**INTER-AMERICAN COMMISSION ON HUMAN RIGHTS**
**RESOLUTION 33/2022**

Precautionary Measures No. 533-21

# Patricio Fabián Vaca Castro and three other persons diagnosed with Chronic myeloid leukemia regarding Ecuador

July 11, 2022
Original: Spanish

## I. INTRODUCTION

1. On June 13, 2021, the Inter-American Commission on Human Rights ("the Inter-American Commission", "the Commission" or "the IACHR") received a request for precautionary measures filed by Patricio Fabián Vaca Castro ("the applicant"), urging the Commission to request that the State of Ecuador ("the State" or "Ecuador") adopt the necessary measures to protect the rights to life, personal integrity, and health of Patricio Fabián Vaca Castro and other persons who are treated at the Carlos Andrade Marín Hospital and who have been diagnosed Chronic myeloid leukemia (blood cancer). The request alleged that the proposed beneficiaries are at serious risk because, on various occasions since 2020, they have lacked access to the medication which is necessary for their medical treatment.

2. Under the terms of Article 25(2) of its Rules of Procedure, the IACHR requested additional information from the applicant on July 13, 2021, and received information on July 14, 2021. The IACHR once again requested additional information from the applicant on January 24, 2022, and received information on January 25, 2022. Subsequently, the IACHR requested information from the State on March 11, 2022, and received it on March 22, 2022. The IACHR requested information from both parties on May 25, 2022. The State submitted a communication on May 26, 2022, and the applicant sent further information on June 2, 2022. The IACHR requested information from the State on June 7, 2022, and it provided the information on June 21, 2022. The applicant provided information on June 23, 2022.

3. Upon analyzing the submissions of fact and law offered by the parties, the Commission considers that the information submitted shows *prima facie* that the identified beneficiaries are in a serious and urgent situation, given that their rights to life, personal integrity, and health are at risk of irreparable harm. Therefore, the Commission requests that Ecuador: a) adopt the necessary measures to protect the rights to life, personal integrity, and health of the beneficiaries by adopting immediate measures that allow access to adequate and timely medical treatment. In particular, guaranteeing consistent access to the necessary medications in accordance with the prescriptions from corresponding health professionals, as well as the diagnoses and examinations that allow regular evaluation of their health status, according to the applicable international standards; and b) consult and agree upon the measures with the beneficiaries and their representatives.

## II. SUMMARY OF FACTS AND ARGUMENTS PROVIDED BY THE PARTIES

### A. Information provided by the applicant

4. The proposed beneficiaries are patients diagnosed with Chronic myeloid leukemia (blood cancer) and are allegedly at risk due to the lack of necessary and timely access to medication for their treatment since 2020. According to the information provided by the applicant, the

proposed beneficiaries are the following: (1) Patricio Fabián Vaca Castro, resident of the city of Quito; (2) Hernán Andrés Zurita Espín, resident of the city of Quito; (3) Jorge Enrique Dobronski Arcos, resident of the city of Quito; (4) Darwin Giovanny Unuzungo Ordoñez, resident of the city of Piñas; (5) Luis Ernesto Rodríguez Cajamarca, resident of the city of Quito; (6) Rodolfo Germán Cahuana Jiménez, resident of the city of Quito; (7) Francisco Iván Campoverde Campoverde, resident of the city of Lago Agrio; (8) Roque Antonio Campoverde Campoverde, resident of the city of Joya de los Sachas; (9) Amparo del Rocio Escobar Galarza, resident of the city of Ibarra; (10) Narcisa de Jesús Guevara Medina, resident of the city of Riobamba; (11) José Francisco Toapanta,[1] resident of the city of Quito.[2]

5. According to the request, the identified persons have been receiving specialized medical attention in the Hematology Service of the Carlos Andrade Marín Hospital (*Hospital Carlos Andrade Marín, HCAM*) of the Ecuadorian Institute of Social Security (*Instituto Ecuatoriano de Seguridad Social, IESS*) for several years. The medical personnel who are treating the proposed beneficiaries prescribed a medication called *tasigna nilotinib*, which is in the National Basic Medicines Chart of Ecuador (*Cuadro Nacional de Medicamentos Básicos de Ecuador*). However, since July 2018, they have been unable to access sufficient quality health care services from HCAM authorities and public servants. In this sense, pharmacological treatments were suspended as the medicine *nilotinib* was not acquired nor administered to patients with blood cancer at the HCAM.

6. In December 2018, communications were sent to hospital authorities, but no response was received. Subsequently, on January 4, 2019, 15 patients with HCAM blood cancer, including the 11 proposed beneficiaries,[3] filed a claim for an Action for Protection[4] (*Acción de Protección*) to protect their constitutional rights. They requested access to pharmacological treatments with the provision of the medicine *nilotinib*, and fulfilment of the responsibilities that arise in administrative and judicial processes of the authorities and public servants who are responsible for the facts.

7. On January 17, 2019, the judge of the Family, Women, Children and Adolescents Unit (*Unidad de Familia, Mujer, Niñez y Adolescencia*) of the Metropolitan District of Quito issued a judgment accepting the request for Protection Measure raised by the proposed beneficiaries in its entirety, and declaring the violation of the right to health.[5] Furthermore, it was determined that the IESS

[1] Mr. José Francisco Toapante has passed away.

[2] The request initially indicated that the proposed beneficiaries were the 53 patients with Chronic myeloid leukemia from the Carlos Andrade Marín Specialty Hospital of the Ecuadorian Institute of Social Security. However, following a request for additional information from the IACHR, the applicant submitted updated information on July 14, 2021 and it specifically indicated the aforementioned 11 persons as proposed beneficiaries.

[3] The Action for Protection was presented by the following proposed beneficiaries: Patricio Fabián Vaca Castro, Hernan Andres Zurita Espin, Jose Francisco Toapanta, Jorge Enrique Dobronski Arcos, Darwin Giovanny Unuzungo Ordoñez, Luis Ernesto Rodriguez Cajamarca, Rodolfo German Cahuana Jimenez, Francisco Iván Campoverde Campoverde, Roque Antonio Campoverde Campoverde, Jacqueline Narcisa de Jesús Guevara Medina and Amparo del Rocio Escobar Galarza, jointly with the following persons: Jorge Vicente Aguilar Mejia, Verti Susan Narvaez Quelal, Andrea del Carmen Real Celleri, and Augusto Marco Suquillo Pila.

[4] Action for Protection Number 17203-2019-0084.

