PROGRAM REPORT

APRIL 2020

Patient Assistance Program for Adcetris®

Takeda

Submitted as part of Access Accelerated

Access Observatory

Contents

The information in this report has been submitted by the company concerned to the Access Observatory at Boston University. The information will be updated regularly. For more information about the Observatory go to www.accessobservatory.org

Program Description

Program Overview

1 Program Name

Patient Assistance Program for Adcetris®

2 Diseases program aims to address

- Cancer: Hematological

3 Beneficiary population

- Age Group: 18 years and above
- Gender: All genders
- Special Populations: Low income, rural, urban

4 Countries

- Malaysia
- Egypt
- Hong-Kong
- Thailand
- Lebanon
- Mexico
- Peru
- Philippines
- Singapore
- Ukraine
- Kenya
- United Arab Emirates
- Indonesia

5 Program start date

January 19, 2017

6 Anticipated program completion date

Completion date not specified.

7 Contact person

Philip Towle, philip.towle@takeda.com

8 Program summary

1) Program context and objectives

The past decade has seen major public health gains and scientific breakthroughs in the discovery of new medicines, but across the world, many people still lack access to the treatment and medicines they need, especially for very severe diseases including many forms of cancers and other NCDs.

NCDs are hard to diagnose, treat and manage and have significant affordability barriers – complex and rare diseases require highly innovative medicines, often without alternatives, and the treatment can be lifelong.

To address these affordability barriers, in 2017, we pioneered our Patient Assistance Programs (PAPs), to ensure our innovative and potentially life-saving medicines reach as many patients as possible, all around the world. We do this through innovative and collaborative financing models, which also maximise the medical benefits of treatment through personalized ongoing support.

Takeda's PAPs are a cornerstone of Takeda's Access to Medicines initiative, a global, cross-functional effort to increase sustainable access to our innovative medicines for complex and rare diseases, addressing affordability barriers.

Our PAP for Adcetris® was launched in 2017, to address affordability barriers for patients diagnosed with relapsed and refractory Hodgkin's Lymphoma (RR HL) or relapsed and refractory systematic anaplastic large cell lymphoma (RR sALCL).

Before the launch of Adcetris®, there was no treatment options for patients with relapsed and refractory Hodgkin's Lymphoma (RR HL) or relapsed and refractory systematic anaplastic large cell lymphoma (RR sALCL) in many developing markets.

2) Program activities and outcomes

Through an independent delivery partner, Axios International, we have adopted an independent and confidential means-based assessment tool to assess patients' ability to contribute to their medication costs, and then determine the appropriate individual payment scheme for each patient.

Program Overview

8 Program summary, cont.

This ensures patients pay only what they can afford, and are able to complete their entire course of treatment even if they cannot pay for it in full. Through our delivery partner, we also provide personalized support including ongoing follow-up from program staff to ensure adherence to their treatment plan and their physician's recommendations - improving the quality of care and efficacy of the treatment.

Takeda's PAPs are sustainable so our innovative medicines reach as many patients as possible, and are tailored to each country to address a country's economic context and local healthcare provisions. They use different collaborative models where patients, Takeda, and at times local authorities, foundations, medical associations, charities and other parties, share the cost of treatment.

In select cases for patients with no ability to pay, we explore routes for them to access medicines included in our PAPs, through additional financial support from local medical societies, charities, and NGOs.

Improving access to our specialty care products for as many patients as possible while ensuring safety and ethical compliance requires the integrity of our programs to be robust. We have a detailed governance process for the consideration, approval, and implementation of new programs, and a dedicated governance committee responsible for reviewing and approving our collaborative financing initiatives.

3) Program partners and achievements:

Axios International, our independent, external third-party organization with more than 20 years of experience in PAPs handles day-to-day management of the program, patient financial eligibility assessment, promotion of the program, answering questions from and providing information to physicians and patients, and delivery and management of free-of-charge medicines.

In some countries, we also involve local expert partners as part of our collaborative approach, e.g. with "Charitable Fund I Will Live", a local charity that manages the program in the Ukraine as well as with Pilipinas Shell Foundation Incorporated (PSFI), the social arm of Shell companies in the Philippines (SciP) to manage the program.

