Contract

This contract is concluded between:

XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXX

- hereinafter referred to as "Supplier" -

and

Informationsstelle für Arzneispezialitäten
IFA GmbH
Hamburger Allee 26 – 28
60486 Frankfurt

- hereinafter referred to as "IFA GmbH" -

Preamble

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IFA GmbH is a clearing house for the pharmaceutical industry, pharmaceutical wholesale trade and pharmacies in the Federal Republic of Germany. The role of the IFA GmbH is to gather information about medicinal and pharmacy typical products, to keep this data current and to support the market participants in the fulfillment of their legal obligations in particular resulting from the German Medicinal Products Act (AMG), the Pharmaceuticals Price Ordinance (AMPreisV) in the relevant versions, the German Medical Devices Act (MPG), the Packing Size Regulation (PackungsV), the Dietary Supplement Ordinance (DiätV) and the German Social Code Book Five (SGB V), and additionally to support the optimization of distribution chain logistics. It fulfills this role mainly through the assignment of PZN Codes (Pharmazentralnummern) and the exchange of information between all levels of distribution. IFA GmbH supports market participants through the control of price ranges for medicinal products subject to the Pharmaceuticals Price Ordinance (AMPreisV). ABDATA Pharma-DatenService (ABDATA), a business branch of Avoxa – Mediengruppe Deutscher Apotheker GmbH, is contracted to perform certain tasks, e.g. the assessment of the pharmaceutical data provided by the Supplier.

§ 1 Purpose

The purpose of this contract is to include medicinal products within the meaning of § 2 German Medicinal Products Act (AMG) or pharmacy typical products in accordance with the German Ordinance on Pharmacy Business (ApBetrO), hereafter referred to as “product” from the Supplier in the IFA-database together with product description, the assignment of PZN Codes (Pharmazentralnummern) as well as the publication of data in the form of periodic information services. The product description includes legal, economic and pharmaceutical details.

§ 2 Applicability

The legal relationship between IFA GmbH and the "Supplier is laid-down in this contract. Any Suppliers General Terms and Conditions do not apply. In case that this contract does not contain rules, the general law shall apply.

§ 3 PZN Code (Pharmazentralnummer)

The IFA GmbH shall assign a PZN Code (Pharmazentralnummer) for all products which have been duly notified to it and at the time of notification are approved or registered in the Federal Republic of Germany as finished medicinal products (§ 2 German Medicinal Products Act) and pharmacy typical products (according to the German Ordinance on Pharmacy Business) with the respectively valid guidelines for the allocation of a PZN Code which the Supplier recognizes with the signing of this contract. The PZN Code uniquely defines a specific product of a specific Supplier (manufacturer, distributor, for medicinal products: pharmaceutical entrepreneur or its local representative in accordance with § 9 paragraph 2 German Medicinal Products Act) together with other product identifying characteristics, in particular package size (commercial form) and pharmaceutical form.

§ 4 IFA Database

(1) All products duly notified to IFA GmbH will be included in the IFA Database with the selected product descriptive information. Product change orders are accepted continuously. The data reported to IFA GmbH will be automatically captured, processed and transmitted to authorized recipients. Upon Supplier's request, access to data stored about the Supplier and its products will be provided.

(2) The IFA GmbH may in duly justified cases, in particular by amendments of laws or regulations, require additional product specific or other information. If a Supplier does not wish to fulfill this request, the Supplier can terminate this contract with immediate effect.

(3) The IFA GmbH is entitled to use the information provided by the Supplier, taking a blocking period into account if applicable, independent of time and place and to use the information unrestrictedly in all ways. This right is not exclusive and can be assigned by IFA GmbH to third parties.

(4) The IFA GmbH will only use the Supplier's personal data within the limits of this contract and will not allow access to unauthorized individuals. The IFA GmbH will make every reasonable effort to employ the technical possibilities to guarantee data protection.

§ 5 Pharmaceutical Assessment

(1) ABDATA carries out the assessment of the pharmaceutical data provided by the Supplier and where necessary completes it with further pharmaceutical information. The assessment includes the compliance with the law and regulations, inter alia AMG, MPG, ApBetrO and SGB V. For this purpose, IFA GmbH is authorized to provide ABDATA with data and documentation handed in by the Supplier.

