

APRIL 2018

---

# Access and Affordability Initiative (AAI)

MSD, Novartis, Pfizer Inc., Sanofi, Bill and Melinda Gates Foundation

Submitted as part of Access Accelerated

# Contents

---

<b>Program Description</b>	<b>3</b>
Program Overview	4
Program Strategies & Activities	6
Companies, Partners & Stakeholders	7
Local Context, Equity & Sustainability	10
Additional Program Information	11
<b>Program Indicators</b>	<b>12</b>
List of indicator data	13
Number of patients on appropriate treatment per study protocol	14
<b>Appendix</b>	<b>15</b>

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](http://www.accessobservatory.org)

The information contained in this report is in the public domain and should be cited as: Access and Affordability Initiative (AAI). (2018), Access Observatory Boston, US 2018 (online) available from [www.accessobservatory.org](http://www.accessobservatory.org)

# Program Description

# Program Overview

---

## 1 Program Name

Access and Affordability Initiative (AAI)

## 2 Diseases program aims to address

- Diabetes (General)
- Cardiovascular disease (Hypertension)

## 3 Beneficiary population

- Women
- Men
- People with low income
- Rural Populations

## 4 Countries

- Ghana
- Philippines

## 5 Program start date

November 1, 2014

## 6 Anticipated program completion date

June 30, 2017

## 7 Contact person

Michael Quinlan (michaeldquinlan@gmail.com)

Hannah Kettler (Hannah.Kettler@gatesfoundation.org)

Ken Gustavsen (ken\_gustavsen@merck.com)

Christine Fajardo (christine.fajardo@novartis.com)

Cheryl Maley (cheryl.maley@novartis.com)

Danielle Rollmann (Danielle.rollmann@pfizer.com)

Luc Kuykens (Luc.Kuykens@sanofi.com)

## 8 Program summary

The Access and Affordability Initiative (AAI) is a global health collaboration between four pharmaceutical companies, Merck & Co., Inc., Kenilworth, NJ USA (MSD), Novartis, Pfizer and Sanofi, and the Gates Foundation. The Initiative examines the role of differential pricing and health system strengthening to help improve access to medicines for underserved populations, particularly low-income groups, in LMICs. The AAI pilot programs are exploring an innovative approach, which measures the ability of patients living with NCDs, specifically hypertension and diabetes, in the same country to access innovative medicines for these conditions when differential pricing is applied.

The AAI pilot programs in Ghana and the Philippines constitute the first multi-stakeholder, private sector effort to partner with governments with the explicit goal of validating intra-country differential pricing as a sustainable access tool. Approximately 3,000 people are enrolled in each study, which are unique in incorporating supplementary health system strengthening efforts. Studies included training of healthcare professionals in the treatment of hypertension and diabetes, including improvements in clinical management and patient monitoring, supply chain solutions to ensure medicines availability, differentially priced medicines for individuals determined to be lower income according to study criteria and the provision of clinically-appropriate patient care.

(Program summary continued)

## 8 Program summary cont.

Consistent with anti-trust laws that govern industry interactions, each participating company independently and voluntarily develops its own marketing and pricing strategies reflecting, among other factors, the Company's product portfolios and the patients it serves. Accordingly, each of the participating companies independently and unilaterally makes decisions involving the AAI.

# Program Strategies & Activities

## 9 Strategies and activities

### Strategy 1: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	Both studies included training of healthcare professionals in the treatment of hypertension and diabetes, including improvements in clinical management and patient monitoring. Training activities concentrated on building capacities of health personnel involved in the implementation of the pilot project at the target facilities in the following areas: Clinical management of target diseases, supply information management, monitoring of patients, clinicians, pharmacists, nurses and all other persons involved in the implementation of the pilot and setting up and running of a registry.

### Strategy 2: Health Service Delivery

ACTIVITY	DESCRIPTION
Treatment	Patients enrolled in the program received care consistent with updated clinical guidelines, aligned with international guidelines from doctors and health care professionals trained in those guidelines and protocols as part of the program.

### Strategy 3: Supply Chain

ACTIVITY	DESCRIPTION
Planning	Supply Chain planning and implementation were part of the studies
Training	Training on supply chain management for health personnel involved in the implementation of the project
Management	New and different supply chain agreements were required to ensure study medicines were available to the target population for the studies.

### Strategy 4: Price Scheme

ACTIVITY	DESCRIPTION
Delivery	Supply of differentially priced medicines to lower income patients in the participating health facilities

## 10 Strategy by country

STRATEGY	COUNTRY
Health Service Strengthening	[No response provided].
Health Service Delivery	[No response provided].
Supply Chain	[No response provided].
Price Scheme	[No response provided].