Across all countries, Takeda's distributors support the logistics and delivery of medication within the health system.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Price Scheme

ACTIVITY	DESCRIPTION
Pricing	The Patient Assistance Programs use an innovative, affordability-based method to increase access to Adcetris® in a sustainable way. They enable eligible patients to complete their course of treatment, even if they cannot afford to pay for it in full. The program uses a Patient Finance Eligibility Tool (PFET), independently conducted by an independent organisation. The PFET is a tool through which a patients ability to pay is assessed based on an individual's real financial situation. What makes the tool innovative, is its unusual ability to segment the entire market, unlike any other patient assessment tools currently available in the market.

Strategy 2: Medicine Donation

ACTIVITY	DESCRIPTION
Donation	In select cases for patients with no ability to pay, and where appropriate and feasable, we may explore other potential routes available for them to access medicines included in our PAPs, such as donations or additional financial support from local medical societies, charities and NGOs.

Strategy 1: Health Service Delivery

ACTIVITY	DESCRIPTION
Retention	Through our delivery partner, we provide personalized support including ongoing follow-up from program staff to ensure adherence to their treatment plan and their physician's recommendations.

Companies, Partners & Stakeholders

10 Strategy by country

STRATEGY	COUNTRY
Price Scheme	Thailand, Malaysia, Philippines, Indonesia, Singapore, Hong-Kong, Lebanon, Ukraine, Egypt, United Arab Emirates, Kenya, Mexico, Peru
Medicine Donation	[No response provided]
Health Service Delivery	[No response provided]

11 Company roles

COMPANY	ROLE
Takeda	Increase sustainable access to our innovative medicines for complex and rare diseases, addressing affordability barriers. Planning, monitoring, and evaluating the program.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Axios International	- Product requirement forecasting for both purchased and FOC packs - Day-to-day management of the program - Patients' application review - Actively promote the program to increase its awareness and provide communication support for physicians and patients who ask to learn more about the program - Ensure timely delivery and management of FOC drugs - Monitoring and Evaluation through monthly reports and analysis of program data - AE Reporting and reconciliations. https://axiosint.com/	Private
Pilipinas Shell Foundation inc.	Axios International works in partnership with Pilipinas Shell Foundation Inc., the social arm of Shell companies in Philippines (SciP) to manage the program in the Philippines. https://www.shell.com.ph/sustainability/communities/social-investment-programmes/psfi.	Private
Charitable Fund I Will live	Axios works in partnership with "Charitable Fund I Will Live", a local charity, to manage the program in the Ukraine.	Voluntary

Companies, Partners & Stakeholders

13 Funding and implementing partners by country

PARTNER	COUNTRY
Axios International	Malaysia, Egypt, Hong-Kong, Thailand, Lebanon, Mexico, Peru, Philippines, Singapore, Ukraine, Kenya, United Arab Emirates, Indonesia.

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKEHOLDER
Government	Takeda works closely with national and local governments on the design of programs, to ensure that they are fully aligned with local regulations for example in terms of prescription, health professional licensing, and marketing authorization for the product. Local physicians treating patients receiving Adcetris®.	Infrastructure: No Human Resources: Yes Funding: No Monitoring or Oversight: No Other resource: No
Non-governmental organization (NGO)	Local physicians treating patients receiving Adcetris®.	Infrastructure: [No response provided] Human Resources: Yes Funding: [No response provided] Monitoring or Oversight: [No response provided] Other resource: [No response provided]
Other	In select cases for patients with no ability to pay, and where appropriate and feasible, we may explore other potential routes available for them to access medicines included in our PAPs, such as donations or additional financial support from local medical societies, charities and NGOs.	

Local Context, Equity & Sustainability

15 Local health needs addressed by program

The past decade has seen major public health gains and scientific breakthroughs in medicines discovery, but across the world, many people still lack access to the treatment and medicines they need, especially for very severe diseases including many forms of cancers and other NCDs.

To address the affordability disparities to our innovative medicines for complex and rare disease, Takeda follows a tiered pricing approach across countries and combine this with a novel, in-country affordability-based approach, the Patient Assistance Program (PAP) in lower-income countries.

Takeda's PAPs are designed to be sustainable, and are tailored to each country to address a country's economic context and local healthcare provisions. They use different collaborative models where patients, Takeda, and at times local authorities, foundations, medical associations, charities and other parties, share the cost of treatment.

