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10 March 2015

Mr. Nicolae Bănicioiu
Minister of Health
Strada Cristian Popişteanu 1-3
Bucureşti 010024
Romania

Via Email: ministru@ms.ro
Via Fax: +40.21.312.4916

Re: Request for non-exclusive compulsory licences on patents to expand access to medicines for hepatitis C

Dear Minister Bănicioiu:

Knowledge Ecology International Europe Association (KEI Europe) is a not-for-profit Swiss association which includes in its mission efforts to improve access to medicines.[1] We write today to request that the Government of Romania take steps to permit the importation of generic versions of certain medicines used in the treatment of hepatitis C (HCV), to be supplied to the government.

Specifically, KEI Europe requests that the Government ask the Court of Bucharest (the "Court") to authorize compulsory licences on patents under Article 46(c) of Romanian Law No. 64/1991 of October 11, 1991 on Patents (as last amended by Law No. 28/2007). This section of the Romanian patent law provides for compulsory licences on patents for cases of public use for non-commercial purposes.

Introduction

Since 2013, several new drugs have entered the market which offer dramatic health benefits to persons currently infected with HCV. These include but are not limited to sofosbuvir (brand name Sovaldi®), a drug marketed by Gilead Sciences (Gilead), and several other drugs marketed or expected to be marketed by Gilead, Bristol-Myers Squibb (BMS), Johnson & Johnson, Merck and AbbVie.

[1] KEI Europe is affiliated with Knowledge Ecology International (KEI), a non-profit corporation created in 2006. KEI Europe is collaborating with KEI on this request. Information about KEI Europe and KEI is available on the web at: http://keieurope.org and http://keionline.org.

Within the European Union, the extremely high prices for these new medicines create barriers to access, rationing, and fiscal challenges for governments and others providing reimbursements. Unfortunately, the pricing in Romania for these products is influenced by the fact that Gilead, BMS and other companies weigh the consequences of discounts in Romania on the prices they can obtain in other countries in the European Union.

Some companies have signed voluntary licences with Gilead to manufacture sofosbuvir, ledipasvir, and GS-5816, and combinations of sofosbuvir and ledipasvir or GS-5816, as highly effective all-oral treatments for HCV. The Gilead voluntary licences include an option for access to manufacturing know-how, and permit the export of medicine to Romania, if compulsory licences are issued in Romania or if there is no patent in Romania.

Although BMS has announced it will expand access to its HCV drug daclatasvir in 90 countries, excluding Romania, details of the BMS initiative are scarce. Other HCV drug manufacturers have given few or no details regarding voluntary licensing or concessionary pricing options.

There are, at present, manufacturers of generic versions of sofosbuvir. And we anticipate generic versions of one or more additional HCV drugs will be available in the near future. The generic versions of these drugs are considerably less expensive, and by authorizing the importation and sale of the generic products in Romania the Government will help people living with HCV to receive treatment.

KEI Europe requests that the Government of Romania permit KEI Europe and/or other designated third parties to supply the government with inexpensive generic versions of HCV drugs, under open non-discriminatory and non-exclusive compulsory licences, subject to the payment of remuneration to patent holders, and other conditions to protect the legitimate interests of patent owners.

KEI Europe's interest is in expanding access to medicines for HCV, and is willing to play a constructive role in overcoming patent and other intellectual property barriers, finding reliable generic manufacturers of products of acceptable quality products, registering generic versions with drug regulators, and addressing supply chain management issues. KEI Europe also recommends that the Government address the patent issues in such a way that the Government can work with any other third party with the competence to address these issues. That is to say, our direct involvement in the supply of drugs may or may not be necessary, once compulsory licences are issued.

HCV in Romania

Estimates suggest that between 3.2 and 6 percent of the Romanian population are infected with HCV.[2] This is either the single highest or one of the two highest rates in the European Union, only exceeded by some estimates of HCV incidence in Italy.[3]

[2] One study estimated the prevalence in 2007 at 6.0 percent (Esteban, Juan I., Silvia Sauleda, and Josep Quer. "The changing epidemiology of hepatitis C virus infection in Europe." Journal of hepatology 48.1 (2008): 148-162.); The incidence rate in 2011 was estimated by one study to be 3.5 percent (Cornberg, Markus, et al. "A systematic review of hepatitis C virus epidemiology in Europe, Canada and Israel." Liver International 31.s2 (2011): 30-60.); another study estimated the prevalence in 2011 to be 4.5 percent (Lavanchy, D. "Evolving epidemiology of hepatitis C virus." Clinical Microbiology and Infection 17.2 (2011): 107-115.).

