



• Dermatology
beyond the skin

COLLABORATION AGREEMENT (PATIENT ORGANIZATIONS) CONSULTANCY SERVICES

between

ATOPISK EKSEM FORENING

and

LEO PHARMA A/S

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LIST OF SCHEDULES

SCHEDULE A1:	DESCRIPTION OF SERVICES
SCHEDULE A2:	TEMPLATE FOR DESCRIPTION OF SERVICES

THIS AGREEMENT ("Agreement") is made and entered into by and between:

- (1) **LEO Pharma A/S**, a company organized and existing under the laws of Denmark and having its registered office at Industriparken 55, 2750 Ballerup, Denmark, with its company registration no. 56759514 ("**LEO Pharma**"), and
- (2) **Atopisk Eksem Forening**, an organization organized and existing under the laws of Denmark and having its registered office at c/o Susse Stannum, Friksvareret 2, 2. lejlighed 13, 3600 Frederikssund, Denmark ("**Patient Organization**"),

hereinafter individually referred to as "**Party**" and collectively as "**Parties**",

WHEREAS:

- (A) LEO Pharma is a research-based pharmaceutical company that develops, manufactures and markets pharmaceutical products to patients within dermatology and thrombosis.
- (B) The Patient Organization is an organization working to improve conditions for people with atopic eczema.
- (C) LEO Pharma wishes to engage the Patient Organization to deliver expert knowledge, insights and advice to LEO Pharma within the LEO Pharma established Expert Partners and Innovation Consultants (EPIC) Panel, so that LEO Pharma may apply such insights and knowledge in its activities related to research and development, patient support, disease awareness and patient information ("**Services**") and the Patient Organization wishes to provide such Services to LEO Pharma.

NOW THEREFORE, the Parties have agreed as follows:

1 PURPOSE

- 1.1 The purpose of this Agreement is to describe the terms and conditions for the collaboration between the Parties in connection with Services to be provided to LEO Pharma and its Affiliates (as defined below) by the Patient Organization within eczema, where the Patient Organization possesses certain valuable knowledge.. For the purpose of this Agreement "**Affiliate**" is defined as any company, corporation, firm, partnership or other entity controlling or controlled by LEO Pharma.

2 THE SERVICES

- 2.1 The Patient Organization agrees to engage in the EPIC Panel and to participate in one or more of the roles below as agreed between the Parties for up to 3 activities ("**Sessions**") for a one year period, collectively referred to as the ("**Services**").
 - Data contributor – e.g. contribute with insights and perspectives in a patient survey
 - Insight provider – e.g. share specific insights and perspectives on e.g. a specific topic related to your disease expertise and experience
 - Advisor – e.g. share advice in the development of a research and/or development strategy or initiative
 - Reviewer – e.g. review of clinical protocols or patient information to be used in a clinical trial or other research

and development context

- Co-developer – e.g. partner in designing a patient preference assessment

The format of the Sessions will be online and in-person depending on activity and nature of the Session. This may include advice on the following project types:

- Investigator Meetings presentations/interviews
- Medical Information responses assessment
- Contesting trial outlines/trial material
- Disease journeys/disease education
- Insights provision to tailor-made assessments (e.g. patient preference surveys)
- Revision of ICFs, IFUs

The first Session is described in Schedule A1 to this Agreement. Subsequent Sessions 2 and 3 will only be conducted if LEO Pharma identifies a need and if the Patient Organization is available to conduct the Services at the given point in time. Additional Sessions shall be described and agreed upon on the bases of the template Schedule A2.

The time commitment for each Session is defined in each Schedule. The total time commitment of all three Sessions combined shall not exceed 15 hours.

The insights shared during the Sessions may be used for research and development activities by LEO Pharma and for internal and external purposes that seek to create disease awareness or patient information on specific topics or products.

- 2.2 The Sessions may be recorded, and pictures may be taken. The data collected during the Sessions, such as, but not limited to, sound and photos, will be used for internal purposes, e.g. for educational purposes or to guide ongoing projects or for external research purposes as defined in writing by LEO Pharma prior to each individual Session and detailed in each Schedule.
- 2.3 The Patient Organization represents and warrants to comply with any and all applicable laws, rules, regulations, government regulatory requirements and guidelines in force from time to time in connection with the Services.
- 2.4 The Patient Organization acknowledges that LEO Pharma has committed to comply with a number of national and international industry ethical codes including but not limited to:
- the International Federation of Pharmaceutical Manufacturers and Association's (IFPMA) Code of Practice;
 - the Consensus Framework for Ethical Collaboration between Patient Organisations, Healthcare Professionals and the Pharmaceutical Industry developed by IFPMA;
 - the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice;
 - the ENLI Ethical Rules for Collaboration between Patient Organizations, etc., and the Pharmaceutical Industry;
 - the ENLI Ethical Rules for Negotiations with Decision-makers (Lobbying Code); and
 - other local industry codes applicable for the pharmaceutical industry relevant for the performance of the Services in: 1) any country where activities related to the Services takes place, and 2) the countries of the HCPs or HCOs involved, engaged or participating in the Services;

The Patient Organization therefore undertakes to comply with these ethical codes to the extent they would apply to LEO Pharma in connection with the Services.

