

PROGRAM ENDED IN 2018

Breast Cancer National Access Programme, Kenya

Roche

Submitted as part of Access Accelerated

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

The information contained in this report is in the public domain and should be cited as: Roche, Breast Cancer National Access Programme, Kenya (2020), Access Observatory Boston, US 2020 (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, Cervical)

3 Beneficiary population

- Women
- Ages: All ages
- Special populations: People with low income, Urban populations, Rural populations

4 Countries

- Kenya

5 Program start date

August 21, 2016

6 Anticipated program completion date

December 31, 2018

7 Contact person

Wambua Jacqueline: Head of Government Affairs - East Africa. Email: jacqueline.wambua@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.^{1,2,3}

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	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.

Strategy 2: Health Service Strengthening

ACTIVITY	DESCRIPTION
Planning	Local planning sessions and meetings with medical societies and MOH to identify and prioritize health system-access challenges.
Training	Sponsor preceptorships, trainings, annual symposia for pathologists, MDs, and Nurses to improve health capacity; dissemination of oncology guidelines/protocols.
Infrastructure	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.
Technology	Subscription at IT Terminal to Oncology Journals, placement of diagnostic machines in 2 public facilities.
Management	Standardization of HER2 testing procedures.

Strategy 3: Health Service Delivery

ACTIVITY	DESCRIPTION
Diagnosis	Placement and use of diagnostic machines in 2 facilities; provision of reagents required for Breast Cancer testing.
Treatment	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).

Program Strategies & Activities

9 Strategies and activities cont.

Strategy 4: Price Scheme

ACTIVITY	DESCRIPTION
Pricing	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.
Delivery	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.

10 Strategy by country

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

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Roche	Roche launched the programme to improve breast cancer care and the breast cancer care environment in Kenya through comprehensive intervention.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Ministry of Health	<p>Funded treatment hand-in-hand with Roche by contributing to total cost of Herceptin treatment.</p> <p>Trained additional oncology providers (pathologist, doctors, nurses).</p> <p>Support retention of health care professionals trained under preceptorship and scholarship programs.</p> <p>Support expansion of oncology treatment facilities.</p> <p>http://www.health.go.ke/</p>	Public
Government	<p>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.</p> <p>http://www.mygov.go.ke/</p>	Public

13 Funding and implementing partners by country

PARTNER	COUNTRY
Ministry of Health	Kenya

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT
Government	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.

Local Context, Equity & Sustainability

15 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).^{1,4}

a How needs were assessed

[No response provided]

b Formal needs assessment conducted

[No response provided]

16 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.^{5,6,7}

17 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 benefitting from potentially life-saving innovative

Local Context, Equity & Sustainability

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

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.^{1,8}

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)

No.

20 Health technologies are part of local standard treatment guidelines

N/A.

21 Health technologies are covered by local health insurance schemes

N/A.

22 Program provides medicines listed on the National Essential Medicines List

N/A.

23 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.

PROGRAM ENDED IN 2018

Additional Program Information

24 Additional program information

A few articles about the project:

<http://allafrica.com/stories/201703300048.html><http://mobile.nation.co.ke/news/Drug-firm-Roche-Group-to-assist-Kenya-in-anti-cancer-fight/1950946-3422142-55e972/index.html>

