

AUGUST 2021

UNMOL (Urdu for Precious): Access to Cancer Medicines in Pakistan

Roche

Submitted as part of Access Accelerated

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The information in this report has been submitted by the company concerned to the Access Observatory as part of its commitment to Access Accelerated. The information will be updated regularly. For more information about the Access Observatory go to www.accessobservatory.org

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Program Description

Program Overview

1 Program Name

UNMOL (Urdu for precious): Access to cancer medicines in Pakistan

2 Diseases program aims to address

- Cancer (Breast; Cervical; Leukemia; Hematological; Colorectal)
- Other NCDs (Arthritis)

3 Beneficiary population

- Genders: All genders
- Ages: Adults aged 15-64
- Special populations: People with low income, Marginalized/ Indigenous people, Rural Populations

4 Countries

- Pakistan

5 Program start date

February 8, 2017

6 Anticipated program completion date

Completion date not specified.

7 Contact person

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8 Program summary

The primary object of “UNMOL” (Urdu for “Precious”) is to provide access to cancer medicines to out of pocket patients in Pakistan. The main hurdle identified is that patients have to pay out-of-pocket for treatment, whether people cannot or can afford to pay for the treatment. Therefore, the program offers a sustainable financial solution for those in need of oncology treatment to ultimately make an impact and increase health population in Pakistan. Pakistan’s per capita income is as low as \$1629 per annum and health care expenditure is only 2.8% of GDP.¹ This means that many patients in Pakistan are denied access to appropriate cancer care. Our aim is to address the lack of cancer care in Pakistan and make medicines affordable to more people.

The program address those challenges with the following strategies:

1) Create a pricing scheme for patients out of pockets:

Overall, Roche offers one vial free for each purchase or one free vial for every two purchasing. Moreover, Patient Behbud Society, The Shaukat Khanum Memorial Trust and SAYLANI would provide the first vial for free to support patients who cannot afford even a single vial.

Roche Pakistan applies a public patient financial evaluation tool (PFET) created by Pakistan Bait-ul-Mal to rank eligible patients to receive free medicines:

- A) ‘Fully affording’ patients, who don’t need support but are very few in number.
- B) ‘Partially affording’ patients, who are unable to complete their treatment.
- C) ‘Non-Affording’ patients who cannot afford even a single treatment cycle.

For those who are completely ‘non-affording’ patients, Roche has also partnered with the Pakistan Federal Government, who will pay 50% of the treatment cost of trastuzumab and bevacizumab and 83% of the treatment cost of rituximab. Roche Pakistan will provide remaining treatment free of cost. The objective of the program is to enable low income patients to afford standard of care medicines to treat their cancers. This will initially be a pilot program and we are expecting around 1500 patients to benefit in its first eighteen months.

2) Create data management system:

The project thanks to the IT provider Collage Solution has created a data management system to improve the patient journey. It would provide information regarding the the treatment cycles and in the future could be helpful to create evidence for policy change.

Finally, the partner Dimension Research provides assistance & guidance to patients through a dedicated team across the country as a third party on behalf of Roche Pakistan. They enroll patients to the program, provide education regarding patient support program to health care providers and allocate the pricing scheme.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	Dimension Research also educate health care professionals (HCPs) on patient support program (PSP). They train doctors to understand the patient support program and apply it as they are the ones who provide the card to enable low income patients to afford standard of care medicines to treat their diseases.
Technology	Thanks to the partnership with Collage Solution, the Program created an data information management tool in order to monitoring patients along the treatment and create internal reporting
Management	<p>Roche Pakistan applies a public patient financial evaluation tool (PFET) created by Pakistan Bait-ul-Mal to rank eligible patients to receive free medicines. The program has designed three segments based on income, assets, expenses and savings, to determine how many vials free of charge to assign:</p> <p>A) 'Fully affording' patients, who don't need support but are very few in number.</p> <p>B) 'Partially affording' patients, who are unable to complete their treatment.</p> <p>C) 'Non-Affording' patients who cannot afford even a single treatment cycle. Following the program offers to 'Partially affording' patients 1 free vial for every two purchases out of pocket and for 'Non-Affording' patients 1 free vial for each first purchase.</p> <p>Lastly, The program partnered with Patient Behbud Society, Shaukat Khanum Memorial Trust and SAYLANI to provide all the treatments for free to Marginalized/ Indigenous people who demonstrate to do not afford even the first vial.</p>
Funding	Roche Pakistan provides fund to Dimension Research for the activities regarding the patient support program

