CONTRACT NUMBER

Assigned by ACS

Cooperation Agreement

As of: 10 May 2022

between

_____

[Company name]

_____

[Street]

_____

[City, Postcode]

_____ (“**Client**“)

[Country]

and

ACS PharmaProtect GmbH,
represented by its management,
Taubenstraße 20, 10117 Berlin, Germany (“**ACS**“)

Anti Counterfeit System
ACS
PharmaProtect GmbH

Table of contents

1. Preamble

1.1 In June 2011, the European Union passed the Falsified Medicines Directive. In accordance with Article 54 para. 1 of Directive 2001/83/EC, which was amended by the so-called Falsified Medicines Directive, generally, all medicinal products subject to prescription must bear safety features that facilitate specifically the identification of individual packs and the verification of their authenticity.

Based on the Falsified Medicines Directive, the European Commission passed the Delegated Regulation, which has been effective since 9 February 2019.

1.2 To implement the Falsified Medicines Directive and the Delegated Regulation in Germany, securPharm was established as the non-profit stakeholder organisation for the implementation and operation of the system for the verification of medicinal products in accordance with the requirements of the Falsified Medicines Directive and the Delegated Regulation for the protection of patients from falsified medicinal products in the legal supply chain.

The Verification System is part of the EMVS. The individual (supra)national parts of the EMVS are linked with each other via the EU Hub. The Verification System is connected with the EU Hub via the ACS MAH System.

1.3 ACS is in equal shares a company of the pharmaceutical associations BAH, BPI, Pro Generika and vfa. In accordance with this Cooperation Agreement, ACS renders services in connection with obligatory functionalities of the ACS MAH System as well as additional voluntary services.

Certain key services by ACS in accordance with this Cooperation Agreement are not rendered by ACS itself but by its Subcontractor Arvato Systems.

1.4 The Client is a Marketing Authorisation Holder or Parallel Distributor of Medicinal Products to be Verified in Germany. Pursuant to the Falsified Medicines Directive and the Delegated Regulation, Marketing Authorization Holders and Parallel Distributors must perform a variety of duties which require the Marketing Authorization Holder, respectively the Parallel Distributor, to connect to the EMVS. The EU Hub transmits in particular the Product Master Data and the Pack-related Data uploaded to the EU Hub for the Client into the ACS MAH System.

1.5 Pursuant to Art. 54a 2 (e) of the Code for Medicinal Products for Human Use and Art. 31 5 of the Delegated Regulation, the costs of the EMVS must be borne by the holders of manufacturing authorisations for medicinal products bearing the Safety Features. The EMVO and the operators of the national and supranational data repositories of the EMVS have agreed that the costs of the EU Hub will be borne by the operators of the national and supranational data repositories of the EMVS.

securPharm bills ACS for those costs of the EU Hub, which must be borne by securPharm according to the agreement with EMVO.

ACS passes on the costs for operation of the EU Hub invoiced by securPharm to its clients. These costs are part of the fee the Client must pay to ACS in accordance with this Cooperation Agreement.

1.6 In light of this background, ACS and the Client, individually also referred to as “Party” and jointly as “the Parties”, conclude this Cooperation Agreement.

2. Definitions

2.1 **ACS MAH System** means the data repository for the pharmaceutical industry in Germany, which is operated by ACS in accordance with this Cooperation Agreement in compliance with the Legal Requirements and the securPharm requirements implementing these legal requirements, and which is part of the Verification System.

2.2 **Pharmaceutical Pack** means the outer packaging of a medicinal product or, if the medicinal product has no outer packaging, the primary packaging (container).

2.3 **Pharmacy Server** means the partial system of the Verification System operated by NGDA through which in particular public pharmacies, pharmaceutical wholesalers, hospital pharmacies and other parties involved in the supply chain are connected to the Verification System.

2.4 **Arvato Systems** means Arvato Systems GmbH, Reinhard-Mohn-Straße 18, 33333 Gütersloh, Germany.

2.5 **BAH** means the Bundesverband der Arzneimittel-Hersteller e.V., Ubierstraße 71-73, 53173 Bonn, Germany.

2.6 **Processing Time** means the time period in accordance with Enclosure 4, which starts when the Response Time has ended.

2.7 **Authorised Third Parties** means legal entities named by the Client in writing to ACS which, as co-distributors of the Client, place Medicinal Products to be Verified of the Client on the market in Germany under their own name, and which have been granted individual rights of use in the ACS MAH System.

2.8 **Authority Information Portal** means the third partial system of the Verification System existing in addition to the ACS MAH System and the Pharmacy Server, in which data from the two aforementioned systems are combined and evaluated in the event of suspected falsification, and where the audit trail is created, and which, as the only interface to the authorities, provides them with processed data.