# Companies, Partners & Stakeholders

## 11 Company roles

COMPANY	ROLE
MSD	Contributing financial support and strategic project design consultation as well as differential pricing of MSD medicines for use in the pilots. Consistent with anti-trust laws that govern industry interactions, each participating company independently and voluntarily develops its own marketing and pricing strategies reflecting, among other factors, the Company's product portfolios and the patients it serves. Accordingly, each of the participating companies independently and unilaterally makes decisions involving the AAI.
Novartis	Contributing financial support and strategic project design consultation as well as differential pricing of Novartis medicines for use in the pilots. Consistent with anti-trust laws that govern industry interactions, each participating company independently and voluntarily develops its own marketing and pricing strategies reflecting, among other factors, the Company's product portfolios and the patients it serves. Accordingly, each of the participating companies independently and unilaterally makes decisions involving the AAI.
Pfizer inc	Contributing financial support and strategic project design consultation as well as differential pricing of Pfizer medicines for use in the pilots. Consistent with anti-trust laws that govern industry interactions, each participating company independently and voluntarily develops its own marketing and pricing strategies reflecting, among other factors, the Company's product portfolios and the patients it serves. Accordingly, each of the participating companies independently and unilaterally makes decisions involving the AAI.
Sanofi	Contributing financial support and strategic project design consultation as well as differential pricing of Sanofi medicines for use in the pilots. Consistent with anti-trust laws that govern industry interactions, each participating company independently and voluntarily develops its own marketing and pricing strategies reflecting, among other factors, the Company's product portfolios and the patients it serves. Accordingly, each of the participating companies independently and unilaterally makes decisions involving the AAI.

## 12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Bill and Melinda Gates Foundation	The Bill and Melinda Gates Foundation is contributing financial support for the development and implementation of evaluation programs for the two pilot projects. <a href="https://www.gatesfoundation.org">https://www.gatesfoundation.org</a>	Voluntary

## 12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Ghana Ministry of Health	<p>The governments of Ghana and the Philippines, through their health agency officers, were closely involved in defining the scope of the pilot programs. National and local government officials, the in-country working groups, the Scientific Oversight Committees (SOCs) and other interested stakeholders comprised a Steering Committee which met periodically to help ensure continued strategic support for the programs.. The studies were implemented by in-country investigators whose work was overseen by the SOCs.</p> <p><a href="http://www.moh.gov.gh/">http://www.moh.gov.gh/</a></p>	Public
Johns Hopkins Bloomberg School of Public Health	<p>Johns Hopkins' Bloomberg School of Public Health is leading the evaluation of the two pilot studies, including study design, protocol development, and supervision of study execution at participating local health facilities.</p> <p><a href="https://www.jhsph.edu/">https://www.jhsph.edu/</a></p>	Voluntary
Philippines Department of Health	<p>The governments of Ghana and the Philippines, through their health agency officers, were closely involved in defining the scope of the pilot programs. National and local government officials, the in-country working groups, the Scientific Oversight Committees (SOCs) and other interested stakeholders comprised a Steering Committee which met periodically to help ensure continued strategic support for the programs. The studies were implemented by in-country investigators whose work was overseen by the SOCs.</p> <p><a href="http://www.doh.gov.ph/">http://www.doh.gov.ph/</a></p>	Public

### 13 Funding and implementing partners by country

PARTNER	COUNTRY
Bill and Melinda Gates Foundation	[No response provided].
Ghana Ministry of Health	[No response provided].
Johns Hopkins Bloomberg School of Public Health	[No response provided].
Philippines Department of Health	[No response provided].

### 14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT
Government	National and local government officials were involved in local development and planning of the programs and together with the in-country working group (ICWG), the Scientific Oversight Committees (SOCs) and other interested stakeholders met periodically to ensure continued support for the programs. The studies were implemented by in-country investigators whose work was overseen by the SOCs.
Commercial Sector	Local company representatives were involved in program support as part of an in-country working group (ICWG), which met regularly and supervised administrative and other support to ensure efficient day-to-day implementation of the studies by the investigators. Companies also had to work with commercial distributors in each country to ensure the discounted medicines were available to patients in the pilots.
Local Hospitals/ Health Facilities	Local academic health experts were involved in design of the treatment protocols and the pilots were executed at local hospitals. Hospital representatives met periodically as part of the Steering Committee.

# Local Context, Equity & Sustainability

---

## 15 Local health needs addressed by program

The AAI through its two pilot programs partners with country governments with the explicit goal of validating intra-country differential pricing as a sustainable access tool when combined with health care strengthening efforts such as patient and provider education, supply chain management and health care capacity building to address other access barriers. The programs were designed in conjunction with health authorities in each country to focus on priority NCD needs of hypertensive and diabetic patients. The governance for both programs in country included companies, governments, local health authorities and other interested stakeholders.

