



NOTFALL/URGENCE 145

TEL +41 44 251 66 66

E-MAIL info@toxinfo.ch
INTERNET www.toxinfo.ch

Services Agreement

between

Tox Info Suisse, Freiestrasse 16, CH-8032 Zürich

(hereinafter referred to as "Tox Info Suisse")

and

CompanyX, Street, CH-XXXX Place

(hereinafter referred to as "CompanyX")

Tox Info Suisse together with CompanyX are hereinafter referred to as the "Parties".

WHEREAS CompanyX is a [Swiss (subsidiary of a)] pharmaceutical company and wishes to procure the services of a callcenter for emergency calls outside of regular office hours

WHEREAS Tox Info Suisse has special expertise and a long-standing experience in providing such services and is willing to render the same on the terms and conditions as set forth below

NOW THEREFORE, the Parties agree as follows:

1. Services

- 1.1. Receipt and forwarding the documentation of all calls that are coming in via CompanyX's phone number at Tox Info Suisse outside of office hours. This includes but is not limited to medical emergencies and adverse drug reactions of CompanyX's products. For a definition of adverse drug reactions see Appendix x.
- 1.2. CompanyX's office hours are Monday to Friday xx:xx a.m. to xx:xx p.m., with the exception of legal holidays in Switzerland and local holidays in the Canton of xxx.
- 1.3. After this agreement takes effect, an announcement text (according to Appendix x) shall be communicated on the answering machine of CompanyX's (central) telephone number (according to Appendix x).
- 1.4. The product information ("Fachinformation") of all CompanyX products is published on www.swissmedicinfo.ch. For products not listed with Swissmedic: If CompanyX requires Tox Info Suisse to give callers more detailed information about these products, Tox Info Suisse must have access to CompanyX's product database (preferred) or receive this information separately from CompanyX.
- 1.5. Tox Info Suisse shall provide the services in German, French and English.







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1.6. Tox Info Suisse shall document the questions within their internal electronic database according to their internal standard. Tox Info Suisse archives these documents for the minimum duration of 20 years.

1.7. Reporting to CompanyX (please choose from the following options):

• Tox Info Suisse shall be responsible for documenting and forwarding all inquiries (with a medical scope) within 1 business day of initial receipt date

or

- Tox Info Suisse shall be responsible for documenting and forwarding all inquiries (with a medical scope) within 24 hours of initial receipt date, independent of weekends and public holidays.
- All reports shall include a Tox Info Suisse ID, the date and time, name and telephone number of the caller, the product involved, and the description of the issue/question as well as the answer given. If applicable the patient's initials, age and gender are included in the report as well. CompanyX will confirm the receipt of each report.
- In case of inquiries with a scope not relating to a Medical emergency or inquiry, an
 Adverse Drug Reaction or a technical complaint, Tox Info Suisse advises the caller to
 contact CompanyX during business hours and writes a short internal memorandum
 ("Aktennotiz"). Examples of such requests may be "ordering of promotional
 material", "requests regarding product orders", "desire to be connected to someone
 at CompanyX" etc.
- Test calls performed by CompanyX are considered as regular calls with respective reporting duties or internal memoranda.
- Reconciliation shall be performed on a monthly basis between the Parties. Tox Info
 Suisse shall provide a list of all inquiries received (incl./excl. the internal
 memoranda) within the first ten business days of the following month. If no inquiries
 have been received, this shall also be confirmed.
- 1.8. CompanyX shall be responsible for confirming, triaging and checking the received information for pharmacovigilance reports. The forwarding of relevant information according to the Swiss Therapeutic Products Act ("Heilmittelgesetz") and the Reporting Standards for Adverse Events of Swissmedic is within the responsibility of CompanyX.

2. Training [only if required by CompanyX]

- 2.1. CompanyX will provide annual training to Tox Info Suisse to enable its personnel to comply with the provisions of this Agreement. The training may be conducted by providing slides or in person, as deemed appropriate.
- 2.2. Trainings shall be announced and will be performed within a timeframe of 2 months (not sooner).