2.9 **Entitled Group Company** means, for the purpose of granting a Group Rebate, a company which is one of several Affiliated Companies and which has been determined by the other Affiliated Companies to be solely entitled to issue declarations and perform actions in connection with the ACS MAH System also for the other Affiliated Companies. The Client may, but does not have to be, the Entitled Group Company.

2.10 **BPI** means the Bundesverband der pharmazeutischen Industrie e.V., Friedrichstraße 148, 10117 Berlin, Germany.

2.11 **Data** means the entirety of Product Master Data and Pack-related Data with regard to Germany.

2.12 **Delegated Regulation** means the "Delegated Regulation (EU) 2016/161 of the European Commission of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and the Council by stipulating exact provisions regarding the safety features on the packaging of medicinal products for human use."

2.13 **GDPR** means the "Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)".

2.14 **EMVO** means the European Medicines Verification Organisation a.s.b.l., Brussels, Belgium, which operates the EU Hub.

2.15 **EMVS** means the "European Medicines Verification System", i.e. the verification system for medicinal products built and operated in accordance with Chapter VII of the Delegated Regulation. It consists of the EU Hub, the Verification System and other national and supranational data repositories in terms of Art. 32 1 (b) of the Delegated Regulation and will facilitate the verification of the authenticity of a medicinal product according to the Falsified Medicines Directive and the Delegated Regulation, also across national borders.

2.16 **EU Hub** means the central information and data router of the EMVS pursuant to Art. 32 1 (a) of the Delegated Regulation, which serves to transmit data to and from the national and supranational systems for the verification of medicinal products.

2.17 **EMVS Cooperation Agreement** means the contractual arrangements between securPharm and the EMVO regarding the operation of the EMVS.

2.18 **Falsified Medicines Directive** means the "European Directive 2011/62/EU of the European Parliament and the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products". It was transposed into German law on 19 October 2012 with the "Second Amendment Act for Pharmaceutical Law and other Regulations".

2.19 **Legal Requirements** mean the entire body of requirements of the Falsified Medicines Directive and the Delegated Regulation.

2.20 **Uploading** means the transmission of files and other information by or on behalf of a Party to IT systems of the other Party or IT systems of a third party as e.g. the EU Hub.

2.21 **Circumstances beyond Control** means any event which is beyond a Party´s control and that makes it permanently or temporarily impossible or economically unreasonable for this Party to perform one or more of its contractual obligations, such as e.g. natural disasters (in particular floods, volcanic eruptions, earthquakes, severe weather), sabotage, strikes, terrorist attacks, riots, fire, civil war, war, legitimate lockouts and interruptions of operations not caused by this Party, as well as official orders which are not based on culpable conduct on the part of this Party, in particular the declaration of an epidemic or comparable situation, at the registered office and/or a location of the respective Party relevant for the performance of this agreement. Supply difficulties and other service disruptions on the part of an agent are only considered Circumstances beyond control of this Party if the agent itself is prevented from rendering the service owed due to an event in accordance with sentence 1.

2.22 **Code for Medicinal Products for Human Use** means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, as amended.

2.23 **Date of Effectiveness** means the time at which at least one version of this Cooperation Agreement was signed by both Parties.

2.24 **IQVIA** means the IQVIA Commercial GmbH & Co. OHG, Unterschweinstiege 2-14, 60549 Frankfurt/Main, Germany.

2.25 **IT Contract** means the "Master Agreement for Rendering IT Services" between ACS and Arvato Systems regarding services in the field of IT consulting, software development and software operation as well as IT infrastructure services with regard to the ACS MAH System.

2.26 **Group Companies** means Affiliated Companies (individually or collectively) that have been named by the Entitled Group Company in the request for a Group Rebate, or are subsequently as being affiliated with the Entitled Group Company.

2.27 **Group** means the Group Companies and the Entitled Group Company collectively.

2.28 **Legitimacy Check** means a check of the identity, role and legitimation of the Client or Authorised Third Parties in accordance with the requirements of securPharm for the use of the ACS MAH System and the Web Interfaces by ACS.

2.29 **Log-in Data** means the data generated by the Client from the Access Information by means of which the Client can access the ACS MAH System and the Web Interfaces.

2.30 **NGDA** means the Netzgesellschaft Deutscher Apotheker mbH, Carl-Mannich-Straße 26, 65760 Eschborn, Germany.

2.31 **Pack-related Data** means information that characterises a single Pharmaceutical Pack and is transferred from the EU Hub to the ACS MAH System. Pack-related Data is determined according to

the respective applicable requirements of the EMVO and, includes, at the Date of Effectiveness, in particular:

2.31.1 Name of the manufacturer;

2.31.2 Serial number;

2.31.3 Batch number;

2.31.4 Expiry date; and the

2.31.5 PZN (*Pharmazentralnummer* = central pharmaceutical number).

2.32 **Parallel Distributor** means a legal entity which is independent of the Marketing Authorization Holder which distributes a centrally authorised medicinal product from one member state in another member state and has undergone a notification procedure with the EMA for that medicinal product.

