Breast Cancer National Access Programme, Kenya

Roche

Submitted as part of Access Accelerated
Contents

Program Description 3
Program Overview 4
Program Strategies & Activities 5
Companies, Partners & Stakeholders 7
Local Context, Equity & Sustainability 9
Additional Program Information 12

Resources 13

Program Indicators 14
Number of patients treated 16
Number of people trained 18
Building/equipment in use 19
Number of patients tested 20

Appendix 21

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

The information contained in this report is in the public domain and should be cited as: Roche, Breast Cancer National Access Programme, Kenya (2018), Access Observatory Boston, US 2018 (online) available from www.accessobservatory.org
Program Description
Program Overview

1 Program Name
Breast Cancer National Access Program, Kenya

2 Diseases program aims to address
• Cancer (Breast)

3 Beneficiary population
• Women

4 Countries
• Kenya

5 Program start date
August 21, 2016

6 Anticipated program completion date
August 21, 2021

7 Contact person
Charles Ngoh (Charles.ngoh@roche.com)

8 Program summary
The primary objective of the program is to improve breast cancer care in Kenya through a comprehensive, systemic approach. The specific aims of the program are to address the totality of resource challenges in the treatment of breast cancer.

Program components include:
1. Developing a funding price reduction mechanism for drug treatment
2. Increasing and strengthening healthcare capacity
3. Improving diagnostic capabilities.

Each of these are further explained below:

1) Developing a price reduction mechanism for drug treatment: Through the program, patients with human epidermal growth factor receptor 2 (HER2) positive+ breast cancer receive Herceptin (Trastuzumab), an innovative biologic treatment, which is given free of charge and funded through a cost-sharing program.

2) Increasing and strengthening healthcare capacity: Roche has provided funding for the training of 5 medical oncologists, 6 oncology nurses, and additional surgical preceptorships to improve biopsy techniques. Improved adherence to standard of care treatment protocols by these healthcare personnel is expected from the additional training, as well as from other activities. These include the dissemination of oncology guidelines/protocols, implementation of annual multi-disciplinary learning symposia, and a funded subscription to oncology journals.

3) Improving diagnostic capabilities: We have successfully placed 1 of 2 committed Roche Ventana diagnostic machines in partnership with the Ministry of Health, and we expect improved adherence to screening and diagnostic protocols and standardization of HER2 testing.

Roche will be providing the reagents for the diagnostic procedure, which can be measured as a proxy for number of patients tested. Ultimately, we expect that the number of patients receiving the standard of care increases. Our current partnership with the Ministry of Health has already benefited 20 patients in one public hospital who otherwise would not have been able to afford or access treatment in the public setting. In summary, Roche’s efforts reach beyond improvement of access to drug treatment, and have had a net positive impact to the overall healthcare system in Kenya. This, includes a commitment from the Ministry of Health to increase the number of oncology treatment centers across the country.
# Program Strategies & Activities

## Strategies and activities

### Strategy 1: Community Awareness and Linkage to Care

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>Ministry of Health’s commitment to increase breast cancer awareness and screening campaigns; additionally, partnership with the First Lady to publicly announce and launch the initiative with a donation of diagnostic machines.</td>
</tr>
</tbody>
</table>

### Strategy 2: Health Service Strengthening

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning</td>
<td>Local planning sessions and meetings with medical societies and MOH to identify and prioritize health system-access challenges.</td>
</tr>
<tr>
<td>Training</td>
<td>Sponsor preceptorships, trainings, annual symposia for pathologists, MDs, and Nurses to improve health capacity; dissemination of oncology guidelines/protocols.</td>
</tr>
<tr>
<td>Infrastructure</td>
<td>Receive commitment from MOH to expand number of oncology treatment centers as part of arrangement Diagnostic machines donation with provision of reagents required for Breast Cancer testing.</td>
</tr>
<tr>
<td>Technology</td>
<td>Subscription at IT Terminal to Oncology Journals, placement of diagnostic machines in 2 public facilities.</td>
</tr>
<tr>
<td>Management</td>
<td>Standardization of HER2 testing procedures.</td>
</tr>
</tbody>
</table>

### Strategy 3: Health Service Delivery

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>Placement and use of diagnostic machines in 2 facilities; provision of reagents required for Breast Cancer test-</td>
</tr>
<tr>
<td>Treatment</td>
<td>Patients will receive standard of care drug treatment in public hospital once diagnosed (As a result of the cost-share with the MoH, patients are receiving treatment in the public hospital).</td>
</tr>
</tbody>
</table>
Strategy 4: Price Scheme

