

Covid-19 | 8th Stakeholder Communiqué | 12th August 2020

Dear Customer, Dear Team-Member, Dear Contractor, Dear Stakeholder,

As we get organized for one more year, maybe two, of this pandemic the tools at our disposal remain limited to combining knowledge, education and discipline with hygiene precautions, social distancing and testing. We remain committed to making our place of work a safe one, to helping our Team Members lead a safe life together with their families and to supply drugs to patients via our clients. The safety of the contractors that work in our premises is equally important and all our measures now also take this group into consideration.

All our sites are located in the Northern Hemisphere and the well managed return to school in September is a central element to the construct of a normal community life, this is a pre-condition to our sites operating normally. As a society we need to overcome this pandemic, each one of us in his or her area of responsibility has the duty to define and put in place the specific appropriate precautions so that we are able to keep our health and also work, study, play and be with whom we want to be. We are counting on the authorities of the cities and regions where we operate to ensure that schools take the necessary measures to ensure parents feel schools are safe, that our children are indeed safe and that the higher risk groups -older teachers- are also protected while they carry out their important mission and help all of us take control of our day to day.

Health, Safety and Work from Home

Extensive measures are in place at all our sites to enable work and operations to be performed safely. We continue to work to a plan where no more than half of those able to work from home will be on premises. We have asked everyone to, as from September, come for a face-to-face meeting with her/his N+1 and co-workers at least once every two weeks – a long absence from physical presence is not advisable considering that our premises are safe. Those that work from home need to maintain high standards, we should avoid allowing standards to decline just because we are not going “to the office” – work from home is work, not an informal activity. Self-discipline and regular hours are a must, your example is important because it sets the pace – at home, for your family, and your example sets the bar during video calls; please encourage others in the right way, you need to be seen to be giving the right example.

We put in place a travel and visitors policy that recognizes that no place, no country is safer than any another, as such we decided to allow travel and to receive visitors based on a risk-based assessment of each case. This is left in the hands of each Team-Member and his/her N+1 but is naturally also subject to local laws.

Portugal	At Hovione in Portugal there have been no new positive cases among our Team Members since the 28 th of May. Because of the large number of TMs in Portugal we test 5% of Team Members and contractors every week. This is voluntary, it is risk-based, it is designed to address the return from holiday (with the likely higher incidence of travel) and especially the test & contact trace situations where we need immediate test results to stop virus infection within our workforce.
Ireland	Ireland deferred by 3 weeks most of the Phase 4 plans for further easing of restrictions to August 31 st as a cautious approach following a small increase in cases. Our site will accommodate increasing attendance on site in a number of weeks' time because of extra Covid-19 driven production. Training regarding the implemented workplace protocols is currently being rolled out in each department. Our Cork site has not had a positive case since the 13 th of April.
Macau	In Macau, the operation is normal with the HSE measures in force. The site has not registered a positive case since the beginning of the pandemic. In the territory there have been no infections between health professionals nor any community outbreaks.
New Jersey	In New Jersey, Governor announced additional states for NJ residents returning home to quarantine for a 14-day period from the time of last contact within the identified state. There are currently 31 states that meet the criteria. At the New Jersey site there are no new positive cases to report since the 22 nd of April. The site continues to keep up on the latest updates and has revised guidelines on traveling to other states as needed. It also continues operating at the highest level of our COVID-19 response plan.

In June, FDA released a [guidance document](#) for the industry, to support response efforts to this pandemic: “Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing” (“FDA Guidance”). An internal assessment indicates that the pre-Covid-19 measures together with the additional measures implemented by our PrepCom are in line with FDA concerns and recommendations at all our sites. We do not have a formal risk assessment to document the adequacy of our GMP controls to protect the API we make from exposure to the virus and to minimize the risk that our product is a vector of infection spread. We will perform this within the next quarter, as we

perceive, based on the nature of our products and currently known virus characteristics that risk to be low enough that other pressing needs must take priority.

In the areas of **Supply chain, Production and Customers** we do not see any changes or different trends from what we reported last month, ie no news here is good news.

Social Responsibility

- Our webpage continues to provide updates and details our response to the crisis.
- We held two webinars to share our fighting Covid-19 practices and to seek others' experience. We invited all our clients, suppliers and stakeholders, this led to enriching Q&A sessions. You can access its recording at the [Covid-19/Coronavirus](#) webpage.
- To support the safe return to school we sponsored the www.ABCovid.pt contest in Portugal, where we give weekly prizes for the best 1 minute video that teaches how to defend oneself from the virus.

Because of the relevance of the information contained in this communiqué we have decided that it applies both internally and externally, and also to our contractors. This is now a Stakeholder Communiqué in 3 languages: English, Portuguese and Chinese.

Yours,

Guy Villax
Chief Executive

[Click here for our previous External Stakeholder Communiqués](#)

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