2.33 **Product Master Data** means information that characterises a product type and is transferred from the EU Hub to the ACS MAH System. Product master data is determined according to the respective applicable requirements of the EMVO and includes, at the Date of Effectiveness, in particular:

2.33.1 MAH-ID;

2.33.2 MAH-name;

2.33.3 Product code;

2.33.4 Product name;

2.33.5 Dosage form;

2.33.6 Size of the Pharmaceutical Pack (quantity/unit); and

2.33.7 Date last changed.

2.34 **Pro Generika** means the Pro Generika e.V., Unter den Linden 32-34, 10117 Berlin, Germany.

2.35 **Response Time** means the time period according to Enclosure 4 at the end of which deficiency handling begins after ACS first became aware of the deficiency (regardless of how awareness occurred). Response times are maximum times.

2.36 **Intellectual Property Rights** means all rights to and arising from patents, utility models, brands, commercial names, copyrights, ancillary copy rights and related rights, designs, business and trade secrets and the registration of such rights.

2.37 **Coding Rules** means the "Coding rules for medicines requiring verification for the German market" published by securPharm, in their current version.

2.38 **Closure of Alarms in the ACS MAH System** means the process by which an alarm is marked as not reportable to the Competent Authority, either by the Client or by an Authorised Third Party, in each case after its verification or automatically.

2.39 **securPharm** means the securPharm e.V., Hamburger Allee 26-28, 60486 Frankfurt/Main, Germany.

2.40 **Safety Feature** means the unique identifier pursuant to the Delegated Regulation that facilitates the authentication and identification of a Pharmaceutical Pack.

2.41 **Security Breach** means events, interventions and attacks of any kind that, from an objective point of view,

2.41.1 Jeopardise or could likely jeopardise the security or functionality of the EMVS (including the ACS MAH System), including unauthorised data processing and uploading of unauthorised data to the EMVS (including the ACS MAH System); and/or

2.41.2 Lead or could likely lead to the destruction, loss, change, unauthorised disclosure of or unauthorised access to Data or (other) Confidential Information.

2.42 **Subcontractor** means a legally independent entity or other legally independent third party used by one Party to fulfil this Cooperation Agreement.

2.43 **Affiliated Companies** means affiliated companies within the meaning of Sections 15 et seq. of the German Stock Corporation Act (*Aktiengesetz*).

2.44 **Availability** means the time period mentioned in Enclosure 5 during which the functionalities of the ACS MAH System in accordance with this Cooperation Agreement are available to the Client without restriction. Planned maintenance work is not part of availability.

2.45 **Verification System** means the data repository system in Germany in accordance with the Delegated Regulation, which consists of the ACS MAH System, the Pharmacy Server and the Authority Information Portal (reportingtool), all of which are connected to each other via interfaces.

2.46 **Medicinal Product to be Verified** means a medicinal product whose packaging must be provided with a Safety Feature in accordance with the Legal Requirements.

2.47 **Confidential Information** means all information for which appropriate, technical, organisational and legal measures have been taken to maintain confidentiality, and that the disclosing Party has disclosed or made accessible to the recipient in connection with the implementation of this Cooperation Agreement at the Date of Effectiveness, will disclose or make accessible in the future or of which the recipient acquires knowledge,

2.47.1 Regardless of whether

(a) The information is in written, electronic, oral or other format; and

(b) The information is deemed or marked confidential, secret or the like,

2.47.2 With the exception of such information that

(a) Was publicly known as of the Date of Effectiveness or became publicly known later, as long as this public knowledge was not based on a violation of the recipient of this Cooperation Agreement;

(b) Was in the possession of the recipient already prior to the first disclosure or being made accessible otherwise by the disclosing Party, without the recipient being obligated to confidentiality towards the disclosing Party and the recipient being able to prove this with written evidence;

(c) The recipient legitimately acquired it through a third party who was not bound by confidentiality towards the disclosing Party;

(d) Was independently developed by the recipient, specifically by legal representatives and/or agents who had and have no access to the Confidential Information of the disclosing Party; or

(e) Whose further disclosure or being made accessible otherwise by the recipient towards any third party was authorised in writing previously by the disclosing Party (pursuant to Section 34).

2.48 **vfa** means the Verband Forschender Arzneimittelhersteller e.V. (German Association of Research-based Pharmaceutical Companies), Hausvogteiplatz 13, 10117 Berlin, Germany.

2.49 **Web Interfaces** means the Web Portal and the Web Service.

2.50 **Web Portal** means the graphic user interface provided via the internet through which ACS offers the Client functionalities in connection with the ACS MAH System according to this Cooperation Agreement voluntarily and free of charge. The Web Portal is not part of the ACS MAH System.