- 2.5 The Patient Organization and its representatives shall at all times conform to the LEO Pharma Third Party Compliance Code as set out from time to time at www.leo-pharma.com/thirdparty ("**Compliance Code**"). Upon request, the Patient Organization shall provide information on its level of compliance with the Compliance Code so that LEO Pharma can assess whether the Patient Organization actually complies with the Compliance Code, or not. The Patient Organization shall at all times and promptly take all appropriate steps to resolve and correct any identified non-conformity.
- 2.6 To the extent required, the Patient Organization shall be responsible for obtaining and maintaining all consents and permissions necessary for the performance of the Services.
- 2.7 Contact persons in matters related to this Agreement:
- From LEO Pharma: Hanne Hemmingsen, Director, Stakeholder Partnership
Email: HGADK@leo-pharma.com
- From the Patient Organization: Anne Skov Vastrup, Chair
Email: anne@vastrup.dk

3 REMUNERATION

- 3.1 (**Fees**) The fees for the Services and the rights assigned to LEO Pharma and/or its Affiliates under this agreement: shall be 700DKK/hour, which is representative of the fair market value for such Services. The Parties agree that the maximum number of hours for the Services conducted under this Agreement is 15 hours, and the remuneration for such Services must not exceed the agreed maximum number of hours. The time commitment shall be specified in each separate Schedule. The Patient Organization shall not be entitled to any additional payments unless agreed upon between the Parties in writing
- 3.2 If agreed in the Schedule(s), LEO Pharma may reimburse the Patient Organization for documented reasonable and customary expenses actually incurred by the Patient Organization in connection with the Patient Organization's furnishing of the Services.
- 3.3 (**Invoices**) The Patient Organization shall send invoices no later than sixty (60) days after the Services have been performed. The Patient Organization shall issue invoice(s) to LEO Pharma A/S, Att.: Hanne Hemmingsen, Stakeholder Partnership, Industriparken 55, 2750 Ballerup, Denmark. Invoices and expense receipts should be sent as a PDF file to HGADK@leo-pharma.com, marked "AEF & LEO Pharma – EPIC Consultancy Agreement 2021" in the subject line in order to receive payment and reimbursement.

The invoice shall include following information:

- LEO Pharma A/S VAT no : DK 56759514
- Name and address of the Patient Organization
- Invoice number and date
- Specification of the Services and time spent
- Invoice currency
- Bank details
- Patient Organization VAT number (EU countries) if applicable
- If the Services are subject to VAT or any other local taxes, any mandatory data in accordance with the provisions of the applicable VAT or tax laws.

Payment terms are date of invoice plus thirty (30) days.

3.4 **(Travel and accommodation)** For In-person Sessions, LEO Pharma will cover below approved, reasonable and documented travel costs and cover meal and beverages during the Session if:

(a) the Patient Organization provides adequate documentation for these expenses; (b) the expenses comply with LEO Pharma travel policy and requirements by national codes in the country of the Patient Organization; and (c) LEO Pharma has authorized such expenses in advance in the applicable Schedule. LEO Pharma reserves the right to audit the expenses claimed by the Patient Organization at any time during the term of this Agreement.

If necessary, LEO Pharma will arrange hotel accommodation and book the necessary and relevant transportation.

LEO Pharma will not reimburse any accommodation and travel booked by the Patient Organization, without prior written approval, and will in no event be able to refund any costs without proper documentation.

