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Glivec International Patient Assistance Program (GIPAP)

Novartis

Submitted as part of Access Accelerated

Access Observatory

Contents

Program Description

Program Overview

① Program Name

Glivec International Patient Assistance Program (GIPAP)

② Diseases program aims to address

- Cancer: Leukemia; Gastrintestinal Stromal Tumour

③ Beneficiary population

- Children (under 5 years)
- Youth (5-18 years)
- Women
- Men
- Elderly (>65 years)
- People with low income, and no reimbursement

④ Countries

- Argentina
- Armenia
- Azerbaijan
- Bahamas
- Bangladesh
- Belarus
- Benin
- Bhutan
- Burkina Faso
- Cambodia
- Cameroon
- Central African Republic
- Chile
- China
- Congo
- Cte d'Ivoire
- Democratic Republic of the Congo
- Dominican Republic
- Ecuador
- El Salvador
- Ethiopia
- Fiji
- Gabon
- Georgia
- Ghana
- Haiti

④ Countries cont.

- Honduras
- India
- Indonesia
- Jamaica
- Kazakhstan
- Kenya
- Kyrgyzstan
- Madagascar
- Malawi
- Malaysia
- Mali
- Mauritania
- Mauritius
- Mexico
- Moldova
- Mongolia
- Morocco
- Mozambique
- Nepal
- Nicaragua
- Niger
- Pakistan
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Rwanda
- Senegal
- Seychelles
- Sierra Leone
- Solomon Islands
- South Sudan
- Sudan
- Suriname
- Tajikistan
- Thailand
- Timor-Leste
- Togo
- Uganda
- Vietnam

Program Overview

4 Countries cont.

- Zambia
- Zimbabwe

5 Program start date

August 7, 2001

6 Anticipated program completion date

June   2020

7 Contact person

David Tremblay: david.tremblay@novartis.com

8 Program summary

A direct-to-patient model, GIPAP opened in 2002 in response to lower-income countries facing access and reimbursement challenges for cancer treatments, and a lack of patient support and oncology infrastructures. GIPAP initially provided Glivec® (imatinib) at no cost to patients diagnosed with chronic myeloid leukemia (CML) with no access to reimbursement or funding mechanisms, and to those unable to pay for the medication in these countries.In GIPAP, Novartis managed the supply chain and direct interaction with local stake-holders (e.g., physicians, treatment centers, NGOs, private companies and governments) while The Max Foundation provided patients psychosocial support and education.Since 2002, it has operated in over 75 countries via a network of 1400 physicians and 450 treatment centers, and has served approximately 75,000 people.

https://www.themaxfoundation.org/

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Health Service Strengthening

ACTIVITY	DESCRIPTION
Management	Disease Management-drug supply administration.

Strategy 2: Health Service Delivery

ACTIVITY	DESCRIPTION
Diagnosis	Assures qualified physician.
Treatment	Provide treatment medication.
Retention	Tracks and monitors patient progress-Unique patient identifiers-implemented by partners.

Strategy 3: Supply Chain

ACTIVITY	DESCRIPTION
Planning	Countries and/or physician communicate with Novartis to share drug supply amount required. Physicians pre-approve all treatments.
Training	New physicians have to be trained on their role in supply chain management.

Strategy 4: Medicine Donation

ACTIVITY	DESCRIPTION
Donation	This is a direct-to-patient program, providing treatment to more than 35,000 patients in >70 countries.
Delivery	As this is a direct-to-patient program, it is important that quality assurance processes are in place.
Communication	There has been ongoing communication to the physician network and others in the supply chain, as well as internal colleague. (e.g., Novartis Regulatory, Drug Supply, Pharmaco Vigilance).

Program Strategies & Activities

10 Strategy by country

STRATEGY	COUNTRY
Health Service Strengthening	[No response provided]
Health Service Delivery	[No response provided]
Supply Chain	[No response provided]
Medicine Donation	El Salvador, Fiji, Gabon, Georgia, Ghana, Haiti, Honduras, Jamaica, Kazakhstan, Kyrgyzstan, Madagascar, Malaysia, Mali, Mauritania, Mauritius, Mexico, Moldova, Mongolia, Morocco, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Paraguay, Philippines, Rwanda, Seychelles, Sierra Leone, Solomon Islands, Sri Lanka, Sudan, Suriname, Tajikistan, Thailand, Timor-Leste, Togo, Uzbekistan, Zambia, Zimbabwe.