2.51 **Web Service** means the application programming interface, which is provided via the internet through which ACS provides the Client voluntarily and free of charge with a connection to the ACS MAH System in accordance with this Cooperation Agreement. The Web Service is not part of the ACS MAH System.

2.52 **Business Day** means any day from Monday to Friday with the exception of public holidays at the place of businees of ACS.

2.53 **Access Information** means the initial passwords that are valid for 30 calendar days after their creation and that the Client receives from ACS.

2.54 **Marketing Authorisation Holder** means the holder of the marketing authorisation for a Medicinal Product to be Verified in Germany or, in the case of parallel imported Medicinal Products to be Verified, the holder of the national German marketing authorisation for the parallel import.

2.55 **Marketing Authorisation** describes the regulatory approval valid for Germany of a Medicinal Product to be Verified.

2.56 **Competent Authority** describes each national competent authority in Germany pursuant to Art. 39 of the Delegated Regulation.

3. Contractual object

3.1 In accordance with this Cooperation Agreement, ACS renders services in connection with the obligatory functionalities of the ACS MAH System as well the Web Interfaces.

3.2 The correctness, currency, compatibility and completeness of the data uploaded into the ACS MAH System for the Client via the EU Hub shall be the exclusive responsibility of the Client, unless otherwise specified in this Cooperation Agreement.

3.3 Furthermore, according to this Cooperation Agreement, the following will also not be the responsibility of ACS:

3.3.1 The functional capability of the EMVS with the exception of the ACS MAH System;

3.3.2 The functional capability of the internet; and

3.3.3 The functional capability of the IT Infrastructure of the Client, Authorised Third Parties and Subcontractors used by the Client.

3.4 Prerequisite for the use of the functionalities of the ACS MAH System and the Web Services according to this Cooperation Agreement by the Client is the complete and successful completion of the so-called on-boarding process of EMVO (contractual and technical part) as well as the proper Uploading of the Product Master Data and the Pack-related Data via the EU Hub.

4. Contractual obligations and voluntary services of ACS

4.1 ACS undertakes to provide the Client specifically with the following functionalities for the Client´s Medicinal Products to be Verified via the following interfaces in the ACS MAH System in accordance with this Cooperation Agreement:

4.1.1 EU Hub interface

(a) Verification of Pack-related Data,

(b) Provision and editing of Pack-related Data,

(c) Status change with subsequent deactivation of the safety feature,

4.1.2 Pharmacy Server interface

(a) Verification of Pharmaceutical Packs without status change,

(b) Dispensing of a Pharmaceutical Pack with integrated verification with status change,

(c) Recall of a dispensed Pharmaceutical Pack as part of defined rules.

4.2 Furthermore, in accordance with this Cooperation Agreement, but without being obligated, ACS provides the Client with the following local functionalities via the Web Interfaces:

4.2.1 Verification of Pack-related Data,

4.2.2 Status change with subsequent deactivation of the Safety Feature,

4.2.3 Report functionalities (reporting) for the Client.

ACS will make an effort to render the Web Interfaces according to the Availability, whereas for ACS a certain duration of usability of the local functionalities of the Web Interfaces does not represent part of the performance object in accordance with this Cooperation Agreement.

4.3 If ACS is obligated to grant to the Competent Authority access to the Client's Data available in the ACS MAH System pursuant to Section 20.3, ACS must inform the Client about the access granted unless this is legally prohibited.

5. Participation duties of the Client

5.1 The Client undertakes to provide ACS in a timely manner with the complete information required for ACS to be able to fulfil its duties in accordance with this Cooperation Agreement. The Client is obligated to inform ACS immediately of any changes to the information provided.

5.2 The Client is obligated to ensure that the Product Master Data and the Pack-related Data transferred for it to the EU Hub are correct, complete, compatible with the system, unambiguous and current, and that they meet the applicable requirements of the EMVO and securPharm.

5.3 The Client is obligated to comply with the Coding Rules.

5.4 If the Client intends to use the Web Interfaces, it is obligated to immediately set up two administrators in the Web Interfaces upon receipt of the Access Information from ACS, if and to the extent that ACS has not carried out the setup for the Client.

5.5 The Client is obligated to protect its IT system and connections of its IT system to the ACS MAH System, the Web Interfaces and the EU Hub by means of state-of-the-art security precautions in order to prevent Security Breaches of the ACS MAH System as well as of its system with an impact on the ACS MAH System.