The PAPs are embedded in our broader Access to Medicines initiatives which enhance disease awareness, diagnosis, treatment, and ongoing patient care and support, to ensure we are radically increasing access and standards of care across the entire patient journey.

a How needs were assessed

Takeda completed a thorough affordability assessment across each of the countries where the Patient Assistance Program have been launched.

b Formal needs assessment conducted

No.

16 Social inequity addressed

NCDs are hard to diagnose, treat and manage and have significant affordability barriers – complex and rare diseases require highly innovative medicines, often without alternatives, and the treatment can be lifelong.
Our PAPs address these affordability barriers, to ensure our innovative and potentially life-saving medicines medicines reach as many patients as possible, all around the world. We do this through innovative and collaborative financing models, which also maximise the medical benefits of treatment through personalized ongoing support.

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	Takeda works closely with national and local governments on the design of programs, to ensure that they are fully aligned with local regulations for example in terms of prescription, health professional licensing, and market authorisation of the product.
Procurement procedures	[No response provided]	[No response provided]
Standard treatment guidelines	Yes	Patients are made aware of the PAP by their prescribing physician. Together, a patient and physician submit the single program application form to our partner Axios International. To be eligible for the PAP, patients must be prescribed the respective medicine for a locally- approved indication.
Quality and safety requirements	Yes	Takeda works closely with national and local governments on the design of programs to ensure that they are fully aligned with local regulations for example in terms of prescription, health profesional licensing, and market authorisation of the product.
Remuneration scales and hiring practices	[No response provided]	[No response provided]
Other, please specify	Yes	A central element of our PAPs is the individual, confidential and advanced means-based assessment tool to evaluate patients' ability to contribute to their medication costs, and then determine the appropriate individual payment scheme for each patient, a methodology developed and run today by an independent delivery partner, Axios International.

Local Context, Equity & Sustainability

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

This is a Takeda led initiative, which is delivered with the support of an independent organisation and therefore does not divert resources away from other public health priorities.

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

Yes.

TYPE	COMMERCIAL NAME	INTERNATIONAL NON-PROPRIETARY NAME AND/OR INN
Medicine	Adcetris	Brentuximab Vedotin

20 Health technology(ies) are part of local standard treatment guidelines

No. This program is about improving access to our innovative speciality medicines for patients suffering from Hodgkin Lymphoma. Before the launch of Adcetris®, there were no treatment options for patients with relapsed and refractory Hodgkin's Lymphome (RR HL) or relapsed and refractory systematic anaplastic large cell lymphoma (RR sALCL) in many developing markets.

21 Health technologies are covered by local health insurance schemes

No. In some markets it is covered, and other markets not.

22 Program provides medicines listed on the National Essential Medicines List

No. This program is about improving access to our innovative speciality medicines for patients suffering from Hodgkin Lymphoma. Before the launch of Adcetris®, there were no treatment options for patients with relapsed and refractory Hodgkin's Lymphome (RR HL) or relapsed and refractory systematic anaplastic large cell lymphoma (RR sALCL) in many developing markets.

23 Sustainability plan

- Sustainability is a key element to this program, and is indeed what it is geared around.
- Our targeted, affordability-based approach allows Takeda to optimize both the number of patients that can access treatment and the related treatment benefits in a sustainable way, by enabling patients to complete their full course of treatment, even they cannot afford to pay for it in full.
- We believe this provides more sustainable access to medicines for eligible patients than untargeted price reductions or donations.
- To ensure program sustainability, enrolled patients will be asked to pay for what they can afford.
- In select cases for patients with no ability to pay, and where appropriate and feasible, we may also explore other potential routes available for them to access medicines included in our PAPs, such as donations or additional financial support from local medical societies, charities and NGOs.
- The performance of our PAPs are monitored and reported on continuously – with KPIs integrated into both the design and implementation of each.
- We produce monthly country level reports to monitor the performance of each PAP to ensure that we can adjust and adapt them according to need and performance.

Additional Program Information

24 Additional program information

[No response provided]

a Potential conflict of interest discussed with government entity

Yes. In certain countries we have done so, and others not.

25 Access Accelerated Initiative participant

Yes.

