

AGREEMENT
regarding the determination of the respective responsibilities as
Joint Controllers (Art. 26 GDPR)
between

Norgine GmbH
registered under number HRB 1039,
with registered offices at Im Westpark 14,
35435, Wettenberg, Germany

hereinafter referred to as **“Norgine”** or **“CONTROLLER A”**

and

For ALFASIGMA DEUTSCHLAND GmbH
registered under number HRB 271804,
with registered offices c/o Regus Center, Josephspitalstrasse 15,
80331, München, Germany

hereinafter referred to as **“Alfasigma”** or **“CONTROLLER B”**

Controller A and B each a **“CONTRACTING PARTY”** and collectively referred to as the
“CONTRACTING PARTIES”

PREAMBLE

Norgine and Alfasigma entered into a co-promotion agreement dated 18 April 2023 in relation to XIFAXAN® (the **“Product”**) whereby Norgine continues to place on the market and sell the Product in Germany acting as ‘pharmaceutical entrepreneur’ (pharmazeutischer Unternehmer), and Alfasigma will support Norgine in its promotional efforts with a view to enhance the sales of the Product (the **“Co-Promotion Agreement”**).

Norgine and Alfasigma have agreed to jointly determine the purposes and means of processing the personal data relating to their activities under the Co-Promotion Agreement, which shall commence on or around 1st October 2023, as per the terms defined in this joint controller agreement (the **“AGREEMENT”**).

Terms in capital letters which are not defined in the present AGREEMENT shall have the meaning provided for by the General Data Protection Regulation EU 679/2016 (**“GDPR”**).

1. Joint responsibility and description of processing

The CONTRACTING PARTIES shall carry out the processing operations described in ANNEX 1 with joint responsibility. Accordingly, both parties are responsible within the meaning of Art. 4 No. 7 of the

GDPR regarding personal data that is subject to processing in this context and are each subject to the provisions applicable to responsible persons.

The subject, nature and purpose of the processing, the nature of the data and the categories of data subjects are described in *ANNEX 1*.

2. Compliance with obligations and responsibilities

The division of tasks between the CONTRACTING PARTIES and the definition of which person responsible assumes which tasks and obligations from the GDPR are set out in *ANNEX 2*.

3. Term

Unless otherwise agreed, this AGREEMENT shall enter into force upon signature of the last signing party.

It shall remain in effect, as long as the Co-Promotion Agreement is valid and effective, and CONTRACTING PARTIES process personal data as described in *ANNEX 1* as Joint Controllers.

4. Technical and organizational measures, obligations of the CONTRACTING PARTIES

Within their defined scope (*ANNEX 2*), the CONTRACTING PARTIES shall provide sufficient guarantees that the appropriate technical and organizational measures are implemented to ensure that the processing of personal data complies with the data protection rules and the rights of the data subject.

The CONTRACTING PARTIES confirm that they are aware of the applicable data protection regulations. They declare that, within their area of responsibility, their internal organization was and still is set up in a way to comply with the applicable data protection laws.

The CONTRACTING PARTIES warrant that they familiarize the employees employed in the performance of the work with the data protection provisions applicable to them. They also warrant that the persons involved in the processing of personal data are obliged to maintain confidentiality or are subject to an appropriate statutory duty of confidentiality. The CONTRACTING PARTIES monitor compliance with data protection regulations.

The CONTRACTING PARTIES warrant that the data processed under the present AGREEMENT will not be further processed in a manner that is incompatible with the purposes for which they were originally collected by the CONTROLLER sharing the data.

The CONTRACTING PARTIES will communicate data protection officers contact details within 30 days.

5. Data Processors

Within their defined scope (*ANNEX 2*), the CONTRACTING PARTIES may engage their own Processors, duly appointed pursuant to Article 28 GDPR. The respective other CONTRACTING PARTY must be informed in advance and may object the subcontracting. An objection must be timely, reasonable and specify the grounds on which it is made.

With regard to third ancillary services that are contracted by one CONTRACTING PARTY in order to help with performing this AGREEMENT, the CONTRACTING PARTIES are required to act in strict

compliance with Article 28 GDPR in order to guarantee the protection and security of the jointly processed personal data.

As a consequence, any access to personal data can only be granted to a Processor, once the relevant CONTRACTING PARTY has ensured by means of adequate contractual agreement that processing is carried out in compliance with the relevant data protection rules.

6. Communication of breaches

The CONTRACTING PARTIES shall inform each other of any identified infringement upon this AGREEMENT's obligations as well as of any Personal Data Breach occurred. This applies in particular to situations that may result in a data subject taking legal action against a CONTRACTING PARTY.

Personal Data Breach will be communicated to each party as soon possible and in any case within 48 hours from when they occurred.

The information described above shall include a description of the possible consequences deriving from either the infringement of the AGREEMENT or the Personal Data Breach occurred, as well as a description of the measures taken to remedy or mitigate any damages caused.

In addition, the Parties agree to exchange every 30 days, on the first week of the month, reports on data subject requests related to the processing activities in *ANNEX 1* in order to ensure the Parties' responsible and timely fulfilment of obligations under EU GDPR and the applicable data protection laws.

