

NOVEMBER 2021

India Fights Back

Merck KGaA, Darmstadt, Germany

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: Merck KGaA, Darmstadt, Germany, India Fights Back (2021), Access Observatory Boston, US 2021 (online) available from www.accessobser-

Program Description

Program Overview

1 Program Name

Merck Cancer Access Program

2 Diseases program aims to address

- Cancer (general)

3 Beneficiary population

- General population

4 Countries

- India

5 Program start date

December 19, 2019

6 Anticipated program completion date

December 31, 2021

7 Contact person

Nitesh Sharma
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8 Program summary

The objective of the partnership program on cancer care with employee state insurance corporation and Indian railways is to enable maximum number of eligible patients to get Faster access to standard of care, Early diagnosis and to the Right treatment, Identify the Patient access barriers and to drive suitable interventions to address them. The scope of this partnership is to increase Cancer diseases awareness and early detection and ensuring early treatment of Head and Neck Cancer through certain program i.e. Awareness campaigns; patient screening camps and training / capability enhancement programs for doctors and pharmacists on early signs and symptoms of the diseases for effective management of the disease.

The broad program activities are:

1) Disease Awareness Campaigns:

Drive public awareness campaigns on Cancer Education, Signs & Symptoms and its related complications among Employees and beneficiary's population.

Continued impetus on health education initiatives such as anti-tobacco campaigns, Educational efforts to promote physical exercise and diet management

Execute digital campaigns through the kdoey consultants driven Knowledge videos, information microsites on diseases awareness and Head and Neck Cancer and Colorectal cancer websites

2) Patient Screening and Diagnosis:

Organize Screening / Health Check-up Camps for Oral examinations at health centers for early screening of the patients.

3) Capability and Training Programs:

Support the railways medical department ecosystem to channel / navigate the patient flow to the right Cancer care centers within Railways.

Continuous Medical Education Programs for oncology specialists' / ENT and Oral Dental clinicians at ESIC and Railways Hospitals.

Training and Education of Paramedical Staff and Nurses of Cancer drug delivery and palliative care.

Employees State Insurance Corporation is the largest social security government organization under Ministry of Labour with self-sustainable medical Insurance scheme in India with a healthcare delivery network of more than 35 tertiary hospitals, 144 secondary hospitals and 1500 primary health centers in India. The employees covered under this medical scheme are 33 Mio with total beneficiary's base of 120 Mio.

Indian Railways (Health) are the largest government employers in Asia with 1.4 Mio employees and total of 6.4 Mio beneficiaries with healthcare delivery of 20 tertiary centers, 125 secondary hospitals and 300 sub -divisional health units across India.

The implementation of these activities will support ESIC and Railways to improve on the Patient Health outcomes, significantly enhance quality of life of cancer patients and thereby address increase in the disease burden and the cost burden in the treatment of Cancer and its complications while the patients can be detected and diagnosed early and can be put on the treatment at Tertiary care centers. This will support the Government payors vision of non-communicable diseases to achieve self-sufficiency in providing the standard of care in the interest of Public Health.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	Raise awareness for early detection of H&NC

Strategy 2: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	Train HCPs to detect and treat H&NC early

Strategy 3: Health Service Delivery

ACTIVITY	DESCRIPTION
Screening	Through Patient screening camps for oral cancer examinations

10 Strategy by country

[No response provided]