(2) These assessment is no service which is an obligation resulting from this contract. IFA GmbH and ABDATA therefore do not assume any liability or warranty for the outcome of the assessments.

(3) Should the assessment of the reported pharmaceutical data be inaccurate according to § 5 Abs. 1, IFA GmbH can, after informing the Supplier, correct them. The Supplier can object to the corrections. If the Supplier objects to the corrections, IFA GmbH can refrain from publishing the product in dispute until an amicable settlement has been reached.

§ 6 Plausibility Check and Price Calculation

(1) The product data reported by the Supplier will be generally checked for plausibility.

(2) IFA GmbH assumes that the Supplier fully complies with the legal and actual requirements for the marketing and distribution of the reported product.

(3) For medicinal products subject to the Pharmaceuticals Price Ordinance (AMPreisV), IFA GmbH will use the Supplier's reported distribution price according to § 78 paragraph 3 AMG (ApU) to verify the Pharmacy Purchase Price (excluding VAT) and Pharmacy Retail Price (including VAT) based on the pharmacy mark-up in accordance with the relevant version of the Pharmaceuticals Price Ordinance (AMPreisV).

(4) In case these checks reveal any obstacle to the publication of the data submitted by the Supplier, IFA shall inform the Supplier immediately thereof.

§ 7 Responsibilities of the Supplier

(1) The Supplier is solely responsible to ensure that all legal and actual requirements for the marketing and distribution of the submitted product are fulfilled and has to provide to IFA GmbH, prior to the launch of a product, full information about the product and its specific features in the respective IFA GmbH data structure. The Supplier must provide the following proof:

- for pharmacy-only medicinal products the SPC – summary of product characteristics, for other medicinal products the package leaflet (Information for the user) and for other products the production information leaflet;
- for medicinal products which have to be authorized or registered, a copy of the accompanying approval letter from the appropriate approval or registering authority;
- by the application for additional medicinal products during the period of patent protection, the agreement of the patent owner.

In case that one or more of these elements is not submitted or the documentation is not provided, there is no claim to have the product data published. If unclear declarations or documentation are submitted or provided which are open to interpretation or doubt and is checked by IFA GmbH, the Supplier is obliged to indemnify IFA GmbH for the resulting additional processing work.

(2) Changes to the product specifying information, in particular in pricing or distribution or the discontinuance of sale should be reported to IFA GmbH with the PZN Code and the appropriate valid data structure in sufficient time before the changes take effect.

(3) The Supplier informs the IFA GmbH immediately if the Supplier knows that details of one or more of its products in the IFA database needs or will need correction. Similarly, the Supplier shall inform IFA GmbH without delay if the requirements for inclusion of one or more of its products in the IFA database is not or will not be fulfilled.

(4) The Supplier warrants and is liable to the IFA GmbH that the details it provides are complete and correct and all legal and statutory requirements are fulfilled e.g. AMG, AMPreisV, SGB V, NemV, DiätV and MPG. It is obliged to indemnifiy IFA GmbH against liabilities which could occur for IFA GmbH through incomplete, inaccurate or for legal purposes insufficient details.

(5) Without limiting the responsibility of the Supplier, IFA GmbH reserves the right, after informing the Supplier, to correct any submitted incorrect data. § 5 paragraph 3 applies analogously.

(6) The Supplier is liable for marketing of notified products in the Federal Republic of Germany does not infringe third party property rights. The Supplier shall indemnify IFA GmbH against claims asserted by third parties because one of the Supplier’s notified products may not be marketed in the Federal Republic of Germany.