[5] The judgment of January 17, 2019 determined the following: "(...) 2.- The violation of the constitutional right to health, enshrined in Art.32 of the Constitution of the Republic of Ecuador is declared: 3.- The Ecuadorian Institute of Social Security, through its legal representative, inform the health centers that are part of the social security system that they may not, for purely administrative reasons, refrain from prescribing and supplying to persons diagnosed with CHRONIC MYELOID LEUKEMIA disease (blood cancer) the medication that is part of their medical treatment and prescribed by the attending physician of each of the patients suffering from the described illness, according to the medical assessment of each of the patients, guaranteeing the right to health in accordance with Art.363, subsection 7 of the Constitution of the Republic of Ecuador, thereby having to administer quality, safe, and effective drugs. The legal representative of the institution must report on compliance with the measure within a period of fifteen days; 4.- To order the institutions of the public health network, which must be stocked with the necessary and sufficient medication prescribed and supplied to patients diagnosed with CHRONIC MYELOID LEUKEMIA disease (blood cancer), which is recorded in each of

cannot refrain, for purely administrative reasons, from prescribing and supplying the medication that is part of the treatment for persons diagnosed with Chronic myeloid leukemia and which is prescribed by medical personnel. In view of the foregoing, it was ordered to have a permanent and sufficient supply of the necessary medication to treat patients with this cancer, thereby ensuring that pharmacy does not experience a shortage of this drug at any time. On September 11, 2019, the judge requested the IESS and the National Ombudsperson's Office to report on the compliance of the judgment. The request reported that IESS authorities did not comply with the judgment. They did not purchase sufficient doses of *nilotinib* for all patients and, in addition, the requirement to have a drug supply for a period longer than six months was not fulfilled. Therefore, in November 2019, the patients' treatment was again interrupted due to medication shortage.

8. Faced with this situation, on February 18, 2020, an Action for Breach (*Acción de Incumplimento*) to comply with the judgment of January 17, 2019, was filed.[6] On March 11, 2020, the judge forwarded the Action for Breach[7] to the Constitutional Court of Ecuador. The constitutional judge heard the case on June 17, 2020, and requested a report from the trial-court judge, the general director of the IESS, and the legal representative of the HCAM regarding compliance with the judgment. In addition, on June 9, 2020, the plenary of the Constitutional Court authorized the priority treatment of the matter as the petitioners reportedly suffer from a "catastrophic disease". On July 2, 2020, the IESS reported that the Technical Pharmacy Unit (*Unidad Técnica de Farmacia*) scheduled the purchase of 59,686 doses of the 200 mg drug *tasigna nilotinib*, as a requirement included in the 2019 Annual Purchase Plan (*Plan Anual de Compras, PAC*). It was indicated that those doses arrived to the HCAM warehouse on May 27, 2019, and July 27, 2019. Subsequently, the purchase of 30,305 additional doses was requested. These were partially delivered to the patients on June 10 and 11, 2020.

9. On July 13, 2020, the public hearing was held in relation to the Action for Breach of the judgment. On that occasion, the applicant reported that treatment with the drug was allegedly interrupted between January to June 2019 and, subsequently, in February 2020. They reported that one of the reasons that the public procurement auction process has not been successful was allegedly because IESS offered a price which was much lower than the actual cost of the medication. For its part, the HCAM indicated that it has complied with the complete judgment; ratified that all patients have received medical care in the external consultation of the hospital's hematology service; indicated that the public procurement process of 2020 was caused by the commercial struggle between two pharmaceutical companies due to the patent of the drug and that it ended with a single supplier. These circumstances were reportedly beyond the control of the IESS.

10. On August 12, 2020, the Constitutional Court issued Judgment No. 25-20-IS/20, in the framework of the Action for Breach of the judgment. It was declared herein that the HCAM and the IESS had partially complied with the judgment from January 17, 2019, and subsequently ordered that they take the necessary measures to comply with the judgment in full. The Constitutional Court of Ecuador verified the following: (i) the patients had received specialized and permanent care from the physicians of the HCAM Hematology Service, who prescribed the drug *nilotinib* in a timely manner; (ii) the HCAM did not provide the patients with the drug as the pharmacies did

the clinical histories of the patients' medical records, as prescribed by the attending physician, so that their respective pharmacies do not run out of stock of the required medication. To this purpose, let an official notice be sent to the Minister of Public Health and the Director of the Ecuadorian Institute of Social Security (...) ".

[6] The Breach of Failure of the Judgment was filed by the same persons who filed the Action for Protection Number 17203-2019-0084 (including the proposed beneficiaries).

[7] Case No. 25-20-IS.

not have a supply from January to June 2019, nor between the months of February to May 2020; (iii) the HCAM has been administering the drug to the patients since the end of May 2020 and the first days of June 2020; (iv) the failure to administer the drug in a timely manner causes serious health problems and anguish in the patients.[8] Accordingly, the relevant authorities should ensure the continuous and timely delivery of the drug *nilotinib* and prevent drug shortages by submitting the trial-court judge a report detailing the doses required for the treatment of each patient. In that sense, the judgment resolved the following:

> 1. Declare that the IESS and the HCAM have partially complied with the judgment from January 17, 2019, issued by the Family, Women, Children and Adolescents Unit based in the Mariscal Sucre parish of the Metropolitan District of Quito.
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> 2. Provide that the IESS and HCAM take the necessary and appropriate measures to fully comply with the judgment, guarantee the continuous and timely delivery of the drug nilotinib and prevent shortages, in accordance with the provisions of paragraph 27 of this judgment. In addition, that they present the trial-court judge with a report detailing the number of patients with leukemia who were in treatment up until October 31, 2020, along with the specification of the doses of nilotinib that they require for their treatment.
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> 3. Order that the judge who issued the judgment follow-up the fulfilment of the judgment. […][9]

11. The request states that IESS authorities did not comply with the ruling of the Constitutional Court of Ecuador either. Since August 2020, the proposed beneficiaries reportedly stopped receiving the drug *nilotinib* from the IESS general pharmacy. In that sense, on October 20, 2020, a court order was filed for the IESS to immediately purchase and provide the proposed beneficiaries with *nilotinib*. On April 5, 2021, the competent trial-court judge who issued the judgment ordered that the IESS should deliver the drug to patients diagnosed with Chronic myeloid leukemia within 48 hours.[10] This requirement was not complied with. It was indicated that the IESS reportedly suspended the outpatient care of the special care which is necessary to provide follow-up on the health problem.

12. On July 14, 2021,[11] it was reported that nine of the proposed beneficiaries experienced alleged failure of remission, which implies that the cancer returned more aggressively. As a result, all symptoms and aches of the disease returned. These cause a disabling condition with a high probability of death. Likewise, the proposed beneficiary Patricio Fabián Vaca Castro is reportedly experiencing chronic renal failure. The applicant expressed that Chronic myeloid leukemia could lead to death and irreparable organic consequences, such as damage to the bone marrow, problems in the immune system, or sporadic bleeding which could result in reduced blood platelet count.

[8] Ruling No. 25-20-IS/20 of the Plenary of the Constitutional Court of Ecuador on August 12, 2020
[9] Ruling No. 25-20-IS/20 of the Plenary of the Constitutional Court of Ecuador on August 12, 2020.
[10] On April 5, 2021, the judge determined that "it is provided that, within 48 hours, the authorities of the Carlos Andrade Marion Specialty Hospital (HCAM) and the Social Security Institute (IESS) carry out the immediate delivery of the drug TASIGNA NILOTINIB to patients with CML diagnostics ordered by the Constitutional Court of Ecuador and as resolved in the Action for Protection Case No.17203- 2019-00084, under legal precautions and without prejudice to this being the matter in which the corresponding responsibilities are determined, a report be submitted of dates and doses delivered to the legitimates of this matter prior to reporting these to the Constitutional Court, for the purposes of the Law."
[11] According to the applicant, the following persons are reportedly in a state of failure of remission of the disease: (1) Patricio Fabián Vaca Castro, (2) Hernán Andrés Zurita Espín, (3) Jorge Enrique Dobronski Arcos, (4) Luis Ernesto Rodríguez Cajamarca, (5) Rodolfo German Cahuana Jiménez, (6) Francisco Iván Campoverde Campoverde, (7) Roque Antonio Campoverde Campoverde, (8) Amparo del Rocio Escobar Galarza, and (9) Narcisa de Jesús Guevara Medina.