Strategy 2: Health Service Delivery

ACTIVITY	DESCRIPTION
Retention	Dimension Research after signing the patients to the program makes telephone calls to all enrolled patients, 3 days before the dosage to arrange the free of charge medicine. Similarly, they call the patients to verify if the patient has started the treatment and then record that information in the system.

Program Strategies & Activities

9 Strategies and activities, cont.

Strategy 3: Price Scheme

ACTIVITY	DESCRIPTION
Pricing	<p>The program offer different pricing scheme dependent from the financial situation of the patient enrolled to the program. It is developed in the following ways:</p> <ul style="list-style-type: none"> - 1 free vial for each first purchase - 1 free vial for every two purchases out of pocket <p>Lately, The program partnered with Patient Behbud Society, Shaukat Khanum Memorial Trust and SAYLANI which provide also the first vial for free for patients who cannot even effort the first purchase.</p>
Communication	Dimension Research make calls to Patients and health care providers for free to enrollment to the program.

10 Strategy by country

STRATEGY	COUNTRY
Health Service Strengthening	Pakistan
Health Service Delivery	Pakistan
Price Scheme	Pakistan

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Roche	UNMOL is a Roche Pakistan initiative. Roche has collaborated with the government and an independent third party to implement the patient support program.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Pakistan Bait-ul-Maal	It is federal government entity and has charitable fund. They assess patients' requests to provide funds for the purchase of medicines they need. In this patient support program as per Memorandum of Understanding (MOU) they provide funds for the 50% of the total treatment cost of Herceptin and Avastin and 83% treatment cost of Ristova to the eligible deserving patients. Roche Pakistan provides remaining treatment free of cost. www.pbm.gov.pk	Public
Dimension Research	They enroll those patients in the program who get approval from Pakistan Bait-ul-Maal (PBM) and provide free of cost medicine to them after they have purchased cycles from PBM fund as per the memorandum of understanding. They also enroll partially affording patients and perform their assessment and allocate free of charge (FOC) scheme accordingly and then also provide FOC medicine as per approved plan. They also educate health care professionals (HCPs) on patient support program (PSP). Dimension Research Third Party URL: www.drcro.com	Private
The Shaukat Khanum Memorial Trust	The Shaukat Khanum Memorial Trust has established a number of centres all over Pakistan that help in the awareness, diagnosis, and treatment of cancer in Pakistan. At the core they provide free medicines "To act as a model institution to alleviate the suffering of patients with cancer through the application of modern methods of curative and palliative therapy irrespective of their ability to pay, the education of health care professionals and the public and perform research into the causes and treatment of cancer." Thanks to the MoU with Roche they also provide the first vials for free to patients who cannot even afford it. https://shaukatkhanum.org.pk/	Private
SAYLANI	Saylani Welfare International Trust was built on the fundamentals of breaking the cycle of poverty, alleviating the financial troubles of the poorest. Today, it has a network of 125 branches operating in major cities including Karachi, Lahore, Islamabad, Rawalpindi, Hyderabad and Faisalabad. Apart from Pakistan, they also have overseas offices in the UK, USA and UAE as well. Their team has over 2,000 working professionals who help almost 125,000 people on a daily basis. Thanks to the MoU with Roche they also provide the first vials for free to patients who cannot even afford it. http://www.saylaniwelfare.com/home	Private

