

contract

between

Refdata Services GmbH, Baarerstrasse 2, 6300 Zug (hereinafter referred to as "RDS")

and

Company, address, postcode, town

GLN:

(hereinafter referred to as "Company")

Regarding the digital management and publication of technical and patient information/package inserts for human and veterinary medicinal products. This agreement also covers the digital management and publication of information relating to non-pharmaceutical items.

Preamble

The Refdata Foundation was established with the aim of ensuring the referencing of partners and products in the Swiss healthcare system. Since 1 January 2019, it has also been entrusted with the publication of professional information, patient information and package inserts, as well as structured medicinal product information on human and veterinary medicinal products, in accordance with Art. 67 para. 3–8 of the Therapeutic Products Act (TPA; SR 812.21).

The foundation thus ensures a central basis for the availability and marketing of these products on the Swiss market. It has transferred the operation of the systems used for this purpose and the administration of the underlying databases to its subsidiary Refdata Services GmbH.

1 Subject matter of the contract

This contract governs the business relationship between RDS and the company regarding the use of the www.simisinfo.ch platform, which is operated by RDS. Via www.simisinfo.ch, RDS provides a modular application landscape that enables marketing authorisation holders to fulfil their regulatory obligations under Swiss therapeutic products legislation.

The company can use the relevant modules on www.simisinfo.ch to independently record and manage human and veterinary medicinal products as well as non-pharmaceutical items and have this data published.

2. Services

RDS operates an integrated platform at www.simisinfo.ch for referencing, managing and publishing data on human and veterinary medicinal products and non-pharmaceutical products (hereinafter referred to as "ARTICLES"). The platform consists of several functional modules and enables the company to independently record and maintain data that is relevant for regulatory and commercial purposes and to release it for electronic publication.

To publish this data, RDS also operates various websites on which user-oriented content is published. In addition, RDS regularly provides digital content in the form of downloadable files. These files are used for further processing and support the interoperability and digitalisation of the supply chain – from product completion to delivery or sale to patients or customers.

2.1 Modules on www.simisinfo.ch

The modules available at www.simisinfo.ch and a brief description of their respective services and functionalities are listed in Appendix 2.1. The list may change over time in terms of functionality, scope and content due to regulatory or technical requirements; provided that this does not result in any change in costs for the company, there shall be no entitlement to a contract adjustment.

2.2 Publication websites

The websites for the publication of regulatory and commercially relevant data are listed in Appendix 2.2. The list may change over time in terms of functionality, scope and content due to regulatory or technical requirements; provided that this does not result in any change in costs for the company, there shall be no claims for a contract adjustment.

2.3 Provision of digital files

The downloadable files published by RDS, including their content, file formats and update frequency, are listed in Appendix 2.3. The list may change over time in terms of functionality, scope and content due to regulatory or technical requirements; provided that this does not result in any change in costs for the company, there shall be no claims for a contract adjustment.

2.4 Operation

RDS may commission third parties to perform the services specified in section 2.

2.5 User support

RDS provides the company with tiered support for the use of the services described in section 2:

- User support (1st and 2nd level support) is provided by RDS during normal office hours, Monday to Friday from 8 a.m. to 12 p.m. and 2 p.m. to 5 p.m. (except public holidays at the RDS headquarters). Contact can be made by telephone or email via the contact channels published at www.refdata.ch.
- Technical and infrastructure support (third-level support) is outsourced to specialised third-party providers. RDS coordinates and escalates technical enquiries to third parties.

RDS endeavours to remedy operational disruptions to the platforms and services as quickly as possible. There is no entitlement to uninterrupted availability or to rectification within specific response times.

3. Liability and warranty

The company is solely responsible for the content and data (including specialist and patient information, structured information and product master data) recorded in the modules at www.simisinfo.ch and released for publication. This applies in particular to their accuracy, completeness, timeliness and compliance with legal and regulatory requirements.

RDS accepts no responsibility for the factual or legal accuracy of the information provided by the company. RDS does not check this content.