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pricing</td>
<td>Price reduction due to direct distribution agreement with Government distributor, reducing middlemen and markups – additionally, designed cost-share agreement with Ministry of Health to fund patients in public hospital; reduce OOP cost for 20 patients to receive treatment in public setting to $0.</td>
</tr>
<tr>
<td>Delivery</td>
<td>Direct distribution agreement with Government distributor for pilot program to optimize end to end supply chain ownership, control, and visibility; optimize cold chain and safety management; and reduce price with fewer middlemen and no distribution markups.</td>
</tr>
</tbody>
</table>

Strategy by country

<table>
<thead>
<tr>
<th>STRATEGY</th>
<th>COUNTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community Awareness and Linkage to Care</td>
<td>Kenya</td>
</tr>
<tr>
<td>Health Service Strengthening</td>
<td>Kenya</td>
</tr>
<tr>
<td>Health Service Delivery</td>
<td>Kenya</td>
</tr>
<tr>
<td>Price Scheme</td>
<td>Kenya</td>
</tr>
</tbody>
</table>
## Companies, Partners & Stakeholders

### Company roles

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>ROLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche</td>
<td>Roche launched the programme to improve breast cancer care and the breast cancer care environment in Kenya through comprehensive intervention.</td>
</tr>
</tbody>
</table>

### Funding and implementing partners

<table>
<thead>
<tr>
<th>PARTNER</th>
<th>ROLE/URL</th>
<th>SECTOR</th>
</tr>
</thead>
</table>
| Ministry of Health | Funded treatment hand-in-hand with Roche by contributing to total cost of Herceptin treatment.  
                     | Trained additional oncology providers (pathologist, doctors, nurses).  
                     | Support retention of health care professionals trained under preceptorship and scholarship programs.  
                     | Support expansion of oncology treatment facilities.  
13 Funding and implementing partners by country

<table>
<thead>
<tr>
<th>PARTNER</th>
<th>COUNTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministry of Health</td>
<td>Kenya</td>
</tr>
</tbody>
</table>

14 Stakeholders

<table>
<thead>
<tr>
<th>STAKEHOLDER</th>
<th>DESCRIPTION OF ENGAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>Engagement with the Ministry of Health was facilitated through a joint project implementation committee. This committee was in charge of identifying and prioritizing the key systemic issues preventing access to standard of care and innovative medicines. Strategies were developed hand-in-hand to address infrastructure needs and access challenges found throughout the patient journey. The project plan specifically outlined where and how each partner would support the shared commitments for funding and sponsorship.</td>
</tr>
</tbody>
</table>
Local Context, Equity & Sustainability

Local health needs addressed by program

Cancer is the 3rd leading cause of morbidity in Kenya and breast cancer is the 2nd most common type of cancer. 80% of cancer patients are diagnosed with late-to-end stage disease. While the disease burden is very high, systemic challenges limit patient access to early diagnosis and treatments, such as, the lack of diagnostic capabilities, poor human capacity, infrastructure, and funding. With a novel biologic treatment for breast cancer and awareness of the challenges in Kenya for appropriate and quality care, Roche pursued a step-by-step approach with the government. This primarily required understanding challenges from the lens of local stakeholders, and to develop comprehensive and sustainable solutions together.

This partnership, which included commitments from both the Ministry of Health as well as Roche, was built on a foundation of trust and incorporated sustainable solutions for the macro-level health system. It was important that the approach consisted of a comprehensive package of solutions, not a pre-fabricated response. In order to address the systemic access issues and constraints, such as the lack of trained healthcare professionals and diagnostic capabilities, the program was designed to improve the capacity of medical oncologists, oncology nurses, trained pathologists and immunohistochemistry technicians.

For this, Roche provided, all the funding for the training and capacity development of these health personnel. Through the partnership, Roche is also committing to improve diagnostic capacities in the two national referral hospitals by providing tissue testing machines and reagents free of charge, thus enabling free access to HER2 diagnostic testings for breast cancer patients. The efforts have resulted in a positive healthcare system impact, far beyond breast cancer – including a strengthened healthcare system (better standardization of care, facilitation of evidence-based diagnosis and testing, increased access to the latest medical research and information) and increased access to more affordable, quality, and safe medicines (greater end-to-end supply chain ownership, control and visibility, optimizing cold chain and safety management, fewer middle-men and markups leading to a net price reduction).

Social inequity addressed

The program addresses social inequity and the inherent unfairness in the healthcare system by improving the chances of survival for women with breast cancer in Kenya, regardless of income-level. Herceptin (Trastuzumab) is included in the National Essential Medicines list and delivers unparalleled survival benefit for HER2+ breast cancer patients. Individuals with HER2+ breast cancers represent 18% of the breast cancer patients in Kenya. Roche’s project addresses the systematic failure of the healthcare environment in Kenya in providing appropriate standard of care for breast cancer patients. The program also seeks to address the gaps in care between those who are able to afford access to the private healthcare system in Kenya versus those accessing care in the public arena.

