AUGUST 2021

Perjeta Patient Support Programme, Egypt

Roche

Submitted as part of Access Accelerated

Access Observatory

Contents

Program Description

Program Overview

1 Program Name

Perjeta Patient Support Programme

2 Diseases program aims to address

• Cancer (breast)

3 Beneficiary population

• Gender: All genders
• Age: All ages, Adults aged 15-64
•Special populations: People with low income, Rural populations, Urban populations

4 Countries

• Egypt

5 Program start date

January 01, 2016

6 Anticipated program completion date

Completion date not specified.

7 Contact person

Gehad Refky (Patient Experience Chapter Lead, Roche Egypt), gehad.refky@roche.com

8 Program summary

The Perjeta Patient Support Program (PSP) in Egypt was introduced in June 2016 and is designed to improve access to innovative treatment for women with breast cancer. Budget constraints in the public healthcare system have meant that Perjeta (Pertuzumab), a treatment for HER2 positive breast cancer patients, is not reimbursed. Treatment is currently only available for patients in the private sector, so the program is designed to serve out of pocket patients through patient support program. There is no eligibility criteria to include patients, except for the fact that the patient needs to purchase the drug by herself - not by a hospital or center. This ensures that the offer/ benefit is given to the patient only and not to a hospital or private insurance company. Once the patient is enrolled into the program, she gets a membership card and vouchers for testing. Once she completes purchasing two vials (two cycles), she get one free vial (third cycle).The program objectives are to:

- Provide financial support to out of pocket patients: with free medicine doses and diagnostic tests for women with breast cancer. Specifically, the program collaborates with health care providers (HCP) which inform the patients and provide one vial free for every two vials purchase.

- Increase patients awareness on breast cancer: Educational brochures designed for patients to give them more information about disease and medicine, and it is distributed through HCPs.

- Retain people into health care: Third party call center reminds the patients about their doses due dates and advise them to buy the dose and go for injection at the private clinics.

- Improve health service delivery: Roche gives fund to Cairo Scan Lab to provide free diagnosis to patients enrolled into the program.

(continued on next page)

Program Overview

8   Program summary cont.

Three main stakeholders are involved in the program with Roche:

1. Raya Call Center: Raya Call center is one of the top vendors in Egypt that has an experience with patient support program. They manage the registration of the patients in the program, and their access to the financial support and they remind them of the doses dates and private clinics appointments.

2. Cairo Scan Lab: We work with laboratory group that has a significant number of branches all over the country and provides the patients with the free diagnostic tests on our behalf.

3. Healthcare providers (HCPs): They are responsible for providing patients with an initial overview of the program with a membership card to start use it with the call center and educational brochure for better understanding of the disease.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	The program provides educational brochures to increase community awareness on breast cancer. Till 2018 it also provided life coach sections and patient supports thanks to Can Survive. In 2019 , after considerations with the patients through calls and face to face meetings the activity was labelled not efficient or not needed by the patients, therefore, the main resources have been shifted to other activities.

Strategy 2: Health Service Delivery

ACTIVITY	DESCRIPTION
Screening	Screens breast cancer patients for HER2 oncogene by Cairo Scan Lab.
Diagnosis	The diagnostic test provided by Roche Egypt by partnering with Roche Diagnostics is not limited to the PSP because we sponsor the Her2 tests for every breast cancer patient in Egypt regardless of whether she will be enrolled or not in the PSP. This is to make sure we have the highest quality HER2 tests done for everyone and not just for the PSP patients. Also Echo + CT scans and Brain MRI or PET is sponsored every 3 cycles to make sure the patient is evaluated right.
Retention	Third party call center reminds patients of medicine doses and hospital appointments.

Strategy 3: Price Scheme

ACTIVITY	DESCRIPTION
Pricing	Provides Perjeta (Pertuzumab) to eligible patients. Roche is offering a free vial on each 2 vials purchased.
Communication	Health care providers inform patients about the program.

