APPENDIX 6.
NATIONAL REQUIREMENTS IN ICELAND

0 GENERAL INFORMATION ABOUT THIS APPENDIX

This Appendix lays down the special terms and conditions that apply to purchase of pharmaceuticals in Iceland under the Agreement. The provisions thus supplement the terms and conditions of the Agreement to the relevant extent according to conditions in Iceland.

The provisions of the Appendix (any given sections) are not separately consecutively numbered but are numbered according to the clause of the Agreement to which they relate.

2. ABOUT THE AGREEMENT / PRODUCTS INCLUDED

2.2.a Landspítali Hospital (hereinafter referred to as "Landspítali") is the National University Hospital of Iceland providing multidisciplinary specialized medical services. Landspítali is the contracting authority on behalf of all public hospitals in Iceland, listed below:

- Sjúkrahússið á Akureyri.
- Heilbrigðisstofnunun Vesturlands, Akranes.
- Heilbrigðisstofnunun Suðurlands, Selfoss.
- Heilbrigðisstofnunun Suðurnesja,Reykjanesbær.
- Heilbrigðisstofnunun Austurlands, umdæmissjúrahús Neskaupsstaður.
- Heilbrigðisstofnunun Norðurlands; Sauðárkrókur, Fjallabyggð.
- Heilbrigðisstofnunun Vestfjarða, Ísafjörður.

2.2.b Landspítali enteres into the Agreement in order to procure the pharmaceuticals for Landspítali and in order to supply all other public hospitals in Iceland, referred to as Customers in the Agreement.

2.2.1.a Icelandic marketing authorisation shall be valid for offered product[1]. Summary of product characteristics (Smpc) and leaflet for offered products shall be translated into Icelandic and be available in the Register of Special Medicines found on the Icelandic Medicines Agency (IMA) website[2]. According to regulation No. 545/2018 sections D and E, articles 30 and 31, exemptions from this rule regarding printed labels and leaflets are possible. Upon request from the Supplier or Marketing Authorization Holder the Icelandic Medicines Agency (IMA) can grant an exemption from Icelandic labeling and Patient Information Leaflets (PIL) for products that are not given directly to the patient for self-medication and therefore permit labeling and PILs to be in English or in a Nordic language (other than Finnish). Applications for exemptions from the Icelandic leaflet and / or Icelandic labeling on the packaging can be sent via e-mail to lyfjastofnun@lyfjastofnun.is. See further information on IMA´s website[3]

If IMA does not accept the request for an exemption under this provision, the Supplier is not bound by the Agreement regarding Iceland (Landspitali). If this is the case, it will be considered that this precondition for an agreement regarding Iceland no longer exists. Then, neither party, Landspitali (Iceland) or the Supplier, has any claims on the other. However, the Agreement remains unchanged regarding Denmark and Norway.

2.3.a Following a public procurement procedure Landspitali will entrust an Icelandic wholesaler to manage storage, supply and distribution of the products purchased under this agreement. This wholesaler will be specified in time before the first order takes place following the framework agreement. The Supplier is responsible for transporting the product to Iceland. Delivery shall be DDP (Delivered Duty Paid) (Incoterms 2020) to the address stated by the wholesaler in the order. Upon arrival to Iceland the wholesaler takes over by receiving the product from a transport company. In addition to storing and delivering goods to customers in Iceland the wholesaler will manage orders and payments to the Supplier. The Supplier can also use an Icelandic wholesaler with whom he is contractualy bound.

3. SUPPLIER REQUREMENTS

3.1.a The wholesaler shall have an authorization from the Icelandic Medicines Agency in accordance with the Icelandic regulation no. 699/1996 on import and wholesale distribution on pharmaceuticals.

[1] Zero day procedure - Icelandic Medicines Agency (ima.is)
https://www.ima.is/licences/marketing-authorisations/conditions-for-marketing/
[2] https://www.ima.is/
[3] Package labelling and leaflets - Icelandic Medicines Agency (ima.is)

11. CONTACT PERSONS

11.2 The contact persons of Landspítali

Name: Friðjón Már Viðarsson, project manager

Contact information: phone numbers /email address:+354-543-1534 / +354-824-5057 / fridjonm@landspitali.is

Name: Hulda Harðardóttir, project manager for Pharmaceutical Procurment

Contact information: phone numbers /e-mail address: +354-543-1512 / +354-824-5854 / huldahar@landspitali.is

13. ORDERING / PLACING OF ORDERS

13.1 The Customer will place continuous orders with the wholesaler. The wholesaler will then place continuous orders with the Supplier.

14. TERMS OF DELIVERY

14.1 Delivery shall take place not later than 3 working days after the Supplier's receipt of the order. "Working days" shall mean Mondays through Fridays, except for Icelandic public holidays.

Delivery shall be DDP (Incoterms 2020) to the address stated by the wholesaler in the order. See further above, clause 2.2.1.a.

16. RETURN OF PRODUCTS

16.3 Return of products in accordance with clause 16.2 in the Agreement may take place using PostNord or other carrier chosen by the Customer to the Supplier’s address as stated in the Agreement, unless the Supplier on delivery of the products informs that any return is to take place in another manner or to a different address. The Customer’s liability for any returned products shall cease upon delivery of the pharmaceuticals to an independent carrier.

Upon return of pharmaceuticals, the Customer will enclose a return slip with information on the product, package size, batch number, shelf life and quantity, as well as the name of the Customer and contact person, including contact details. The Customer will furthermore state on the return slip that the products are returned due to the delivery of products with short shelf life. The Customer will at the same time inform Landspítali of the retuned products.

The Supplier shall not later than 8 days after receipt of the returned pharmaceuticals issue a credit note to the wholesaler.

20. TERMS OF PAYMENT

20.2.a Approved invoices from the wholesaler will be paid by the customer, no later than 30 days after the end of the month in which the sale occurred. The final due date shall be the same as the due date.

20.2.b Suppliers may use remittance slips in order to manage payments for their convenience, but may not enter transaction fees on the invoice, or other charges that are not connected to sold supplies/services. Government agencies reserve the right to pay such invoices through bank transfer or to return them.

20.2.c Wholesaler shall follow the technical standard order for technical standards for simplified electronic accounts according to Icelandic Standards: technical standard TS-136 for invoices and technical standard TS-137 for credit notes (or editions that have replaced these). The standards can be accessed at the Standards Iceland website free of charge: http://stadlar.is/stadlastarf/fagstadlarad-i-upplysingataekni/taekniforskriftir/rafraenar-taekniforskriftir.aspx.

20.2.d In addition find further guidelines for electronic accounts at the Financial Management Authority website: http://www.fjs.is/fraedsla-og-verklagsreglur/rafraenir-reikningar/

32. THE CONTRACTING AUTHORITIES´OBLIGATION TO PAY

32.2 In the event that Customer is in breach of its payment obligations under the Framework Agreement, the Supplier shall be entitled to interest pursuant to the provisions of the Act on interest and price indexation No. 38/2001.