Local policies, practices, and laws considered during program design

The program is designed to enable access to an innovative biologics medicines for patients with breast cancer in Kenya. In designing the program, we recognized that several systemic hurdles including, disease awareness, capacity of healthcare professionals, and gaps in testing/diagnostic capabilities needed to be addressed. Without an improvement in the provision of these services, patients would not be properly diagnosed, or only diagnosed at later stages, thus preventing them from benefiting from potentially life-saving innovative treatments. We also had to address affordability concerns, considering the low-income levels in the general population.

(continued on next page).
In order to overcome these hurdles, we pursued a step-by-step comprehensive approach in partnership with local teams. We engaged with relevant stakeholders to identify and fully understand the access hurdles in Kenya. We built trust early-on with the government and medical societies, reinforcing our common purpose and presenting ourselves as a responsible partner. By looking at the whole picture and ensuring a sustainable solution, we demonstrated a long-term commitment to improving the healthcare system in Kenya. This resulted in commitments to deliver these solutions hand-in-hand with the Ministry of Health. The signed Memorandum of Understanding between Roche and the Ministry of Health committed both parties to sharing responsibilities along the access journey, including the cost of treatment. The program builds on the existing momentum consigned in national agendas and objectives since 2015. The partnership program is supported by the Ministry of Health’s 2015-2020 National Strategy for the Prevention and Control of Non-Communicable Diseases, launched in 2015. This strategy recognizes the need to reduce the overall burden and premature deaths from NCDs (Non-communicable Diseases), including breast cancer. In line with this strategy, the African First Ladies recognized the need to promote sustainable local and international partnerships for the prevention and control of NCDs, especially breast cancer, at the Declaration of the 9th SCCA meeting, which convened in July 2015.\textsuperscript{1,8}

How program meets or exceeds local standards

Through this program, breast cancer patients in Kenya are receiving an innovative biologic drug fully funded through the public system – a first-of-its-kind program in Sub-Saharan Africa. Herceptin delivers unparalleled survival benefit for HER2+ Breast Cancer patients. In total, 1.8 million patients worldwide have been treated with Herceptin, which is today recognized as the current standard of care for this disease. Moreover, it has been included in the WHO Essential Medicine List since 2015. Prior to the program, patients’ ability to access treatment was hindered due to access challenges related to lack of or delay in diagnostic services, limited healthcare capacity, and no ability to access funding for treatment through the public health system. The program has resulted in positive healthcare system impacts beyond breast cancer treatment and diagnosis.\textsuperscript{9,10}

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

Yes.

Health technologies are part of local standard treatment guidelines

Yes.

Health technologies are covered by local health insurance schemes

Yes.

Program provides medicines listed on the National Essential Medicines List

Yes.
Sustainability plan

A core component of the program is the design of a cost-share scheme between the MoH and Roche in order to ensure access to innovative medicines by breast cancer patients in Kenya. However, cost-sharing is only one component of our commitments. Other aspects, including funding of trainings to improve healthcare capacity and optimized distribution channels will have long-term benefit to the overall healthcare system. The Ministry of Health has been involved in all steps of the process to develop and deliver hand-in-hand comprehensive yet sustainable solutions. Going forward, sustainability of drug provision under this program and other government efforts to improve access to innovative medicines will require sustainable budgeting, funding and reimbursement decision-making processes. Roche is leading efforts to support the Ministry to develop and institutionalize such processes in the future.
Additional Program Information

A few articles about the project:

http://allafrica.com/stories/201703300048.html

Access Accelerated Initiative participant
Yes.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership
Yes.
Resources


4. Kenyan Network of Cancer Organizations Website: https://kenyacancernetwork.wordpress.com/kenya-cancer-facts/


6. Mendes D. et al. The benefit of HER2-targeted therapies on overall survival of patients with metastatic HER2-positive breast cancer – a systematic review.


8. Kenyan Network of Cancer Organizations Website: https://kenyacancernetwork.wordpress.com/kenya-cancer-facts/


Program Indicators
Breast Cancer National Access Programme, Kenya

List of indicator data to be reported into Access Observatory database

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>TYPE</th>
<th>STRATEGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients treated</td>
<td>Output</td>
<td>Health Service Delivery</td>
</tr>
<tr>
<td>Number of people trained</td>
<td>Output</td>
<td>Health Service Strengthening</td>
</tr>
<tr>
<td>Building/equipment in use</td>
<td>Output</td>
<td>Health Service Delivery</td>
</tr>
<tr>
<td>Number of patients tested</td>
<td></td>
<td>Health Service Delivery</td>
</tr>
</tbody>
</table>
### Definition
Number of patients that have received Herceptin treatment as a consequence of our PSP program.