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

Yes.

Program Indicators

PROGRAM NAME

Patient Assistance Program for Adcetris

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

	INDICATOR	TYPE	STRATEGY	2017	2018	2019
1	Number of patients reached with pricing scheme	Output	Price Scheme	---	---	561 people
2	Volume of medicines sold	Output	Price Scheme	---	---	59,100 mg
3	Volume of medicines donated	Output	Medicine Donation	---	---	572,750 mg
4	Provider awareness of program	Outcome	Price Scheme	---	---	494 people

INDICATOR

Number of patients reached with pricing scheme

1

STRATEGY PRICE SCHEME

	ITEM	DESCRIPTION
	Definition	Number of individuals that received medicines included in the price scheme
	Method of measurement	Counting the number of individuals that received medicines included in the price scheme CALCULATION Sum of the number of individuals that received medicines included in the price scheme
28	Data source	Routine program data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Company, Implementing partner: Axios International	Axios international keeps a record of the number of individuals that are benefiting from Takeda's Patient Assistance Program (PAP) - Adcetris®. This data is then reported to Takeda's Access to Medicines office.	Every month
31	Data processing	Company, Implementing partner: Axios International	Once a month, Axios International provides aggregated and anonymized data of the total number of patients benefiting from the Takeda's Patient Assistance Program (PAP) - Adcetris® across each of the countries. This data is reported to Takeda's Access to Medicines Office. Takeda's Access to Medicines office correlate data from different sources, to validate our reporting.	Ongoing
32	Data validation		Takeda's Access to Medicines Office will review and validate the data submitted by Axios International on a monthly basis. An audit of our implementing partner is performed annually / every two years.	

33 Challenges in data collection and steps to address challenges

None.

INDICATOR	2017	2018	2019
2 Number of patients reached with pricing scheme	---	---	561 people

Comments: 2019: The data represented is collected by our implementing partner, Axios International. 561 represents the number of patients who are currently ACTIVE on Takeda's Patient Assistance Program (PAP) - Adcetris® (as of 31 December 2019) . Breakdown of the 561 ACTIVE patients on the Patient Assistance Program for Adcetris® per country as of 31 December 2019 is as follows: Thailand - 57 Malaysia - 35 Philippines - 80 Indonesia - 30 Lebanon - 8 UAE - 2 Ukraine - 111 Egypt - 74 Kenya - 8 Mexico - 123 Peru - 33 The number of NEW PATIENTS who have entered Takeda's Patient Assistance Program (PAP) - Adcetris® between 01 January 2019 to 31 December 2019 is 551. Breakdown of the 551 NEW PATIENTS who have entered Patient Assistance Program for Adcetris® between 01 January 2019 and 31 December 2019 is as follows: Thailand - 57 Malaysia - 36 Philippines - 80 Indonesia - 30 Lebanon - 8 UAE - 2 Ukraine - 111 Egypt - 68 Kenya - 8 Mexico - 123 Peru - 33.

INDICATOR **Volume of medicines sold**

STRATEGY PRICE SCHEME

2

	ITEM	DESCRIPTION
	Definition	Milligrams of active ingredient sold to patients in pricing scheme
	Method of measurement	Number of vials sold multiplied by Milligrams of active ingredient per vial as stated in Summary of Product Characteristics (SmPC)
28	Data source	Routine Program Data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Company, Distributor, Implementing partner: Axios International, Other: Distributor	The implementing partner Axios International coordinates the supply of Adcetris® vials from the distributor to various hospital pharmacies based on a prescription from a licensed HCP on an on-going basis. Both the distributor and Axios International maintain records. The distributor maintains records of number of total vials supplied to hospitals, whilst Axios International maintains records of number of total vials received to hospitals and disaggregates this data as vials sold and vials provided free of charge. Every month the distributor and Axios International provide aggregated and anonymized data to Takeda.	Ongoing
31	Data processing	Company, Implementing partner: Axios International	Axios International reports data to Takeda regarding number of vials sold on a monthly basis. Takeda convert number of vials to total number of milligrams sold. This is based on number of milligrams per vial stated in the Summary of Product Characteristics. One vial of Adcetris® contains 50mg of active ingredient (brentuximab vedotin). The calculation of total number of milligrams of Adcetris® (brentuximab vedotin) sold is made as follows: number of vials sold multiplied by 50 mg brentuximab vedotin.	Every month
32	Data validation		Takeda correlate data from external sources i.e. the distributor and Axios International with internal data from finance and supply systems, to validate our reporting of volume of medicines sold.	