## 16 Social inequity addressed

The program examines the role of differential pricing and health system strengthening to help improve access to medicines for underserved populations, particularly low-income groups, in LMICs. Social inequities exist in Ghana and the Philippines, e.g., B.I.I.Saeed/M. Louis/E.N.Aidoo/N.N.N.N.Nuamah/A.E.Yawson/X.Zhao, Socio-economic Inequalities and Healthcare Utilization in Ghana, International Journal of Business and Social Research (IJBSR), Volume -3, No.-1, January 2013; e.g., WHO, The Philippines health system review. (Health Systems in Transition, Vol. 1 No. 2 2011)

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

With the advice of counsel and other knowledgeable advisors in Ghana and the Philippines, applicable local laws, regulations and practices were followed in developing and implementing the studies.

## 18 How program meets or exceeds local standards

[No response provided].

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

Yes.

## 20 Health technologies are part of local standard treatment guidelines

Yes.

## 21 Health technologies are covered by local health insurance schemes

No. Patients' local physicians determined the need for the medicine consistent with clinical guidelines.

## 22 Program provides medicines listed on the National Essential Medicines List

No. EML inclusion varied by medicine. Patients' local physicians determined the need for the medicine consistent with clinical guidelines.

## 23 Sustainability plan

The results of the pilots are being analyzed by Johns Hopkins and the implications for the effectiveness of differential pricing in conjunction with health system strengthening relative to other interventions and future programs will be assessed by each company once the analysis is complete. In the interim, companies independently decided whether to continue providing differentially priced medicines for the benefit of patients following conclusion of the studies.

# Additional Program Information

---

## 24 Additional program information

Johns Hopkins is analyzing the data generated by these pilot studies. Publications will follow.

## 25 Access Accelerated Initiative participant

Yes.

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

Yes.

# Program Indicators

PROGRAM NAME

# Access and Affordability Initiative (AAI)

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

INDICATOR	TYPE	STRATEGY
1 Number of patients on appropriate treatment per study protocol	Output	Health Service Delivery

INDICATOR **Number of patients on appropriate treatment per study protocol**

STRATEGY HEALTH SERVICE DELIVERY

ITEM	DESCRIPTION
Definition	Number of patients who have received treatment through the program.
Method of measurement	Research Assistants at study site health facilities operating under the direction of the study investigators (see additional detail below).
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Research Assistants at study site health facilities operating under the direction of the study investigators	Consistent with the study protocol, a research assistant at the participating health facility recruited, obtained consent, screened patients and enrolled them into the study. Registries of patients participating in the study were maintained at the local level. Data collection on enrolled patient visits, follow-ups, medicines, test results and other elements were collected by the local health facilities in an electronic record at the time of the visit.	Ongoing
31 Data processing	Research Assistants at study health facilities, investigators and Johns Hopkins University personnel	Study data was collected and managed using electronic data capture tools. In Ghana, REDCap (Research Electronic Data Capture) was used while in the Philippines, Magpi was the data collection platform. Research assistants collected information locally and entered patient enrollment forms and data into the system.	Johns Hopkins is analyzing the study data at completion. At the sites data was processed periodically according to study SOPs.
32 Data validation		Companies were not responsible for this directly. The study Principal Investigators and program support staff visited the pilot facilities regularly to monitor implementation of the interventions and data capture as well as provide needed support to the facility level health information officers who captured data. Monthly monitoring and supervisory reports were produced and submitted to the Program consultant. Key components were entered into the electronic databases. Routine monitoring systems were established to ensure the quality of the data. Day-to day oversight was provided by a focal person in charge of project activities and/or a clinical coordinator in the participating health care facility.	

33 **Challenges in data collection and steps to address challenges**

Collecting robust data required establishing a clear study protocol, detailed operating processing, a strong M&E framework, and training. It requires expertise, training, time, and effort.

# 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)?

### 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 program meets or exceeds local standards

Is there anything else that you would like to report on how your program meets or exceeds local standards?

### 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?

**25** Access Accelerated Initiative participant

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

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

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

# Program Indicators

## INDICATOR DESCRIPTION

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

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

**28** Data source

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

**29** Frequency of reporting

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

**30** Data collection

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

**31** Data processing

- Responsible party: Please indicate all parties that conduct any processing of this data.
- Data processing— Description: Please briefly describe all processing procedures the data go through. Be explicit in describing the procedures, who enacts them, and the frequency of processing.
- Data processing — Frequency: What is the frequency with which this data is processed?

**32** Data validation

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

**33** Challenges in data collection and steps to address challenges

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