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Life Sciences, Regulatory & Intellectual Property

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COVID – 19: Survey Latin America

1. **Market access**

(a) How has the regulator in charge been addressing the urgent needs for medicines, medical devices and medical supplies? Has the focus been faster review and grant of marketing authorization, or exceptions to or relaxation of import / use / licensing restrictions, or any other available mechanisms?

The Brazilian Federal Health Agency (ANVISA) has issued several regulations to provide exceptions on regulatory requirements for pharmaceutical products, medical supplies and medical devices related to COVID-19. Requirements for corporate permits for sanitizers and certain medical devices, as well as for the extraordinary acceptance of importation of products that are not registered in Brazil, have been relaxed under certain conditions.

For example, companies were allowed to manufacture alcohol 70% in the Brazilian market without previous registration before ANVISA and without Operating Authorization - AFE. ANVISA also allowed the manufacturing and import of determined medical devices (such as masks, protection, face shields, disposable hospital gowns, caps and thongs, valves, circuits and respiratory connections for use in healthcare services) by companies without AFE and other authorizations issued by the health authorities. The acquisition of these products without registration/regularization was also permitted.

Also, there is a commitment of faster analysis of products that are connected, but not directly related to COVID-19.

Finally, the federal government enacted a law allowing the waiver of public tender procedures for the acquisition of medicines, medical devices and medical supplies, and reducing the formalities

needed for such procurements.

(b) What opportunities and challenges the COVID-19 outbreak has brought for market access in terms of regulatory approval?

In addition to the exemption of registration in certain cases as well as the expedited analysis (for example, at least 17 medical devices for diagnostic of COVID-19 have been approved until this moment), the authorities are more open to discuss with companies the strategy for regularizing products. On the other hand, the incremental workload made ANVISA and Ministry of Health officers more focused on matters related to COVID-19, so other demands not related to the outbreak are somehow neglected.

(c) Other than impact felt for clinical trials (see Section 2 below) and IP risks (see Section 3 below), what challenges the COVID-19 outbreak has brought for market access in terms of regulatory approval?

We have seen issues due to changes in the supply chain and to the annual readjustment in drugs price, since the Government suspended for a period of 60 days the annual readjustment.

Also, the expropriation of product by the government and force majeure contractual are topics commonly questioned by companies.

We are not aware about problems related to delays occurring in normal regulatory work for matters unrelated to COVID-19, however we are sure that this will be a problem in the next future, considering that we are still at the beginning of the pandemic period.

2. **Clinical trials**

(a) What have been the major impacts of the COVID-19 outbreak on the management of clinical trials?

The main issue is in connection with the on-site clinical trials and the isolation measures, which makes recruitment for and the development of the trials more challenging. ANVISA has invited the relevant stakeholders to discuss the challenges and to implement pathways to resolving the matter.

(b) Have there been measures adopted by the regulator in charge to assist with clinical trial management whether in the interim or on an on-going basis?

There has been no concrete measure, but ANVISA issued the Technical Note No. 3/2020, as a guidance sponsors, researchers and institutions involved in ongoing clinical trials, in order to mitigate the issues during COVID-19 crisis. The Agency has invited the relevant stakeholders to discuss the challenges and to implement pathways to deal with that.

(c) Any general tips and recommended solutions under the local regulatory framework?

Our general tip is to communicate with ANVISA about eventual problems or concerns regarding clinical trials. ANVISA is concerned about the continuity of ongoing procedures and is flexible to align different approaches, if needed (i.e., delivery of the investigational drug at research subject's home).

In case the company enjoys or uses any of the exceptions or relaxations measures, it is crucial that the company keep records of the relevant supporting documents regarding the security and efficiency of the products, as well as other quality-related aspects of the plant, such as quality control policies and data, which must be aligned with good practices requirements.

3. **IP risks**

(a) Are there any state emergency supply measures for medicines, medical devices and biocides and what are the implications on IP protection of the product in question?

There have been reported emergency purchases of medicines, medical devices and biocides, but up to the this moment there has not been any impact on the IP protection.

For the sake of completeness, the Brazilian Industrial Property Law provides for compulsory licenses of patents in certain circumstances, including in the event of national emergencies or public interest which have been declared as such by the Executive Branch - and the Covid-19 pandemic has been acknowledged as an event of public health emergency through Ordinance # 188/20 issued by the Ministry of Health (which is part of the Executive Branch). In such circumstances, a temporary and non-exclusive compulsory license may be granted ex officio if the patent owner or its licensee do not meet market needs. However, no compulsory licenses have been granted as of this date.

As regards importation, products must be imported by the registration holder, so there has not been a relaxation on parallel importation.

(b) Any issued or discussions on likely issuance in response to the COVID-19 outbreak in your jurisdiction?

The Brazilian Patent and Trademark Office (INPI) announced that it will prioritize the examination of patent applications related to processes, equipment and materials used in the diagnosis, prophylaxis and treatment of COVID-19. Applicants must apply for priority by June 31, 2021 to be eligible for this special procedure.

4. **Telemedicine**

How has the COVID-19 outbreak changed the use and provision of telemedicine services? Are there interim measures or anticipated legislative changes?

The Ministry of Health has temporarily allowed telemedicine through Ordinance No. 467, issued on March 23, 2020. Such Ordinance provides for the possibility of telemedicine in both public and private health system during the coronavirus pandemic in Brazil. The appointment must be made directly between HCP and patient only, through an IT system that ensures integrity, security and confidentiality of patient information. E-prescriptions are also temporarily permitted, but it is necessary to use systems with certifications and keys issued by the Brazilian organization of e-signature.

Subsequently, Federal Law No. 13,989/2020, published on April 16, confirming the authorization for the use of telemedicine in any activities of health services during the coronavirus pandemic in Brazil.

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