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Merck & Co., Inc.	In this partnership program Merck will support the Government payors ESIC and Railways with conducting regular diseases awareness campaigns , early screening camps for Patients and enable the payors with capability building programs for their HCP's. Merck shall be responsible to coordinate for resources externally with Payors for administrative approval, allocation of resources and internally for implementing the above Program in the manner.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Employees State Insurance Corporation	ESIC and Railways will provide administrative support to the partnership program with providing the timely administrative approvals; access to their Health care delivery; beneficiary population; allocation of resources i.e. Hospitals and existing infrastructure. There is no financial liability or obligation of the partnership program on the payors. Employee State Insurance corporation – is the largest social security government organization under Ministry of Labour with self-sustainable medical Insurance scheme in India with a healthcare delivery network of 35 tertiary hospitals, 144 secondary hospitals and 1500 primary health centers in India. There are approximately 50 million beneficiaries currently covered in this scheme. There is a significant disease burden of cancer and lack of awareness in the low socio-economic strata of India, certain parts of which are represented within Employees State Insurance Corporation beneficiaries. https://www.esic.in/	Public
Indian Railways	Indian Railways is the largest government employers in Asia with 1.4 Mio employees and total of 6.4 Mio beneficiaries with healthcare delivery of 20 tertiary centers, 125 secondary hospitals and 300 sub -divisional health units across India. All employees and their family members are provided free-of-cost healthcare within the network of Indian Railways facilities. Underscoring its purpose of 'As One for Patients', Merck Specialties Private Ltd signed a first of its kind strategic collaboration with Employees State Insurance Corporation and Indian Railways to propel access to relevant cancer treatment options through key initiatives focused on creating awareness about cancer symptoms, early diagnosis of these symptoms for the payor beneficiaries. Another significant objective of the program is to support and enable the current healthcare system within these payors through Training and Capability Enhancement Program. https://indianrailways.gov.in	Public

Companies, Partners & Stakeholders

13 Funding and implementing partners by country

PARTNER	COUNTRY
Employees State Insurance Corporation	India
Indian Railways	India

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKEHOLDER
Government	Merck has engaged with both ESIC and India railways to seek the formal approval on the partnership model on cancer care offered by Merck. ESIC and Indian railways has given access / approval to use the existing Hospital infrastructure , availability of the HCP's , Nurses and Pharmacists to attend the training programs and also given permission to their doctors for the patients screening camps at the premises.	Infrastructure: Yes Human Resources: No Funding: No Monitoring or Oversight: No Other resource: No

Local Context, Equity & Sustainability

15 Local health needs addressed by program

There is a very high disease burden of cancer in India. In 2015, the prevalence of cancer in India is estimated to be 3.9 million people. The reported cancer incidence in (please indicate time period) was 1.1 million (insert source).

Head and Neck cancer is the 2nd most common cancer in India. Every year, 2 lakh (200,000) new cases are diagnosed with this particular cancer. In India, the main reason for such high prevalence is tobacco and betel nut chewing habits.

According to the EY report "Call for action: Expanding cancer care in India" (July 2015), nearly 40% of cancer cases remain undiagnosed in India. Head and Neck cancer remains a poor man's disease in India. So, healthcare schemes like those provided by ESIC and Railways are absolutely critical in filling the affordability gap. The partnership program focuses on the central government payors high focus on the NCD program especially Cancer. In India NCD's disease like Cancer causes considerable loss in potentially productive years of life. Losses due to premature deaths related to poor access to Cancer care are also projected to increase over the years. At present, the objectives of the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) are being implemented under the National Health Mission (NHM). The components of the programme include awareness generation for cancer prevention, screening, early detection and referral to an appropriate institution for treatment. For cancer, the focus is on three common types of cancer; breast, cervical and oral cancer. Following the WHO Framework Convention on Tobacco Control (FCTC), the government had also launched the National Tobacco Control Programme to create awareness about the harmful effects of poor oral hygiene, tobacco consumption, reduce the demand and supply of tobacco products.

There is a significant disease burden of cancer and lack of awareness in the low socio-economic strata of India, certain parts of which are represented within Employees State Insurance Corporation (ESIC) beneficiaries and large government employers such as Indian Railways. This population belongs to TIER-II and Tier-III cities (smaller peripheral towns with primary or secondary healthcare infrastructure; non-metro cities; limited healthcare infrastructure with low income groups) where awareness, screening, diagnosis, and access to treatment is a challenge. In case of Employees State Insurance and Railways, by design, the beneficiaries have very low-income levels, and low awareness of various diseases. Through this initiative, Merck's objective is to use the captive infrastructure of ESIC and Indian Railways to spread awareness of the symptoms of Head and Neck cancer. All aspects of this project and subsequent initiative has undergone thorough evaluation and review as per the locally applicable protocols that includes medical, legal, compliance and regulatory framework.