INDICATOR **Volume of medicines sold**

STRATEGY PRICE SCHEME

2

33 Challenges in data collection and steps to address challenges

None.

INDICATOR	2017	2018	2019
4 Volume of medicines sold	---	---	59,100 mg

Comments:

2019: TThe data represented is collected by our implementing partner, Axios International. One vial of Adcetris® contains 50 mg of brentuximab vedotin. 1,182 vials of Adcetris® (equivalent to 59,100 mg brentuximab vedotin) were SOLD as part of the Patient Assistance Program (PAP) - Adcetris® as of 31 December 2019. Breakdown of SOLD Adcetris® Vials and equivalent in Milligrams of brentuximab vedotin per country: Thailand - 96 vials – 4,800 mg Malaysia – 166 vials – 8,300 mg Philippines – 69 vials – 3,450 mg Indonesia – 60 vials – 3,000 mg Lebanon – 395 vials – 19,750 mg UAE – 33 vials – 1,650 mg Ukraine – 38 vials – 1,900 mg Egypt – 241 vials – 12,050 mg Kenya – 32 vials – 1,600 mg Mexico – 51 vials – 2,550 mg Peru – 1 vial - 50 mg.

INDICATOR **Volume of medicines donated**

STRATEGY MEDICINE DONATION

3

	ITEM	DESCRIPTION
	Definition	Milligrams of active ingredient donated to patients in pricing scheme
	Method of measurement	Number of vials sold multiplied by Milligrams of active ingredient per vial as stated in Summary of Product Characteristics (SmPC)
28	Data source	Routine Program Data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Company, Implementing partner: Axios International, Other: Distributor	The implementing partner Axios International coordinates the supply of Adcetris® vials from the distributor to various hospital pharmacies based on a prescription from a licensed HCP on an on-going basis. Both the distributor and Axios International maintain records. The distributor maintains records of number of total vials supplied to hospitals, whilst Axios International maintains records of number of total vials received to hospitals and disaggregates this data as vials sold and vials provided free of charge. Every month the distributor and Axios International provide aggregated and anonymized data to Takeda.	Ongoing
31	Data processing	Company, Implementing partner: Axios International	Axios International reports data to Takeda regarding number of vials donated on a monthly basis. Takeda convert number of vials to total number of milligrams donated. This is based on number of milligrams per vial stated in the Summary of Product Characteristics. One vial of Adcetris® contains 50mg of active ingredient (brentuximab vedotin). The calculation of total number of milligrams of Adcetris® (brentuximab vedotin) donated is made as follows: number of vials donated multiplied by 50 mg brentuximab vedotin.	Ongoing
32	Data validation		Takeda correlate data from external sources i.e. the distributor and Axios International with internal data from finance and supply systems, to validate our reporting of volume of medicines donated. Further, an internal audit performed annually / every two years, to verify data collection and management procedures.	

INDICATOR Volume of medicines donated

STRATEGY MEDICINE DONATION

3

33 Challenges in data collection and steps to address challenges

None.

INDICATOR	2017	2018	2019
5 Volume of medicines donated	---	---	572,750 mg

Comments:

2019: The data represented is collected by our implementing partner, Axios International. One vial of Adcetris® contains 50 mg of brentuximab vedotin. 11,455 vials of Adcetris® (equivalent to 572,750 mg brentuximab vedotin) were provided Free of Charge (FOC) & DONATED as part of the Patient Assistance Program (PAP) - Adcetris® between 1 January 2019 and 31 December 2019. Breakdown of FOC & DONATED Adcetris® Vials and equivalent mg of brentuximab vedotin per country between 1 January 2019 and 31 December 2019 is as follows: Thailand - 695 vials – 34,750 mg Malaysia – 718 vials – 35,900 mg Philippines – 1942 vials – 97,100 mg Indonesia – 339 vials – 16,950 mg Lebanon – 0 vials – 0 mg UAE – 29 vials – 1,450mg Ukraine – 2879 vials – 143,950 mg Egypt – 1432 vials – 71,600 mg Kenya – 191 vials – 9,550 mg Mexico – 2550 vials – 127,500 mg Peru – 680 vials – 34,000 mg.

