

APRIL 2020

Hope to Her in India

Eisai

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: Eisai, Remember I Love You (2020), Access Observatory Boston, US 2020 (online) available from www.accessobservatory.org

Program Description

Program Overview

1 Program Name

Hope to Her in India

2 Diseases program aims to address

- Cancer (Breast)

3 Beneficiary population

- Age Group: All ages
- Gender: Female
- Special Populations: Low income

4 Countries

- India

5 Program start date

October 1, 2013

6 Anticipated program completion date

Completion date not specified

7 Contact person

Chika Kuwahara (c-kuwahara@hhc.eisai.co.jp)

8 Program summary

1) OBJECTIVE

To realize affordability by using a tiered-pricing model* and partnering with various stakeholders to improve access to medicines. Breast cancer is the most common type of cancer among women, and the fourth most common cause of cancer-related deaths in the Asia-Pacific region. On the other hand, with the continued economic growth in Asia, many countries are making efforts to expand Universal Health Coverage (UHC). However due to financial challenges and operational issues, the coverage is usually limited to essential medicines only. Furthermore, economic growth leads to wider income disparity, but does not necessarily benefit lower-income groups and then force lower income patients who are not covered by insurance to pay out-of-pocket to access innovative medicines.

* tiered-pricing model sets the multiple cost burden to patients from full payment by the patient to free of charge in accordance with their income levels

2) Activities

Aiming to fulfill the gap between current reimbursement coverage and achievement of full UHC, "Hope to Her" was initiated to ensure patients' access to Eisai's innovative metastatic breast cancer treatment where it is not reimbursed by UHC. Eisai developed the tiered-pricing model in which the cost burden to patients is differentiated according to income level. This model sets different tiers including free of charge, by considering socio-economic factors, treatment cycles, benefits for patients and their families, and so on.

3) Partnership

Third-parties such as financial assessment agencies and public foundations conduct independent assessments on patients' financial status in order to determine which tier they should be allocated to, as well as guidance on drug compliance, and tracking progression of health status.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Price Scheme

ACTIVITY	DESCRIPTION
Pricing	Eisai developed tiered pricing model in which the cost burden to patients is differentiated according to income level. This model sets different tiers including free of charge, by considering socio-economic factors, treatment cycles, benefits for patients and their families, and so on.

10 Strategy by country

STRATEGY	COUNTRY
Price Scheme	India

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Eisai	Eisai developed and has been managing tiered-pricing in which the cost burden to patients is differentiated according to income level. This model sets different tiers, by considering socio-economic factors, treatment cycles, and patients and their families' benefits.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
	Third-parties like financial assessment agencies and public foundations help to make independent assessments on patients' financial status in order to determine which tier they should be allocated to, as well as guidance on drug compliance, and tracking progression of health status.	Private

13 Funding and implementing partners by country

PARTNER	COUNTRY
Third-parties like financial assessment agencies and public foundations	India

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKEHOLDER
Local Hospitals/ Health Facilities	Eisai places order to distributor and then delivers order to pharmacy or clinic. Physician and pharmacist can engaged in receiving drug delivery.	Infrastructure: No Human Resources: No Funding: No Monitoring or Oversight: No Other resource: No

Local Context, Equity & Sustainability

15 Local health needs addressed by program

The number of women diagnosed with breast cancer in India has increased in recent years, with an estimated 163,000 new cases of breast cancer and approximately 87,000 related deaths in 2018.¹ Breast cancer is now the most frequently diagnosed cancer in Indian women.¹

While the Indian economy has grown significantly in recent years, income disparity has become wider in the last two decades. India's income pyramid is divided into 5 segments – below poverty line, lower middle, upper middle, rich and super rich. The Indian income pyramid is in a dynamic state as affluence is rising. With rising affluence, the below poverty line segment at the bottom of the pyramid is shrinking continuously, and with increasing income across the income groups, the pyramid is moving upwards over time. The biggest change has been observed in the below poverty line segment wherein a huge share of the population has moved upwards to enter the 'lower middle' segment. A substantial shift has also been observed among the 'lower middle' and 'upper middle' segments.