Companies, Partners & Stakeholders

12 Funding and implementing partners, cont.

PARTNER	ROLE/URL	SECTOR
Collage Solution	They provide IT based solution to the project UNMOL and also worked on data safety and security. Collage Solutions is a team of diverse web development and design experts who provide IT support and solutions to business and organizations around the world. They created for the project the data information management tool with clouds and information technology and provide report for example on treatment cycles. http://www.collagesolutions.com/default.html	Private
Patient Behbud Society	The Patients' Behbud Society for Aga Khan University Hospital? is an independent, charitable society responsible for collecting and disbursing zakat. Zakat is used to help mustehiq patients access high quality medical treatment at the Aga Khan University Hospital (AKUH) and its secondary hospitals. Therefore, their main object in the program is to provide the first vial for free to patients who cannot even afford it and they use their internal financial evaluation to assign it. http://pbs.akuh.org/	Private

13 Funding and implementing partners by country

PARTNER	COUNTRY
Pakistan Bait-ul-Maal	Pakistan
Dimension Research	Pakistan
The Shaukat Khanum Memorial Trust	Pakistan
SAYLANI	Pakistan
Collage Solution	Pakistan
Patient Behbud Society	Pakistan

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	DESCRIPTION OF ENGAGEMENT
Government	UNMOL partners with Pakistan's federal government to provide treatment to eligible cancer patients who will benefit from Roche's biologics.	Infrastructure: [No response provided] Human Resources: [No response provided] Funding: Yes Monitoring or Oversight: [No response provided] Other resources: Yes
Other	UNMOL is working with Dimension Research to do the financial assessment of patients and ensuring patient	

Local Context, Equity & Sustainability

15 Local health needs addressed by program

Pakistan is an out of pocket market where per capita income is as low as \$1629 per annum and health care expenditure is only 2.8% of GDP. This means that very few patients can afford treatment with biologic medicines. With this in mind, Roche approached the federal government with a partnership proposal to address these issues and make the medicines affordable to many more patients. For those patients who do not meet the federal government low income status, Roche has appointed an independent third party to perform a financial assessment of the patient and then allocate assistance plan for free of cost medicine from Roche.¹

a How needs were assessed

The needs assessment was derived from a number of Roche internal and external sources, there is no 'one' document.

b Formal needs assessment conducted

[No response provided]

16 Social inequity addressed

UNMOL addresses social inequity in Pakistan providing cancer medicine to out of pocket patients who cannot afford. Every patient has the right to access standard of care medicines, but since Pakistan is an out-of-pocket market, it is very difficult for low- and middle-income patients to afford treatment. Roche's program helps low- and middle-income patients access innovative biologics which are a standard of care in other countries. Moreover, thanks to its partnerships it provides access to healthcare to the poorest population after financial reviewing.

17 Local policies, practices, and laws considered during program design

POLICY, PRACTICE, LAW	APPLICABLE TO PROGRAM	DESCRIPTION OF HOW IT WAS TAKEN INTO CONSIDERATION
National regulations	Yes	[No response provided]
Standard treatment guidelines	Yes	There are no national guidelines on patient support program therefore, Roche Global guidelines are followed.

Local Context, Equity & Sustainability

18 How diversion of resources from other public health priorities is avoided

UNMOL is working with Dimension Research to do the financial assessment of patients and ensuring patient retention. This prevents diverting resources away from public health priorities.

19 Program provides health technologies (medical devices, medicines, and vaccines)

Yes

TYPE	COMMERCIAL NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)
Medicine	Herceptin	Trastuzumab
Medicine	Ristova	Rituximab
Medicine	Avastin	Bevacizumab
Medicine	Perjeta	Pertuzumab
Medicine	Gasyva	Obinutuzumab
Medicine	Ocrevus	Ocrelizumab
Medicine	Mab Thera	Rituximab

20 Health technologies are part of local standard treatment guidelines

No. There are no local treatment guidelines, international treatment guidelines are followed.