5.6 The Client is obligated to ensure that

5.6.1 Using its Access Information and Log-in Data, only the Client and Authorised Third Parties have access to the Web Interfaces;

5.6.2 The Access Information and Log-in Data that ACS will issue to the Client following the Date of Effectiveness, are managed and kept secret as instructed by ACS;

5.6.3 No attempts are made or caused to be made by the Client and Authorised Third Parties to view, alter or delete any data of other clients stored in the ACS MAH System without authorisation, or to spread viruses, worms, trojans or other malware or deterioration mechanisms in the ACS MAH System; and

5.6.4 Employees of the Client and Authorised Third Parties which are granted access to the Web Interfaces are obligated in writing to comply with the requirements according to Sections 5.6.2 and 5.6.3. before they receive access to the Web Interfaces.

5.7 The Client is obligated to use the ACS MAH System and the Web Interfaces only in accordance with their intended use and with the greatest possible diligence. Specifically, the Client is obligated to refrain from all actions that jeopardise or may jeopardise the functional capability of the ACS MAH System and the Web Interfaces, such as e.g. regular, automated queries of the status of all or nearly all of the Client's Pharmaceutical Packs in the ACS MAH System. If ACS becomes aware that the ACS MAH System and/or the Web Interfaces are used by the Client or Authorised Third Parties in a way that is not intended, ACS is entitled to request the Client to cease performing such actions or to ensure that they are refrained from, and/or to limit or interrupt such actions by means of suitable technical measures in order to ensure the contractual functional capability of the ACS MAH System and the Web Interfaces for all users.

5.8 ACS is entitled to invoice the Client separately for any expenses incurred in the event the Client violates its obligations pursuant to Section 5.7.

6. Authorised Third Parties

6.1 The Client is obligated to notify ACS of Authorised Third Parties, stating the company name and full address, in writing in accordance with Section 34 of the Cooperation Agreement. After notification by the Client, ACS will carry out a Legitimacy Check of the Authorised Third Party in accordance with Section 10, if not yet carried out otherwise.

6.2 ACS agrees to allow the Client to provide the Authorised Third Party access to the Client's system account in the ACS MAH System. A transfer of this right by the Authorised Third Party is not permitted.

6.3 The Client is obligated to notify ACS in writing (Section 34 of the Cooperation Agreement) without undue delay that and on what date an Authorised Third Party loses its status as Authorised Third Party, e.g. due to termination of the co-distribution agreement. As soon as an Authorised Third Party has lost its status as Authorised Third Party, the Client is further obligated to immediately ensure that any access to the Client's system account in the ACS MAH System is withdrawn from the Authorised Third Party.

6.4 The Client undertakes, by written agreement with Authorised Third Parties, to ensure that Authorised Third Parties comply with the obligations under Sections 5.1, 5.2, 5.3, 5.5, 5.6, 5.7, 21 and 29 and under the Confidentiality Agreement as set out in Enclosure 1. Any breach by an Authorised Third Party of any of the aforementioned obligations shall be deemed to be the Client´s own breach. ACS' own claims against the Authorised Third Party shall remain unaffected.

6.5 In the event that an Authorised Third Party infringes the obligations under Section 5.7, the Client undertakes to compensate ACS for the expenses incurred as a result of the breach.

6.6 No separate agreement is concluded between ACS and Authorised Third Parties.

7. Disruptions/restrictions

7.1 Pursuant to the EMVS-Cooperation Agreement,

7.1.1 The EMVO is entitled to disconnect the Verification System immediately from the EU Hub, if the EMVO has reason to assume based on reasonable and objective facts that the continued operation of the Verification System would immediately and considerably jeopardise the security and functional ability of the entire EMVS or parts thereof.

7.1.2 The EMVO is obligated to immediately reconnect the Verification System to the EU Hub, if securPharm has proven that the risk according to Section 7.1.1 no longer exists.

7.1.3 After the mandatory execution of a series of de-escalating interim steps with a suspensive effect, the EMVO is entitled to disconnect the Verification System from the EU Hub, if and as long as securPharm has not paid fees according to the EMVS Cooperation Agreement.

7.1.4 securPharm is both entitled and obligated pursuant to Sections 7.1.1 and 7.1.2.

7.1.5 After the mandatory execution of a series of de-escalating interim steps with a suspensive effect and under the condition that the security or functional ability of the entire EMVS or parts thereof are not directly and considerably jeopardised, securPharm is entitled to disconnect the Verification System from the EU Hub, if and as long as the EMVO violates the EMVS-Cooperation Agreement.

7.2 If the EMVO or securPharm exercise their rights pursuant to Section 7.1,

7.2.1 There can be restrictions or outages of individual or all services of ACS in accordance with this Cooperation Agreement;

7.2.2 The Client remains obligated to pay the fee pursuant to Section 8, unless ACS is responsible for the disruption.

7.2.3 ACS is obligated to inform the Client immediately of an upcoming disconnection from the EU Hub, a completed disconnection from the EU Hub as well as the reasons for the upcoming or completed connection to the EU Hub, provided ACS is in a position to do so.

