Karup, 5 May 2022

To whom it may concern

Re: Cystic fibrosis diagnosis and the new EU Medical Device Regulation, REGULATION (EU) 2017/745

Dear Sir/Madam,

Cystic fibrosis is the most common severe genetic disease in Europe with approximately 1 in 3000 people affected. The diagnosis is dependent on the sweat test (the gold standard) and molecular genetic testing showing variants in the gene called *CFTR*. The sweat test is crucial to all national newborn screening programmes supported by Ministries of Health.

The sweat test was first developed in the 1950s. It is a very safe highly standardized test with guidelines published by European and American experts in the field. The stringent standardized methodology ensures high quality reliable, repeatable, reproduceable and accurate results. The sweat test consists of 3 steps: 1) inducing sweat secretion, 2) collecting the secreted sweat, and 3) measuring sweat chloride concentrations which are elevated in cystic fibrosis, as this is due to faulty CFTR protein. The first step consists of applying pilocarpine to the skin with the "iontophoresis technique" (ie. topical administration only). It uses commercially available consumables made of gel containing a specified quantity of pilocarpine.

These consumables containing pilocarpine fall under the new EU Medical Device Regulation (MDR), REGULATION (EU) 2017/745, and are considered high risk because pilocarpine, a drug, is used. However, these consumables have been used for decades in thousands of patients all over the world and they are known to be extremely safe. There are a few companies working to recertify their products to the new MDR. The review is taking significantly longer than expected and at present we know of no product that has been recertified. We understand that no importation of these crucial consumables is allowed until they have been recertified and we fear their supply will be completely exhausted within the next few weeks or months. If these consumables were to become unavailable until their recertification, cystic fibrosis diagnosis and national newborn screening programmes will close or risk the use of unstandardised methods leading to unreliable diagnosis, delays in care and poorer prognosis. The new EU MDR is to increase patients' safety, but not at the expense of lower patient care and treatment.

Therefore, given the extensive safety track record of sweat testing and the huge delays in product certifications, we ask for an exception to allow for the continued importing of consumables containing pilocarpine used for sweat testing during the review process for recertification under the new MDR.

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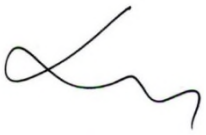
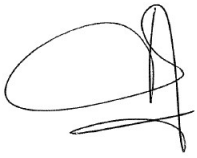
Summary

- Standardised high quality sweat testing is critical to confirming the diagnosis of cystic fibrosis
- Sweat testing is safe (pilocarpine is administered topically only)
- The delay in recertification under the EU MDR risks the loss of accurate sweat testing in Europe, jeopardizing cystic fibrosis diagnosis and national newborn screening programmes
- Our request is a temporary authorisation of import and use of these consumables during the review process until they are recertified under the new MDR.

We thank you for your consideration.

Yours sincerely,

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