Program Strategies & Activities

10 Strategy by country

STRATEGY	COUNTRY
Community Awareness and Linkage to Care	Egypt
Health Service Delivery	Egypt
Price Scheme	Egypt

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Roche	Roche has initiated and implemented the program and provides financial support so that patients have access to free medicine and diagnostic tests.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Cairo Scan Lab	We work with a laboratory group that has a significant number of branches all over the country. They provide patients with free screening and diagnostic tests on our behalf. http://www.cairoscan.com.eg/	Private
Can Survive Egypt	The Oncology Patient Group ('Can Survive') is the only oncology patient support group in Egypt. It helps with the emotional support by conducting group therapy sessions and individual life coach sessions for cancer patients. Roche is working closely with the group to support adherence to treatment. Since 2019 it is no longer available. https://www.facebook.com/CanSurvive/	Voluntary
Raya Call center	Raya call center is one of the top vendors in Egypt and has experience with similar programs for the other companies. They manage the registration of the patients in the program and their access to financial support. Moreover, they remind patients of medicine doses and hospital appointments. http://www.rayacc.com/	Private

13 Funding and implementing partners by country
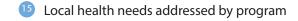
PARTNER	COUNTRY
Cairo Scan Lab	Egypt
Can Survive Egypt	Egypt
Raya Call center	Egypt

Companies, Partners & Stakeholders

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKE-
Government	Government was briefed on and approved the PSP.	Infrastructure: No Human Resources: No Funding: No Monitoring or Oversight: No Other resource: Yes
Non-government organization (NGO)	Roche engaged with CanSurvive Egypt. An agreement was signed with this entity to provide group therapy sessions for the patients enrolled in our program and initiate for them individualized life coach sessions.	Infrastructure: No Human Resources: No Funding: No Monitoring or Oversight: No Other resource: Yes
Commercial Sector	Raya Call center is one of the top vendors in Egypt that has experience with patient support programs. They manage the registration of the patients in the program, and their access to financial support and they remind them of the doses dates and private clinics appointments.	Infrastructure: No Human Resources: No Funding: No Monitoring or Oversight: No Other resource: Yes
Local Hospitals/ Health Facilities	Local labs have been involved the program through contract to provide the free testing to patients. Healthcare providers (HCPs) are responsible to provide patients with an initial overview of the program, with a membership card that could be used at the Cairo Scan Lab, call center, and selected pharmacies, and with an educational brochure to better understand the disease.	Infrastructure: No Human Resources: Yes Funding: No Monitoring or Oversight: Yes Other resource: No

Local Context, Equity & Sustainability

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15 Local health needs addressed by program

The disease burden of breast cancer in Egypt is increasing. The annual mortality rate per 100,000 people from breast cancer in Egypt has increased by 10.4% since 1990. In 2017, the annually mortality rate (per 100 000) people was as high as 5.7. This means that a total of about 5500 people die of breast cancer each year. The health system in Egypt has one of the lowest GDP Per Capita in the Middle East. In addition, the treatment adherence for metastatic breast cancer is low due to unaffordability since the treatment is all out of pocket, as targeted therapy in not reimbursed in metastatic breast cancer treatment. Today, Breast Cancer represents around 35% of total women cancer patients in Egypt.[1,2,3]

a How needs were assessed

[No response provided]

b Formal needs assessment conducted

[No response provided]

16 Social inequity addressed

Breast cancer is the number one killer cancer of Egyptian women. According to the National Cancer Institute, the disease accounts for as much as 35% of all cancer cases treated at the institution. If detected early, 95 percent of breast cancer can be cured. However, in Egypt recovery rates remain alarmingly low due to female-related taboos and patriarchal values that hinder the detection and diagnose of the fatal disease. When designing the Perjeta Patient Support Program (PSP) we recognized that several systemic hurdles, including cultural aspects, need to be addressed. Following, this program addresses the global inequitable access to Perjeta (Pertuzumab), a treatment for HER2 positive breast cancer patients, between patients in Egypt and high-income countries. The program also tackles the inequity locally in Egypt among patients who have access to reimbursement and out-of-pocket patients. The program addresses inequitable access to important cancer medicine by enabling eligible patients in the public sector hospitals to start and complete their entire course of treatment even when they cannot afford to pay for it in full.