21 Health technologies are covered by local health insurance schemes

No. The medicines that Roche provides are currently not covered by the local health insurance schemes. Hence, Roche is supporting patients and offers them at reduced price depending on the patient ability to pay.

22 Program provides medicines listed on the National Essential Medicines List

No.

23 Sustainability plan

We designed the program to be sustainable by using a cost sharing strategy in which individuals, government and Roche share the cost of treatment. This strategy is more sustainable in the long term than a medicine donation program and also covers more patients than a traditional donation program. Roche is looking for new partners through public private partnerships in order to have a larger scale impact. Ultimately, the data information system could generate evidence to bring to the Pakistan Government for policy change.

Additional Program Information

24 Additional program information

[No response provided]

a Potential conflict of interest discussed with government entity

No.

25 Access Accelerated Initiative participant

Yes.

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Yes.

Program Indicators

PROGRAM NAME

UNMOL (Urdu for Precious): Access to Cancer Medicines in Pakistan

27 List of indicator data to be reported into Access Observatory database

INDICATOR	TYPE	STRATEGY	2017	2018	2019	2020	2017-2020
1 Number of patients enrolled in patient support program	Output	Price Scheme	678 people	3,049 people	3,448 people	3,552 people	---
2 Number of patients reached with pricing scheme	Output	Price Scheme	678 people	3,049 people	3,448 people	---	---
3 Number of medicines received	Outcome	Price Scheme	666 medicines	6,148 medicines	11,897 medicines	14,684 medicines	---
4 Tools in use	Output	Health Service Strengthening	---	---	---	---	1 tool

Number of patients enrolled in patient support program

STRATEGY PRICE SCHEME

ITEM	DESCRIPTION
Definition	Number of individuals that are enrolled in the patient support program
Method of measurement	Count of the number of patients enrolled in the program
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Dimension Research	<p>The program uses a software to record the number of patients enrolled in the program, the number of patients that have started and is going to record the count of patients that complete treatment. Dedicated Patient support officers who are third party employees (Dimension Research) perform this role. The patient support officers who record the data for this patient support program, are trained and provided with a guidance book about how to collect the information. They have also been trained on adverse event reporting.</p> <p>The process looks as follows: Physicians refer patients to the patient support officer who assesses the financial eligibility of the patients. Eligible patients are enrolled in the scheme after an in-person assessment of the patient's eligibility (caregivers can represent the patient if the patient is unable to attend) at the Third party's (Dimension Research) office. After this evaluation, patients sign a consent form and are thus officially enrolled. The patient support officers make telephone calls to all enrolled patients on the day when treatment cycle is due in order to verify if the patient has started the treatment and then record that information in the system. They also record when all the cycles have been completed for which they ask patient to submit hospital stamp/infusion report that shows that patient has received prescribed cycles. Patients receive medicines either directly or medicines are delivered to the pharmacy and patients can get them from there.</p>	Ongoing

Number of patients enrolled in patient support program

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
31 Data processing	Dimension Research	Once a month, Dimension Research uses routine program records to add the number of patients enrolled in the program and provides the total aggregated value to Roche."	Ongoing
32 Data validation	Audit firm	Roche has appointed an audit firm to audit the Third party who is implementing this program. The audit firm will do monthly audits on a randomly selected sample (sample size is 20% of entire population) and quarterly audits on the entire population. The audit firm verifies that the data collected is correct. To do so they refer to defined standard operating procedures (SOP) and other procedures already in place.	

33 Challenges in data collection and steps to address challenges

Roche faced the following challenges: Incomplete documentation, Missing Safety Reporting, and Dosage delay.

In order to mitigate them, Quarterly SDQC audit and external auditors audit the incomplete documentation and proper safety reporting at each & every location. Moreover, Each free-of-cost (FOC) medicine expedites through an online process of approval.