7.2.4 ACS is obligated to inform the Client immediately of a completed disconnection from the EU Hub upon becoming aware of it and about the reason for it as well as to inform the Client of an upcoming connection to the EU Hub.

8. Fee

8.1 The Client is obligated to pay the fee to ACS in accordance with this Section 8.1 as well as Enclosure 2 (initial set-up fee). The fee pursuant to this Section 8.1 is non-refundable, except in cases prescribed by mandatory law, and becomes due 30 calendar days after the corresponding invoice date. Pursuant to this Section 8.1, ACS is entitled to issue the invoice for the fee according to this Section 8.1 any time after the Date of Effectiveness.

8.2 The Client is obligated to pay an annual fee to ACS in accordance with this Section 8.2 as well as Enclosure 2. Pursuant to this Section 8.2, the fee becomes due 30 calendar days after the respective invoice date.

8.2.1 ACS is entitled to issue an invoice for the fee pursuant to Section 8.2.

8.2.2 The obligation to pay a fee pursuant to this Section 8.2 as well as Enclosure 2 also continues to be in effect after a termination of this Cooperation Agreement, until

(a) All Medicinal Products to be Verified for which Data have been uploaded to the ACS MAH System for the Client, either directly or via the EU Hub, have been dispensed to the public;

(b) The Client has recalled all Medicinal Products to be Verified for which Data have been uploaded to the ACS MAH System for the Client, either directly or via the EU Hub;

(c) The Marketing Authorisations for all Medicinal Products to be Verified and for which Data have been uploaded to the ACS MAH System for the Client, either directly or via the EU Hub, were transferred to another Marketing Authorisation Holder; or

(d) Other processes have been concluded that free the Client from all of its responsibilities in accordance with the Legal Requirements with regard to all Medicinal Products to be Verified and for which Data have been uploaded to the ACS MAH System for the Client.

8.3 ACS is entitled to adjust the fee pursuant to Section 8.2 through unilateral performance determination based on reasonable discretion (Section 315 of the German Civil Code (*Bürgerliches Gesetzbuch*)).

8.3.1 The Client is entitled to have the equity of the adjustment of the fee examined in civil court. ACS is entitled to adjust the fee in the event of cost increases, but is obligated to do so in the case of cost reductions. When determining the fee, ACS is obligated to only take into account cost increases while simultaneously considering contrary cost reductions and to offset cost increases and cost reductions.

8.3.2 ACS must determine the extent and time of the adjustment of the fee in such a manner as to take into account cost reductions according to the same business standards as cost increases. Specifically, ACS must not pass on cost reductions later than cost increases. ACS shall examine the cost developments at least every 12 months.

8.3.3 Adjustments of the fee shall become effective only upon written notification of the Client, which must be made at least six weeks prior to the intended change.

8.3.4 If ACS adjusts the fee, the Client has the right to terminate the Cooperation Agreement without observing a period of notice as of the effective date of the adjustment of the fee. If, in the event of an increase of the fee, the Client has initiated a civil court examination of the adjustment of the fee, the Client is entitled to pay the fee applicable prior to the adjustment until a legally binding decision on the equity of the adjustment of the fee has been rendered. If the Client exercises its right to pay the fee applicable prior to the adjustment, it is obligated, in the event of an increase of the fee, to deposit any difference in money or to provide a written, irrevocable, unconditional and unlimited guarantee from a credit institution

authorised to do business in Germany. In this context, the deposited or secured difference must be increased at least semi-annually in line with its increase.

8.3.5 The Client's right to an ordinary termination and to an extraordinary termination for important reasons remains unaffected pursuant to Section 30.2.

8.4 All fees are listed in Euro and are subject to the legal value-added tax rate applicable at the time.

8.5 The Client is obligated to transmit the fully filled out Enclosure 3 (Form for Client information) to ACS no later than on the Date of Effectivenes.

9. Default

9.1 If the Client is fully or partially in default of payment for an invoice amount, ACS is entitled to charge 8.5% default interest per year on top of the overdue invoice amount to bill this interest retroactively on a monthly basis in pro-rated manner.

9.2 In addition to the other contractual and legal rights to which ACS is entitled, ACS has the right to do the following when the Client is fully in default with the payment of at least one invoice amount:

9.2.1 Revoke the granting of rights to use the Web Interfaces for the duration of the default;

9.2.2 Immediately inform the EMVO regarding the Client's default, so that the EMVO can suspend the Client's access to the EU Hub; and

9.2.3 To notify the Competent Authority that the Client is not fulfilling its payment obligation under this Cooperation Agreement.

The same rules apply if the Client is in default with a considerable part of at least one invoice amount. A considerable part is at least 10% of an invoice amount.

