:** Does national patent legislation incorporate flexibilities available under TRIPS and the Doha Declaration on TRIPS and Public Health? Has there been any assessment of national IP legislation with regard to public health? (Elements 5.2.a,c,d, 6.3.a) If your country is a least-developed country, has it used transitional periods offered by TRIPS for pharmaceutical processes? (Element 6.1.b)

48. **Intra-ministerial coordination:** What mechanism does your country use to coordinate policies on public health, intellectual property and trade? (Element 5.1.h)

**Patents and clinical trial data excludivity**

49. **National patent office:** Does your country have a national patent office? Is it a member of a relevant regional organization? Please, provide details. Does your country maintain a national database on patent applications and patents’ legal status (patent registry)? Is this information available electronically and accessible online?

50. **Protection of data disclosed to regulatory authorities:** Does your country provide for protection of clinical test data submitted to the national regulatory authority (as required by TRIPS to prevent unfair commercial use)? If yes, how?

**IMPROVING DELIVERY AND ACCESS**

**Access to quality medicines**

51. **Policies:** Is there a national poverty reduction strategy in your country, and does it address the health sector? (Element 6.1.f, 6.3.b) Is there a national medicines policy in the country, and a national essential medicines list? Does the national medicines policy include improving access to affordable medicines as one of its objectives? (Element 6.3.b, 6.1.f)

52. **Product quality:** Are any of the following standards/guidelines available in your country: Good Manufacturing Practices (Element 6.2.c); Good Clinical Practice (Elements 2.2.f, 3.3.b, 3.3.c, 6.2.f); and Good Laboratory Practice. Is there a national quality control laboratory in your country? Are any medical products from your country prequalified by the WHO? (Element 6.2.d) If yes, please list them.

**Delivery infrastructure and incentives**

53. **Procurement mechanisms:** What is the per-capita expenditure on medicines by government in your country, and what have been the trends over the past 5-10
14 years? (Element 6.1.a) Is your country part of any pooled procurement program for health products? (Element 6.1.g) If yes, please list them.

54. **Delivery infrastructure:** What are the strengths and weaknesses in the health delivery infrastructure in your country? Has there been any formal assessment of this infrastructure?\(^\text{15}\) (Element 6.1.a)

55. **Local incentives for delivery innovation:** What mechanisms are in place to create incentives for local delivery innovation, and for the adoption and adaptation of cost-effective health product and service delivery approaches from other countries or other sociocultural contexts?

**Regulation of safety and efficacy**

56. **Capacity and practice:** What are the staff numbers, budget and other capacity measures for the national regulatory authority (NRA) of your country. Is there any formal assessment report available on the NRA? Does the NRA regulate clinical trials? If so, does it require that all clinical trial data must be obtained from ethically approved trials? (Elements 3.2.a, 6.2.a)

57. **Harmonization or creation of regional authorities:** Is your country’s NRA part of any regional or sub-regional regulatory harmonization program? (Element 6.2.e) Is your country involved in negotiations that could lead to the creation of a regional regulatory authority to improve economies of scale, transparency and governance?

**Affordability of medical products**

58. **Promoting generics:** Are users, doctors and pharmacies in your country encouraged to use generic medicines. (Element 6.3.g) Please provide details. Does the national patent law in your country have a regulatory exception ("Bolar" type provision) by which generic versions can be introduced immediately after the expiration of a patent? (Element 6.3.a, 5.2.a,c,d)

59. **Understanding costs:** Has there been any medicine price survey in your country? Is there a price monitoring mechanism? (Element 6.3.e) Has any study been conducted to understand different price components (e.g., tariffs, whole-sale and retail-sale margins, etc.)? Does the government impose import duties on essential medicines and health technologies? (Element 6.3.c)

\(^\text{15}\) Refer to WHO assessments
PROMOTING SUSTAINABLE FINANCING MECHANISMS

Public-private R&D partnerships (PDPs)

60. **Global PDPs:** Is your country involved in partnerships with any global public-private product development partnership (PDP; e.g., International AIDS Vaccine Initiative, Medicines for Malaria Venture, Global Alliance for TB Drug Development, DNDi)? If yes, please provide details on the partnership(s).

61. **Domestic support for global PDPs:** Does your country give either financial or in-kind support to global PDPs? Please, provide details. (Element 7.2c) Does your country periodically assess the performance of local collaboration with global PDPs? If yes, please provide methodology. (Element 7.2b)

New sources of funding

62. **Revenue generation:** Has your country considered any of the options reviewed by the WHO Expert Working Group on R&D Financing, or its successor the WHO Consultative Expert Working Group on R&D Financing, for revenue generation to support domestic health innovation?

TRADITIONAL MEDICINE

Health, health research and health innovation policies

63. **National policies:** Does your country have a national policy on traditional medicine? If yes, does it cover issues related to innovation in the field of traditional medicine? (Element 3.4 a,b,c) Has your country included traditional medicine in its national health R&D strategy, and are there any R&D priorities identified in traditional medicine? (Element 1.3.a)

Production, regulation and protection

64. **Production and development:** Is there any local production of traditional medicines in your country? If yes, do publicly funded research institutions and/or private manufacturers have an ability to systematically evaluate and screen

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traditional medicines for successful compounds to be identified, developed and marketed?

65. **Regulation:** What is the status of regulation of traditional medicine in the country? Are there any national standards for quality production and R&D for traditional medicine? (Element 3.4.c)

66. **Protection of traditional knowledge:** What mechanism does your country use to prevent the misappropriation of traditional (medicinal) knowledge? Are there digital libraries for traditional medical knowledge, and do patent examiners have access to such information when examining patent applications? (Element 5.1.f.e)

**MONITORING AND REPORTING**

67. **Health metrics and health information system:** How are health and health system-related data and information collected in your country? In what form are such data and information available? Are there any on-going or planned national surveys on health-related issues in your country? If yes, please list them. Does your country participate in international initiatives to monitor progress in achieving the Millennium Development Goals? If yes, please list them.

68. **Domestic M&E profession:** Does your country have professional associations or organizations of experts in monitoring and evaluation (M&E) in the social sector? If yes, please provide a list.

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17 i.e.: clinical trials, epidemiology data (burden of diseases), medical records, healthcare facility and hospital management data, human resources for health