13. On January 25, 2022, the applicant provided medical examinations [12] carried out on six proposed[13] beneficiaries. These indicate failure of remission of the disease through the increase of the disease detection index:

a. Patricio Fabián Vaca Castro: it was indicated that he experienced failure of remission of the cancer, as the detection index of the disease has been increasing after lacking the drug *nilotinib*. On December 3, 2020, the disease detection index was 0.03%. On August 12, 2021, that level rose to 2.2%, which reportedly indicates the progression of the cancer. In addition, his medical records since 2008 was included the Chronic myeloid leukemia diagnosis[14]. In it, the drug *nilotinib* was prescribed. On July 14, 2021, at a medical appointment, the proposed beneficiary was still indicated treatment with the drug *nilotinib*.

b. Roque Campoverde Campoverde: presented the disease detection index of 12% in December 2021, according to a medical examination.

c. Francisco Campoverde Campoverde: presented the index of 27% in November 2021, according to a medical examination.

d. Amparo Escobar Galarza: presented an index of 66% in October 2021, according to a medical examination.

e. Darwin Unuzungo Ordoñez: presented the index of 0.00064% in November 2021, according to a medical examination.

f. Luis Rodriguez Cajamarca: presented an index of 0.017% in November 2021, according to a medical examination.

14. On January 17, 2022, a criminal complaint was filed with the Attorney General's Office of Ecuador. The complained reported non-compliance with legitimate decisions of competent authority as the public servants of the IESS disobeyed the judicial orders issued by the Constitutional Court. On June 2, 2022, the applicant indicated that after 18 months, the reparation measure determined by constitutional judgment of August 12, 2020, had not been executed or complied with. Likewise, the HCAM did not have supplies or reagents "to carry out hematological analysis and evaluation of BCR ABL translocation". Patients must therefore bear high costs to be able to obtain results from external clinical laboratories. Due to the *nilotinib* medication shortage, the proposed beneficiaries resorted back to the use of neoplastic drugs (*cytarabine*), that is, chemotherapy, and a *tyrosine kinase* inhibitor (*imatinib*). This treatment is allegedly ineffective in their organisms as they had undergone this treatment 10 years ago and had already presented resistance previously.

15. According to Patricio Fabián Vaca Castro's medical certificate from May 2022, treatment with the tyrosine inhibitor *imatinib* was initiated in 2008. However, since July 2017, due to loss of molecular response, it was switched to another *tyrosine* inhibitor, *nilotinib*. However, as of December 2020, he has not been receiving this drug as there is reportedly no stock in the HCAM pharmacy. According to Amparo del Rocio Escobar Galarza's medical certificate from February 2022, she is being treated with *tyrosine kinase* inhibitor, due to the *nilotinib shortage,* since May 2021. In addition, it was reported that she experienced loss of hematological and molecular response. According to Francisco Iván Campoverde Campoverde's medical certificate from April 2022, he is being treated with the *tyrosine kinase* inhibitor, due to the *nilotinib* shortage.

16. In January 2022, they indicated that they reportedly received information from a public procurement process which aims to acquire oral solid *nilotinib* 200mg for the HCAM hospital

[12] From the provided information, molecular biology tests for the detection of BCR/ABL genes in the blood of the patients were identified. The BCR/ABL genes detection values allegedly indicate the presence of Chronic myeloid leukemia disease in the patients' blood.
[13] The applicant submitted medical examinations regarding the following proposed beneficiaries: (1) Patricio Fabián Vaca Castro; (2) Roque Antonio Campoverde Campoverde; (3) Francisco Iván Campoverde Campoverde; (4) Darwin Unuzungo Ordoñez; (5) Luis Rodriguez Cajamarca; and (6) Amparo Escobar Galarza, carried out in August, September, October, and November 2021.In addition, the application also had attached the examinations of three other persons who were not identified as proposed beneficiaries.
[14] The attached medical document contains records of the proposed beneficiaries' medical examinations and appointments over the years at the Ecuadorian Institute of Social Security, from August 2008 to July 2020.

pharmacy of the IESS. This process should have been completed in March 2022.[15] However, it is alleged that the deadline for signing the contract and executing the process had already been exceeded by over 20 days. Furthermore, regarding the alleged contract between HCAM and a state company dated May 20, 2022, for the provision and administration of a generic drug that reportedly refers to *nilotinib*, despite the five day deadline for delivery, on June 1, 2022, the delivery of nilotinib had not been complied with.

17. The proposed beneficiaries informed the competent trial-court judge which executed the judgment about the persistent shortage of drug *nilotinib*. They have also reported that, as they are being administered generic drugs, they require reports, studies, or substantiation of their equivalence with the original drug. In this regard, on May 20, 2022, the judge issued a decision[16] finding that the public servants of the IESS and the HCAM have not complied with the constant provisions in the judgments. The decision was reportedly "a severe wake-up call" to the General Director of the IESS and the General Manager of the HCAM for not complying with the judgment. It also informs the IESS Board of Directors of the corresponding sanctioning procedures. In addition, the court decision provided that HCAM and IESS should administer the drug *nilotinib* to the proposed beneficiaries within 15 days. The 126 other HCAM patients with blood cancer presented a new Action for Protection, sponsored by the National Ombudsperson's Office. On May 12, 2022, the judge issued a judgment which determined the violation of the rights to health, life, and a dignified life. It also ordered the IESS and the Ministry of Public Health to have the drug *nilotinib* available for the patients within a period of no more than 15 days from the judgment.

18. On June 23, 2022, the applicant referred to a contract signed on May 20, 2022, which appears on the Official Public Procurement System (*Sistema Oficial de Compras Públicas*) portal. It stipulated that the Ginsberg laboratory would deliver 33,650 units of the generic *nilotinib* drug within five days after signing the contract. However, as of June 22, 2022, this drug had not yet been provided to the patients diagnosed with blood cancer.

19. On June 1, 2022, the National Agency for Sanitary Regulation and Control (*Agencia Nacional de Regulación y Control Sanitario, ARCSA*) ordered the temporary suspension of the Certificates of Good Manufacturing Practices (*Certificados de Buenas Prácticas de Manufacturas*) in Ginsberg laboratory establishments, as a regulatory measure. This action was carried out as result of surveillance actions performed at the Ginsberg laboratory establishments, and after receiving

[15] Contract No. 111011101-CT-080-CGJ-202. Contractor *Empresa Pública de Producción y Desarrollo Estratégico de la Universidad Técnica Estatal de Quevedo*. Administrator: Head of the Hematology Technical Unit of the Carlos Andrade Marín Specialties Hospital.