Roche is now in a process of developing a live dashboard that shows an overall picture of the project e.g. Number of new patients, city-wise, product wise and Scheme wise and similarly the timely FOC deliveries which we are dependent upon the service provider to share a report on a monthly basis. So the dashboard will give us a clear picture on a daily basis.

INDICATOR	2017	2018	2019	2020
1 Number of patients enrolled in patient support program	678 people	3,049 people	3,448 people	3,552 people

Comments: Preliminary data from 01/01/21 to 03/31/21: 990 patients enrolled.

Number of patients reached with pricing scheme

ITEM	DESCRIPTION
Definition	Number of individuals that received medicines included in the price scheme
Method of measurement	Counting the number of individuals that received medicines included in the price scheme Calculation: Sum of the number of individuals that received medicines included in the price scheme
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Dimension Research	<p>The program uses a software to record the number of patients enrolled in the program and the numbers that have actually started and completed treatment. Dedicated Patient support officers who are third party (Dimension Research) employees perform this role. These patient support officers who record the data of the number of patients that have started and completed the treatment through this patient support program, are trained and provided with a guidance book on how to collect this information. They have also been trained on adverse event reporting.</p> <p>Physicians refer patients to the patient support officer who assesses the financial eligibility of the patients using documents supplied by the patients. Eligible patients are enrolled in the scheme after an in-person assessment of the patient's eligibility (caregivers can represent the patient if patient is unable to come) at the Third party's (Dimension Research) office.</p> <p>After this evaluation, patients sign a consent form and are thus officially enrolled. The patient support officers make telephone calls to all enrolled patients on the day when treatment cycle is due in order to verify if the patient has started the treatment and then record that information in the system. They also record when all the cycles have been completed for which they ask patient to submit hospital stamp/ infusion report that shows that patient has received prescribed cycles. Patients receive medicines either directly or medicines are delivered to the pharmacy and patients can get them from there.</p>	Once per year

Number of patients reached with pricing scheme

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
31 Data processing	Dimension research	Once a month, Dimension Research verifies routine program data to add the number of patients enrolled in the program who have received medicine through the pricing scheme and then provides the total aggregated value to Roche.	Ongoing
32 Data validation	Audit firm	Roche has appointed an audit firm to audit the Third party who is implementing this program. The audit firm will do monthly audits on a randomly selected sample (sample size is 20% of entire population) and quarterly audits on the entire population. The audit firm verifies that the data collected is correct. To do so they refer to defined standard operating procedures (SOP) and other procedures already in place.	

33 Challenges in data collection and steps to address challenges

Roche faced the following challenges: Incomplete documentation, Missing Safety Reporting, and Dosage delay.

In order to mitigate them, Quarterly SDQC audit and external auditors audit the incomplete documentation and proper safety reporting at each & every location. Moreover, Each free-of-cost (FOC) medicine expedites through an online process of approval.

Roche is now in a process of developing a live dashboard that shows an overall picture of the project e.g. Number of new patients, city-wise, product wise and Scheme wise and similarly the timely FOC deliveries which we are dependent upon the service provider to share a report on a monthly basis. So the dashboard will give us a clear picture on a daily basis.

INDICATOR	2017	2018	2019	2020
2 Number of patients reached with pricing scheme	678 people	3,049 people	3,448 people	3,552 people

Comments: Preliminary data from 01/01/21 to 03/31/21: 990 patients were reached with pricing scheme.