a How needs were assessed

There is a need assessment done with both the payors i.e ESIC and Indian Railways to identify the unmet medical needs; key gaps in the system and barriers to early access of patients to the standard of care. The assessment has been done through the interviews with HCP's; Day care and referral centers; panel discussions with key govt stakeholders; based on the epidemiology data from the hospitals; market intelligence and reference to the current patient journey in these payors.

b Formal needs assessment conducted

Yes.

16 Social inequity addressed

The partnership program for cancer care with these two national payors ESIC and Indian railways covering the population which is predominantly workmen or industrial labor's with low socio-economic strata or low income groups, who have the poor awareness and limited access to the standard of care on cancer treatment.

Local Context, Equity & Sustainability

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

POLICY, PRACTICE, LAW	APPLICABLE TO PROGRAM	DESCRIPTION OF HOW IT WAS TAKEN INTO CONSIDERATION
National regulations	Yes	The National government's initiative to increase the number of medical colleges and overall healthcare infrastructure, there is a country wide issue in relation to sector skills gap and indicates an urgent need for augmenting the medical staff graduating from formal training programs. In this context, private players can play a key role in creating disease awareness , capacity building and training through PPP modes by working with the public sector payors to better utilize the infrastructure of government hospitals. Government district hospitals will be appropriate in terms of size and availability of clinical material (for in-patient and out-patient care), for providing training to nurses and other auxiliary medical staff. Such an arrangement integrates well with other PPP programs.
Procurement procedures	Yes	Procurement procedures: Aligned with the National Procurement policies. The procurement procedure is aligned with the National Public tender procurement policy and the General Financial Rules guidelines issued by the Govt of India . https://doe.gov.in/order-circular-archives/GENERAL%20FINANCIAL%20RULES
Standard treatment guidelines	Yes	Taken references of global and local treatment guidelines i.e. NCCN , ASCO etc.
Quality and safety requirements	No	The partnership program is fully compliant with the safety and quality measures and completely aligned with the medical council; pharma industry and local laws & guidelines; also in accordance to the guidelines put in place by the ESIC and Indian Railways. The program initiatives have also followed the Ministry of Health Govt of India guidelines on the disease awareness campaigns and patient screening camps.
Remuneration scales and hiring practices	No	The remuneration scales and hiring practices for the HCP's are in full compliance with the local laws and as per The OPPI (Organization of Pharmaceutical producers of India) code of pharmaceutical practices 2019.
Other, please specify	No	N/A

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

Cancer care and treatment is an important imperatives of the Government payors and the resources allocated during the program are solely involved in the Cancer diagnosis and its treatment.

Local Context, Equity & Sustainability

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

Cancer care and treatment is an important imperatives of the Government payors and the resources allocated during the program are solely involved in the Cancer diagnosis and its treatment.

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

TYPE	COMMERCIAL NAME	INTERNATIONAL NON-PROPRIETARY NAME (INN)
Medicine	Erbixux	Cetuximab

20 Health technologies are part of local standard treatment guidelines

Yes, Erbitux:

<https://www.indiancancer.com/article.asp?issn=0019-509X;year=2016;volume=53;issue=4;spage=487;epage=492;aulast=Tiwari>
<https://www.indiancancer.com/article.asp?issn=0019-509X;year=2020;volume=57;issue=5;spage=22;epage=25;aulast=Prabhash>

21 Health technologies are covered by local health insurance schemes

Yes. Both ESIC and Indian railways drug formulary has Cetuximab included for the approved indications . The current health insurance scheme of ESIC and Indian Railways offers Free drug policy to their patients covered under the Insurance scheme.