Kommentiert [AD1]: Easiest option: whatever happens, you'll get the information the next business day. Please bear in mind that in case of Easter this could take 5 days. E.g. someone calls on Thursday before Good Friday at 6:30 pm and we will write to you on Tuesday after Easter Monday.

Kommentiert [AD2]: Choose this bracket only if you choose

Kommentiert [AD3]: If you require information very fast, i.e. within 24 hours no matter what, please choose this option. Please bear in mind that this comes at an additional cost.

Kommentiert [AD4]: Choose this bracket only if you choose "Aktennotiz" further below

Kommentiert [AD5]: Please choose this if you choose the option "Aktennotiz". Please also indicate how you want the test calls to be treated.

Kommentiert [AD6]: Choose this if you need test calls to be reported by email within the above described timeline.

Kommentiert [AD7]: Choose this if a "Aktennotiz" is sufficient

Kommentiert [AD8]: Choose this only if you chose "Aktennotiz" further above

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3. Legal and regulatory requirements

3.1. CompanyX personnel as well as the competent authorities of the territories where CompanyX's products are being marketed have the right to audit Tox Info Suisse for matters relevant for this contract.

- 3.2. CompanyX shall give at least 6 weeks prior written notice to Tox Info Suisse of its intention to audit or if the respective department at CompanyX is being audited and Tox Info Suisse needs to be available for answering questions. In case one of these activities has to be performed at a shorter notice, an extra fee of up to CHF 500 applies. Tox Info Suisse may determine the exact amount based on the additional effort Tox Info Suisse was experiencing.
- 3.3. The Parties undertake not to disclose to outside parties any non-public business and trade secrets that become known to them during the term of the agreement. The confidentiality obligation regarding business and trade secrets shall remain in effect after the termination of the contractual relationship. Personal data in particular may not be transferred to third parties.

4. Compensation

- 4.1. The services provided by Tox Info Suisse shall be compensated with CHF xxx plus VAT per year. This amount is calculated as follows and may be adapted according to the model if the number of calls varies significantly in a given year: (see separate Excel with module-based fee calculation which will be inserted here once agreed-upon).
- 4.2. Tox Info Suisse shall bill the annual fee in January of every year. CompanyX will pay such invoice within thirty (30) days from the date of receipt of the invoice. If a contract starts during the year or if there are changes to the contract, the fee will be billed pro rata temporis within thirty (30) days after signing.
- 4.3. Additional fees (1): Planned test calls, additional coverage days, calls during office hours, additional instructions to answering calls (list is not exhaustive) which are not included within the above pricing model, will be billed separately.
- 4.4. Additional fees (2): If Tox Info Suisse is required to perform work which is not outlined in paragraph 1 ("Services"), e.g. audits, inspections, analyses or additional documents (e.g. adaptation of existing SOPs) requested by CompanyX or other additional administrative effort (list is not exhaustive), the effective hours spent by Tox Info Suisse are charged for CHF 250/ hour (excl. VAT). In case of an audit, CompanyX pays the costs for the auditor and Tox Info Suisse's preparation, execution of the audit and the administrative work to set up a corrective and preventive action plan. The remediation of potential issues of the Quality System of Tox Info Suisse, identified in the audit, needs to be paid by Tox Info Suisse. In all above-mentioned cases, the additional costs to be covered by CompanyX must be discussed and agreed between CompanyX and Tox Info Suisse before any of the above activities start.
- 4.5. Fees as described in 4.3 and 4.4. shall be billed each time, within reasonable time after incurrence of the activity.





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5. Effective date, term and termination

- 5.1. The Service Agreement shall take effect on xx. Month 20xx ("Effective Date").
- 5.2. This agreement shall be concluded for an unlimited period.
- 5.3. The agreement may be terminated to the end of each calendar year by giving three months written notice.
- 5.4. Any changes of this Agreement and the Services shall only be effective after a written change order was signed by both parties.