RDS is only liable for damages caused by intentional or grossly negligent behaviour. Any further liability, in particular for indirect damages, consequential damages, data loss or loss of profit, is excluded to the extent permitted by law.

4 Annual fee

4.1 Composition

owes RDS an annual fee for the services described in section 2, in particular the use of www.simisinfo.ch-Module for referencing, managing and publishing article data, the provision of publication websites, the provision of downloadable files and the provision of support services. The annual fee is calculated in accordance with Appendix 1.

4.2 Self-declaration

The company undertakes to report the applicable sales category to RDS by 31 January of each calendar year by means of a self-declaration in accordance with Appendix 1. RDS is

entitled to verify the reported information using, for example, IQVIA data, and reserves the right to make a retroactive contribution correction in the event of discrepancies.

The cut-off date for determining the number of referenced articles in the article ref database is 31 December. The company can update the trade status of medicinal products and non-pharmaceutical articles at any time independently via the Article module at www.simisinfo.ch.

4.3 Terms of payment

The annual contribution is invoiced in the first quarter of each year. The invoice is due within 30 days of receipt and is payable without any deductions. Unless otherwise notified by the company, an invoice is deemed to have been accepted after the payment deadline has expired. If full payment is not made within the payment deadline, the company shall be in default of payment without a reminder and RDS may charge statutory default interest.

4.4 Tariff adjustment

RDS is entitled to adjust the contribution rate (Appendix 1) with effect from the beginning of a calendar year, subject to a notice period of at least 3 (three) months. In this case, the company is entitled to terminate this contract in writing within a period of 1 (one) month from receipt of the notification of the tariff change, with effect from the date on which the new tariff comes into force.

5. Contact

The company shall appoint a contact person (SPOC), a company administrator (for www.simisinfo.ch) and a contact person for receiving the invoice for the annual membership fee, and shall complete the forms in Appendix 3 for this purpose.

Any changes to the contact persons shall be reported to RDS without delay.

6. Contract term, ordinary and extraordinary termination

This contract shall enter into force upon signature by the parties for an indefinite period. Each party shall be entitled to terminate the contract in writing at the end of a calendar year, subject to a notice period of 3 (three) months, otherwise it shall be extended for a further 1 (one) calendar year. The right to extraordinary termination is reserved.

6.1 Consequences of termination of the contract

Upon termination of this contract – for whatever reason – the company shall lose access to all modules, as specified in Appendix 2, on www.simisinfo.ch after the notice period. At the same time, the right to use the prefix 7680 shall expire. In this context, particular attention shall be paid to Appendix 1, Point 4. Special provisions for GTINs with the prefix "7680".

6.2 Publication obligations on AIPS and SAI platforms

Regardless of the termination of the contract, the company shall continue to be obliged to comply with the statutory publication requirements, e.g. regarding specialist and patient information or package inserts, as well as structured drug information.

The company shall continue to bear the occasional costs and contributions incurred for these services in accordance with the applicable contribution tariff (see Appendix 1) even after termination of the contract.

7. Final provisions, integral parts of the contract, written form

This contract and its annexes conclusively regulate the rights and obligations of the parties in connection with the services described in point 2. If further services and/or contract amendments are agreed subsequently, these shall be regulated by the parties in the relevant annex to this contract. Any amendments and additions to this contract must be made in writing and signed by both parties. Terminations must be made by registered letter.

8. Partial invalidity

Should any provision of this contract and/or an appendix be or become invalid or legally ineffective, the contract and/or the appendices shall continue to apply and the invalid or legally ineffective provision shall be replaced by a provision that comes as close as possible to the economic purpose of the original provision.

9. Entry into force, applicable law and place of jurisdiction

This agreement shall enter into force upon signature by the company. Substantive Swiss law shall apply, excluding international private law. The place of jurisdiction shall be the domicile of RDS.

10. Annexes

The following appendices form an integral part of this contract:

- **Annex 1:** Annual contributions
- **Appendix 2:** Services
- **Appendix 3:** Company contacts

11. Signatures

Refdata Services GmbH

Zug,

President

Managing Director

Company

Place, date: _____