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

Breast cancer is the number one killer cancer of Egyptian women. According to the National Cancer Institute, the disease accounts for as much as 35% of all cancer cases treated at the institution. If detected early, 95 per cent of breast cancer can be cured. However, in Egypt recovery rates remain alarmingly low due to female-related taboos and patriarchal values that hinder the detection and diagnose of the fatal disease. When designing the Perjeta Patient Support Program (PSP) we recognized that several systemic hurdles, including cultural aspects, capacity issues (i.e. the limited time each doctor has for each patient) and testing/diagnostic capabilities need to be addressed. For this reason, Roche works closely with CanSurvive Egypt to give emotional and individual life coaching support to patients and to provide them with tools for self-advocacy. Roche also works closely with Cairo Scan Lab to provide patients with free screening and diagnostic tests. All activity complies strictly with local policies, practices and laws[4,5]

Local Context, Equity & Sustainability

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

POLICY, PRACTICE, LAW	APPLICABLE TO PROGRAM	DESCRIPTION OF HOW IT WAS TAKEN INTO CONSIDERATION
National regulations	Yes	Medicines are included in the program only after their registration.
Procurement procedures guidelines	Yes	In Egypt there is not a unified purchasing method for reimbursement system yet.
Standard treatment guidelines	Yes	HCPs are aware of international guidelines but there were no Egypt-specific guidelines.
Quality and safety requirements	No	
Remuneration scales and hiring practices	No	

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

[No response provided]

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

Yes, Medicine, Perjeta [Pertuzumab].

20 Health technologies are part of local standard treatment guidelines

Yes.

21 Health technologies are covered by local health insurance schemes

Yes.

22 Program provides medicines listed on the National Essential Medicines List

No.

23 Sustainability plan

Local transition is currently not an option in Egypt. However, a plan is ongoing to merge other Roche medicines into the PSP in order to help out-of-pocket patients across different disease areas with getting better access to life-saving treatments. Roche aims to increase the price discount, provide extra services (e.g. digitalized and get budget from Roche) for patients who stay in therapy.

The project is considering to include other labs and pharmacies in order to increase its geographical expansion and impact a bigger portion of the population. In the next phase of the project Roche is trying to combine Kadcyla and Herceptin with an innovative pricing model. Lastly, Roche and its partners is implementing a gap analysis along the patient journey on order to provide innovative and better solutions to the patient.

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.

Resources

1. HealthGrove. Breast Cancer in Egypt. http://global-disease-burden.healthgrove.com/l/33025/Breast-Cancer-in-Egypt

2. Salhia B, Tapia C, Ishak EA, Gaber S, Berghuis B, Hussain KH, DuQuette RA, Resau J, Carpten J. Molecular subtype analysis determines the association of advanced breast cancer in Egypt with favorable biology. BMC women's health. 2011 Dec;11(1):44. https://bmc-womenshealth.biomedcentral.com/track/pdf/10.1186/1472-6874-11-44?site=bmcwomenshealth.biomedcentral.com

3. World Health Organization, Globocan, International Agency for Research on Cancer, Egypt. 2020. http://gco.iarc.fr/today/data/fact-sheets/populations/818-egypt-fact-sheets.pdf