[3] For study estimating Italy's rate of HCV infection at 6.9 percent in 2013, see Hahné, Susan JM, et al. "Infection with hepatitis B and C virus in Europe: a systematic review of prevalence and cost-effectiveness of screening." BMC infectious diseases 13.1 (2013): 181.

The average age of patients with HCV in Romania is approximately 50 years old.[4] Most of these patients were infected due to unsafe sterilization and blood transfusion practices, prior to the implementation of improved medical practices in the mid-1990's, including disposable syringes and other materials, and blood testing.[5] Of patients over the age of 60, the rate of HCV prevalence is over 6 percent.[6]

There are six different genotypes of HCV, numbered 1 through 6. In Romania, over 99 percent of the HCV-infected population is genotype 1.[7]

In 2009, 88,124 HCV-infected patients in Romania had cirrhosis, and 1,708 had hepatocelluar carcinoma.[8] These figures are predicted to increase to 146,209 and 2,686, respectively, by 2030.[9]

In 2013, Romania's gross national income (GNI) per capita was $9,060[10]. The overall GNI per capita for the European Union during the same year was $35,551.[11]

Romania thus has one of the highest rates of HCV while having one of the lowest GNI per capita in the EU, a combination that exacerbates the problem of high prices for HCV medicines.

The Medicines and Patents Necessary to Treat HCV in Romania

For many years, the medicines prescribed to treat HCV were inadequate. Most require injection and had intolerably toxic side-effects for many patients. To make matters worse, these treatments, in addition to being longer, typically have lower rates of success.

The treatment of pegylated interferon (Peg-IFN) + ribavirin (RBV), for example, often requires a 48-week treatment with unbearable side-effects, and only yields a sustained virological response (SVR) of ~55 percent, with efficacy declining for patients with greater amounts of liver damage.[12] The extensive list of side-effects include influenza-like symptoms, neutropenia, anemia, thrombocytopenia, psychiatric events and worsening of existing, or occurrence of de novo, autoimmune disorders (*e.g.* type 1 diabetes, thyroid dysfunction, psoriasis, rheumatoid arthritis); one in four patients is unable to tolerate the treatment, and the fear of side-effects has become a barrier to treatment in and of itself.[13]

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[4] Mircea Grigorescu, "HCV Genotype 1 is Almost Exclusively Present in Romanian Patients with Chronic Hepatitis C"; Journal of Gastrointestinal Liver Diseases, March 2009 Vol. 18 No 1, 45-50.
[5] *See, e.g.*, Camelia Sultana, *et al.*, "Molecular Epidemiology of Hepatitis C Virus Strains from Romania," J Gastrointestin Liver Dis September 2011 Vol. 20 No 3, 261-266.
[6] Liana Gheorghe, *et al*., "The Prevalence and Risk Factors of Hepatitis C Virus Infection in Adult Population in Romania: a Nationwide Survey 2006-2008." Journal of Gastrointestinal Liver Diseases, December 2010 Dec; 19(4): 373-9.
[7] Grigorescu, 45-50.
[8] Gheorghe, 375.
[9] *Id.*, 373.
[10] Current USD; Atlas Method. Source: World Bank.
[11] *Id.*
[12] UNITAID, "2015 Hepatitis C Medicines Technology and Market Landscape," February 2015, 18-19. Available at http://unitaid.org/images/marketdynamics/publications/HCV_Meds_Landscape_Feb2015.pdf
[13] *Id.*

Recently, however, a new group of game-changing direct-acting antiviral (DAA) medications has emerged -- the medicines that are the focus of this request. These medicines include:

sofosbuvir (Brand name Sovaldi®)
sofosbuvir/ledipasvir fixed-dose combination (Brand name Harvoni®)
GS-5816 (investigational compound)
GS-5816/sofosbuvir fixed-dose combination (investigational compound)
daclatasvir (Brand name Daklinza®)
dasabuvir/ombitasvir/paritaprevir + ritonavir fixed-dose combination (Brand name Viekira Pak™)
simeprevir (Brand name Olysio®)

These drugs make treatment shorter and easier on patients, are oral, and have cure rates of approximately 90 percent or higher. All are effective against genotype 1, which is most prevalent in Romania, with some of the new drugs, including GS-5816, being pan-genotypic, which would obviate the need for complicated and expensive diagnostic testing.