(7) In case that IFA GmbH receives an indication from an appropriate authority that a product notified by a Supplier may not be marketed in the Federal Republic of Germany, IFA GmbH can require a written assurance from

the Supplier within a reasonable time period set by IFA GmbH that the product is marketable in the Federal Republic of Germany. Additionally, IFA GmbH can request a declaration from the Supplier indemnifying IFA GmbH from costs and liabilities which could arise from the notified product appearing in the IFA database as marketable. If the authority should issue a decision, subject to appeal, that the product may not be marketed in Federal Republic of Germany and the Supplier is not prepared to provide the indemnity declaration mentioned above, IFA GmbH may mark the product clarified with a corresponding explanation. Should IFA GmbH receive a non-appealable or an immediately enforceable decision from the competent authority that the product is non-marketable in the Federal Republic of Germany, IFA GmbH can without the consent of the Supplier mark the product as nonmarketable.

§ 8 Publication Calendar

(1) For data publication in the particular IFA Information Services, appropriate deadlines stated in the publication calendar, acknowledged by the Supplier in signing this contract, shall apply. The deadlines in the publication calendar apply analogously also in case of an objection of the Supplier against a planned correction of the data provided by the Supplier (§ 5 para. 3 and § 7 para. 6). The publication calendar will be sent to the Suppliers annually and in due time.

(2) In order to avoid bottlenecks, the Supplier is required to submit orders for first publications and changes as early as possible and legally permissible. The terms for placing an order shall apply. In this regard, the appropriate IFA files, forms and information provided by IFA GmbH are to be followed.

(3) IFA GmbH is not obliged to notify the Supplier of late receipt of data submitted.

§ 9 Communication with IFA GmbH

(1) For the transfer of orders the Supplier must use the appropriate specified data structure provided by IFA GmbH for the respective form of communication. The data structure for orders submitted in written form is determined by the corresponding valid order form. When submitting the order as electronic file, the Supplier must use the predefined data storage medium and file format as defined by IFA GmbH. IFA GmbH may, with suitable notice and appropriate deadline, change the data structure as well as the data storage medium and file format. Binding are the appropriate current and valid information documents, files, forms and guidelines e.g. the guidelines for the allocation of the PZN Code (Pharmazentralnummer), the guidelines for notification of product and address data, the guidelines for current product status and change of status, as well as the current valid price list. Full information is available on the IFA website http://www.ifaffm.de.

(2) Orders for the first publication and allocation of a PZN Code (Pharmazentralnummer), as well as changing descriptive information of a product, must be carried out by the Supplier by one of the following means. Wherever possible use communication form a):

a) sending an order processing request by email;
b) sending an order processing request with a data storage device;
c) written order submission (letter, fax).

(3) The guidelines for notification of product and address data apply to orders sent by email.

IFA GmbH is not responsible for delays or any other possible adverse effects concerning the submission of emails. The Supplier must not misuse the possibility of electronic communication with IFA GmbH. It must refrain from any communication contrary to this agreement. IFA GmbH does not guarantee that the internet server will be available and operational at all times. IFA GmbH will in each individual case exploit all existing possibilities to take into account notifications for the current updating of its information service which have been delayed solely by the failure of its internet server.

(4) IFA GmbH confirms the Supplier the processing of the notified product changes with an order confirmation. Upon request it will put at the Supplier's disposal certain messages or data in particular its assortment data by email.

§ 10 Periodic Information Services

(1) IFA GmbH maintains, for those in § 11 mentioned authorized recipients, regular information services with which, based on contractual agreements, the recipients can be provided with information from the IFA database, selected according to content, size and period. Concomitance and uniformity are of great importance here.

(2) Notified first publications and changes will be included in the next available information service taking account of the deadline stated in the publication calendar. Earmarked notifications will be considered on schedule.

(3) Where prices are notified in the information services for products that are not subject to the Pharmaceuticals Price Ordinance (AMPreisV) or other price commitments, the final selling price is the recommended retail price.

§ 11 Authorized Recipients

(1) Authorized Recipients of the periodic information services are:

- suppliers of medicinal products and/or pharmacy typical products;
- pharmaceutical wholesalers;
- pharmacies (via ABDATA).

(2) IFA GmbH can include other persons or institutions into the group of authorized Recipients, e.g.:

- physicians/doctors;
- statutory health insurance organizations or private health insurance companies;
- as well as their corresponding associations if they can demonstrate a legitimate interest.

