APRIL 2020

Max Access Solutions (MAS)

Takeda

Submitted as part of Access Accelerated

Access Observatory

Contents

Program Description

Program Overview

1 **Program Name**

Takeda Max Access Solutions (MAS)

2 **Diseases program aims to address**

• Cancer: Leukemia

3 **Beneficiary population**

• Age Group: All ages
• Gender: All genders
• Special Populations: People with low income, Rural populations, Urban populations

4 **Countries**

• Malaysia
• Thailand
• India
• Nepal
• Kenya
• Ethiopia
• Philippines
• Ghana
• Brazil
• Paraguay
• Senegal
• Seychelles
• Tunisia
• Kazakhstan
• Niger

5 **Program start date**

November 1, 2015

6 **Anticipated program completion date**

Completion Date not specified.

7 **Contact person**

Philip.towle@takeda.com

8 **Program summary**

Launched by The Max Foundation, Max Access Solutions (MAS) program is an operational program through which humanitarian donations of approved oncology products are channelled to patients in need. The Max Access Solutions program aims to bridge the gaps in access to treatment specifically in countries where the burden of disease is high and local government access programs may not be currently feasible.

The MAS Iclusig® (ponatinib) program is especially critical to CML patients for whom other treatments have proven ineffective and for those who have T315I-positive CML or Ph+ ALL.

Through this program, Takeda donates Iclusig® (ponatinib), effective for the treatment of refractory chronic myeloid leukemia (CML) or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL), to The Max Foundation to help cancer patients in low- and middle-income countries (LMICs), who would otherwise lack access to the drug due to unavailability in local markets. The Max Foundation provides access to Takeda's Iclusig® (ponatinib) product to patients in need through their treating physicians. Healthcare providers (HCP) in LMICs initiate the product request and manage the treatment of patients receiving the product from The Max Foundation. The Foundation works through a third-party logistics provider (3PL) who, as its agent, receives the product from manufacturers and ships it to end users on the organization's behalf. This ensures the fastest possible time between the drug being prescribed, and is administered to the patient.

Takeda in collaboration with the Foundation support partner physicians on the use of the treatment, as well as to providing wrap-around support in areas such as diagnostics and adherence support.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Medicine Donation

ACTIVITY	DESCRIPTION
Donation	Within Max Access Solution Iclusig® program, Takeda donates product to The Max Foundation and the organization channels product at its discretion to patients in need through their treating physician.
Delivery	Takeda have collaborated with The Max Foundation, which has allowed them to significantly strengthen their program management and supply chain capabilities, shortening the time between when a drug is prescribed to when it reaches the hands of patients.
Communication	At the center of the Max Access Solution model is a patient who has been diagnosed with and prescribed a treatment for refractory chronic myeloid leukemia (CML) or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) where no local access exists. Working in collaboration with a robust network of leading cancer treating institutions and physicians, Takeda Pharmacueticals, an international distributor, and local patient support organizations, The Max Foundation provide humanitarian access to the Iclusig® (ponatinib) with the aim that each required dose reaches the intended patient at the right time, while strengthening the local healthcare system.

10 Strategy by country

[No response provided]

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Takeda	Takeda donates product and collaborates with The Max Foundation to strengthen program management and supply chain capabilities.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Max Foundation	The Max Foundation through their Max Access Solution bridges access to treatment, specifically within low- and middle-income countries (LMICs) where the burden of disease is high and local government access programs may not be currently feasible. https://www.themaxfoundation.org/max- access-solutions/	Voluntary

13 Funding and implementing partners by country

[No response provided]

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKEHOLDER
Non-governmental organization (NGO)	The Max Foundation works alongside various local patient support organizations in the delivery of the Max Access Solution.	Infrastructure: [No response provided] Human Resources: [No response provided] Funding: [No response provided] Monitoring or Oversight: [No response provided] Other resource: [No response provided]

Local Context, Equity & Sustainability

15 Local health needs addressed by program

The need has been identified by our partner, The Max Foundation, and we align the program based on our partners findings.
The Max Foundation reviews the World Bank's Country and Lending Groups, as well as local access channels for each specific product, when assessing country eligibility for product donations. Takeda then works with The Max Foundation to jointly select countries in scope of the program.

a How needs were assessed

Max Access Solutions is meant to be a bridge for access to treatment specifically within low- and middle-income countries (LMICs) where the burden of disease is high and local government access programs may not be currently feasible.
Vetted health care providers (HCP) in LMICs initiate the product request and manage treatment of patients receiving product from The Max Foundation.
The Max Foundation has extensive experience in managing patient access programs for oncology products.

b Formal needs assessment conducted
Yes

16 Social inequity addressed

The Takeda Max Access Solution for Iclusig® is meant to be a bridge for access to treatment specifically within low- and middle-income countries (LMICs), where the burden of disease is high and local government access programs may not be currently feasible.

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	Our partner, The Max Foundation ensure all National regulations are adhered to for each country in scope of the program.
Procurement procedures	No	N/A
Standard treatment guidelines	No	N/A
Quality and safety requirements	Yes	Quality and safety are all managed through our partner, The Max Foundation.
Remuneration scales and hiring practices	No	N/A

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

No resources are diverted from public health priorities.

Local Context, Equity & Sustainability

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

TYPE	COMMERCIAL NAME	INTERNATIONAL NON-PROPRIETARY NAME AND/OR INN
Medicine	Iclusig®	Ponatinib

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

No

21 Health technologies are covered by local health insurance schemes

No

22 Program provides medicines listed on the National Essential Medicines List

No

23 Sustainability plan

The Max Access Solution program for Iclusig® is meant to be a bridge for access to treatment specifically within low- and middle-income countries (LMICs), where the burden of disease is high and local government access programs may not be currently feasible.