Number of medicines received

ITEM	DESCRIPTION
Definition	Number of patients receiving the medicines included in the pricing scheme
Method of measurement	Counting the patients who received the medicines included in the pricing scheme Calculation: Sum of all patients who received the medicines included in the pricing scheme
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Collage Solution	<p>The program uses software developed by Collage Solution to record the number of patients enrolled in the program and the numbers that have actually started and completed treatment. Dedicated Patient support officers who are third-party (Dimension Research) employees perform this role.</p> <p>These patient support officers who record the data of the number of patients that have started and completed the treatment through this patient support program are trained and provided with a guidebook on how to collect this information. They have also been trained on adverse event reporting. Physicians refer patients to the patient support officer who assesses the financial eligibility of the patients using documents supplied by the patients. Eligible patients are enrolled in the scheme after an in-person assessment of the patient's eligibility (caregivers can represent the patient if the patient is unable to come) at the Third party's (Dimension Research) office. After this evaluation, patients sign a consent form and are thus officially enrolled. The patient support officers make telephone calls to all enrolled patients on the day when the treatment cycle is due in order to verify if the patient has started the treatment and then record that information in the system. They also record when all the cycles have been completed for which they ask the patient to submit a hospital stamp/infusion report that shows that patient has received prescribed cycles. Patients receive medicines either directly or medicines are delivered to the pharmacy and patients can get them from there. The number of medicine is further controlled by the stock of medicine delivered.</p>	Ongoing

Number of medicines received

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
31 Data processing	Roche; Collage Solution	Roche thanks to its partnership with Collage Solution receive reports on the cycle treatment. Data is registered in the system and analyzed by them and finally checked by Roche. Roche double-checks the number of medicine received by its stock system.	Once per year
32 Data validation	Audit firm	Roche has appointed an audit firm to audit the Third party who is implementing this program. The audit firm will do monthly audits on a randomly selected sample (sample size is 20% of entire population) and quarterly audits on the entire population. The audit firm verifies that the data collected is correct. To do so they refer to defined standard operating procedures (SOP) and other procedures already in place. A member of Roche Global team review the data annually and help building new systems or awareness on the importance of trustful data	

33 Challenges in data collection and steps to address challenges

Roche faced the following challenges: Incomplete documentation, Missing Safety Reporting, and Dosage delay.

In order to mitigate them, Quarterly SDQC audit and external auditors audit the incomplete documentation and proper safety reporting at each & every location. Moreover, Each free-of-cost (FOC) medicine expedites through an online process of approval.

Roche is in a process of developing a live dashboard that shows an overall picture of the project e.g. Number of new patients, city-wise, product wise and Scheme wise and similarly the timely FOC deliveries which we are dependent upon the service provider to share a report on a monthly basis. So the dashboard will give us a clear picture on a daily basis

INDICATOR	2017	2018	2019	2020
3 Number of medicines received	666 medicines	6,148 medicines	11,897 medicines	14,684 medicines

Comments: Preliminary data from 01/01/21 to 03/31/21: 4,808 medicines were received in 2021.

Tools in use

ITEM	DESCRIPTION
Definition	Number of tools (e.g., mHealth, EMR, etc.) introduced and in use by the program
Method of measurement	Counting the number of tools created and in use by the program Calculation: Sum of number of tools created by the program
28 Data source	Non-routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Collage Solution	The Data Information Management Tool has been created by the implementing partner, Collage solution. The tool provided by Collage Solution is a software that is used by Service Provider to enroll patients and save their data in the software to track the individual patient and process their FOC medicines and maintain the inventory. Roche LSR (Local Safety Responsible) has access to the data for the SDQC audit. Collage is only providing technical support in terms of Software maintenance and development while Roche has no access except for the LSR for SDQ audit. Service provider share reports which are extracted from the same software to share with the Roche PSP Lead.	Ongoing
31 Data processing	Roche	Same as above.	Every month
32 Data validation	Audit firm	Roche has appointed an audit firm to audit the Third-party who is implementing this program. The audit firm will do monthly audits on a randomly selected sample (sample size is 20% of the entire population) and quarterly audits on the entire population. The audit firm verifies that the data collected is correct. To do so they refer to defined standard operating procedures (SOP) and other procedures already in place.	