[16] On May 20, 2022, the judge decided the following: "4.1. Admonish the Director General of the Ecuadorian Institute of Social Security and the General Director of the Carlos Andrade Marín Specialty Hospital for not having given compliance and adequate follow-up to the provisions of the Authority. For this purpose, please inform the Board of Directors of the Ecuadorian Institute of Social Security in order to, prior to the corresponding sanctioning procedure, determine the administrative responsibilities of these and of the direct or indirect officials who by action or omission cause the lack of prevention in the supply of the NILOTINIB drug ordered in Ruling No.25-20-IS/20 dated August 12, 2020 dictated by the Constitutional Court of Ecuador. From the content of the provisions herein, the term of sixty days is granted in order to submit a documented report detailing the sanctions and the officials sanctioned for their action or omission. 4.2. Admonish the Provincial Delegation of Pichincha of the National Ombudsperson's Office for its lack of diligence in following-up the case and sending the timely verification report of compliance with the Ruling dated January 17, 2019, at 14: 47 and Ruling No.25-20-IS/20 dated August 12, 2020, please inform the highest Authority of the National Ombudsperson's Office so that, prior to the corresponding sanctioning procedure, it determines the administrative responsibilities of these and of the official or officials who, by action or omission, did not submit the monitoring reports or request to materialize compliance with the Constitutional Judgment. 4.3. The actors involved (hematology service, pharmacy, warehouse of the Carlos Andrade Marín Specialty Hospital, Department of Public Procurement, and the Ecuadorian Social Security Institute) are ordered to prevent shortages in the future, and continuously and timely deliver the NILOTINIB medication in the manner established by the Authority. Under its responsibility, it must inform patients about the existing dose in the pharmacy every six months in order to avoid shortages. 4.4. The HCAM and the Ecuadorian Institute of Social Security, through their representation in the peremptory term of fifteen days, make available or deliver the drug NILOTINIB to patients and legitimate assets, unless by corresponding legal dispositions they dispose a longer time for their acquisition, which will be informed in a timely manner to coordinate any action that is necessary with the aim of finding critical obstacles."

health alerts and complaints from health establishments and citizens. It additionally ordered the immobilization of the products corresponding to 742 health records. The aforementioned will allegedly remain in force until compliance with the "good practice regulations for pharmaceutical laboratories" is verified. Given the above, to date, the generic drug *nilotinib* from the Ginsberg laboratory is allegedly no longer on the list of drugs which are authorized for marketing in Ecuador.

## B. Response from the State

20. The State indicated that a judgment was issued in an Action for Protection (*Acción de Protección*), in favor of the proposed beneficiaries,[17] on January 17, 2019, by the Judge of the Judicial Unit of the Family, Women, Children and Adolescents (*Unidad Judicial de Familia, Mujer, Niñez y Adolescencia*) of the Metropolitan District of Quito. The judgment resolved to accept the action brought against the then General Director and Legal Representative of IESS and the General Director of HCAM. In addition, it declared the violation of the right to health. The ruling ordered the IESS to provide patients diagnosed with Chronic myeloid leukemia disease (blood cancer) with the medication that is part of their medical treatment.

21. On February 17, 2020, the proposed beneficiaries filed an Action for Breach (*Acción de Incumplimiento*) which was resolved by the Constitutional Court of Ecuador by ruling of August 12, 2020. This ruling resolved to declare partial compliance with the judgment of January 17, 2019. It ordered the IESS and the HCAM to take the necessary and appropriate measures to ensure the continuous and timely delivery of the drug *nilotinib* and prevent its shortages. In view of the foregoing, the proceedings were referred back to the Judge of the Judicial Unit of the Family, Women, Children and Adolescents of the Metropolitan District of Quito, who is monitoring the fulfillment of the Constitutional Court's ruling.

22. The State reported that the Organic Law on Jurisdictional Guarantees and Constitutional Control (*Ley Orgánica de Garantías Jurisdiccionales y Control Constitucional, LOGJCC*) has mechanisms to enforce judgements on jurisdictional guarantees.[18] In this regard, if it is verified that the Constitutional Court's ruling is not being complied with, the judge has the obligation to initiate the procedure for the eventual dismissal of the responsible public servants.

23. According to the official letter from the General Legal Coordinator of the HCAM, dated March 17, 2022, there were two contractual procedures for the acquisition of the drug, oral solid *nilotinib* 200mg. The first was initiated on February 4, 2020, within which no offer was received and was subsequently declared void by Resolution of February 27, 2020. The second was initiated on December 10, 2021 through a special regime between public entities. No offer was received, and it was therefore declared void by Resolution of January 19, 2022. HCAM indicated that a new procurement process for the *nilotinib* drug product is allegedly underway. In this regard, the schedule for this process has a reported estimated award date for March 25, 2022.

24. The State indicated that the proposed beneficiaries received the following last doses of the medication *nilotinib* in the HCAM between December 2020 and August 2021. In that sense, Rodolfo

[17] Protective Action No.17203-2019-00084.

[18] "Organic Law on Jurisdictional Guarantees and Constitutional Control (*Ley Orgánica de Garantías Jurisdiccionales y Control Constitucional, LOGJCC).* Art. 22.- Procedural breaches.- In case of violation of the constitutional guarantees procedure or non-compliance with the judgment or reparation agreement, the judge must penalize the person or institution that fails to comply, in accordance with the following guidelines: 1.In the event that the breach causes damage, the same judge will substantiate damages, by means of a summary procedure, for this fact and against the responsible person, either private or public, and the amount will be charged through court order.(...) 4. In the event that public servants fail to comply with a judgment or reparation agreement, the judge will order the initiation of the procedure for their eventual dismissal. In case of dismissal of the omitted server, the replacement must comply with the failure under the same precautions (...)".

Germán Cahuana Jiménez has not received *nilotinib* since August 2021; Roque Antonio Campoverde Campoverde has not received *nilotinib* since December 2020; Francisco Iván Campoverde Campoverde has not received *nilotinib* since December 2020; Jorge Enrique Dobronski Arcos has not received *nilotinib* since February 2021; Amparo del Rocio Escobar Galarza has not received *nilotinib* since February 2021; Narcisa de Jesús Guevara Medina has not received *nilotinib* since December 2020; Luis Ernesto Rodríguez Cajamarca has not received *nilotinib* since February 2021; José Francisco Toapanta has not received *nilotinib* since September 2020; Darwin Giovanny Unuzungo Ordóñez has not received *nilotinib* since September 2020; Patricio Fabián Vaca Castro has not received *nilotinib* since January 2021; and Hernán Andrés Zurita Espín has not received *nilotinib* since February 2021.

