APRIL 2020

# Perjeta Patient Support Programme, Egypt

Roche

Submitted as part of Access Accelerated

Access Observatory

# Contents

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# 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**

Moafaz Elhattab (Senior Market Access, Pricing & Regulatory Manager Roche Egypt)
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**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 with free medicine doses and diagnostic tests for women with breast cancer.

• Provide education support: Educational brochures designed for patients to give them more information about disease and medicine, and it is distributed through health care providers (HCPs).

• Adherence:  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.

• Provide emotional support through patient advocacy group (Cansurvive): individualized life coaching and group therapy sessions are offered to patients.

# Program Overview

8   Program summary cont.

Four main stakeholders are involved in the program with Roche:

1.  Oncology Patient Group: Can-survive is the only oncology group in Egypt. It helps with patients' emotional support by conducting group therapy sessions and individualized life coach session as well as group therapy sessions.

2.  Third party call center: Raya Call center is one of top vendor 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.

3.  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.

4.  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. Until 2018 it also provided life coach sessions and patient support groups by CanSurvive Egypt. In 2019, following considerations with the patients through calls and face to face meetings, the activity was labelled as not efficient or not needed by the patients. Thus, 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 Oncology Patient Advocacy Group provides adherence support to patients. |

## 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.<br><br>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.<br><br>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.<br><br>http://www.rayacc.com/ | Private |

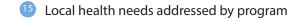**13** Funding and implementing partners by country

| 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<br>Human Resources: No<br>Funding: No<br>Monitoring or Oversight: No<br>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<br>Human Resources: No<br>Funding: No<br>Monitoring or Oversight: No<br>Other resource: Yes |
| Commercial Sector | Raya Call Center is one of the top vendors in Egypt and has experience with PSPs. The call center manages the registration of patients to the program, ensures access to financial support and reminds patients about doses. | Infrastructure: No<br>Human Resources: No<br>Funding: No<br>Monitoring or Oversight: No<br>Other resource: Yes |
| Local Hospitals/ Health Facilities | Local labs have been involved the program through contract to provide the free testing to patients.<br><br>Healthcare providers (HCPs) are responsible to provide patients with an initial overview of the program, with a membership card and with an educational brochure to better understand the disease. | Infrastructure: [No response provided]<br>Human Resources: Yes<br>Funding: [No response provided]<br>Monitoring or Oversight: [No response provided]<br>Other resource: [No response provided] |

# Local Context, Equity & Sustainability

**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 5,500 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. HER2 Breast Cancer in Egypt is almost 25% of total Breast cancer patients.[1,2]

**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 cancer killer of Egyptian women. According to the National Cancer Institute, the disease accounts to 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. For this reason, Roche works closely with CanSurvive Egypt to give emotional and individual life coaching support to breast cancer patients and to provide them with tools for self-advocacy. 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.

**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 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, 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.[3,4]

# 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

**20** Health technologies are part of local standard treatment guidelines

Yes

**21** Health technologies are covered by local health insurance schemes

Yes, Parjeta.

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

4.  Breast cancer: Survival. http://www.cancerresearchuk.org/about-cancer/breast-cancer/survival

# Program Indicators

# Perjeta Patient Support Programme

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

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

# INDICATOR 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<br><br>Calculation:<br>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 | Company | The program uses a sales tracking sheet from the field team that is updated weekly regarding patients that got reached through the patient support programme (PSP). Input gets collected from the physicians', pharmacies' and hospitals' feedback and is validated through a report sent monthly from the third party (Raya call center) for all the PSP tracking key performance indicators (KPIs). Raya Call Center manages the registration of patients in the program and keeps a record of all the registered patients. | Ongoing |
| 31 | Data processing | Company; 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. | Ongoing |
| 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

[No response provided]

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

| 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 | Company | The program uses a sales tracking sheet from the field team that is updated weekly regarding patients that got reached through the patient support programme (PSP). Input gets collected from the physicians', pharmacies', and hospitals' feedback, and this is validated through a report sent monthly from the third party (Raya call center) for all the PSP tracking key performance indicators (KPIs). Raya Call Center manages the registration of patients in the program and keeps a record of all the registered patients. | Ongoing |
| 31 Data processing | Implementing partner: 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**

[No response provided]

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

# INDICATOR  Volume of medicines received through pricing scheme

**3**

STRATEGY    PRICE SCHEME

| ITEM | DESCRIPTION |
|------|-------------|
| Definition | [No response provided] |
| Method of measurement | [No response provided]<br><br>Calculation:<br>[No response provided] |
| 28 Data source | Routine program data |
| 29 Frequency of reporting | Once per year |

| | RESPONSIBLE PARTY | DESCRIPTION | FREQUENCY |
|--|-------------------|-------------|-----------|
| 30 Data collection | Company: 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 | Roche | 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. | |

### 33 Challenges in data collection and steps to address challenges

There is a lack of code of conduct in the data collection and processing. This enhances delays and a bigger deviation. In order to mitigate these hurdles Roche local team works hand by hand with the scientific associations and creates contracts which can end if delayes and deviation in data reporting. Lastly, Roche double checks more than one source through both the commercial team and the pharmacy.

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

Comments: N/A

# Patients adherent to treatment

INDICATOR **Patients adherent to treatment**

STRATEGY    HEALTH SERVICE DELIVERY

# 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 mediation, following a diet, and/or executing lifestyle changes, corresponds to agreed recommentations 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.<br><br>Calculation:   $\dfrac{\text{Number of patients taking their treatment as prescribed by their health care provider}}{\text{Total number of patients with NCDs visiting the facility}}$ |
| 28 Data source | Routine program data |
| 29 Frequency of | Once per year |

| | RESPONSIBLE PARTY | DESCRIPTION | FREQUENCY |
|---|-------------------|-------------|-----------|
| 30 Data collection | Implementing partner: Raya Call | 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. | More than once per month |
| 31 Data processing | Company | Roche local verify the number by double check 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 | Roche | a member of my company visits the local team once per year or work closely with team by video conference. | |

### 33  Challenges in data collection and steps to address challenges

In order to mitigate lack of conduct in data collection and processing,  Roche local team work hand by hand with the scientific associations and creat contracts which can end up if delays and deviation in data reporting. Lastly, Roche double check more than one source through the commercial team and the pharmacy

| INDICATOR | 2017 | 2018 | 2019 |
|-----------|------|------|------|
| 4  Patients adherent to treatment | 32% | 45% | 48% |

Comments: The report is directly sent by Raya 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 + left overs from the previous years over people continuing the treatment till the end over year .

# Number of patients supported through therapy reminders

STRATEGY    HEALTH SERVICE DELIVERY

| 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:<br><br>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 | Implementing part-ner: Raya Call | Raya collects the data of how many calls and thereby how many patients are supposed in its database and checks data-base, patient data and email from the scan center monthly. | Ongoing |
| 31 Data processing | Implementing part-ner: Raya Call | 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 | Roche | A member of Roche visits the local team once per year or closely work with team by video conference. | |

**33  Challenges in data collection and steps to address challenges**

There is a lack of code of conduct in data collection and processing. It enhances delays and a bigger deviation. To mitigate these hurdles, Roche local team will work with the scientific associations and create contracts which can end in case of delays and deviation of data reporting. Lastly, Roche double checks more than  one source through the commercial team and the pharmacy.

| INDICATOR | 2017 | 2018 | 2019 |
|---|---|---|---|
| 5  Number of patients supported through therapy reminders | 30 people | 39 people | 75 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.