7. Allocation of GDPR compliance obligations

7.1. General GDPR Compliance

Except as specifically set out in this AGREEMENT, each CONTRACTING PARTY shall bear responsibility for its own compliance obligations as a Controller under the GDPR, in particular regarding the lawfulness of data processing with regard to the processing operations described in *ANNEX 1*. The CONTRACTING PARTIES shall provide one another with all reasonable assistance necessary to demonstrate compliance with the GDPR, in accordance with Article 24 and 26 of the GDPR. The CONTRACTING PARTIES shall also take all necessary technical and organisational measures to ensure that the rights of the Data Subjects, in particular pursuant to Articles 12 to 22 GDPR, can be guaranteed at all times.

7.2. Information of Data Subjects

Each CONTROLLER shall be responsible for providing Data Subjects with notice in accordance with Articles 13 and 14 of the GDPR and information about the essence of this AGREEMENT (Art. 26 (2) GDPR), as set out in *ANNEX 2*.

7.3. Data Subject Rights

In the event that a Data Subject makes a request to either CONTRACTING PARTY to exercise one or more of the rights afforded to Data Subjects under the GDPR:

- that CONTRACTING PARTY shall promptly notify the other CONTRACTING PARTY of such request; and
- the CONTRACTING PARTY that receives the Data Subject's request shall be responsible for giving effect to those rights.

To the extent that either CONTRACTING PARTY reasonably requires input or assistance from the other CONTRACTING PARTY in order to give effect to any of the rights afforded to Data Subjects under the GDPR, that other CONTRACTING PARTY shall provide all such input or assistance.

The CONTRACTING PARTIES undertake to forward Data Subject requests - especially in the event of requests for deletion - without delay to the other CONTRACTING PARTY, irrespective of the obligation set out in this AGREEMENT, in order to guarantee the rights of the data subjects.

The CONTRACTING PARTIES acknowledge that, irrespective of the terms of this AGREEMENT, a Data Subject may choose to exercise any of the rights afforded to Data Subjects under the GDPR against either CONTRACTING PARTY in its capacity as a joint controller.

8. Liability and Indemnification

The CONTRACTING PARTIES liability towards third parties and in relation to one another is set out in Art. 82 para. 4 and 5 GDPR.

In the event that data subjects exercise their rights granted by the GDPR and provided that this leads to a CONTROLLER's liability within the meaning of Art. 26 para. 3 GDPR, the CONTRACTING PARTIES agree that internally the CONTRACTING PARTY that ultimately and culpably infringed upon an obligation assigned to that CONTRACTING PARTY by ANNEX 2, shall indemnify the other CONTRACTING PARTY.

In the event that a Personal Data Breach occurs and provided that this leads to a CONTROLLER's liability, the CONTRACTING PARTIES agree that internally the party that ultimately and culpably caused and/or suffered the Personal Data Breach shall indemnify the other party.

If the CONTRACTING PARTIES in relation to the processing operations described in ANNEX 1 have agreed on certain implementation, processes or relevant documents or if these have been approved by the CONTRACTING PARTIES, the CONTRACTING PARTIES are jointly and severally liable for any damages incurred with regard to violations of the GDPR in this respect.

9. Termination

Prior to the termination of the underlying cooperation, the CONTRACTING PARTIES must determine who and to what extent shall be responsible for the personal data. If desired and legitimate, the other CONTROLLER to this AGREEMENT shall provide the possibility to continue to use the data on their own systems, provided that the data will be processed in strict compliance with the GDPR and any other applicable laws.

Any change in the distribution of responsibility shall be communicated to the data subjects in accordance with the obligations set out in ANNEX 2.

10. Final Provisions

Should the property of a CONTRACTING PARTY be endangered by measures of third parties (such as seizure or confiscation), by insolvency proceedings or by other events, this CONTROLLER must notify the other responsible party promptly.

This AGREEMENT requires the written or the electronic form to be effective. This also applies to any changes or amendments to this AGREEMENT as well as to any side and / or ancillary provisions.

Should individual parts of this AGREEMENT be ineffective, invalid or not applicable, this shall not affect the validity of the rest of the AGREEMENT.

ANNEX 1: Processing of Personal Data under Joint Controllership

Table 1: Promotional activities (including setting up and reporting on contact objectives)