25. The State forwarded the proposed beneficiaries' medical records.[19] The available information is presented below:

a. Patricio Fabián Vaca Castro: On December 4, 2008, the Chronic myeloid leukemia diagnosis was confirmed. Treatment with the drug imatinib was *initiated*. In 2010, the patient was suffering from the accelerated phase of the cancer. On October 3, 2012, physicians identified that the disease was in complete molecular remission. However, in July 2017, the loss of molecular remission of the disease was verified. In April 2018, the treatment was changed and treatment with the drug *nilotinib* was initiated. On April 9, 2020, it was observed that there was no more stock of the drug *nilotinib* in the HCAM pharmacy. On August 25, 2020, treatment with *nilotinib* was reinitiated. However, in his medical appointments on April 21, July 20, and October 1, 2021, it was indicated that there was still a *nilotinib* shortage at the HCAM pharmacy. In addition, according to the medical records, the detection percentage of the disease (BCR/ABL) in the blood was decreasing since treatment with *nilotinib* started in April 2018. However, since January 2021, he has been experiencing an increase in that percentage based on medical examinations. Thus, in January 2021 the detection percentage of the disease was 0.39% and in December 2021, it rose to 2.2%.

b. Roque Antonio Campoverde Campoverde: On October 25, 2010, the Chronic myeloid leukemia diagnosis was confirmed. Treatment with the drug *imatinib* was initiated. On February 25, 2019, the treatment was changed and treatment *nilotinib* was initiated. However, on February 6, 2020, the drug *nilotinib* was reported to be out of stock. On May 15, 2020, treatment with the drug *nilotinib* was restarted. On February 24, 2022, the physicians affirmed that the patient did not take *nilotinib* for over six months as there was a shortage of this drug in the HCAM pharmacy. A high risk of complications of his disease was therefore verified. According to his medical records, in December 2020 the detection percentage of the disease (BCR/ABL) of 4.59% in the blood was identified, and in December 2021 this index increased to 12%.

c. Amparo del Rocio Escobar Galarza: On August 15, 2016, the Chronic myeloid leukemia diagnosis was confirmed. Treatment with the drug *imatinib* was initiated. On February 23, 2017, the treatment for the drug *nilotinib* was modified. On June 7, 2019, it was indicated that since March 2019, the patient was not administered *nilotinib* as there was a shortage of this drug at the HCAM pharmacy. In June 2019, treatment with this medicine was restarted. In January 2021, it was again indicated that from March to May 2020, the patient was not administered this medication. In October 2021, it was also indicated that the patient was not administered this medication since May 2021. In October 2019, it was stated that the patient was experiencing failure of remission of the disease and loss of molecular response. In November 2021, chemotherapy was initiated. This treatment was also recommended in January and February 2022. In December 2021, the physicians indicated that the patient was experiencing a "decay". On February 3, 2022, physicians continued to recommend treatment with the drug *nilotinib*, which was still in shortage. The clinical history of the proposed beneficiary indicates an increase in detection percentage of the disease (BCR/ABL) since 2020. In August 2020, the percentage was 13%; in October 2021, it was 66%; and in December 2021, this index was 73%.

d. Francisco Iván Campoverde Campoverde: diagnosed with Chronic myeloid leukemia on December 9, 2013. Treatment with the drug *nilotinib* was initiated on December 9, 2014. On June 11, 2019, it was indicated that the

[19] The medical records of the following proposed beneficiaries were submitted: (1) Patricio Fabián Vaca Castro; (2) Hernán Andrés Zurita Espín; (3) Jorge Enrique Dobronski Arcos; (4) Darwin Giovanny Unuzungo Ordoñez; (5) Luis Ernesto Rodríguez Cajamarca; (6) Rodolfo Germán Cahuana Jiménez; (7) Francisco Iván Campoverde Campoverde; (8) Roque Antonio Campoverde Campoverde; (9) Amparo del Rocio Escobar Galarza; and (10) José Francisco Toapanta. The proposed beneficiary José Francisco Toapante died on July 21, 2021.No information was provided regarding the proposed beneficiary Narcisa de Jesús Guevara Medina.

patient presented drug resistance to *imatinib* and *nilotinib*. On January 4, 2022, the drug *nilotinib* was still recommended for treatment, but it was indicated that the patient was not yet being administered the drug.[20]

e. Hernán Andrés Zurita Espín: diagnosed with Chronic myeloid leukemia on August 31, 2015. Treatment with the drug *nilotinib* was initiated on January 26, 2016. On April 4, 2019, this drug was in shortage. Since May 12, 2021, it was again observed that the patient is not taking the drug as there is a confirmed shortage.[21]

f. Jorge Enrique Dobronski Arcos: diagnosed with Chronic myeloid leukemia on September 28, 2007. Treatment with the drug nilotinib was initiated on September 28, 2012. As of March 26, 2020, the prescribed drug was out of stock. However, on December 1, 2020, the patient was able to start taking the medication. On May 12, 2021, it was again indicated that the patient was not taking the drug *nilotinib* due to another shortage.[22]

g. Darwin Giovanny Unuzungo Ordoñez: diagnosed with Chronic myeloid leukemia on May 19, 2016. Treatment with the drug *nilotinib* was initiated on October 26, 2016. On November 16, 2018, it was indicated that the prescribed drug was out of stock. This shortage occurred again on February 21, 2020. Subsequently, on June 15, 2021, it was noted that the patient had not taken the medication since May 2021 due to shortages.[23]

h. Luis Ernesto Rodríguez Cajamarca: diagnosed with Chronic myeloid leukemia on May 14, 2010. Treatment with the drug *nilotinib* was started in January 2015. On June 16, 2021, it was indicated that the patient had not taken the prescribed medication for four months as the HCAM pharmacy still had no stock in February 2022.[24]

i. Rodolfo Germán Cahuana Jiménez: diagnosed with Chronic myeloid leukemia on April 27, 2016. Treatment with the drug *nilotinib* was initiated in February 2017. On April 4, 2021, the prescribed drug was out of stock. On January 4, 2022, it was observed that the patient was still waiting to receive the medication for treatment.[25]

j. José Francisco Toapanta: diagnosed with Chronic myeloid leukemia on March 11, 2013. Treatment with the drug *nilotinib* was initiated in August 2014. Since October 2019, his treatment was irregular due to the scarcity of the prescribed drug. Subsequently, in March 2020, it was indicated that there was a *nilotinib* shortage. In July 2020, the patient was hospitalized in the HCAM for over month due to a "blast crisis" when he began treatment with chemotherapy. In March 2021, the patient was also diagnosed with Acute myeloid leukemia. On July 21, 2021, Mr. José Francisco Toapanta died.[26]

26. On June 21, 2022, the State reported that the HCAM, in conjunction with the Public Strategic Development Company of the State Technical University of Quevedo (*Empresa Pública de Desarrollo Estratégico de la Universidad Técnica Estatal de Quevedo*) signed a contract dated May 20, 2022[27] for the acquisition of 84,130 units of the 200 mg oral solid *nilotinib* drug for the HCAM Hospital Pharmacy Unit. It was noted that, at the time of signing the contract, the Ginsberg Laboratory Health Registry was operational. However, prior to signing the contract, ARCSA was requested to extend the validity of the Good Medical Practice certificate. Notwithstanding, it was informed via written communication that the request for extension of validity of the certificate is reportedly inadequate for Ginsberg Ecuador S.A laboratory. Therefore, in order to renew the aforementioned certificate, it is allegedly necessary to carry out a new inspection of the laboratory. Subsequently, by Resolution of the ARCSA of May 20, 2022, it was decided to temporarily suspend the Good Manufacturing