33 Challenges in data collection and steps to address challenges

Roche faced the following challenges: Incomplete documentation, Missing Safety Reporting, and Dosage delay. In order to mitigate them, Quarterly SDQC audit and external auditors audit the incomplete documentation and proper safety reporting at each & every location. Moreover, Each free-of-cost (FOC) medicine expedites through an online process of approval. Roche is now in a process of developing a live dashboard that shows an overall picture of the project e.g. Number of new patients, city-wise, product wise and Scheme wise and similarly the timely FOC deliveries which we are dependent upon the service provider to share a report on a monthly basis. So the dashboard will give us a clear picture on a daily basis.

INDICATOR	2017	2018	2019	2017-2020
4 Tools in use	---	---	---	1 tool

Comments: N/A.

Appendix

This program report is based on the information gathered from the Access Observatory questionnaire below.

Program Description

PROGRAM OVERVIEW

- 1 Program Name
- 2 Diseases program aims to address:
Please identify the disease(s) that your program aims to address (select all that apply).
- 3 Beneficiary population
Please identify the beneficiary population of this program (select all that apply).
- 4 Countries
Please select all countries that this program is being implemented in (select all that apply).
- 5 Program Start Date
- 6 Anticipated Program Completion Date
- 7 Contact person
On the public profile for this program, if you would like to display a contact person for this program, please list the name and email address here (i.e. someone from the public could email with questions about this program profile and data).
- 8 Program summary
Please provide a brief summary of your program including program objectives (e.g., the intended purposes and expected results of the program; if a pilot program, please note this). Please provide a URL, if available. Please limit replies to 750 words.

PROGRAM STRATEGIES & ACTIVITIES

- 9 Strategies and activities
Based on the BUSPH Taxonomy of Strategies, which strategy or strategies apply to your program (please select all that apply)?
- 10 Strategy by country
If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g. some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have you selected from above (program strategies), please identify which country/countries these apply.

COMPANIES, PARTNERS AND STAKEHOLDERS

- 11 Company roles
Please identify all pharmaceutical companies, including yours, who are collaborating on this program:

What role does each company play in the implementation of your program?
- 12 Funding and implementing partners
Please identify all funding and implementing partners who are supporting the implementation of this program (Implementing partners is defined as either an associate government or non-government entity or agency that supplements the works of a larger organization or agency by helping to carry out institutional arrangements in line with the larger organization's goals and objectives.)
 - a. What role does each partner play in the implementation of your program? Please give background on the organization and describe the nature of the relationship between the organization and your company. Describe the local team's responsibilities for the program, with reference to the program strategies and activities. (response required for each partner selected).
 - b. For each partner, please categorize them as either a Public Sector, Private Sector, or Voluntary Sector partner.

(Public Sector is defined as government; Private Sector is defined as A business unit established, owned, and operated by private individuals for profit, instead of by or for any government or its agencies. Generation and return of profit to its owners or shareholders is emphasized; Voluntary Sector is defined as Organizations whose purpose is to benefit and enrich society, often without profit as a motive and with little or no government intervention. Unlike the private sector where the generation and return of profit to its owners is emphasized, money raised or earned by an organization in the voluntary sector is usually invested back into the community or the organization itself (ex. Charities, foundations, advocacy groups etc.))

c. Please provide the URL to the partner organizations' webpages

13 Funding and implementing partners by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g., some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have you selected from above (funding and implementing partners), please identify which country/countries these apply.

14 Stakeholders

Please describe how you have engaged with any of these local stakeholders in the planning and/or implementation of this program. (Stakeholders defined as individuals or entities who are involved in or affected by the execution or outcome of a project and may have influence and authority to dictate whether a project is a success or not (ex. Ministry of Health, NGO, Faith-based organization, etc.). Select all that apply.

- Government, please explain
- Non-Government Organization (NGO), please explain
- Faith-based organization, please explain
- Commercial sector, please explain
- Local hospitals/health facilities, please explain
- Local universities, please explain
- Other, please explain

LOCAL CONTEXT, EQUITY & SUSTAINABILITY

15 Local health needs addressed by program

Please describe how your program is responsive to local health needs and challenges (e.g., how you decided and worked together with local partners to determine that this program was

appropriate for this context)?