The most important of these drugs are those developed by Gilead -- sofosbuvir, ledipasvir and GS-5816 (an investigational compound). Sofosbuvir has been called the "backbone" of HCV treatment, because while it cannot stand alone, it has high success rates when used in combination with other drugs. Together with RBV and/or Peg-IFN, sofosbuvir has a success rate in excess of 90 percent[14]. Sofosbuvir in combination with ledipasvir has success rates in excess of 90 percent, eliminates the need for the RBV/Peg-IFN injections for genotype 1, and has an 86 to 100 percent cure rate for patients whose HCV has progressed to the cirrhosis stage[15].

Other sofosbuvir combinations look to be very promising. The sofusbuvir/GS-5816 combination, still in pipeline, has had preliminary SVR of 100 percent in non-cirrhotic genotype 1 patients[16]. The BMS product daclatasvir can also be used in combination with sofosbuvir for multiple HCV genotypes.

Other drugs, including AbbVie's combination of dasabuvir/ombitasvir/paritaprevir + ritonavir, or Janssen's simeprevir may also be effective in treating HCV.

We believe the patents on these products are held by Gilead (sofosbuvir, sofosbuvir/ledipasvir, GS-5816, and GS-5816/sofosbuvir), Bristol Myers Squibb (daclatasvir), AbbVie (dasabuvir/ombitasvir/paritaprevir + ritonavir), and Janssen (simeprevir).

Several patents have been filed with the European Patent Office (EPO) and the Romania Patent Office relating to various HCV drug treatment regimes.[17] New patent applications may yet be filed and/or granted, and there is extensive ongoing patent litigation, some of which is detailed in the corporate disclosure reports and press releases by Gilead,

[14] UNITAID report, p.23.
[15] *Id.*, p.30.
[16] *Id.*, p.32.
[17] The WHO has released patent landscapes for sofosbuvir (available here: http://www.who.int/phi/implementation/ip_trade/sofosbuvir_report_2014_09-02.pdf) and ledipasvir (available here: http://www.who.int/phi/implementation/ip_trade/ledipasvir_report_2014-09-02.pdf).

Merck/Idenix, AbbVie, Janssen and other companies[18]. These cases, drawn out by lengthy appeals processes, may take years to conclude.

Because the patent landscape is in state of flux, and because the treatment landscape for HCV is rapidly evolving with new data continually emerging as to the benefits of certain medicines in combination and on their own, we believe that the best approach is to issue a compulsory licence broad enough to cover many HCV medicines, rather any one single medicine.

Legal Basis for Compulsory License

Romanian Law No. 64/1991[19] allows for the issuance of a non-exclusive, non-voluntary licence (the "Licence"). Specifically, Article 46 paragraph 4(c) provides for such a licence in cases of public use for non-commercial purposes, bypassing any required waiting period from the time of the patent application or the grant of the patent (as limited to Article 46 paragraph 1).

Romania's authority for the Licence is supported by (1) European Regulation 1257/2012[20], paragraph 10, which states that, "Compulsory licences for European patents with unitary effect should be governed by the laws of the participating Member States as regards their respective territories;" and (2) Article 31 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which permits use of a patent without authorization of the rights holder "where the law of the Member allows…" The TRIPS provision was further clarified by the Doha Declaration on TRIPS and Public Health, paragraph 5(b), which states that, "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

Proposed Action Regarding Compulsory License

The terms of the Licence described below are intended to provide a lawful path to authorize competitive supply of generic HCV drugs, consistent with the conditions of Articles 46 through 50 of Romania's Law No. 64/1991, and Article 31 of the TRIPS Agreement.