[20] According to his medical records, the percentages of BCR/ABL genes in the proposed beneficiary's blood was allegedly the following: 49% (August 2018); 69% (August 2019); 39% (January 2020); 27% (November 2021).
[21] According to his medical records, the percentages of BCR/ABL genes in the proposed beneficiaries' blood was allegedly the following: 0.00079% (June 2018); 0.00066% (December 2018); 0.00026% (March 2019); and 0.00054% (September 2019).
[22] According to his medical records, the percentages of BCR/ABL genes in the proposed beneficiaries' blood was allegedly the following: 0, 16% (May 2018); 0.00025% (September 2018); 0.023% (May 2019); 0.003% (June 2020); 0.0025% (February 2021).
[23] According to his medical records, the percentages of BCR/ABL genes in the proposed beneficiaries' blood was allegedly the following: 0.003% (July 2018), 0.00062% (October 2018), 0.00089% (March 2019); 0.00086% (June 2019); 0.001% (September 2019); 0.0016% (February 2020); 0.00053% (March 2021); 0.00071% (August 2021); 0.00064% (November 2021).
[24] According to his medical records, the percentages of BCR/ABL genes in the proposed beneficiaries' blood was allegedly the following: 0.02% (March 2018); 0.016% (December 2018); 0.0027% (October 2019); 0.026% (August 2020); 0.0042% (February 2021); 0.018% (August 2021); 0.017% (November 2021).
[25] According to his medical records, the percentages of BCR/ABL genes in the proposed beneficiaries' blood was allegedly the following: 0.0041% (April 2018); 0.0013% (April 2019).
[26] According to his medical records, the percentages of BCR/ABL genes in the proposed beneficiaries' blood was allegedly the following: 0.11% (March 2018); 0.025% (October 2018); 0.022% (February 2019); 1.8% (May 2019); 0.00094% (September 2019); 0.016% (December 2019); 0.015% (May 2020); 0.00074% (July 2020); 0.0062% (October 2020); 0.081% (March 2021).
[27] Agreement No. 111011101-CT-080-CGJ-2022.

Practices certificate which was granted until the "Regulations of Good Practices for Pharmaceutical Laboratories" are complied with. Therefore, it was required to cease activity of the products whose sanitary registrations have been suspended.[28]

27. Faced with the provisional suspension of the sanitary registration of medicines of the Ginsberg laboratory, among which is the drug *nilotinib*, the HCAM issued a memorandum. In it, HCAM[29] stated the need to acquire an unplanned, small supply of the drug with report that justifies the need dated June 13, 2022. Lastly, by written document of June 16, 2022,[30] the ARCSA informed that the immobilization of the drugs mentioned in the Resolution of May 20, 2022 applies only to products manufactured after the resolutions were issued. Therefore, "the 742 health records of the drugs that are in stock in the health centers, which have been manufactured and received prior to the issuance of the resolutions, will not be subject to immobilization". The State indicated that the foregoing will expedite the delivery and distribution of medicines to the proposed beneficiaries.

28. Lastly, regarding the proposed beneficiaries' health care, the State reported that the HCAM patients have had medical appointments from April to May 2022. In addition, they reportedly have scheduled new medical appointments for June, July, and August 2022, to evaluate their health status.

## ANALYSIS OF THE ELEMENTS OF SERIOUSNESS, URGENCY, AND IRREPARABLE HARM

29. The mechanism of precautionary measures is part of the Commission's function of overseeing compliance with the human rights obligations established in Article 106 of the Charter of the Organization of American States, as well as in Article 18(b) of the Statute of the IACHR. The mechanism of precautionary measures is described in Article 25 of the Commission's Rules of Procedure. In accordance with that Article, the IACHR grants precautionary measures in serious and urgent situations in which these measures are necessary to avoid irreparable harm.

30. The Inter-American Commission and the Inter-American Court of Human Rights ("the Inter-American Court" or "I/A Court H.R.") have repeatedly established that precautionary and provisional measures have a dual nature, both protective and precautionary.[31] Regarding the protective nature, these measures seek to avoid irreparable harm and protect the exercise of human rights.[32] To do this, the IACHR shall assess the problem raised, the effectiveness of state actions to address the situation described, and how vulnerable the persons proposed as beneficiaries would be left in case the measures are not adopted.[33] Regarding the precautionary nature, the precautionary measures have

[28] Resolution ARCSA-CGTC-00702022-MEZM of May 20, 2022: "Article 1. TEMPORARILY SUSPEND, on a preventive basis, the certificate of Good Manufacturing Practices, granted by the company Establishment GINSBERG ECUADOR S.A. (...) until the Good Practice Regulations for Pharmaceutical Laboratories are complied with, the Sanitary Records of the products detailed below (...) GINSBERG. [...] Article 3. ORDER that the establishment GINSBERG ECUADOR S.A. (...) IMMOBILIZE, on a preventive basis in the market, the products whose sanitary records have been suspended and that are mentioned in the previous article. "

[29] Memorandum No. IESS-HCAM-JUTFH-2022-4510-M of June 14, 2022.

[30] File No. ARCSA-CGTC-2022-0136-0 of June 16, 2022.

[31] See in this regard: I/A Court H.R. Matter of the Yare I and Yare II Capital Region Penitentiary Center. Request for Provisional Measures submitted by the IACHR regarding the Bolivarian Republic of Venezuela. Order of the Inter-American Court of Human Rights of March 30, 2006, considerandum 5; I/A Court H.R. Case of Carpio Nicolle et al. v. Guatemala. Provisional Measures. Order of July 6, 2009, considerandum 16. 5 [only in Spanish].

[32] See in this regard: I/A Court H.R. Matter of Capital El Rodeo I and El Rodeo II Judicial Confinement Center. Provisional Measures regarding Venezuela. Order of the Court of February 8, 2008, considerandum 8; I/A Court H.R.Case of Bámaca Velásquez. Provisional Measures regarding Guatemala. Order of the Court of January 27, 2009, considerandum 45 [only in Spanish]; I/A Court H.R. Matter of Fernández Ortega et al. Provisional measures regarding Mexico. Order of the Court of April 30, 2009, considerandum 5; I/A Court H.R. Matter of Milagro Sala. Request for Provisional Measures regarding Argentina. Order of the Inter-American Court of Human Rights of November 23, 2017, considerandum 5 [only in Spanish].

[33] See in this regard: I/A Court H.R. Matter of Milagro Sala. Request for Provisional Measures regarding Argentina. Order of the Inter-American Court of Human Rights of November 23, 2017, considerandum 5 [only in Spanish]. I/A Court H.R.Matter of Capital El Rodeo I and El Rodeo II Judicial Confinement Center. Provisional Measures regarding Venezuela. Order of the Court of February 8, 2008, considerandum 8; I/A Court H.R. Matter

the purpose of preserving a legal situation while it is being considered by the IACHR. Their precautionary nature aims at protecting the rights at risk until the request pending before the inter-American system is resolved. Their object and purpose are to ensure the integrity and effectiveness of an eventual decision on the merits and, thus, avoid any further infringement of the rights at issue, a situation that may adversely affect the useful effect of the final decision. In this regard, precautionary or provisional measures enable the State concerned to comply with the final decision and, if necessary, to implement the ordered reparations.[34] In the process of reaching a decision, according to Article 25(2) of the Rules of Procedure, the Commission considers that:

a. "serious situation" refers to a grave impact that an action or omission can have on a protected right or on the eventual effect of a pending decision in a case or petition before the organs of the inter-American system;

b. "urgent situation" refers to risk or threat that is imminent and can materialize, thus requiring immediate preventive or protective action; and

c. "irreparable harm" refers to injury to rights which, due to their nature, would not be susceptible to reparation, restoration or adequate compensation.