INDICATOR **Provider awareness of program**

STRATEGY PRICE SCHEME

4

	ITEM	DESCRIPTION
	Definition	Number of providers in the target audience that are aware of the pricing scheme
	Method of measurement	Implementing partner keeps a record of providers who are made aware of the pricing scheme
28	Data source	Routine Program Data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Implementing partner: Axios International	The local staff from the implementing partner Axios International keep a record of Physicians they have visited each month to inform them about Takeda's Patient Assistance Program (PAP) - Adcetris®.	Ongoing
31	Data processing	Company, Implementing partner: Axios International	Our implementing partner Axios International, sums up the data and reports to Takeda.	Ongoing
32	Data validation		An internal audit is performed annually / every two years, to verify data collection and management procedures.	

33 Challenges in data collection and steps to address challenges

None.

INDICATOR	2017	2018	2019
6 Provider awareness of program	---	---	494 people

Comments:

2019: he data represented is collected by our implementing partner, Axios International. 494 represents the Physicians were informed about the PAP - Adcetris ® The breakdown per country is as follows: Egypt - 16 Indonesia - 13 Kenya - 36 Lebanon - 28 Malaysia - 39 Mexico - 20 Peru - 94 Philippines - 125 Thailand - 24 UAE - 9 Ukraine - 90.

Appendix

This program report is based on the information gathered from the Access Observatory questionnaire below.

Program Description

PROGRAM OVERVIEW

1 Program Name

2 Diseases program aims to address:

Please identify the disease(s) that your program aims to address (select all that apply).

3 Beneficiary population

Please identify the beneficiary population of this program (select all that apply).

4 Countries

Please select all countries that this program is being implemented in (select all that apply).

5 Program Start Date

6 Anticipated Program Completion Date

7 Contact person

On the public profile for this program, if you would like to display a contact person for this program, please list the name and email address here (i.e. someone from the public could email with questions about this program profile and data).

8 Program summary

Please provide a brief summary of your program including program objectives (e.g., the intended purposes and expected results of the program; if a pilot program, please note this). Please provide a URL, if available. Please limit replies to 750 words.

PROGRAM STRATEGIES & ACTIVITIES

9 Strategies and activities

Based on the BUSPH Taxonomy of Strategies, which strategy or strategies apply to your program (please select all that apply)?

10 Strategy by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g. some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have you selected from above (program strategies), please identify which country/countries these apply.

COMPANIES, PARTNERS AND STAKEHOLDERS

11 Company roles

Please identify all pharmaceutical companies, including yours, who are collaborating on this program:

What role does each company play in the implementation of your program?

12 Funding and implementing partners

Please identify all funding and implementing partners who are supporting the implementation of this program (Implementing partners is defined as either an associate government or non-government entity or agency that supplements the works of a larger organization or agency by helping to carry out institutional arrangements in line with the larger organization's goals and objectives.)

a. What role does each partner play in the implementation of your program? Please give background on the organization and describe the nature of the relationship between the organization and your company. Describe the local team's responsibilities for the program, with reference to the program strategies and activities. (response required for each partner selected).

b. For each partner, please categorize them as either a Public Sector, Private Sector, or Voluntary Sector partner.

(Public Sector is defined as government; Private Sector is defined as A business unit established, owned, and operated by private individuals for profit, instead of by or for any government or its agencies. Generation and return of profit to its owners or shareholders is emphasized; Voluntary Sector is defined as Organizations whose purpose is to benefit and enrich society, often without profit as a motive and with little or no government intervention. Unlike the private sector where the generation and return of profit to its owners is emphasized, money raised or earned by an organization in the voluntary sector is usually invested back into the community or the organization itself (ex. Charities, foundations, advocacy groups etc.))

c. Please provide the URL to the partner organizations' webpages

13 Funding and implementing partners by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g., some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have you selected from above (funding and implementing partners), please identify which country/countries these apply.