In accordance with the above, KEI Europe proposes the following:

1. **Non-exclusive compulsory licences to all current, pending and future patents covering uses of drugs for the treatment of HCV, including in combination treatments.**

   The Government of Romania should ask the Court to provide non-exclusive compulsory licences to all current, pending and future patents covering uses of drugs for the treatment of HCV, including in combination treatments. This action may be a matter of first impression for the Court. Specifically, the Court should permit any generic producer, on a non-exclusive basis, to use any patented

[18] Peter Loftus, Lucrative Drug Niche Sparks Legal Scramble. Battle Escalates for Dominance in Treatments for Hepatitis C, Wall Street Journal, July 20, 2014. See more generally: http://keionline.org/hcvtimeline.
[19] The relevant portions of this law are attached at the end of this letter.
[20] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0001:0008:en:PDF

inventions necessary to import, export, manufacture, offer for sale, sell, or use HCV medicines[21], either as standalone drugs or as part of a combination therapy, subject to the conditions set out below;

2. **Royalty:** Any generic producer that uses the patents described in (1) shall be required to pay royalties to patent owners. The generic manufacturers and the patent holders should be given an opportunity to negotiate a reasonable royalty. Failing to reach agreement within 90 days, the Court should order the generic producer to choose among the following options:

    a. an amount equal to 7 percent of the generic price; or

    b. an amount consistent with the World Health Organization (WHO) Tiered Royalty Method[22];

    The Court should further provide that the royalties be paid to patent holders on a quarterly basis, with royalty payments due no later than thirty (30) days after the end of each quarter;

3. **Division of Royalties Among Multiple Patent Owners:** When a product consists entirely of multiple patented inventions, the royalties will be allocated among patent owners according to one of the following methods:

    a. Upon agreement among the patent owners, or failing agreement among the patent owners, either,

    b. Mutually agreed upon arbitration of the dispute, with the costs of arbitration to be paid by the patent owners, or

    c. According to the recommendation of an expert appointed by the Court, with the costs of the expert paid by patent owners.

    d. When a product consists of a combination of patented and unpatented inventions, the total royalty will be adjusted down to account for the partial patent coverage.

    e. For option c, the allocations should be based upon the "utilization ratio," which considers the relative importance of each patented invention relative to the product.

4. **For Use in Romania:** The authorization should be “solely for supply of the domestic market in Romania.” KEI Europe has discussed with European Commission officials the issue of parallel trade within the European Union or more generally to markets outside of Romania. To address concerns about this issue, a

[21] Including but not limited to: sofosbuvir (Brand name Sovaldi®), sofosbuvir/ledipasvir fixed-dose combination (Brand name Harvoni®), GS-5816 (investigational compound), GS-5816/sofosbuvir fixed-dose combination (investigational compound), daclatasvir (Brand name Daklinza®), dasabuvir/ombitasvir/paritaprevir + ritonavir fixed-dose combination (Brand name Viekira Pak™), simeprevir (Brand name Olysio®).

[22] James Love, “Remuneration Guidelines for a Non-Voluntary Use of A Patent on Medical Technologies,” NDP and World Health Organization. Health Economics and Drugs, TCM Series No. 18, 2005. Available at http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf

non-voluntary licence could provide that, for additional clarity, that (a) The compulsory licenses are to use and sell products for the field of use of the treatment of HCV in the Territory of Romania, and (b) Nothing will be construed as granting any rights under any patents to use or sell the products for ultimate use outside of the field of use and/or outside of the Territory of Romania. KEI Europe can also provide under separate cover a memorandum reviewing options and best practices to address concerns over diversion.[23]

5. **Registration:** Upon the Court's approval, the Licence shall be communicated to Romania's State Office for Inventions and Trademarks (OSIM) for registration;

6. **Extent and Duration of licence:** The Licence shall be for the term of the patent, for any quantity that is used solely in Romania, and remain in effect unless HCV ceases to be a public health issue in Romania and a reduction in the term does not unduly prejudice the interests of the generic supplier;

7. **Other Limitations:** The Licence shall be non-transferable and non-assignable;

8. **Notification:** Upon issuance of the Licence, KEI Europe is willing to assist the Government of Romania in promptly notifying the patent owners of the authorization.

