APRIL 2020

Improving Access to our Anticancer Product in India

Astellas

Submitted as part of Access Accelerated



Contents

Program Description	3
Program Overview	4
Program Strategies & Activities	5
Companies, Partners & Stakeholders	6
Local Context, Equity & Sustainability	7
Additional Program Information	9
Program Indicators	10
Appendix	11
Company-submitted Situation Analysis	14

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: Astellas, Improving Access to our Anticancer Product in India (2020), Access Observatory Boston, US 2020 (online) available from www.accessobservatory.org

Program Description

Program Overview

Program Name

Action on Fistula

- 2 Diseases program aims to address
- · Cancer: Prostate cancer
- Beneficiary population
- · Gender: Men
- Age: Elderly (>65 yrs)
- Special populations: People with low income
- 4 Countries
- India

Program start date

July 28, 2017

6 Anticipated program completion date

Completion date not specified.

Contact person

N/A

8 Program summary

With changes in lifestyle-related behavior, the incidence rate of prostate cancer is constantly and rapidly increasing in India. Some cancer projection data show that the number of cases will double by 2020 (as compared to 2012). In India, most patients have to pay the full cost when purchasing a prescription.

Astellas is introducing a new program structured according to patients' income levels to improve patient' access to our anticancer product in India in collaboration with local partners. We believe that this new program will increase the number of patients able to access our anticancer product in India.

http://www.accessaccelerated.org/initiative/improving-access-anticancer-product-india/

Program Strategies & Activities



9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	Medical representative of Astellas India will outreach medical doctors. Doctors are expected to inform patients of programs.

Strategy 2: Health Service Delivery

ACTIVITY	DESCRIPTION
Treatment	Introducing a new program structured according to patients' income level to improve patients' access. it is believed that this new program will increase the number of patients able to access our anticancer product in India.

Strategy by country

STRATEGY **COUNTRY**

Community Awareness and Linkage to Care	India
Health Service Delivery	India

Companies, Partners & Stakeholders

Company r	oles			
COMPANY	ROLE			
Astellas	Astellas introduces a new program structured according to patients' income levels. Based on the financial assessment of patients, our anticancer products are provided to patients via local partners.			
12 Funding ar	d implementing partners			
PARTNER	ROLE/URL		SECTOR	
Local partners	One partner conducts a financial assessment of patients (to assess eligibility) and the other partner provides our anticancer product to patients based on the assessment. URL not applicable.		Private	
13 Funding ar	d implementing partners by country			
PARTNER	(COUNTRY		
Local partners		India		
14 Stakeholde	rs			
STAKEHOLDER	DESCRIPTION OF ENGAGEMENT			
Commercial	One partner conducts a financial assessment of patients (to assess eligibility) and the other partner provides ou			

anticancer product to patients based on the assessment.

Sector

Local Context, Equity & Sustainability

Local health needs addressed by program

With changes in lifestyle-related behavior, the incidence rate of prostate cancer is constantly and rapidly increasing in India. Some cancer projection data show that the number of cases will double by 2020 (as compared to 2012). The incidence and prevalence of metastatic castration resistant prostate cancer (mCRPC) whose disease has progressed on or after Docetaxel therapy assumed to be 140 patients annually based on data from Epic oncology. Given the fact that the prevalence of mCRPC whose disease has progressed on or after Docetaxel therapy is low, it is considered an orphan disease in India. In India, the out-of-pocket expenditure as a percentage of total health expenditure as of 2014 is 62% with most patients have to pay the full cost when purchasing a prescription.

We believe that this new program will increase the number of patients able to access our anticancer product in India.

- How needs were assessed [No response provided]
- Formal needs assessment conducted
- Social inequity addressed

Most patients have to pay the full cost when purchasing a medicine in India however economic gaps exist.

We believe that our program helps to improve patients' access of lower income patients who cannot afford to pay the full cost.

Local policies, practices, and laws considered during program design

Economic gaps in the country were considered when we designed this program. We designed this program referring to other companies' programs in India.

How diversion of resources from other public health priorities is avoided

[No response provided]

Local Context, Equity & Sustainability

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

[No response provided]

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

N/A

4 Health technologies are covered by local health insurance schemes

N/A

22 Program provides medicines listed on the National Essential Medicines List

N/A

Sustainability plan

To ensure improvement of access to health in India, Astellas seeks sustainable approaches which may provide stable and long-term benefits to patients We believe that our program may provide sustainable and long term benefits to the patients.

Additional Program Information

24 Additional program information

Not applicable.

Potential conflict of interest discussed with government entity

[No response provided]

Access Accelerated Initiative participant

Yes

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Yes

Program Indicators

Not yet available for this program.

Appendix

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

Program Description

PROGRAM OVERVIEW

- **Program Name**
- Diseases program aims to address:

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

Beneficiary population

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

Countries

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

- **Program Start Date**
- **Anticipated Program Completion Date**
- 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).

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)?

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

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 describethenature 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.

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)?

- 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).

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)

40 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?

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?

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?

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

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?

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)

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

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.

- 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.
- 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?
- 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.

Company-submitted Situation Analysis

1. Jain, S., Saxena, S., Kumar, A. Epidemiology of prostate cancer in India. Meta Gene 2014; 2: 596-605.

Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4287887/pdf/main.pdf