

# **Donation agreement between Shire Denmark A/S and Sjællands Universitetshospital, Hæmatologisk afdeling ("Donation Agreement")**

## **1. Parties**

The parties to this Donation Agreement are

- (1) Shire Denmark A/S ("**Shire**"), CVR-no. 36392290, registered place of business at Larsbjørnsstræde 3, 1454 København, Denmark,  
  
and
- (2) Sjællands Universitetshospital, Hæmatologisk afdeling ("**Hospital**"), CVR-no. 29190658 registered place of business at Vestermarksvej 9, 1. sal, 4000 Roskilde, Denmark.

## **2. Background**

Assisted Care is a new healthcare offer from Shire where nurses provide support for the treatment of immunodeficiency in the home of the patients. Assisted Care is targeted at patients already under treatment with the immunology product HyQvia or patients who are about to get a treatment with HyQvia, and where Hospital estimates that the patients (or relatives) need assistance to achieve the optional treatment ("**the Assisted Care**").

As this healthcare methodology is not standard practice or routinely available to patients, it is a valuable benefit for patient care specifically targeted at patients with immunodeficiency.

Shire has entered into a separate consulting agreement with SOS Vikar A/S, a Danish company with registered place of business at Frejasvej 8, 4700 Næstved, Denmark ("**SOS Vikar**"). SOS Vikar hires nurses as consultants ("**the Nurses**") that specialize in hematology, anti-infection medicine and oncology. These Nurses will provide services relevant for the Assisted Care. The services are subject to a separate consulting agreement, including, without limitation, infusions and administration of HyQvia in the patient's home.

## **3. The Donation**

As a pilot project, from the entry into force (cf. section 12 below) of this Donation Agreement, Hospital may at Shire's cost request Assisted Care directly from SOS Vikar (cf. section 5 below) (the "**Donation**").

#### **4. Purpose of the Donation**

The purpose of the Donation is to improve patient welfare by facilitating the Hospital's activities regarding treatment of patients with immunodeficiency through the use of the Assisted Care.

The following persons within the Sjællands Universitetshospital, Hæmatologisk afdeling are responsible for the monitoring of the Assisted Care:

- Kristine Work, nurse
- Anne Struer, nurse

The following person is the head of the Sjællands Universitetshospital, Hæmatologisk afdeling

- Mikkel Helleberg Dorff, Head of Clinic

It is only Hospital, who oversees the Donation, and Shire will therefore not affect Hospital's concrete operations, business processes, tasks, or actual use of the Donation.

However, Hospital understands and accepts that the Donation may be used for the purpose of the Donation only and that Shire is entitled to terminate the Donation Agreement without further notice, if e.g. the Nurses and/or HyQvia are used for purposes outside the scope of the Donation Agreement, or e.g. if the Nurses and/or HyQvia are otherwise used for purposes, which run contrary to applicable law and/or applicable industry codes.

#### **5. Value of the Donation**

Shire will cover any costs related to Hospital using the Assisted Care based upon the following:

The value of the Assisted Care can be estimated to approx. DKK 1,200 per patient/visit. Based on this and that the Hospital will provide the patient with the Assisted Care on a monthly basis, and the value of the Donation can be estimated to approx. DKK 14.400 per patient/year.

However these figures will ultimately depend on the number of patients, their location in relation to the Hospital and the Hospital's independent decision on which patients should be eligible for the Assisted Care. Therefore, at this point in time it is not feasible to project a final realistic estimate of the total value of the Donation.

For the avoidance of doubt and for clarity, it should be added that Shire will reimburse the Nurses' travel costs according to the fees specified by the local authorities.

#### **6. Duration of the Donation**

The duration of the Donation is 12 months from the entry into force (cf. section 12 below).

## **7. Responsibilities of the parties**

Shire ensures that the Nurses have the requisite expertise, ability and legal right to render the Assisted Care and will perform the Assisted Care in an efficient and timely manner. Furthermore, Shire ensures that the Nurses will abide by all laws, rules and regulations and generally accepted industry standards that apply to the performance of the Assisted Care, including, without limitation, any internal hospital or institutional rules that apply to the Nurses.

Hospital is responsible for appointing patients subject to the Assisted Care, including securing that the patients are already under treatment with HyQvia or about to get a treatment with HyQvia. Furthermore, Hospital is responsible for obtaining consent from every patient. Hospital retains the sole responsibility for their medical treatment and assumes full liability for the actions performed by its employees.

## **8. Processing of personal data**

Shire will not receive, have access to, gain knowledge of, store, handle, or transfer any patient personal or health information neither from Hospital nor from SOS Vikar.

Hospital undertakes to comply with all applicable rules on the protection of patient data, including - but not limited to - the Danish Data Protection Act and the Danish Health Act. Hospital acknowledges that any data relating to the health of a person is considered as sensitive personal data, and undertakes - to the extent required under Danish law - to inform each patient of the full extent of the processing of personal data under the Assisted Care and to obtain consent from each patient.

## **9. Independence of the parties**

This Donation Agreement does not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products or to otherwise influence Hospital or its employees. The decision to use the Assisted Care for a patient will be taken independently and solely by Hospital.

Nothing in this Donation Agreement or any agreements pertaining hereto shall contain, or have as its effect, any exclusivity, direct or indirect, for Shire to provide certain products or services to the Hospital.

## **10. Termination**

In addition to the termination possibilities mentioned under section 4 above, Shire is also entitled to terminate the Donation Agreement, if the separate consulting agreement made between Shire and SOS Vikar terminates.

## **11. Compliance and transparency**

The parties agree that the Donation and the Assisted Care will be conducted in accordance with all applicable laws, ordinances, regulations and notably, the ENLI Donation Code. Hospital accepts that Shire may be required to make public this Donation Agreement on its website for a period of two (2) years, and that Shire may be required to provide copies to third parties when it is no longer available on the website for a period of ten (10) years.

**12. Entry into force**

This agreement enters into force with effect from the date it is signed by both parties and has been drawn up in two (2) originals, of which each party takes one.

**on behalf of Hospital**

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Name: *Mette Kærstoft* **Sjællands Universitetshospital**  
..... **Sygehusledelsen**  
..... **Lykkebakvej 1**  
..... **4600 Køge**  
Title: *direktør (købschef)*  
Date: *26/11 2018*

**on behalf of Shire Denmark A/S**

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Name: *Anders Pade Milwertz*  
Title: *Adm. dir.*  
Date: 2018-10-24