§ 12 Conditions for transfer of data

(1) If IFA GmbH should provide access to the IFA database to third parties apart from the PZN Code (Pharmazentralnummer) and information provided to it in Suppliers' documentation, then IFA GmbH will require the third parties contractually to:

- only use the data provided to it by IFA GmbH from the IFA database and information from the Suppliers' documentation in accordance with validity dates and possible blocking restrictions as well as, if applicable, provisions of the German Federal Data Protection Act;
- to use the information in the Suppliers' documentation either unchanged or only with changes permitted by the Supplier;
- to carry out additions with agreement of the IFA GmbH only;
- to publish additional, product-comparing statements, in particular about the bio equivalence (with the exception of statements deriving from legal provisions or regulations) together with data from the IFA database with agreement of the IFA GmbH only.

(2) IFA GmbH will enter agreements with the third parties so that the Supplier in case of culpable violation of the above obligations can claim damages directly from the third party.

§ 13 Costs

(1) IFA GmbH charges for its services. The current valid version of the price list is relevant, available online: http://www.ifaffm.de. Suppliers will be informed in writing about changes in the price list at least four weeks prior to their effect.

(2) IFA GmbH will usually charge for its services on a quarterly basis. All prices are excluding VAT. Invoices are due for payment within two weeks of receipt, strictly nett without deductions.

§ 14 Warranty/Liability

(1) IFA GmbH warrants the correct recording, processing and storage of the data notified to it by the Supplier as well as the timely transmission of the information services to the direct customers.

(2) Incorrectly recorded, processed or stored data will be amended free of charge. Incorrectly communicated data will be amended in the next possible publication in compliance with the publication calendar at IFA GmbH's expense following IFA GmbH becoming aware of the error. Should the correction not be carried out, the Supplier may either terminate the contract or request a reduction of the charges. The Supplier is not entitled to independently amend the data with the recipients at the cost of IFA GmbH.

(3) IFA GmbH is liable -regardless of whether based on contract or law- only in cases of gross negligence or willful intent. For the absence of warranted qualities, in case of breach of contractual obligations which are strictly necessary for attainment of the contract goal (cardinal duties) as well as personal injuries, IFA GmbH is liable in the case of ordinary negligence.

(4) Any liability of IFA GmbH is limited to damage which is foreseeable by IFA GmbH. IFA GmbH is not liable for consequential or incidental damages in particular for loss of profit. The total liability of IFA GmbH for all damages arising from this contract is limited to a maximum of 5,000.00 Euro per calendar year. The exclusion of liability and the limitation of liability do not apply if legal representatives of IFA GmbH are responsible for willful intent or gross negligence. The IFA GmbH is not liable for indirect or direct damages arising from violations of Supplier's duty to cooperate, in particular non-compliance with deadlines.

§ 15 Term and Termination

(1) The contract is valid upon signature and is concluded for an undetermined period of time. Each contracting partner can give three months' written notice to the other contract partner of its termination. The right of termination for cause remains unaffected.

(2) IFA GmbH can terminate the contract for cause and delete the product data especially if the Supplier, despite warnings with deadline and threat of deletion, does not fulfill the payment demand.

(3) Upon termination of the contract, the rights and obligations which can by their nature continue after the end of the contract, in particular limitation of liability, data protection and the right of use of the data remain effective. The Supplier can however request that following termination of the contract IFA GmbH does not publish or distribute information received from the Supplier. This request shall be submitted in writing and shall be included in the termination declaration. In this case, IFA GmbH will perform deletion of the product data in the information services and in information media IFA GmbH supplies. The PZN Code (Pharmazentralnummer) for this product returns to IFA GmbH's disposal and may be reallocated.

§ 16 Final provisions

(1) This contract includes all aspects concerning the contractual relationship of the parties. Verbal agreements do not exist. Modifications and amendments to this contract must be in writing in order to be effective.

(2) The law of the Federal Republic of Germany applies. Legal venue and place of performance concerning all disputes relating this contract is Frankfurt am Main, Germany.

(3) If individual provisions of this contract are or become ineffective, this shall not affect the validity of the contract as a whole. The ineffective provision shall be replaced by an effective provision which comes closest to the purpose of the ineffective provision.