31. In analyzing those requirements, the Commission reiterates that the facts supporting a request for precautionary measures need not be proven beyond doubt; rather, the purpose of the assessment of the information provided should be to determine *prima facie* if a serious and urgent situation exists.[35] In the same way, by its own mandate, the Commission is not called upon to determine any criminal liabilities of specific individuals in light of the facts alleged. Moreover, in this proceeding, it is not appropriate to rule on violations of rights enshrined in the American Convention or other applicable instruments.[36] This is better suited to be addressed by the Petition and Case system The analysis performed herein relates exclusively to the requirements established in Article 25 of its Rules of Procedure, which can be resolved without making any determinations on the merits.[37]

32. As a *preliminary point,* the Commission observes that the applicant referred to the situation of persons who: (i) have a medical diagnosis of Chronic myeloid leukemia (blood cancer) made by a public authority (see *supra para.*4); (ii) they are being treated at the Carlos Andrade Marín Hospital (*Hospital Carlos Andrade Marín, HCAM*) of the Ecuadorian Institute of Social Security (*Ecuatoriano de*

of the Criminal Institute of Plácido de Sá Carvalho. Provisional Measures regarding Brazil. Order of the Inter-American Court of Human Rights of February 13, 2017, considerandum 6 [only in Spanish].

[34] See in this regard: I/A Court H.R. Matter of Capital El Rodeo I and El Rodeo II Judicial Confinement Center. Provisional Measures regarding Venezuela. Order of the Court of February 8, 2008, considerandum 7; I/A Court H.R. Matter of "El Nacional" and "Así es la Noticia" newspapers. Provisional Measures regarding Venezuela. Order of the Court of November 25, 2008, considerandum 23 [only in Spanish]; I/A Court H.R.Matter of Luis Uzcátegui. Provisional Measures regarding Venezuela. Order of the Court of January 27, 2009, considerandum 19.

[35] See in this regard: I/A Court H.R. Matter of Members of the Miskitu Indigenous Peoples of the North Caribbean Coast regarding Nicaragua. Extension of Provisional Measures. Order of the Inter-American Court of Human Rights of August 23, 2018, considerandum 13 [only in Spanish]; I/A Court H.R.Matter of the children and adolescents deprived of their liberty in the "Complexo do Tatuapé" of the Fundação CASA. Request for extension of provisional measures. Provisional Measures regarding Brazil. Order of the Inter-American Court of Human Rights of July 4, 2006, considerandum 23.

[36] IACHR. Resolution 2/2015. Precautionary Measures No. 455-13. Matter of Nestora Salgado regarding Mexico. January 28, 2015, para. 14; IACHR. Resolution 37/2021. Precautionary Measures No. 96-21. Gustavo Adolfo Mendoza Beteta and family regarding Nicaragua. April 30, 2021, para. 33 [only in Spanish].

[37] In this regard, the Court has indicated that it **"cannot, in a provisional measure, consider the merits of any arguments pertaining to issues other than those which relate strictly to the extreme gravity and urgency and the necessity to avoid irreparable damage to persons."**." See in this regard: I/A Court H.R. Matter of James et at. regarding Trinidad and Tobago. Provisional Measures. Order of the Inter-American Court of Human Rights of August 29, 1998, considerandum 6; I/A Court H.R.Case of Barrios Family v. Venezuela. Provisional Measures. Order of the Inter-American Court of Human Rights of April 22, 2021, considerandum 2 [only in Spanish].

*Seguridad Social, IESS*) (see *para.*5); (iii) a public entity has issued them a medical prescription for the drug *tasigna nilotinib* or *nilotinib* (see *supra para.*5); (iv) its prescribed drug is part of the National Basic Medicines Chart of Ecuador (*Cuadro Nacional de Medicamentos Básicos de Ecuador*) (see *above para.*5); and (v) they had been receiving this medicine for several years from the public medical entity until deliveries ceased (see *para.*5). Although the universe of patients is reportedly greater than 126 persons, according to the information provided by the applicant, the Commission observes that the parties referred to a smaller number of persons in greater detail and with the respective documentary medical support. Considering the foregoing, and understanding the nature of the precautionary measures mechanism, the Commission identifies that, at this time, it has sufficient elements of assessment regarding the following persons: (1) Patricio Fabián Vaca Castro, (2) Roque Antonio Campoverde Campoverde; (3) Amparo del Rocio Escobar Galarza; and (4) Francisco Iván Campoverde Campoverde. Notwithstanding, the Commission reminds the State that it must guarantee the human rights recognized in the American Convention and other applicable instruments in favor of the rest of the persons not included in this resolution, to the extent that all its obligations continue in force. Similarly, the health situation of the population in Ecuador has been monitored by the Office of the Special Rapporteur on Economic, Social, Cultural and Environmental Rights (REDESCA). In this measure, the IACHR recalls that its REDESCA expressed its concern in 2022 regarding the shortage of medicines in hospitals in Ecuador and the impact of this situation on the population's right to health.[38]

33. With regard to the requirement of *seriousness*, the Commission considers that it has been met. When assessing this requirement, the Commission observes, on the basis of the information available and the medical documentation submitted by both the applicant and the State recently, that the four proposed beneficiaries are in the following situation:

i. The persons reportedly stopped receiving the medical treatment they were prescribed for the drug *nilotinib*. In this regard, the Commission notes that, after periods of interrupted delivery of the drug, the proposed beneficiaries reportedly did not receive the drug towards the end of 2020 and the beginning of 2021. According to information from the State from March 2022, the dates are reportedly the following: Patricio Fabián Vaca Castro, since January 2021, approximately 15 months having elapsed; Roque Antonio Campoverde Campoverde and Francisco Iván Campoverde Campoverde, since December 2020, approximately 16 months having elapsed; and Amparo del Rocio Escobar Galarza, since February 2021, approximately 14 months having elapsed (see *supra para.*14 and 20).

ii. The Commission notes that the Constitutional Court of Ecuador described the disease as a "catastrophic disease". According to specialized medical entities, Chronic myeloid leukemia is an uncommon type of bone marrow cancer, it reportedly causes an increase in the number of white blood cells in the blood.[39] The phase refers to the aggressiveness of the disease, with a higher proportion of diseased cells meaning that the Chronic myelogenous leukemia is at a more advanced stage.[40] The chronic phase is the earliest phase and is when treatment is most

[38] REDESCA, V Annual Report of the IACHR's DESCA Special Rapporteurship, OEA/SER.L/V/II Doc. 64 rev.1, May 26, 2022, para. 706
[39] MAYO CLINIC, Chronic myelogenous leukemia, Symptoms and causes. Chronic myelogenous leukemia can also be called chronic myeloid leukemia and chronic granulocytic leukemia.
[40] MAYO CLINIC, Chronic myelogenous leukemia, Diagnosis and Treatment.

efficient.[41] In this sense, the Commission understands that this is a key phase for medical treatment in order to better protect the proposed beneficiaries.

iii. Some patients reported failure of remission. According to the applicant, this allegedly implies that the disease is returning. This could potentially cause a disabling situation, with a high probability of death (see *para.*12). It could also cause irreparable organic consequences, such as damage to the bone marrow, problems in the immune system, or sporadic bleeding as a result of a reduced number of blood platelets (see *para.* 12). The State did not properly dispute the impacts on health caused by the drug shortage.