Once health systems have further evolved, Takeda considers registering and launching of the product, either directly or through a distribution partner, offering various sustainable access solutions, as happened in Malaysia and Thailand during 2019.

Additional Program Information

24 Additional program information

[No response provided]

a Potential conflict of interest discussed with government entity

No

25 Access Accelerated Initiative participant

Yes

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

Yes

Program Indicators

Takeda Max Access Solution (MAS)

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

INDICATOR	TYPE	STRATEGY	2018	2019
1 Number of individuals receiving donated medicines	Output	Medicine Donation	---	125 people
2 Volume of medicines donated	Output	Medicine Donation	---	27,680 defined daily doses (DDD)

Number of patients receiving donated medicines

STRATEGY   MEDICINE DONATION

ITEM	DESCRIPTION
Definition	Number of patients receiving donated medicines
Method of measurement	Counting the patients who received the donated medicines Calculation: Sum of all patients who received the donated medicines
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Implementing partner: Max Foundation	The Max Foundation, an independent, external third party organization keeps a record of the number of individuals that are benefiting from the Max Access Solution - Iclusig® across each of the countries. Aggregated and anonymized data per country is provided to Takeda Pharmaceuticals. Takeda correlate data from internal finance and supply systems and compare against The Max Foundation data, to validate the number of individuals receiving donated medicines.	Ongoing
31 Data processing	Implementing partner: Max Foundation, Company: Takeda	Once a month, The Max Foundation provides aggregated and anonymized data of the total number of patients benefiting from the Max Access Solution across each of the countries. Aggregated and anonymized data per country is provided to Takeda Pharmaceuticals. Takeda correlate data from internal finance and supply systems and compare against The Max Foundation data, to validate the number of individuals receiving donated medicines.	Every month

Number of patients receiving donated medicines

STRATEGY   MEDICINE DONATION

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
32 Data validation		Takeda's Access to Medicines Office will review and validate the data submitted by The Max Foundation 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	2018	2019
1 Number of patients receiving donated medicines	---	125 people

Comments:

2019: The data represented is collected by our implementing partner The Max Foundation, an independent third-party organization. 125 represents the number of patients who are ACTIVE on the Takeda Max Access Solution - Iclusig® program for treatment of chronic myeloid leukemia (CML) and Philadelphia-positive acute lymphoblastic leukemia (Ph+ ALL) as of 31 March 2020. The 125 ACTIVE patients as of 31 March 2020 may be disaggregated by country as follows: Bahamas - 1 Brazil - 2 Dominican Republic - 2 Ethiopia - 9 Ghana - 2 India - 37 Kazakhstan - 0 Kenya - 13 Malaysia - 0 Nepal - 21 Niger - 0 Paraguay - 4 Philippines - 22 Senegal - 1 Seychelles - 1 Tanzania - 1 Thailand - 0 Tunisia - 1 Uganda - 3 Uruguay - 0 Venezuela - 5 Patient enrollment decreased significantly between October 2019 and December 2019 due to the transition of all 108 existing patients in Malaysia to a new donations program following market authorization in Malaysia, effectively almost halving the number of patients in the global Takeda MAS Iclusig® program -- the total active enrolled patients decreased from 219 patients as of 30 September 2019 to 122 patients as of 31 December 2019. 270 cases have been closed as of 31 March 2020; as follows: Bahamas - 0 Brazil - 2 Dominican Republic - 0 Ethiopia - 2 Ghana - 1 India - 35 Kazakhstan - 1 Kenya - 10 Malaysia - 142 Nepal - 5 Niger - 1 Paraguay - 0 Philippines - 9 Senegal - 0 Seychelles - 0 Tanzania - 0 Thailand - 61 Tunisia - 1 Uganda - 0 Uruguay - 0 Venezuela - 0 A TOTAL of 395 patients in 20 countries (i.e. ACTIVE and CLOSED cases) have benefited from the Takeda Max Access Solution - Iclusig® program as of 31 March 2020.

	ITEM	DESCRIPTION
	Definition	Volume of donated medicines received by the intended recipient
	Method of measurement	Volume of donated medicines received by the intended recipient Calculation: {No response provided]
28	Data source	Routine program data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Implementing partner: Max Foundation, Company: Takeda	On a quarterly basis, The Max Foundation provides data of the volume of medicines donated across each of the countries. Aggregated and anonymized data per country is provided to Takeda Pharmaceuticals. Takeda correlate data from internal finance and supply systems and compare against The Max Foundation data, to validate our reporting of volume of medicines donated.	Ongoing
31	Data process-ing	Company: Takeda	On a quarterly basis, The Max Foundation provides data of the volume of medicines donated across each of the countries. Aggregated and anonymized data per country is provided to Takeda Pharmaceuticals. Takeda correlate data from internal finance and supply systems and compare against The Max Foundation data, to validate our reporting of volume of medicines donated.	Every three months
32	Data validation		A member of the Sanofi Espoir Foundation team records from official accounting record of our entity the annual payment of the grant allocated for each of the 3 years.	

33   Challenges in data collection and steps to address challenges

None.

INDICATOR		2018	2019
2	Volume of medicines donated	---	27,680 defined daily doses (DDD)

Comments:
2019: Defined Daily Doses are calculated by our partner, The Max Foundation using the formula: # of bottles received or shipped in defined time period * dosage * # of capsules per bottle / FDA label recommended daily dosage of 45mg. # of bottles shipped from 1 July 2019 - 31 March 2020 = 2,768 dosage = 15 mg # of capsules per bottle = 30

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 is 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.