4. National Cancer Institute. Cairo University. http://www.nci.cu.edu.eg/Cancer Research UK

5. Cancer Researck UK, Breast cancer: Survival. http://www.cancerresearchuk.org/about-cancer/breast-cancer/survival

Program Indicators

PROGRAM NAME

Perjeta Patient Support Programme

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

INDICATOR	TYPE	STRATEGY	2017	2018	2019	2020
1 Number of patients reached with pricing scheme	Output	Price Scheme	72 people	132 people	240 people	197 people
2 Number of patients enrolled in patient support program	Output	Price Scheme	45 people	78 people	108 people	88 people
3 Number of patients supported through therapy reminders	Output	Health Service Delivery	30 people	39 people	75 people	97 people
4 Volume of medicines received through pricing scheme	Outcome	Price Scheme	---	571 medicines	800 medicines	835 medicines
5 Patients adherent to treatment	Outcome	Health Service Delivery	32%	45%	48%	48%

Comments: Patients adherent to treatments: 23 of 72 (2017), 59 of 132 (2018), 117 of 240 (2019), 117 of 240 (2020)

Number of patients reached with price scheme

STRATEGY   PRICE 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	Raya Call Center	Raya who is the 3rd party managing the whole program, do follow-up calls with patients and pharmacists to make sure that they have correct tracking for the patients enrolled, they send Roche reports on a monthly and quarterly basis where they show to Roche the PSP performance without patient details.	Ongoing
31	Data processing	Roche; Raya Call center	Raya Call Center reviews the register of the patients enrolled in the scheme and those benefitting from the price scheme (receives one free vial after purchase of two vials) and sums the number of people in the scheme. Raya Call Center sends a report to Roche each month. Roche reviews all received reports on a monthly basis.	Every month
32	Data validation	3rd party audit company	Every 6 month Roche conducts a regular audit on the Raya Call Center through a 3rd party audit company.	Every 6 months

33 Challenges in data collection and steps to address challenges

The current lack of code of conduct in data collection and processing by Ray Call Center can result in delays in their data transfer. Roche is working with Ray Call Center to develop terms of references and enforcement strategies to prevent delays in data transfer and ensure data quality.

INDICATOR	2017	2018	2019	2020
1 Number of patients reached with pricing scheme	72 people	132 people	240 people	197 people

Comments: The number of people reached with pricing scheme in 2017 is higher than people enrolled in 2017 because this number includes people who got enrolled in previous years and are still on treatment, i.e. still benefit from the pricing scheme in 2017.

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	Raya Call Center	Raya who is the 3rd party managing the whole program does follow-up calls with patients and pharmacists to make sure that they have correct tracking for the patients enrolled, they send Roche reports on a monthly and quarterly basis where they show to Roche the PSP performance without patient details.	Ongoing
31 Data processing	Raya Call	Raya Call Center reviews the register of the patients enrolled in the scheme and those benefitting from the price scheme (receives one free vial after purchase of two vials) and sums the number of people in the scheme. Raya Call Center sends a report to Roche each month. Roche reviews all received reports on a monthly basis.	Every month
32 Data validation	3rd party audit company	Every 6 months, Roche conducts a regular audit on the Raya call center through a 3rd party audit company.	Every 6 months

33 Challenges in data collection and steps to address challenges

The current lack of code of conduct in data collection and processing by Ray Call Center can result in delays in their data transfer. Roche is working with Ray Call Center to develop terms of references and enforcement strategies to prevent delays in data transfer and ensure data quality.

INDICATOR	2017	2018	2019	2020
2 Number of patients enrolled in patient support program	45 people	78 people	108 people	88 people

Comments: N/A.

Volume of medicines received through pricing scheme

STRATEGY   PRICE SCHEME

ITEM	DESCRIPTION
Definition	Number of medicines received by individuals
Method of measurement	Counting the number of medicines provided included in the price scheme Calculation: Sum of the number of medicines received 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	Raya Call Center	A member of Raya Call Center collects the data from pharmacies who provide medicines to the patients.	Every month
31 Data processing	Roche	A member of Roche commercial team matches the monthly reports by Raya call with the medicines supplied to pharmacies every month.	Once per year
32 Data validation		A member of Roche Global team reviews the data annually and helps to build new systems or awareness on the importance of trustful data where needed.	Annually

33 Challenges in data collection and steps to address challenges

The current lack of code of conduct in data collection and processing by Ray Call Center can result in delays in their data transfer. Roche is working with Ray Call Center to develop terms of references and enforcement strategies to prevent delays in data transfer and ensure data quality.