6. Miscellaneous

- 6.1. Tox Info Suisse hereby confirms to hold the required infrastructure, human resources and medical-scientific knowledge to fulfil the requirements for providing the Services of this section.
- 6.2. Any liability claims of the contracting party or third parties against Tox Info Suisse that are based on notifications made by Tox Info Suisse on the basis of the information about the corresponding product provided by the contracting party shall be excluded and shall be borne in full by the contracting party insofar as there is no fault or gross negligence on the part of Tox Info Suisse.
- 6.3. **Entire Agreement.** This Agreement represents the entire agreement and understanding between the Parties relating to the subject matter of this Agreement, and supersedes all documents or verbal consents or understandings (if any) given or made between the Parties prior to the date of this Agreement. None of the terms of this Agreement may be amended or modified except by an instrument in writing signed by authorized representatives of the Parties
- 6.4. **Applicable law, Venue.** This Agreement shall be construed in accordance with, and governed by, the laws of Switzerland, without regard to the conflicts of law provisions. Any dispute arising out of this Agreement shall be submitted exclusively to the competent courts of Zurich, Switzerland, without restricting any rights of appeal.
- 6.5. **Force Majeure.** Neither Party shall be liable to the other Party for any failure to perform any obligation on its part hereunder to the extent that such failure is due to circumstances beyond its control which it could not have avoided by the exercise of reasonable diligence. The affected Party shall however notify the other Party as soon as practicable of the occurrence of any such circumstance, and the Parties shall meet to consider what steps, if any, can be taken to overcome any issues.
- 6.6. **Appendixes.** All Appendixes to this Agreement shall form an integral part of this Agreement. With regard to any conflict between the terms of such Appendixes and the terms of this Agreement, this Agreement shall govern.





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Damaris Ammann Name
General Manager Function

Dr. Cornelia Reichert Name
Head Physician Function

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APPENDIX 1: Telephone Numbers

The telephone number of CompanyX from where calls are forwarded to Tox Info Suisse is: Oxx xxx xx xx

The telephone number of Tox Info Suisse to where the calls originating from CompanyX are forwarded to Tox Info Suisse is 043 xxx xx xx.





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APPENDIX 2: Wording of the Announcement Text at CompanyX

The following announcement text shall be communicated on CompanyX's answering machine (example):

"If you require information about medical emergencies or wish to report an undesired effect or quality defect of a CompanyX product, we can connect you to Tox Info Suisse, the national poisons information center. Please note that such calls will be recorded. Please press $\frac{\mathbf{x}}{\mathbf{x}}$ to be connected".

"If you require information about urgent medical emergencies or wish to report an undesired effect or quality defect of a CompanyX product, please call Tox Info Suisse, the national poisons information center at 043 xxx xx xx. Please note that such calls will be recorded".





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APPENDIX 3: Contact List and Emergency Contact List

2-3 contacts from CompanyX incl. email address for reports

Tox Info Suisse:

Correspondance with regards to this Service Agreement:
Damaris Ammann
Tox Info Suisse
Freiestrasse 16
CH-8032 Zurich
+41 44 251 66 66
+41 78 712 20 50
Damaris.Ammann@toxinfo.ch

Deputy contact person:
Cornelia Reichert
Tox Info Suisse
Freiestrasse 16
CH-8032 Zurich
+41 44 251 66 66
+41 79 213 01 51
Cornelia.Reichert@toxinfo.ch

All administrative questions and matters should be directed to: firmen@toxinfo.ch.

Additional email address in case of emergencies: info@toxinfo.ch, 044 251 51 51

Confirmation of call reporting and reconciliation has to be sent to the email addresses contained within the original email (i.e. "from" and "cc").





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APPENDIX 4: Definition of Adverse Drug Reactions

CompanyX may fill in their definition here. Alternatively, if this section is not required, leave it

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