### Method of measurement
Calculation:
Number of patients that received Herceptin treatment through our PSP

### Data source
Routine program data

### Frequency of reporting
Once per year

### Data collection
<table>
<thead>
<tr>
<th>RESPONSIBLE PARTY</th>
<th>DESCRIPTION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company; Hospital Pharmacy</td>
<td>Program data is collected by hospital pharmacist and recorded upon patients initiating treatment; drug utilization is tracked as part of business per usual administrative procedures. Local stakeholder (hospital pharmacist) has centralized visibility to patients on treatment. Number of patients who initiate treatment and continue through treatment are recorded by the pharmacists. These counts are provided to Roche as part of regular program updates. In addition, hospital pharmacy systems regularly track number of drug vials utilized as part of administrative system procedures anytime product is dispensed. Both of these metrics are regularly tracked and provided to Roche as leading indicators and metrics on patients treated.</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>

### Data processing
<table>
<thead>
<tr>
<th>RESPONSIBLE PARTY</th>
<th>DESCRIPTION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company; Hospital Pharmacy</td>
<td>The hospital pharmacy aggregates the number of patients receiving treatment and provides this count to Roche. The hospital pharmacy will also extract data on the number of vials utilized/administered from the system and provide the data to Roche.</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>

### Data validation
<table>
<thead>
<tr>
<th>RESPONSIBLE PARTY</th>
<th>DESCRIPTION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>When provided with aggregate information from local partner, Roche will perform basic triangulation and data validation to ensure that the number of patients tallies with the total number of vials utilized and vice versa.</td>
<td></td>
</tr>
</tbody>
</table>

### Challenges in data collection and steps to address challenges
[No response provided].
### INDICATOR: Number of people trained

#### STRATEGY: HEALTH SERVICE STRENGTHENING

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Number of people trained.</td>
</tr>
<tr>
<td><strong>Method of measurement</strong></td>
<td>Calculation: Number of scholarships for oncology nurses + Number of medical professionals trained through preceptorship (surgical) = Number of people who received training</td>
</tr>
</tbody>
</table>

| 28 | Data source | Routine program data |
| 29 | Frequency of reporting | Once per year |

<table>
<thead>
<tr>
<th>RESPONSIBLE PARTY</th>
<th>DESCRIPTION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Data collection</td>
<td>Company</td>
</tr>
<tr>
<td>31</td>
<td>Data processing</td>
<td>Company</td>
</tr>
<tr>
<td>32</td>
<td>Data validation</td>
<td>An onsite Roche team member is present during the training and is involved in collecting the attendance data.</td>
</tr>
</tbody>
</table>

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

[No response provided].
### Definition
Number of diagnostic machines donated by Roche and placed at dedicated site.

### Method of measurement
Calculation:
Number of diagnostic machines donated.

### Data source
Routine Program Data

### Frequency of reporting
Once per year

### Data collection
**RESPONSIBLE PARTY**: Company

**DESCRIPTION**
Roche has made commitments to donate a set number of machines. Upon machine being placed at dedicated site, this will be considered a verified donation.

**FREQUENCY**: Ongoing

### Data processing
**RESPONSIBLE PARTY**: Company

**DESCRIPTION**
Roche will incorporate and validate a donation upon placement of diagnostic machine at dedicated site. The number of machines donated is summed at the end of the year.

**FREQUENCY**: Once per year

### Data validation
**RESPONSIBLE PARTY**: Company

**DESCRIPTION**
Roche will incorporate and validate a donation upon placement of diagnostic machine at dedicated site.

### Challenges in data collection and steps to address challenges
[No response provided].

---

**INDICATOR**: Building/ Equipment in use

**STRATEGY**: HEALTH SERVICE DELIVERY
**INDICATOR**  Number of patients tested  
**STRATEGY**  HEALTH SERVICE DELIVERY

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Number of patients that got IHC (immunohistochemistry) tested through the program.</td>
</tr>
<tr>
<td><strong>Method of measurement</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Data source</strong></td>
<td>Routine Program Data</td>
</tr>
<tr>
<td><strong>Frequency of reporting</strong></td>
<td>Once per year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RESPONSIBLE PARTY</th>
<th>DESCRIPTION</th>
<th>FREQUENCY</th>
</tr>
</thead>
</table>
| **Data collection** | Hospital  
A member of Roche team who is responsible of bio-marker testing education provides a count of the number of patients tested as part of the program tracking. The Roche team receives this data from the hospital-collected program information. The hospital keeps a record of patients tested through the program. | Ongoing |
| **Data processing** | Company; Hospital  
Information on patients tested is collected by the hospital. Every three months the hospitals sum the number of patients tested and send this information to Roche Biomarker testing contact. | Ongoing |
| **Data validation** |  
The number of patients tested will be triangulated against the number of diagnostic kits donated by Roche. The two numbers should align close to 1:1 ratio. | |

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

[No response provided].
Appendix

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)?

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 program meets or exceeds local standards
Is there anything else that you would like to report on how your program meets or exceeds local standards?

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?

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.