Subject of Processing	Promoting XIFAXAN in Germany Alfasigma and Norgine will share targeted Health Care Professionals' (HCP) personal data. The information will be stored in the parties' respective CRMs (TrueBlue and Veeva). Both parties will use the contact details to contact their respective assigned HCPs via agreed communication channels (in person meetings, email, phone, etc.) to promote the XIFAXAN® product. Both Parties will report to each other on their achievement of their assigned contact objectives. The exchange of personal data of HCPs at congresses within the joint teams working on XIFAXAN® also forms part of this activity and is included here.
Type and Purpose of Processing	The parties will collect, transmit, organize, store and erase personal data for the purpose of promoting the product XIFAXAN®, including setting up and reporting on contact objectives.
Categories of Personal Data	First name, surname; address, telephone number; fax; email address; function; hospital/clinic; Veeva "network ID"; specialty; physician registration number; number of years in practice; specific product interests; HCP level of adherence with respect to the product; questions/comments raised in meetings; dates and number of interactions and future interactions planned (meetings online and in-person, phone calls, emails, etc.).
Categories of Data Subjects	Health Care Professionals (physicians, pharmacists, nurses) in Germany
Description of the actual roles and relationships between the Joint-Controllers	Initially, Norgine will provide target HCPs databases to Alfasigma for the promotion of XIFAXAN®. As the collaboration progresses, Norgine and Alfasigma will determine which HCPs will be contacted by which party, the contact frequency and each party will report to the other on their respective contacts. Personal data deriving from the interaction of both Alfasigma and Norgine with HCPs will be exchanged by both parties (data flows in both directions).

Table 2: Scientific and PR Activities

Subject of Processing	Promotion of XIFAXAN in Germany. In the case of scientific and PR activities (e.g. advisory boards, scientific articles, congresses), Alfasigma and Norgine will share HCPs personal data. The information will be stored in the respective existing CRMs (TrueBlue and Veeva). Both partners will use the contact details to contact participants via different agreed communication channels (in person meetings, email and phone) to: - Invite HCPs to attend or speak at events; - Invite HCPs to contribute/participate in advisory boards; - Collect relevant information to draft scientific articles; - ...
Type and Purpose of Processing	The parties will collect, transmit, organize, store and erase personal data for the purpose of scientific and PR activities of the product XIFAXAN®.
Categories of Personal Data	First name, surname; address, telephone number; fax; email address; function; hospital/clinic; specialty; specific product interests, questions/comments raised in meetings; dates of interactions (meetings, phone calls, emails); participation to events (e.g. attendance, guest-speaker, member of an advisory board)
Categories of Data Subjects	Health Care Professionals (physicians, pharmacists, nurses) in Germany.
Description of the actual roles and relationships between the Joint-Controllers	Norgine and Alfasigma will determine and conduct the scientific and PR activities jointly.

ANNEX 2: Allocation of obligations and responsibilities

An 'x' signifies which Controller assumes which obligation and / or responsibility.

GDPR Obligation	CONTROLLER A	CONTROLLER B	NOTES
	Norgine	Alfasigma	
Determination of purpose and means of personal data processing	x	x	
Determination of categories of personal data	x	x	
Art. 26 para. 2: Information of the data subjects on material contents of this AGREEMENT	x	x	Each CONTRACTING PARTY will be responsible to inform its respective assigned HCPs
Art. 13: Information to be provided where personal data are collected from the data subject	x	x	Each CONTRACTING PARTY will be responsible to inform its respective assigned HCPs
Art. 14: Information to be provided where personal data have not been obtained from the data subject	x	x	Each CONTRACTING PARTY will be responsible to inform its respective assigned HCPs
Art. 15: Complying with the right of access	x	x	Each CONTRACTING PARTY will comply with the right of access with regard to its respective assigned HCPs – the CONTRACTING PARTY receiving the request of exercising rights will inform the other CONTRACTING PARTY without undue delay
Art. 16: Managing the right to rectification	x	x	Each CONTRACTING PARTY will comply with the right to rectification with regard to its respective assigned HCPs – the CONTRACTING PARTY receiving the request of exercising rights will inform the other CONTRACTING PARTY without undue delay
Art. 17,18, 19: Processing of data erasure requests, restriction of processing and communication of the duty to erasure	x	x	Each CONTRACTING PARTY will comply with the rights provided for by Articles 17, 18, and 19 GDPR with regard to its respective assigned HCPs – the CONTRACTING PARTY receiving the request of exercising rights will inform the other CONTRACTING PARTY without undue delay
Art. 20: Managing the right to data portability (if applicable)	x	x	Each CONTRACTING PARTY will comply with the right to data portability with regard to its respective assigned HCPs – the CONTRACTING PARTY receiving the request of exercising rights will inform the

			other CONTRACTING PARTY without undue delay
Art. 21: Complying with the right to object	x	x	Each CONTRACTING PARTY will comply with the right to object with regard to its respective assigned HCPs – the CONTRACTING PARTY receiving the request of exercising rights will inform the other CONTRACTING PARTY without undue delay
Art. 24, 32, 35, 36: Determination and documentation of technical and organizational measures, risk assessment, if required personal data impact assessments and consultation with supervisory authorities	x	x	In case of possible consultation under Article 36 GDPR, both CONTRACTING PARTIES will jointly determine the content, timing, and ways for contacting the competent Supervisory Authority
Art. 28: Employing and auditing of processors and sub-processors	x	x	
Art. 30 Maintaining ROPAs (records of processing activities)	x	x	
Art. 33, 34: Data Breach communications	x	x	The CONTRACTING PARTY that ultimately and culpably caused and/or suffered the Personal Data Breach shall be responsible to comply with Articles 33 and 34 (notification to the supervisory authority and communication to data subjects).