22 Program provides medicines listed on the National Essential Medicines List

Yes. Both ESIC and Indian railways drug formulary has Cetuximab included for the approved indications . The current health insurance scheme of ESIC and Indian Railways offers Free drug policy to their patients covered under the Insurance scheme.

Currently Cetuximab is not the part of National List of Essential medicines. However it is currently features in the government payors essential drug list i.e ESIC , Defense and Central Govt Health Scheme

23 Sustainability plan

The partnership program for the cancer care with both payors is currently addressing largely to the existing unmet need and challenges of access in the system. The support provided by Merck through various initiatives i.e. Disease awareness campaigns ; early screening and diagnosis and continuous medical education programs for Doctors , Pharmacists and Nurses is greatly been appreciated and acknowledged by the Government payors. ESIC has recently adopted the Medical training on Head and Neck Cancer in National Training curriculum for Doctors . Indian Railways and ESIC have started dedicated Oral cancer detection clinics in their Out-patients departments for early examination and referral of the patients for treatment. Merck has also continuously kept the engagement under CSR program with the payors supporting them during COVID with Face Masks for healthcare workers and KRAS testing subsidized patients coupons under patient support programs for cancer diagnosis and analysis.

Additional Program Information

24 Additional program information

Employees State Insurance and Indian Railways ; conflicts of interests included in the part of Letter of Intent (attached).

The LOI clearly suggests that the focus and the scope of our program is only for diseases awareness , early screening and capability building through continuous medical education programs for doctors.

a Potential conflict of interest discussed with government entity

Yes.

25 Access Accelerated Initiative participant

Yes.

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

Yes.

Program Indicators

PROGRAM NAME

India Fights Back

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

INDICATOR	TYPE	STRATEGY	2020
1 Population exposed by community awareness campaign out of total target population	Output	Community Awareness and Linkage to Care	60%
2 Population Screened	Output	Health Service Delivery	400 people
3 Number of People Trained	Output	Health Service Strengthening	300 people

Population exposed by community awareness campaign out of total target population

ITEM	DESCRIPTION
Definition	Percentage of population reached through a community awareness campaign out of total population targeted.
Method of measurement	Counting of participants that attend campaign meetings or reached by media messaged disseminated and number of people in the target population. Calculation: Sum of people/participants in the target audience segment participated/attended the community awareness campaign recorded divided by the number of people targeted by the campaign
28 Data source	Non-routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Employees State Insurance Corporation; Indian Railways	The data source will be the different communication levers used for creating Diseases awareness campaigns like TV Shows, News Papers advertisements, Market activation campaigns and Radio FM announcements. The data will be captured on the total population covered or target audience reach out under the different initiatives of community communication and awareness campaigns. The data will be collected by the implementing partners.	Once per year
31 Data processing	Merck KGaA	The community communication awareness campaigns will be done through the local newspapers, Radio FM announcement on the disease's awareness and sign symptoms of the diseases. The awareness will also be done through the market activation programs through disease awareness pamphlets/ brochures among populations visiting malls, markets, universities, and hospitals. The implementing partner will capture the total population covered under the disease awareness campaigns and which will be reviewed by the company project team.	Once per year

INDICATOR **Population exposed by community awareness campaign out of total target population**

STRATEGY COMMUNITY AWARENESS AND LINKAGE TO CARE

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
32 Data validation		The data will be validated through the actuals prints in the news papers, radio bytes, TV advertisements and Number of kiosks for the awareness campaigns. The quality of the data will be validated through different sources including local teams, institutions, total population reach by the campaigns.	

33 Challenges in data collection and steps to address challenges

The major challenge is to capture the data of the full and complete population attended and reached out by different community communication awareness campaigns. To address this challenge, the ESIC has an online data platform source where audience data can be captured (treatments, follow-up, progress, etc.)

INDICATOR	2020
1 Value of funding provided	60%

Comments: Numerator:1000000 Denominator: 1666666 - Ratio of 60%. Population size covered under the program: 1 million.