9.3 If ACS has exercised its right pursuant to Section 9.2.1, ACS is obligated to immediately reactivate the Client's rights upon full payment of overdue invoices. If ACS has exercised its rights pursuant to Section 9.2.2 and/or Section 9.2.3, ACS is upon full settlement of the overdue invoices obligated to immediately inform the EMVO and/or the Competent Authority that the Client is no longer in default.

10. Legitimacy Check

10.1 ACS is entitled and obligated to perform a Legitimacy Check of the Client and Authorised Third Parties prior to granting the Client and Authorised Third Parties access to the ACS MAH System and the Web Interfaces.

10.2 ACS is further entitled and obliged to carry out Legitimacy checks of the Client and Authorised Third Parties on a regular or occasion-related basis. An occasion-related Legitimacy Check may be carried out in particular in the following cases:

10.2.1 Conspicuities during the monitoring of suspected falsifications, which objectively provide a reason for conducting a Legitimacy Check;

10.2.2 Conspicuities within the Client's data in the ACS MAH System, which objectively provide a reason for conducting a Legitimacy Check;

10.2.3 A check demanded by securPharm or the Competent Authority;

10.2.4 A negative result of a regular Legitimacy Check; and

10.2.5 Other information that objectively provides a reason for conducting a Legitimacy Check.

10.3 ACS is obligated to establish or maintain the legitimaty of the Client or the Authorised Third Parties with a positive result of a Legitimacy Check for the first time.

10.4 If a regular or occasion-related Legitimacy Check has brought a negative result, ACS is obligated to immediately conduct an (or a further) occasion-related Legitimacy Check.

10.4.1 If the (further) occasion-related Legitimacy Check pursuant to sentence 1 brings a positive result, ACS is obligated to maintain the legitimacy of the Client or Authorised Third Party.

10.4.2 If the (further) occasion-related Legitimacy Check pursuant to clause 1 has a negative result, ACS is obligated

(a) To withdraw the legitimacy of the Client or the Authorised Third Party for use of the ACS MAH System and Web Interfaces and to block the corresponding user account; and

(b) To inform the Client or the Authorised Third Party immediately about the withdrawal and blockage; and

(c) To inform the EMVO immediately about the withdrawal and blockage of the Client in order to enable the EMVO to suspend the Client´s access to the EU Hub.

In the event of a negative result of a (further) occasion-related Legitimacy Check of an Authorised Third Party, ACS will inform the Client immediately about the result. The Client is obligated to immediately change its Access Information or Log-in Data and not to provide the new Log-in Data to the Authorised Third Party.

10.4.3 ACS is obligated to conduct a new occasion-related Legitimacy Check at the request of the Client or the Authorised Third Party, if the Client or the Authorised Third Party have provided ACS with reasons in writing which objectively give rise to the assumption that a new occasion-related Legitimacy Check will lead to a positive result. ACS is only obligated to reactivate the legitimacy of the Client or the Authorised Third Party for use of the ACS MAH System and the Web Interfaces and to remove the blocking of the corresponding user accounts, if a new occasion-related Legitimacy Check has led to a positive result.

11. Collaboration of the Parties

To coordinate the collaboration of the Parties as part of this Cooperation Agreement, each Party is obligated to name two responsible contacts to the other Party immediately after the Date of Effectiveness (Enclosure 3). The contacts of the Parties shall coordinate the rendering of services of the Party for which they work. Each of the contacts is authorised to make declarations of intent on behalf of the Party in question in connection with this Cooperation Agreement or to make and receive other notifications with binding effect.

12. Audits

ACS will, at its own expense, conduct or have conducted, either itself or through third parties, an audit regarding compliance with its contractual and legal duties with regard to the ACS MAH System (specifically all technical and organisational security aspects in connection with the operation of the ACS MAH System) at least once a year, from 2024 onwards at least every three years. At the Client's request, ACS is obligated to grant the Client insight into subject areas of the audit log that are relevant to him.

13. Alerts by the Client

13.1 The Client is obligated to inform ACS immediately and in writing about relevant changes, e. g. regarding its billing or contact information.

13.2 After the conclusion of the respective contractual agreement with an Authorised Third Party, the Client is obligated to provide ACS with the complete contact information of the Authorised Third Party immediately and in writing. The Client is, in addition to the obligations under Sections 6.1 and 6.3, further obligated to ensure that relevant changes of an Authorised Third Party, e.g. regarding its contact information, are submitted to ACS without undue delay and in writing.

13.3 The Client is obligated to investigate each potential falsification incident reported to it by the ACS MAH System immediately and to identify whether

13.3.1 There is a handling error by the Client or a technical error for which the Client is responsible;

13.3.2 The Client cannot exclude a suspected falsification upon its investigation; or

13.3.3 A confirmed falsification is present upon its investigation.

13.4 The Client is obligated pursuant to Section 13.3 to immediately remedy errors and to avoid the same type of errors in the future.