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Novartis	Novartis' primary role on the GIPAP program is as the overall owner of the program working in close collaboration with partners. Specific responsibilities include: (1) supplying the appropriate amounts of needed Glivec® medicine to partners/physicians for distribution; (2) Approving new request to add hospitals/clinics and new physicians into the program; and (3) For other rare indications, Novartis Global Medical Affairs reviewed and approved/denied use based on clinical situation and on label indications.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Axios International	Axios International, with input from The Max Foundation and subject to Novartis' final approval, is responsible for identifying and qualifying leading medical centers, charity organizations, and/or physicians, as the case may be (together the "GIPAP Qualified Institution") in a GIPAP country. Axios is also responsible (in countries without Local Novartis Country Pharma organization) for coordinating the necessary drug logistics and distribution requirements to ensure timely delivery and consistent availability of the drug supplies. Axios International was formed in 1997 from the work of its founders operating as Axios, a group of health experts who shared the vision of an organization that could work effectively with patients, and private and public sector stakeholders to improve access to healthcare in developing countries and emerging markets. Today, Axios designs and implements market access solutions across Africa, Asia, Latin America, Middle East and Europe. https://axiosint.com/	Private

Companies, Partners & Stakeholders

12 Funding and implementing partners cont.

Max Foundation	As partners in the administration of GIPAP TMF: • Accepts and reviews applications for GIPAP • Has the sole and final responsibility for processing and assessing patients' eligibility for GIPAP • Follows up on patients' applications and re-evaluations for GIPAP • Provides emotional support, information, and referral assistance to patients • Provides information concerning adverse events to Novartis for reporting to Health Authorities as required https://www.themaxfoundation.org/	Voluntary
China Charity Federation	China Charity Federation sets up the Glivec Project Management Office which will be responsible for the application and review of patients of the Project, organizing registered physicians to launch medical examination and review on patients, organizing and participating in the distribution of donated medicines via regional charity institutes, and supervising the project delivery throughout the process. http://www.chinacharityfederation.org:8081/WebSite/English/index	Public
Axios International	Axios International, with input from The Max Foundation and subject to Novartis' final approval, is responsible for identifying and qualifying leading medical centers, charity organizations, and/or physicians, as the case may be (together the "GIPAP Qualified Institution") in a GIPAP country. Axios is also responsible (in countries without Local Novartis Country Pharma organization) for coordinating the necessary drug logistics and distribution requirements to ensure timely delivery and consistent availability of the drug supplies. Axios International was formed in 1997 from the work of its founders operating as Axios, a group of health experts who shared the vision of an organization that could work effectively with patients, and private and public sector stakeholders to improve access to healthcare in developing countries and emerging markets. Today, Axios designs and implements market access solutions across Africa, Asia, Latin America, Middle East and Europe. https://axiosint.com/	Private

Companies, Partners & Stakeholders

13 Funding and implementing partners by country

PARTNER	COUNTRY
China Charity Federation	China

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT
Government	Government officials are informed of the donation program, along with the physicians and institutions involved.
Non-governmental organization (NGO)	A NGO helps to implement the program - The Max Foundation and the China Charity Federation.
Local hospitals/health facilities	Closed distribution for certain institutions that have capabilities to support CML care.

Local Context, Equity & Sustainability

15   Local health needs addressed by program

Novartis partners with a global health organization -- The Max Foundation – and interacts with private companies and local physicians, government officials and to facilitate access to Glivec via GIPAP. Each has roles and processes to follow. Before 2001, chronic myeloid leukemia (CML) was a life-threatening condition with a median survival of often fewer than 5 years.[1,2] The Novartis medicine Glivec® (imatinib*) demonstrated such outstanding clinical benefit that it changed the standard of care for people living with CML. The significance of the data prompted executive leadership at Novartis to establish GIPAP in 2002 to provide free Glivec to patients in lower-income countries who could not have access to the drug without it. The program eventually expanded to include people diagnosed with other conditions for which Glivec and second-line Tasigna are approved to treat.

In 2017 a new patient-centered access model, CMLPath to Care™, will replace GIPAP. Under the new initiative, The Max Foundation will assume from Novartis the responsibility for delivering treatment to these patients, including supply chain management. Novartis will provide funding and drug donation support[1,2].

https://www.themaxfoundation.org/what/treatment/glivec/

    a   How needs were assessed
       [No response provided]

    b   Formal needs assessment conducted
       [No response provided]

16   Social inequity addressed

GIPAP was designed to address the lack of access to Glivec in lower-income countries based on whether patients were insured or reimbursed and have no other financial recourse to obtain the therapies. Through its partnership with The Max Foundation, it also address psychosocial support and education for patients.