- a How were needs assessed
- b Was a formal need assessment conducted

(Yes/No) If yes, please upload file or provide URL.

16 Social inequity addressed

Does your program aim to address social inequity in any way (if yes, please explain). (Inequity is defined as lack of fairness or justice. Sometime 'social disparities,' 'structural barriers' and 'oppression and discrimination' are used to describe the same phenomenon. In social sciences and public health social inequities refer to the systematic lack of fairness or justice related to gender, ethnicity, geographical location and religion. These unequal social relations and structures of power operate to produce experiences of inequitable health outcomes, treatment and access to care. Health and social programs are often designed with the aim to address the lack of fairness and adjust for these systematic failures of systems or policies.*)

*Reference: The definition was adapted from Ingram R et al. Social Inequities and Mental Health: A Scoping Review. Vancouver: Study for Gender Inequities and Mental Health, 2013.

17 Local policies, practices, and laws considered during program design

How have local policies, practices, and laws (e.g., infrastructure development regulations, education requirements, etc.) been taken into consideration when designing the program?

18 How diversion of resources from other public health priorities is avoided

Please explain how the program avoids diverting resources away from other public health priorities? (e.g. local human resources involved in program implementation diverted from other programs or activities).

19 Program provides health technologies

Does your program include health technologies (health technologies include medical devices, medicines, and vaccines developed to solve a health problem and improve quality of lives)? (Yes/No)

20 Health technology(ies) are part of local standard treatment guidelines

Are the health technology(ies) which are part of your program part of local standard treatment guidelines? (Yes/No) If not,

what was the local need for these technologies?

21 Health technologies are covered by local health insurance schemes

Does your program include health technologies that are covered by local health insurance schemes? (Yes/No) If not, what are the local needs for these technologies?

22 Program provides medicines listed on the National Essential Medicines List

Does your program include medicines that are listed on the National Essential Medicines List? (Yes/No) If not, what was the local need for these technologies?

23 Sustainability plan

If applicable, please describe how you have planned for sustainability of the implementation of your program (ex. Creating a transition plan from your company to the local government during the development of the program).

ADDITIONAL PROGRAM INFORMATION

24 Additional program information

Is there any additional information that you would like to add about your program that has not been collected in other sections of the form?

a Potential conflict of interest discussed with government entity

Have you discussed with governmental entity potential conflicts of interest between the social aims of your program and your business activities? (Yes/No) If yes, please provide more details and the name of the government entity.

25 Access Accelerated Initiative participant

Is this program part of the Access Accelerated Initiative? (Yes/No)

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Is your company a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)? (Yes/No)

Program Indicators

INDICATOR DESCRIPTION

27 List of indicator data to be reported into Access Observatory database

For this program, activities, please select all inputs and impacts for which you plan to collect and report data into this database.

28 Data source

For this indicator, please select the data source(s) you will rely on.

29 Frequency of reporting

Indicate the frequency with which data for this indicator can be submitted to the Observatory.

30 Data collection

- a. Responsible party: For this indicator, please indicate the party/parties responsible for data collection.
- b. Data collection — Description: Please briefly describe the data source and collection procedure in detail.
- c. Data collection — Frequency: For this indicator, please indicate the frequency of data collection.

31 Data processing

- a. Responsible party: Please indicate all parties that conduct any processing of this data.
- b. Data processing— Description: Please briefly describe all processing procedures the data go through. Be explicit in describing the procedures, who enacts them, and the frequency of processing.
- c. Data processing — Frequency: What is the frequency with which this data is processed?

32 Data validation

Description: Describe the process (if any) your company uses to validate the quality of the data sent from the local team.

33 Challenges in data collection and steps to address challenges

Please indicate any challenges that you have in collecting data for this indicator and what you are doing to address those challenges.