Registration of products, and Rights in Test Data

One of the challenges facing generic suppliers will be to register the product with the Romania National Agency for Medicines and Medical Devices. This will be easier if Romania can waive the exclusive rights in test data that establishes the safety and efficacy of products, and permit the generic suppliers to proceed with registration based upon bioequivalence to products already registered in Romania or with the European Medicines Agency. However, in the event that this is not possible, it may be necessary to conduct new clinical trials, replicating evidence already provided to government regulators. This is feasible, in part because of the robust end-points of clinical tests involving these drugs with patients living with HCV, but it will lead to delays, and the outlays on the clinical trials are wasteful, and will have to be replaced by each generic supplier, thereby limiting the benefits of competition and creating a conflict with the Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects. Here we note the World Health Assembly Global strategy on public health, innovation and intellectual property (WHA61.21), Element 6.2(g), which calls upon national and regional regulatory agencies to:

> "promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical

[23] For example, according to Paragraph 4 of the WTO's Decision of the General Council of 30 August 2003, on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, one important mechanism for importing medicines manufactured under exceptions to patent rights includes an obligation that "importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system." [WT/L/540 and Corr.1 1 September 2003]

principles for medical research involving human subjects, including good clinical practice guidelines"

An alternative to enforcing or waiving exclusive rights in test data is for the court to grant a compulsory license to rely upon test data, subject to payment of a royalty or a contribution toward the costs of the originator's clinical tests. KEI Europe recommends that the cost sharing contribution be based upon a pro-rata share of documented trial costs, adjusted for the risks of success by stage of the trial. The pro-rata share should be based upon the percent of revenue generated by the sales of the drugs in Romania, compared to the global revenues for the drugs.[24]

The European Commission has issued a series of Directives which create obligations on the Government of Romania to recognize certain time-limited rights in test data which may be relevant, including Directive 2001/83 on the Community code relating to medicinal products for human use. This directive does provide for possible exceptions regarding registration of products, if the testing on human subjections "would be contrary to generally accepted principles of medical ethics to collect such information," a circumstance that appears relevant in the case of duplicative clinical trials for HCV medicines. There may also be other legal options for waiving or modifying approaches to the rights in test, such as implementing non-voluntary authorizations to use certain test data, as a remedy to an anticompetitive price, which in this case, would include excessive prices. KEI Europe will provide under separate cover a memorandum exploring such options.

Conclusion

Given the high rate of HCV and the population's lack of access to name-brand HCV medications, the Government of Romania has a significant opportunity to demonstrate decisive leadership by issuing this Licence. Doing so would save Romanian lives while saving Romania money.

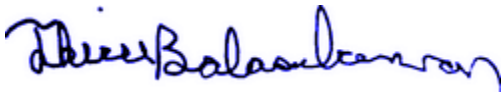
The Licence proposed is consistent with Romanian law and the TRIPS agreement.

For your convenience, we have attached a proposed order for the Licence that is in accord with the contents of this letter.

We appreciate your consideration of this request, and we request a meeting to discuss the matter further.

[24] This approach is similar to that required by the European Commission to avoid duplicative testing on vertebrate animals, in cases where duplication of tests creates conflicts regarding ethics.

Sincerely,



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Annex - KEI Europe's previous request for voluntary licenses from BMS and Gilead

Gilead and BMS have both denied previous attempts by KEI Europe to obtain voluntary licences for HCV drugs.

On 29 July, 2014, KEI Europe sent a letter to BMS requesting licence of daclatasvir, asunaprevir, BMS791325 and the daclatasvir/asunaprevir/BMS791325 combination patents for use in the territory of Romania. On the same day, KEI Europe requested that Gilead grant a licence for sofosbuvir, ledipasvir, the sofosbuvir/ledipasvir combination, and the sofosbuvir/GS-5816 combination patents for use in the territory of Romania.

BMS declined our request on 16 September 2014; Gilead declined on 26 August 2014. We are attaching copies of our requests and the BMS and Gilead refusals to license.