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. 2015-2020 National Strategy for the Prevention and Control of Non-Communicable Diseases: <http://www.who.int/nmh/ncd-task-force/kenya-strategy-ncds-2015-2020.pdf>
2. <http://www.iccp-portal.org/news/kenya-launches-national-cancer-control-strategy-2017-2022>
3. http://www.iccp-portal.org/system/files/plans/KENYA%20NATIONAL%20CANCER%20CONTROL%20STRATEGY%202017-2022_1.pdf
4. Kenyan Network of Cancer Organizations Website: <https://kenyacancernetwork.wordpress.com/kenya-cancer-facts/>
5. Kenya National Essential Medicines List 2016: <http://apps.who.int/medicinedocs/documents/s23035en/s23035en.pdf>
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.
7. Breast Cancer Research. 2015; 17:140. <https://breast-cancer-research.biomedcentral.com/articles/10.1186/s13058-015-0648-2>
8. Kenyan Network of Cancer Organizations Website: <https://kenyacancernetwork.wordpress.com/kenya-cancer-facts/>
9. African First Ladies Renew Fight against Cancer <https://www.edufrika.com/2015/07/african-first-ladies-renews-fight-cancer/>
10. WHO EML List 2015: <http://www.who.int/bulletin/volumes/94/10/BLT-15-163998-table-T1.html>
11. Sayed S, Moloo Z, Wasike R, Bird P, Oigara R, Govender D, Kibera J, Carrara H, Saleh M. Is breast cancer from Sub Saharan Africa truly receptor poor? Prevalence of ER/PR/HER2 in breast cancer from Kenya. The Breast. 2014 Oct 31;23(5):591-6. <http://dx.doi.org/10.1016/j.breast.2014.06.006> | *Joint Analysis of NSABP B-31 and NCCTG N9831

Program Indicators

PROGRAM NAME

Breast Cancer National Access Programme, Kenya

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

INDICATOR	TYPE	STRATEGY	2016	2017	2018
1 Number of patients on treatment	Output	Health Service Delivery	---	58 people	81 people
2 Number of people trained	Output	Health Service Strengthening	47 people	40 people	87 people
3 Diagnostics machines donated and in use	Output	Health Service Delivery	---	2 diagnostics machines	---
4 Number of patients tested	Output	Health Service Delivery	---	168 people	373 people

INDICATOR **Number of patients on treatment**

STRATEGY HEALTH SERVICE DELIVERY

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

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company: Roche; Other: Hospital Pharmacy	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.	Ongoing
31 Data processing	Company: Roche; Other: Hospital Pharmacy	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.	Ongoing
32 Data validation		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.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2017	2018
1 Number of patients on treatment	58 people	---

Comments: N/A.

ITEM	DESCRIPTION
Definition	Number of people trained
Method of measurement	Calculation: Number of scholarships for oncology nurses +Number of medical professionals trained through preceptorship (surgical)=Number of people who received training
28 Data source	Routine program data.
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company: Roche	Roche team member who is onsite during preceptorship will ask each attending nurse and/or surgeon to sign his or her name on an attendance form. This form is then copied and a soft copy is uploaded into system. A count of the signatures will be performed to track the number of attendees.	Ongoing
31 Data processing	Company: Roche	A member of Roche team will review uploaded copies of attendance sheets annually. A count of the signatures will be performed to determine the total number of people trained.	Once per year
32 Data validation		An onsite Roche team member is present during the training and is involved in collecting the attendance data.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2016	2017	2018
2 Number of people trained	47 people	40 people	---

Comments: N/A.

ITEM	DESCRIPTION
Definition	The number of diagnostics machines donated and in use
Method of measurement	Calculation: Number of diagnostic machines donated
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company: Roche	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.	Ongoing
31 Data processing	Company: Roche	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.	Once per year
32 Data validation		Roche will incorporate and validate a donation upon placement of diagnostic machine at dedicated site.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2017	2018
3 Diagnostics machines donated and in use	2 diagnostics machines	---

Comments: N/A.

INDICATOR **Number of patients tested**

STRATEGY HEALTH SERVICE DELIVERY

4

ITEM	DESCRIPTION
Definition	Number of patients that got IHC (immunohistochemistry) tested through the program
Method of measurement	Calculation: Sum of the people who received immunohistochemistry testing through the program
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Other: 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
31 Data processing	Company: Roche, Other: 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
32 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.	

33 Challenges in data collection and steps to address challenges

[No response provided]

INDICATOR	2017	2018
4 Number of patients tested	168 people	373 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' web-pages

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 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

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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.