ITEM	DESCRIPTION
Definition	<p>Number of individuals screened for disease as a result of the screening test or procedure being provided by the program.</p> <p>Screening activities could include any screening procedures (mammogram, cholesterol measurement, colonoscopy, etc.) delivered directly to a specified population, by the program. Screening activities are often preventive in nature and aim to look for diseases or conditions prior to symptoms developing.</p>
Method of measurement	<p>Counting of people who were screened for disease in the program</p> <p>Calculation: Sum of the number of people screened</p>
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Employees State Insurance Corporation; Indian Railways; Merck KGaA	The data source will be the total number of patient populations got screened or examined by the clinicians for specified disease indications during the patient screening camps / health check- up camps. The data will be collected by the local implementing partners (ESIC and Indian Railways) and later reviewed by the company project team. The screening procedure includes the basic oral examinations, histopathology and biopsy tests. The implementing partners have an online software in place with 'health cards'. When the patients enter the clinic, the data is updated.	Once per year
31 Data processing	Employees State Insurance Corporation; Indian Railway	The Patient screening camps for early screening is done within the specified Institutions under the supervision of the qualified clinicians and Paramedics. The basic screening includes the oral examinations, histopathology and biopsy if recommended. The data of the total number of the populations appears for the screening will also be maintained by the specified institutions and implementing partners. The data will be validated and reviewed by the company project team.	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
32 Data validation		The data will be validated through the actual checks on the total number of population attended the patient screening camps site and actually examined for the specific indication of the diseases.	

33 Challenges in data collection and steps to address challenges

The major challenge is that during the patient screening camps the patients insist for complete body check-ups and this we have addressed by explicitly creating awareness on the patient screening camps covering specified indication only like Head and Neck Cancer or Metastatic Colorectal cancer. We address this challenge by doing a groundwork communication with examining doctor and patient counseling to make sure the patients understand the exact aim of these health camps and the therapeutical scope.”

INDICATOR

2020

2 Population screend	400 people
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Comments: N/A.

ITEM	DESCRIPTION
Definition	Number of trainees
Method of measurement	Counting of people who completed all training requirements Calculation: Sum of the number of people trained
28 Data source	Routine and non-routine program data
29 Frequency of reporting	Three times per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Employees State Insurance Corporation; Indian Railways; Merck KGaA	The data source will be the total number of HCPs, Pharmacists or Nurses trained under the program. The data collection will be done by the local team who will asks each attendees of the training program / CME program to sign his / her name on the attendance sheet. The attendance can be reviewed by the company project team.	Every 4 months
31 Data processing	Company: Sanofi Espoir Foundation	The procedures for imparting training programs will be through Continuous Medical education programs, Training programs for HCPs / Clinicians, Pharmacists, Nurses for the specified diseases covered under the program. The frequency of such training programs conducted in the Institutions will be three times in the quarter. The target audience and trainer of the program is selected by the local team and invitation extended for the program. Merck does the cleaning of the data related to participants and number of people trained. We use "Quantum" (our internal system). This tool and process was approved by our compliance department and Medical Affairs.	Every 4 months
32 Data validation	Merck KGaA	The data will be validated through the actual checks or reviewing the sign of the all the attendees on the attendance sheet and also the training program photos or recording can be reviewed by the company project team.	

33 Challenges in data collection and steps to address challenges

There is no challenge to report for this indicator.

33 Challenges in data collection and steps to address challenges

The major challenge during such training programs is the attendance or turn out of all the participants population invited for the training program. We have started addressing these by increasing the frequency of the such training program to cover and train all the eligible participants/clinicians. Regarding the data collection, the only challenge we encountered was related to the manual collection of signatures.

INDICATOR

2020

3 Number of people trained	300 people
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Comments: 200 Clinicians and 100 pharmacists/Nurses trained.

Program Documents

1. Merck KGaA. Letter of intent on partnership program, to Ministry of Labour and Employment. 9 December 2019.

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 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

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

31 Data processing

- Responsible party: Please indicate all parties that conduct any processing of this data.
- 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.
- 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.