34. In this regard, the Commission observes that Mr. José Francisco Toapanta, diagnosed with Chronic myeloid leukemia, did not have regular access to the drug nilotinib since October 2019, and died on July 21, 2021 (see supra para. 22). For the Commission, this fact reflects the seriousness of the situation that the proposed beneficiaries are facing.

35. According to the medical information available to the parties (see above para. 13 and 20), the Commission understands that the proposed beneficiaries present a progressive increase in the presence of the disease in their organisms, or rather there is a high percentage after the detection evaluations. Thus, the Commission observes the following:

a. Patricio Fabián Vaca Castro: in January 2021 the detection percentage of the disease was 0.39% and in December 2021 it rose to 2.2%.

b. Roque Antonio Campoverde Campoverde: in December 2020 the detection percentage of the disease was 4.59%, and in December 2021 this index increased to 12%.

c. Amparo del Rocio Escobar Galarza: in August 2020, the disease detection percentage was 13; in October 2021, it was 66%; and in December 2021, this rate increased to 73%.

d. Francisco Iván Campoverde Campoverde: presented a disease detection index of 27% in November 2021.

36. The Committee observes that, since 2018, various actions have been presented to address the proposed beneficiaries' situation, of an administrative nature (see *para.*6), the Constitutional Court in various instances, including the Constitutional Court of Ecuador (see *para.* 6 *et seq.)* and criminal law (see para. 14). At the judicial level, the Commission highlights the following decisions that have ordered that the drug *nilotinib* be delivered to the proposed beneficiaries in a continuous and timely manner:

i. decision of January 17, 2019 by a Judge (see *above para.* 7 and 20);

ii. ruling of August 12, 2020 of the Constitutional Court of Ecuador (see *para.* 8, 10, and 21);

iii. decision of April 5, 2021 of the Judge in charge of enforcing the Constitutional Court's judgment (see *above para.* 11 and,

[41] MAYO CLINIC, Chronic myelogenous leukemia, Diagnosis and Treatment.

iv. decision of May 20, 2022 of the Judge in charge of enforcing the Constitutional Court's judgment (see *para.*17).

37. Despite these legal actions that order that the drug be delivered to the proposed beneficiaries, the IACHR observes and emphasizes that, to date, there is no dispute that the patients do not yet receive the drug *nilotinib*. The Committee notes that, despite these court decisions, the proposed beneficiaries still do not receive the medical treatment that health authorities prescribed them. The Commission also observes that all the deadlines granted in the judicial decisions in question have expired to date and, therefore, have reportedly exceeded the deadlines for compliance.

38. The Commission takes into consideration the response provided by the State and acknowledges the actions that were allegedly taken internally to ensure that the persons proposed as beneficiaries have access to adequate medical treatment by receiving the drug *nilotinib.* In particular, efforts to carry out contractual procedures for the procurement of the medicine are acknowledged (see *para* .23 and 24). However, despite the fact that the applicant expressed certain questions regarding the aforementioned procedures (see para. 8, 16, 18, and 19), the Commission understands that notwithstanding these, to date, it is not disputed that the drug *nilotinib* is not being delivered to the proposed beneficiaries. This situation has been ongoing despite at least four judicial decisions that order this delivery between 2019 and 2022, including the decision of a high constitutional court of August 2020.

39. The Committee observes that the State reported on the proposed beneficiaries' health care in 2022, including the medical appointments they had, as well as the upcoming appointments to be scheduled (see *para.* 25). Similarly, it notes that the applicant indicated that proposed beneficiaries had resumed taking neoplastic drugs (*cytarabine*), chemotherapy, and a tyrosine kinase inhibitor (*imatinib*) (see *supra para.*14 and 15). In this regard, the applicant submitted the corresponding medical support. The allegation that this treatment is not effective in their system because they had reportedly overcome it years ago and had previous resistance is of particular concern (see *para.*14). Indeed, the Commission observes that the medical support indicates that the proposed beneficiaries reportedly presented resistance to the drug *imatinib*, which is the reason the drug *nilotinib* was prescribed. Thus, the Commission understands that medical treatment with *nilotinib* continues to be medically prescribed, which is in line with the court orders issued over time, which instruct its delivery since 2019.

40. Therefore, the Commission considers, in an applicable *prima facie* analysis, that the rights to life, personal integrity, and health of the four proposed beneficiaries are at serious risk. When making this assessment, the Commission takes into account their current health conditions, the impact of the disease based on the medical documentary support presented by the parties, as well as the authorities' prolonged delays for the delivery of prescribed medicine, despite judicial decisions that order it.

41. With regard to the *urgency* requirement, the Commission considers that it has been met. The Commission observes that there is a serious deterioration in the health of four proposed beneficiaries after the lack of the necessary medication for their adequate treatment. This is evidenced through the return and progression of the disease, which could lead to disabling situations or even death. Likewise, the Commission notes that the proposed beneficiaries allegedly previously resorted internally to various authorities, including the Constitutional Court of Ecuador. Despite favorable judicial decisions since 2019, they still have been unable to access medical treatment for prolonged periods of time. In these circumstances, immediate action is

necessary to ensure the delivery of the medication which are necessary for the patients to receive proper medical treatment.

42. As for the requirement of *irreparability*, the Commission maintains that it is met, to the extent that the potential impact on the rights to life, personal integrity, and health constitutes, by its very nature, the maximum situation of irreparability.

## I. BENEFICIARIES

45. The Commission declares that the beneficiaries of this precautionary measure are (1) Patricio Fabián Vaca Castro, (2) Roque Antonio Campoverde Campoverde; (3) Amparo del Rocio Escobar Galarza; and (4) Francisco Iván Campoverde Campoverde, who are duly identified in this matter.

## II. DECISION

46. The Inter-American Commission considers that this matter meets *prima facie* the requirements of seriousness, urgency, and irreparable harm set forth in Article 25 of its Rules of Procedure. Accordingly, it requests that Ecuador:

a) adopt the necessary measures to protect the rights to life, personal integrity, and health of the beneficiaries by adopting immediate measures that allow access to adequate and timely medical treatment. In particular, guaranteeing consistent access to the necessary medications in accordance with the prescriptions from corresponding health professionals, as well as the diagnoses and examinations that allow regular evaluation of their health status, according to the applicable international standards; and

b) consult and agree upon the measures to be adopted with the beneficiaries and their representatives.

47. The Commission requests that the State of Ecuador report, within a period of 15 days from the day following notification of this resolution, on the adoption of the required precautionary measures and to update that information periodically.

48. The Commission emphasizes that, in accordance with Article 25(8) of its Rules of Procedure, the granting of this precautionary measure and its adoption by the State do not constitute a prejudgment on any violation of the rights protected under the applicable instruments.

49. The Commission instructs its Executive Secretariat to notify this resolution to the State of Ecuador and the applicants.

50. Approved on July 11, 2022, by Julissa Mantilla Falcón, President; Edgar Stuardo Ralón Orellana, First Vice-President; Esmeralda Arosemena de Troitiño; Joel Hernández García; Roberta Clarke; and Carlos Bernal Pulido, members of the IACHR.

Mario López-Garelli
By authorization of the Executive Secretary