Glivec International Patient Assistance Program (GIPAP)

Novartis

Submitted as part of Access Accelerated
Contents

Program Description 3
Program Overview 4
Program Strategies & Activities 6
Companies, Partners & Stakeholders 8
Local Context, Equity & Sustainability 11
Additional Program Information 12

Resources 13

Program Indicators 14
List of indicator data 15
Value of resources 16
Patients on active treatment 17

Appendix 18

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: Novartis, Glivec International Patient Assistance Program (GIPAP) (2018), Access Observatory Boston, US 2018 (online) available from www.accessobservatory.org
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 5yrs)
• Youth (5-18yrs)
• Women
• Men
• Elderly (>65 yrs)
• People with low income
• Low income with 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

4 Countries Continued
• Ghana
• Haiti
• 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
Countries Continued

- Uganda
- Vietnam
- Zambia
- Zimbabwe

Program start date
August 7, 2001

Anticipated program completion date
Completion date not specified

Contact person
David Tremblay (david.tremblay@novartis.com)

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 stakeholders (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

## Strategies and activities

### Strategy 1: Health Service Strengthening

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management</td>
<td>Disease Management-drug supply administration.</td>
</tr>
</tbody>
</table>

### Strategy 2: Health Service Delivery

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>Assures qualified physician.</td>
</tr>
<tr>
<td>Treatment</td>
<td>Provide treatment medication.</td>
</tr>
<tr>
<td>Retention</td>
<td>Tracks and monitors patient progress-Unique patient identifiers-implemented by partners.</td>
</tr>
</tbody>
</table>

### Strategy 3: Supply Chain

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

### Strategy 4: Medicine Donation

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation</td>
<td>This is a direct-to-patient program, providing treatment to more than 35,000 patients in &gt;70 countries.</td>
</tr>
<tr>
<td>Delivery</td>
<td>As this is a direct-to-patient program, it is important that quality assurance processes are in place.</td>
</tr>
<tr>
<td>Communication</td>
<td>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).</td>
</tr>
</tbody>
</table>
## Strategy by country

<table>
<thead>
<tr>
<th>STRATEGY</th>
<th>COUNTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Service Strengthening</td>
<td>[No response provided].</td>
</tr>
<tr>
<td>Health Service Delivery</td>
<td>[No response provided].</td>
</tr>
<tr>
<td>Supply Chain</td>
<td>[No response provided].</td>
</tr>
<tr>
<td>Medicine Donation</td>
<td>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</td>
</tr>
</tbody>
</table>
## Companies, Partners & Stakeholders

### 11 Company roles

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>ROLE</th>
</tr>
</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>PARTNER</th>
<th>ROLE/URL</th>
</tr>
</thead>
</table>
| 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                  |
| **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** |
### Funding and implementing partners by country

<table>
<thead>
<tr>
<th>PARTNER</th>
<th>COUNTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>China Charity Federation</td>
<td>China</td>
</tr>
</tbody>
</table>

### Stakeholders

<table>
<thead>
<tr>
<th>STAKEHOLDER</th>
<th>DESCRIPTION OF ENGAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>Government officials are informed of the donation program, along with the physicians and institutions involved.</td>
</tr>
<tr>
<td>NGO</td>
<td>A NGO helps to implement the program - The Max Foundation and the China Charity Federation.</td>
</tr>
<tr>
<td>Local Hospitals/Health Facilities</td>
<td>Closed distribution for certain institutions that have capabilities to support CML care.</td>
</tr>
</tbody>
</table>
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.\textsuperscript{1,2} The Novartis medicine Glivec\textsuperscript{*} (imatinib\textsuperscript{*}) 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\textsuperscript{™}, 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.

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

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.

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.

How program meets or exceeds local standards

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.

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

Yes.

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

Yes.

Health technologies are covered by local health insurance schemes

No.

Program provides medicines listed on the National Essential Medicines List

Yes.

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\textsuperscript{™}, 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

Additional program information

In GIPAP, the organizations, partners and local physicians and institutions must agree to their respective roles and responsibilities by signing a Memo- randum 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.

Access Accelerated Initiative participant
Yes.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership
Yes.
Resources


Program Indicators
**Program Name**

Glivec International Patient Assistance Program (GIPAP)

List of indicator data to be reported into Access Observatory database

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Type</th>
<th>Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value of resources</td>
<td>Inputs</td>
<td>All Program Strategies</td>
</tr>
<tr>
<td>Patients on active treatment</td>
<td>Outputs</td>
<td>Health Service Delivery</td>
</tr>
</tbody>
</table>
**Value of resources**

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

<table>
<thead>
<tr>
<th>RESPONSIBLE PARTY</th>
<th>DESCRIPTION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data collection</strong></td>
<td>Company</td>
<td>Novartis pays the implementing partner invoice and records it appropriately within finance.</td>
</tr>
<tr>
<td><strong>Data processing</strong></td>
<td>Company</td>
<td>The information is within the companies accounting systems and is tallied to provide an overall accounting of monies provided to manage and implement the program.</td>
</tr>
<tr>
<td><strong>Data validation</strong></td>
<td>None.</td>
<td></td>
</tr>
</tbody>
</table>

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

No challenges.
### Definition
Aggregate number of active patients on treatment in the program.

### Method of measurement
Pooled patient collection from implementing partners.

### Data source
Routine program data

### Frequency of reporting
Once per year.

<table>
<thead>
<tr>
<th>RESPONSIBLE PARTY</th>
<th>DESCRIPTION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data collection</td>
<td>Max Foundation and China Charity Federation</td>
<td>Physicians/delegates provide data on a quarterly basis to implementing partner who in turn shares aggregate data to Novartis.</td>
</tr>
<tr>
<td>Data processing</td>
<td>China Charity Federation and Max Foundation</td>
<td>The data from each of the implementing partners are summed together to provide a single aggregate number of active number of patients on treatment.</td>
</tr>
</tbody>
</table>
| 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 | | |

#### Challenges in data collection and steps to address challenges
No challenges.
Appendix

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).

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

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)?

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. SocialInequities and MentalHealth: 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)
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.