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

Local customs and regulations were followed for managing the drug supply and applying the treatment indication. Novartis developed medical eligibility criteria for GIPAP in line with WHO guidelines on drug donations and enrolled patients had to have a confirmed diagnosis of an approved indication for Glivec (imatinib) and eventually second-line Tasigna (nilotinib). In addition, GIPAP was only rolled out in countries where regulatory approval or at least an import license for Glivec for CML/GIST had been obtained. GIPAP also ensured that the patients' physicians and clinics participating in the program have the necessary qualifications and approvals based on local laws.

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

Through implementation of GIPAP (i.e., review of institutions and physicians' experience), lower-income countries have received much needed physician training and patients have gained access to life-saving cancer treatments and psychosocial support and education.

Local Context, Equity & Sustainability

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

No.

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

N/A.

21 Health technologies are covered by local health insurance schemes

N/A.

22 Program provides medicines listed on the National Essential Medicines List

N/A.

23 Sustainability plan

Over time, changes in local infrastructures and capabilities, new and innovative treatments, and the growth and impact of patient groups prompted Novartis and The Max Foundation to recognize that a new, more flexible approach to access was needed. In 2017 a new patient-centered access model, CMLPath to Care™, will begin replacing GIPAP. Under the new initiative, The Max Foundation will assume from Novartis the responsibility for delivering treatment to these patients, including supply chain management. Novartis will provide funding and drug donation support.

Additional Program Information

24 Additional program information

In GIPAP, the organizations, partners and local physicians and institutions must agree to their respective roles and responsibilities by signing a Memorandum of Understanding (MOU). This document includes each groups' role; patient consent and financial review; medical personnel, diagnostic and laboratory services; tax and customs processing; reporting of serious adverse events; drug accountability, record-keeping, communications and audits.

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.   The Italian Cooperative Study Group on Chronic Myeloid Leukemia Interferon alfa-2a as compared with conventional chemothera-py for the treatment of chronic myeloid leukemia. N Engl J Med 330:820–825,1994

2.   R Hehlmann, H Heimpel, J Hasford, etal: Randomized comparison of interferon-alpha with busulfan and hydroxyurea in chronic myelogenous leukemia: The German CML Study Group Blood 84:4064–4077,1994

Program Indicators

Glivec International Patient Assistance Program (GIPAP)

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

INDICATOR	TYPE	STRATEGY	2017	2018
1 Value of resources	Input	All Program Strategies	$1.2 billion	---
2 Patients on active treatment	Output	Health Service Delivery	59,415 people	---

INDICATOR **Value of resources**

STRATEGY   ALL PROGRAM STRATEGIES

	ITEM	DESCRIPTION
	Definition	Total expenditure by company to operate program, including all expenditures that can reasonably be defined as necessary to operate the program.
	Method of measurement	Program administrative records or accounting or tax records provide details in the expenditures on the program in a defined period of time. CALCULATION Sum of expenditures (e.g., staff, materials) on program in US$
28	Data source	Routine program data
29	Frequency of reporting	Once per year

		RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30	Data collection	Company	Novartis pays the implementing partner invoice and records it appropriately within finance.	Every three months
31	Data processing	Company	The information is within the companies accounting systems and is tallied to provide an overall account-ing of monies provided to manage and implement the program.	Once per year
32	Data validation		No.	

33   Challenges in data collection and steps to address challenges

No challenges.

INDICATOR	2017	2018
1 Value of resources	$1.2 billion	---

Comments: The value of the program is 1.2 billion USD in over 75 countries.

ITEM	DESCRIPTION
Definition	Aggregate number of active patients on treatment in the program
Method of measurement	Pooled patient collection from implementing partners
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Implementing Partners: Max Foundation and China Charity Federation	Physicians/delegates provide data on a quarterly basis to implementing partner who in turn shares aggregate data to Novartis.	Every three months
31 Data processing	Implementing Partners: China Charity Federation and Max Foundation	The data from each of the implementing partners are summed together to provide a single aggregate number of active number of patients on treatment.	Every three months
32 Data validation		1. Implementing partner provide quality data verification 2. Company uses volume of drug orders and daily dose to verify/confirm number of patients on treatment	

33 Challenges in data collection and steps to address challenges

No challenges.

INDICATOR	2017	2018
2 Patients on active treatment	59,415 people	---

Comments: There are 59,415 patients in this program.

Program Documents

Program Documents

1. Umeh C, Garcia-Gonzalez P, Tremblay D, et al. The survival of patients enrolled in a global direct-patient cencer medicine donation program: The Glivec International Patient Assistance Program (GIPAP). E Clinical Medicine (2020).
Available at: https://www.thelancet.com/action/showPdf?pii=S2589-5370%2820%2930001-8

2. General County Assessment Survey. Glivec® International Patient Assistance Program. Available at: https://bit.ly/Glivec

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.