INDICATOR		2017	2018	2019	2020
3	Volume of medicines received through pricing scheme	---	571 medicines	800 medicines	835 medicines

Comments: The units are the count of medicines. Each vial of Perjeta® contains 420 mg of active ingredient (Pertuzumab). 239820 represents the number of Milligrams of Perjeta® (pertuzumab) delivered through Perjeta Patient Support Programme between 1 January 2018 and 31 December 2018. 336000 represents the number of Milligrams of Perjeta® (pertuzumab) delivered through Perjeta Patient Support Programme between 1 January 2019 and 31 December 2019.

Patients adherent to treatment

4

ITEM	DESCRIPTION
Definition	Percentage of patients that are taking their treatment as prescribed by their health care provider. Adherence to treatment is defined as "the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider".
Method of measurement	Adherence measurement could be subjective or objective. Subjective measurement include patient interview or patient administered questionnaire on adherence. Objective rating of adherence could be process-oriented or outcome-oriented. Process-oriented adherence rating make use of variables such as appointment-keeping, pill counts, or pharmacy records on prescription filling to measure adherence. Outcome-oriented rating use the end-result of treatment, e.g. controlled blood glucose level, as an indicator of adherence. Calculation: $\frac{\text{Number of patients taking their treatment as prescribed by their health care provider}}{\text{Total number of patients with NCDs visiting the facility}}$
28 Data source	Routine program data
29 Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Raya Call Center	The data is directly collected by Raya call, which is charge of number of people enrolled, of monthly reports from the scan lab and of retention calls feedback. Raya Call uses subjective measurement through patients interviews over calls.	Every month
31	Data processing	Raya Call Center	Raya Call center verifies the number by double-checking with calls to patients if they continue on treatment, number matching ith medicines sold by pharmacies and patients received in Scan Lab.	Every month
32	Data validation	3rd party audit company	Every 6 months, Roche conducts a regular audit on the Raya call center through a 3rd party audit company.	

33 Challenges in data collection and steps to address challenges

The current lack of code of conduct in data collection and processing by Ray Call Center can result in delays in their data transfer. Roche is working with Ray Call Center to develop terms of references and enforcement strategies to prevent delays in data transfer and ensure data quality.

INDICATOR	2017	2018	2019	2020
4 Patients adherent to treatment	32%	45%	49%	49%

Comments: The report is directly sent by Raya's call to Roche, giving the result of how many people are adherent to treatment. They calculate by taking into consideration people starting the treatment since January + leftovers from the previous years over people continuing the treatment till the end of the year. We do not have the numerator and denominator but directly the measure: 32%(2017) ; 45%(2018) ; 48%(2019).

Number of patients supported through therapy reminders

5

	ITEM	DESCRIPTION
	Definition	Number of patients supported through therapy reminders by call, email or any other means by one of the project's partners
	Method of measurement	Calculation: Sum of all patients supported through therapy reminders by call, email or any other means by one of the project's partners
28	Data source	Routine program data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Raya Call Center	Raya collects the data of how many calls and thereby how many patients are supposed in its database and checks database, patient data and email from the scan center monthly.	Ongoing
31	Data processing	Roche; Raya Call Center	Raya Call makes sure of therapy reminders by checking the database and report from the scan lab by customer reference number.	One-time event
32	Data validation	3rd party audit company	Every 6 months, Roche conducts a regular audit on the Raya call center through a 3rd party audit company.	

33 Challenges in data collection and steps to address challenges

The current lack of code of conduct in data collection and processing by Ray Call Center can result in delays in their data transfer. Roche is working with Ray Call Center to develop terms of references and enforcement strategies to prevent delays in data transfer and ensure data quality.

INDICATOR	2017	2018	2019	2020
5 Number of patients supported through therapy reminders	30 people	39 people	75 people	97 people

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 are 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.