Reasonable accommodation booked by LEO Pharma, if required	<ul style="list-style-type: none">- Standard business hotel, max 4 star- Arrival and departure date should be as close to the Session as possible.
Reasonable travel costs booked by LEO Pharma	<ul style="list-style-type: none">- Economy+ on transatlantic day flights- Economy flights within Europe and within North America- Arrival and departure date should be as close to the Session as possible
Reasonable ground transportation	Private car (car mileage will apply) Taxi/Uber/Lyft and public transport in connection with Services under this Agreement
Reasonable meal costs in connection with the Session(s)	<ul style="list-style-type: none">- Meals in connection with the Meeting as organised by LEO Pharma- Standard meals during the travel period, based on receipts. Local meal thresholds apply: Meals can only be offered at events consisting of at least two hours of professional content. Maximum value including VAT: Breakfast: DKK 100 Lunch: DKK 400 Dinner: DKK 700 Daily threshold for meals: DKK 1200

The Parties represent and warrant that neither this Agreement nor any amount paid or reimbursed by or on behalf of LEO Pharma is intended to be, nor shall it be construed as, an offer or payment made, whether directly or indirectly, to recommend, arrange for, induce or reward the referral of patients, the purchase, lease or order of any product or service or the promotion of the interest of LEO Pharma.

4 INTERACTION WITH HEALTHCARE PROFESSIONALS ("HCPs"), HEALTHCARE ORGANIZATIONS ("HCOS") AND THE GENERAL PUBLIC

- 4.1 The Patient Organization shall not interact with or make any payments or other transfers of value to HCPs or HCOS directly or indirectly in connection with the Service.
- 4.2 The Patient Organization acknowledges that the promotion of prescription only products towards the general public is prohibited in most countries. If the Patient Organization in connection with the Services on behalf of LEO Pharma shall interact with or as part of the Services shall provide materials targeted at the general public, the Patient Organization shall ensure that such interactions and materials are compliant with all relevant laws, regulations and ethical guidelines applicable to the pharmaceutical industry's interaction and communication with the general public as well as any procedures agreed between the Parties to ensure such compliance.

5 INTELLECTUAL PROPERTY RIGHTS

- 5.1 Any and all information of any kind provided and/or disclosed by or on behalf of LEO Pharma in connection with the Services ("**LEO Pharma Information**") is the exclusive property of LEO Pharma and nothing in this Agreement shall be construed as granting the Patient Organization any license or proprietary right with respect to LEO Pharma Information.
- 5.2 Any and all results including, but not limited to reports, documents and any other work product as well as all intellectual property rights, inventions (whether patentable or not) and know-how generated and/or resulting from the Services ("**Results**"), shall be the exclusive property of LEO Pharma, who shall be entitled to use Results without any restrictions. Nothing in this Agreement shall be construed as granting to the Patient Organization any license or proprietary right hereto.

6 CONFIDENTIALITY

- 6.1 Any and all Results, LEO Pharma Information and other business information or materials (whether or not patentable) of LEO Pharma, its Affiliates or a third party, whether in written, graphical, electronic or oral form or in any other medium disclosed to, communicated to, learned of or otherwise acquired by the Patient Organization under this Agreement except for information which Patient Organization is able to prove is already lawfully in its possession prior to disclosure under this Agreement or is or becomes public knowledge through no fault of the Patient Organization shall be considered as confidential information ("**Confidential Information**").
- 6.2 The Patient Organization shall use the Confidential Information solely in connection with the Services and shall not disclose or exploit, whether directly or indirectly, any Confidential Information for its own benefit or the benefit of any third party (person or entity).
- 6.3 The Patient Organization shall maintain the Confidential Information in confidence for a period of five (5) years from the date of disclosure, and shall upon termination or expiry of this Agreement, if requested by LEO Pharma, promptly return, delete or destroy (at the discretion of LEO Pharma) all Confidential Information in its possession, including all copies, reproductions and summaries thereof.

7 TRANSPARENCY AND DISCLOSURE

- 7.1 LEO Pharma must annually publish a list on its website of the Patient Organizations LEO Pharma have engaged to provide paid-for services. The Patient Organization consents to disclosure of information on such list about this Agreement, including a description of the services and any payments made by LEO Pharma under the Agreement as well as disclosure of the total amount LEO Pharma has paid to the Patient Organization during the year.
- 7.2 LEO Pharma encourages the Patient Organization to declare that it has provided paid services to LEO Pharma whenever the Patient Organization communicates in public on any matter that is related to the Services or any other issue related to LEO Pharma.

8 USE OF THE PATIENT ORGANIZATION'S LOGO

- 8.1 The Patient Organization agrees that LEO Pharma may use the Patient Organization's logo or name, and make use of collaboration with the Patient Organization, as follows: to be mentioned on the website of LEO Pharma.