14 Stakeholders

Please describe how you have engaged with any of these local stakeholders in the planning and/or implementation of this program. (Stakeholders defined as individuals or entities who are involved in or affected by the execution or outcome of a project and may have influence and authority to dictate whether a project is a success or not (ex. Ministry of Health, NGO, Faith-based organization, etc.). Select all that apply.

- Government, please explain
- Non-Government Organization (NGO), please explain
- Faith-based organization, please explain
- Commercial sector, please explain
- Local hospitals/health facilities, please explain
- Local universities, please explain
- Other, please explain

LOCAL CONTEXT, EQUITY & SUSTAINABILITY

15 Local health needs addressed by program

Please describe how your program is responsive to local health needs and challenges (e.g., how you decided and worked together with local partners to determine that this program was appropriate for this context)?

a How were needs assessed

b Was a formal need assessment conducted

(Yes/No) If yes, please upload file or provide URL.

16 Social inequity addressed

Does your program aim to address social inequity in any way (if yes, please explain). (Inequity is defined as lack of fairness or justice. Sometime 'social disparities,' 'structural barriers' and 'oppression and discrimination' are used to describe the same phenomenon. In social sciences and public health social inequities refer to the systematic lack of fairness or justice related to gender, ethnicity, geographical location and religion. These unequal social relations and structures of power operate to produce experiences of inequitable health outcomes, treatment and access to care. Health and social programs are often designed with the aim to address the lack of fairness and adjust for these systematic failures of systems or policies.*)

*Reference: The definition was adapted from Ingram R et al. Social Inequities and Mental Health: A Scoping Review. Vancouver: Study for Gender Inequities and Mental Health, 2013.

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

How have local policies, practices, and laws (e.g., infrastructure development regulations, education requirements, etc.) been taken into consideration when designing the program?

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

Please explain how the program avoids diverting resources away from other public health priorities? (e.g. local human resources involved in program implementation diverted from other programs or activities).

19 Program provides health technologies

Does your program include health technologies (health technologies include medical devices, medicines, and vaccines developed to solve a health problem and improve quality of lives)? (Yes/No)

20 Health technology(ies) are part of local standard treatment guidelines

Are the health technology(ies) which are part of your program part of local standard treatment guidelines? (Yes/No) If not, what was the local need for these technologies?

21 Health technologies are covered by local health insurance schemes

Does your program include health technologies that are covered by local health insurance schemes? (Yes/No) If not, what are the local needs for these technologies?

22 Program provides medicines listed on the National Essential Medicines List

Does your program include medicines that are listed on the National Essential Medicines List? (Yes/No) If not, what was the local need for these technologies?

23 Sustainability plan

If applicable, please describe how you have planned for sustainability of the implementation of your program (ex. Creating a transition plan from your company to the local government during the development of the program).

ADDITIONAL PROGRAM INFORMATION

24 Additional program information

Is there any additional information that you would like to add about your program that has not been collected in other sections of the form?

a Potential conflict of interest discussed with government entity

Have you discussed with governmental entity potential conflicts of interest between the social aims of your program and your business activities? (Yes/No) If yes, please provide more details and the name of the government entity.

25 Access Accelerated Initiative participant

Is this program part of the Access Accelerated Initiative? (Yes/No)

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

Is your company a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)? (Yes/No)

Program Indicators

INDICATOR DESCRIPTION

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

For this program, activities, please select all inputs and impacts for which you plan to collect and report data into this database.

28 Data source

For this indicator, please select the data source(s) you will rely on.

29 Frequency of reporting

Indicate the frequency with which data for this indicator can be submitted to the Observatory.

30 Data collection

a. Responsible party: For this indicator, please indicate the party/parties responsible for data collection.

b. Data collection — Description: Please briefly describe the data source and collection procedure in detail.

c. Data collection — Frequency: For this indicator, please indicate the frequency of data collection.

31 Data processing

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

b. Data processing— Description: Please briefly describe all processing procedures the data go through. Be explicit in describing the procedures, who enacts them, and the frequency of processing.

c. Data processing — Frequency: What is the frequency with which this data is processed?

32 Data validation

Description: Describe the process (if any) your company uses to validate the quality of the data sent from the local team.

33 Challenges in data collection and steps to address challenges

Please indicate any challenges that you have in collecting data for this indicator and what you are doing to address those challenges.