With the above income dynamics in mind, Eisai Group aims to expand access to breast cancer treatment Halaven with the tiered-pricing model in which the cost burden to patients is differentiated according to income level. In India, approximate 30% of patients, who have been treated with the product, used the support program by Tiered-Pricing, and it is assumed that the patients' access to the product was improved by approximate 45% with the program.

a How needs were assessed
International Agency for Research on Cancer¹

b Formal needs assessment conducted
No.

16 Social inequity addressed

Hope to Her is an effort to help patients, who are not able to afford the medication cost. This is open to all strata of society whoever has economic challenges in continuing the treatment.

17 Local policies, practices, and laws considered during program design
[No response provided.]

18 How diversion of resources from other public health priorities is avoided
[No response provided.]

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

TYPE	COMMERCIAL NAME	INTERNATIONAL NON-PROPRIETARY NAME
Medicine	Halaven	Eribulin mesylate

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

21 Health technologies are covered by local health insurance schemes
No.

Local Context, Equity & Sustainability

22 Program provides medicines listed on the National Essential Medicines List No.

23 Sustainability plan

Government procures conventional treatment for below poverty line population and they do not buy expensive drugs. Therefore, the issue of transitioning to local state government does not arise. The universal health coverage which has been recently launched only provides coverage for acute therapies and hospitalization.

Eisai Group positions oncology as a key therapeutic area, and is aiming to discover revolutionary new medicines with the potential to cure cancer.

To solve the above-mentioned issues and contribute to patients continually, Eisai Group will continue to adopt proactive measures aimed at increasing access to its innovative pharmaceutical products in emerging countries and the developing world in order to contribute to an increase in the benefits provided to local patients and their families.

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.

Resources

1. World Health Organization: International Agency for Research on Cancer, Global Cancer Observatory. Available on <http://globocan.iarc.fr/>
2. Partnership objective and information report. Eisai Co., Ltd. Hope to Her.

Program Indicators

PROGRAM NAME

Hope to Her in India

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

INDICATOR	TYPE	STRATEGY	2019
1 Number of patients reached with pricing scheme	Output	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	DESCRIPTION	FREQUENCY
30 Data collection	Company	Patients would be recommended by their doctor to fill out a registration form and then they can be registered after such patients submit documents to a 3rd party Agency. The 3rd party Agency reviews the documentation which patients apply and conducts an evaluation. Once the application is confirmed, a distributor will deliver the drug to patient or pharmacy/clinic where patient can receive the drug. After receiving treatment, the patient will submit the form to a third party. A third party reports to Eisai and Eisai maintains this data. Eisai can also monitor this information and keep track of it at any time. Eisai is responsible for data collection and conducting any processing of data.	Other: The 3rd party updates Eisai about the number of patients for each registration.
31 Data processing	Company	The doctor selects and recommends appropriate patients. The 3rd party Agency evaluates the appropriate patient class and informs Eisai of the evaluation results. Eisai notifies physicians of the patient's approval status and corresponding PAP level, and Eisai verifies the patient's treatment schedule. Eisai provides information and schedule to the distributor.	Other: The 3rd party updates Eisai about the number of patients for each registration.
32 Data validation		Eisai visits the 3rd party agency as needed to confirm the data collection and management procedures.	Other: The 3rd party updates Eisai about the number of patients for each registration.

33 Challenges in data collection and steps to address challenges
Pre-set and manage potential hot spots for communication failures.

1	Number of patients reached with pricing scheme	---
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Comments: N/A

Program Documents

Program Documents

1. Partnership objective and information report. Eisai Co., Ltd. Hope to Her. Available at: <https://bit.ly/hopetoher>

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

- 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.