9 INDEPENDENCE AND CONFLICT OF INTEREST

- 9.1 The Parties declare by signing this Agreement that the Patient Organization shall be free to collaborate with other pharmaceutical companies and that LEO Pharma shall be free to collaborate with other Patient Organizations. The Parties further state that their collaboration shall not involve exclusive rights with respect to specific product or therapeutic areas or do not include any obligation or inducement to recommend a particular medicinal product.
- 9.2 LEO Pharma agrees by signing this Agreement not to impose conditions for the Patient Organization's professional or stakeholder-policy viewpoints. This Agreement shall not be seen as explicit or implicit agreements that confer an obligation on the Patient Organization to recommend or in any other way promote the interest of LEO Pharma.

10 TERM AND TERMINATION

- 10.1 This Agreement shall come into force on the day of the last signature to the Agreement and shall unless terminated earlier, remain in force until the Services have been completed, at which date the Agreement shall be terminated automatically.
- 10.2 If the Patient Organization breaches any of its obligations under this Agreement, LEO Pharma may terminate the Agreement with immediate effect and be entitled to seek other legal redress in Danish law for breach of agreement, including a claim for compensation irrespective of whether the Agreement shall have been terminated.

11 DATA PROTECTION

- 11.1 The Parties undertakes at all times to comply with all applicable laws and regulations applicable to the processing of personal data and data protection.

12 LAW AND VENUE

- 12.1 This Agreement shall be governed by the laws of Denmark without regard to the conflict of laws provisions.
- 12.2 Any dispute arising out of or in connection with this Agreement, including any disputes regarding the existence, validity or termination thereof, shall be settled by arbitration administrated by the Danish Institute of Arbitration in accordance with the rules of arbitration procedure adopted by the Danish Institute of Arbitration and in force at the time when such proceedings are commenced. The arbitral tribunal shall be composed of three arbitrators. Each Party shall appoint one arbitrator, and the Danish Institute of Arbitration shall appoint the chairman of the arbitration tribunal. If a Party has not appointed an arbitrator within thirty (30) business days of having requested or received notice of the arbitration, such arbitrator shall be appointed by the Danish Institute of Arbitration. The place of arbitration shall be Copenhagen, Denmark and the arbitration shall be conducted in English.

13 SIGNATURES

- 13.1 The Agreement may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document. The Parties agree that the execution of this Agreement by standard industry signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures. Any amendments of the Agreement shall be in writing and signed by authorized representatives of the Parties.

LEO Pharma A/S

Atopisk Eksem Forening

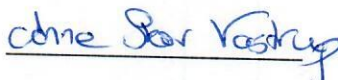
Date: 11 May 2021

Date: 2 May 2021



Name: Hanne Hemmingsen

Title: Director, Stakeholder Partnership



Name: Anne Skov Vastrup

Title: Chair

SCHEDULE A1

Medical Response Letters

Name of Healthcare Partner:	AEF (Anne Skov Vastrup)
Number of sub-activity:	1 out of 3
Describe the activity/meeting:	Patient expert review of Medical Information responses
Agenda attached:	See below.
Describe the purpose of the activity/meeting:	To support the creation of medical information responses
Knowledge gaps to be addressed:	Inclusion of tailor-made patient-oriented standard responses.
Number of hours of Services:	0.5 hours for briefing call 2.5 hours for preparation 1 hour for interview = 4 hours in total
Total Fee:	700*4 hours= 2800 DKK
Location of activity:	Virtual call via Microsoft Teams
Other Transfers of Value (travel, meal, accommodation):	N/A
Use of recordings and pictures:	The session may be recorded for internal usage.
Use of Logo:	N/A

LEO Pharma A/S

Atopisk Eksem Forening

Date: 11 May 2021

Date: 2 May 2021



Name: Hanne Hemmingsen

Title: Director, Stakeholder Partnership



Name: Anne Skov Vastrup

Title: Chair

SCHEDULE A2 TEMPLATE [Name of Session]

Name of Healthcare Partner:	
Number of sub-activity:	X out of 3
Describe the Session:	
Agenda attached:	
Describe the purpose of the Session:	
Knowledge gaps to be addressed:	
Number of hours of Services:	Preparation: XX number of hours Meeting/Workshop/Session: XX number of hours Travel time: XX number of hours
Total Fee:	[insert total fee based on hourly rate defined in clause 3.1]
Location of activity:	
Other Transfers of Value (travel, meal, accommodation):	
Use of recordings and pictures:	[describe purpose of use, plus internal/external, anonymized/non-anonymised]
Use of Logo:	

LEO Pharma A/S

Atopisk Eksem Forening

Date:

Date:

Name: Hanne Hemmingsen

Name: Anne Skov Vastrup

Title: Director, Stakeholder Partnership

Title: Chair