Annex - selected provisions of Romania law on patents

Law No. 64/1991 of October 11, 1991 on Patents (as last amended by Law No. 28/2007):

Art. 46 - Upon request by any interested person, the Court of Bucharest may grant a compulsory licence after 4 years have elapsed from the patent application filing date or after 3 years have elapsed from the grant of the patent, whichever period expires later.

The provisions of paragraph 1 shall only apply where the invention has not been exploited or has been insufficiently exploited on the territory of Romania, and the patent owner cannot justify his inaction and where no agreement has been reached with him regarding the conditions and commercial methods for applying the invention.

The Court of Bucharest shall authorize the compulsory licence, provided that it considers, based on given circumstances, that, in spite of all efforts made by the interested person, no agreement could be reached within a reasonable time period.

Besides the cases referred to in paragraph 2, a compulsory licence may be authorized by the Court of Bucharest:
a) in national emergency cases;
b) in other cases of extreme emergency;
c) in cases of public use for non-commercial purposes.

The grant of the compulsory licence, for one of the reasons provided under paragraph 4, shall not require the fulfilment of the conditions mentioned under paragraph 2. Nevertheless, the licencee shall inform the applicant or patent owner about the authorization given by the Court, within the shortest delay.

In cases of public use for non-commercial purposes, the Government or third parties authorized by the Government, if they know or have demonstrable reasons to know that a valid patent is or will be used by the Government or the third parties, shall inform the patent owner accordingly, within a reasonable time.

In cases where a patent cannot be exploited without infringing the rights conferred by other patent granted for an application having a prior regular national filing date, a compulsory licence for exploiting the second patent may only be authorized if the following additional conditions are cumulatively fulfilled:
a) the invention claimed in the second patent involves an important technical advance of considerable economic significance as compared with the invention in the first patent;
b) the owner of the first patent is entitled to a cross-licence on reasonable terms for using the invention claimed in the second patent;
c) the use authorized in respect of the first patent shall be non-transferable, except for the transfer of the second patent.

Art. 47 - Compulsory licences shall be non-exclusive and shall be granted by the Court of Bucharest, under specific conditions regarding their extent and duration, as well as the amount of royalties to which the right holder is entitled, established in accordance to the commercial value of the granted licences.

Beneficiaries of the compulsory licence can also be the Government or third parties authorized by the Government.

Compulsory licences shall be authorized mainly for supplying the market.

The extent and duration of compulsory licences shall be limited to the purposes for which they have been authorized. In case of the inventions in the semiconductor technology field, the licence shall be granted only for public non-commercial purposes or to remedy a practice declared as anti-competitive, as a result of a judiciary or administrative procedure.

When the owner of a plant variety patent cannot exploit the patent without infringing a prior patent, he may request a compulsory licence for the invention protected by said patent.

When the owner of a patent relating to a biotechnological invention cannot exploit the patent without infringing a prior plant variety patent, he may request a compulsory licence for the exploitation of the plant variety protected by said patent.

Where a compulsory licence is authorized for remedying an anti-competitive practice, the provisions of Art. 46, paragraphs 3 and 4 and Art. 47, paragraph 3 shall not be applicable.

Art. 48 - The compulsory licence shall not be transferred otherwise than with the part of the enterprise or the stock of goods benefitting by said use.

Art. 49 - Upon the justified request presented by the interested person, the Court of Bucharest may withdraw the compulsory licence, when the circumstances leading to the grant of the licence ceased to exist, provided that the legitimate interests of the licencee should be protected adequately. The licence shall not be withdrawn if the circumstances which determined the grant of the licence are likely to occur again.

The decisions of the Court of Bucharest concerning the authorization for using a compulsory licence, as well as those concerning the remuneration prescribed as against the use of the licence, may be appealed against with the Court of Appeal of Bucharest within 15 days from communication.

Art. 50 - The final and irrevocable Court decisions concerning the grant or the withdrawal of the compulsory licence, as the case may be, shall be communicated by the interested person to OSIM, which shall register said decisions in the National Register of Patent Applications or in the National Register of Patents, as the case may be, and publishes the mention of such decisions in the Official Industrial Property Bulletin within one month from communication.