13.5 The ACS MAH System reports all alarms automatically to the Authority Information Portal after seven days at the latest, unless the corresponding alarm was closed within seven days. The reporting by the ACS MAH System to the Authority Information Portal does not release the Client from its other legal obligations to report to authorities.

14. Alerts by ACS

The Client agrees that ACS provides securPharm with all required data and actions available in the ACS MAH System in connection with a Safety Feature to generate an audit trail pursuant to Art. 35 1 (g) and Art. 36 (j) of the Delegated Regulation and the required data for generating alerts pursuant to Art. 37 (d), audit trails pursuant to Art. 37 (f), reports pursuant to Art. 37 (g) and information pursuant to Art. 36 (i) of the Delegated Regulation.

15. Concession of rights

From the time of the first upload of Data via the EU Hub to the ACS MAH System, until the termination of this Cooperation Agreement, subject to Sections 9.2.1 and 10.4.2, ACS grants to the Client the non-exclusive, spatially unrestricted and transferrable pursuant to Section 31.2 right to use the ACS MAH System and the Web Interfaces according to this Cooperation Agreement for the purposes in accordance with the Delegated Regulation and the Falsified Medicines Directive.

The Client shall be entitled to grant the necessary rights pursuant to sentence 1 of this section, with the exception of the right to transfer, to Authorised Third Parties and Subcontractors free of charge to the extent necessary for the performance of the duties assigned to them.

16. External communications

ACS is entitled to publicise the Client's participation in the ACS MAH System and/or the Web interfaces in press releases, on websites, on lecture slides and in other publications by ACS with a mention of the company name. Use of the company name is only permitted for the purposes mentioned in this section.

17. Subcontracting

17.1 The Parties are entitled to use Subcontractors to fulfil their contractual obligations. If Subcontractors are used to fulfil the contractual obligations, Section 278 of the German Civil Code (*Bürgerliches Gesetzbuch*) shall apply. Possible claims of the other Party against a Subcontractor remain unaffected.

17.2 The coordination of the involvement of Subcontractors is the responsibility of the Party that uses the Subcontractors. The obligations under Section 5.6 shall apply accordingly to the Client with respect to Subcontractors.

18. Circumstances beyond Control

18.1 In cases of Circumstances beyond Control, the affected Party is exempt from rendering its services in accordance with this Cooperation Agreement for the duration and to the extent of the impact. The respective other Party shall be exempt from providing its consideration under this Cooperation Agreement for the duration and to the extent of the effect.

18.2 The affected Party will notify the other Party immediately of the onset and the end of such Circumstances beyond Control and put forward its best effort to remedy the Circumstances beyond Control and to limit their effects as far as possible.

18.3 If it is ascertained that the Circumstances beyond Control last longer than three (3) months, each Party is entitled to terminate this Cooperation Agreement.

19. Material defects and defects of title

19.1 Material defects

19.1.1 If the services to be rendered by ACS in accordance with this Cooperation Agreement are deficient, ACS is obligated to eliminate the defect by reworking or through a replacement delivery. A service is deficient, if the performance is not rendered at all or not rendered to the full extent by ACS because of circumstances for which ACS is responsible, and if this results in not meeting the Availability agreed upon for the service in question.

19.1.2 ACS is obligated to start the elimination process for the deficient services within the Response Times and to eliminate the defects within the Processing Time. The Response Time and Processing Time pursuant to Enclosure 4 to this Cooperation Agreement shall apply that result from the classification of the defect in accordance with the following error categories, in each case related to the ACS MAH System:

(a) Error category 1: An economically or technically meaningful use is not possible and cannot be achieved even through other means than the one suggested.

(b) Error category 2: The core functionality is ensured, but there is a key error in a partial module that either prevents work with this module or makes working with it significantly more difficult.

(c) Error category 3: The core functionality is ensured, but an error occurs in non-essential partial functions (Example: A report is interrupted, but the necessary information is available.).

(d) Error category 4: Errors that impair the functionality of a service in a non-essential manner (Example: Spelling errors in the screen mask, errors in the documentation).

19.1.3 If ACS does not manage to eliminate the defective performance within the elimination time mentioned in Section 19.1.2 and not within an additional extension period set by the Client, the Client is entitled to assert its legal warranty rights.

19.1.4 The warranty by ACS does not apply, if a defective performance was caused through improper handling by the Client, an Authorised Third Party or a Subcontractor engaged by the Client, improper interference by the Client, an Authorised Third Party or a Subcontractor engaged by the Client, services not provided by one of them in accordance with this Cooperation Agreement (specifically Data) or based on the existing system environment at the place of business of one of them, for which ACS bears no responsibility. The Client is entitled to prove that the events according to sentence 1 were not the cause for the occurrence of the deficient performance.

19.2 Defects of title

19.2.1 If any third party asserts intellectual property rights against the Client because of the services to be rendered by ACS in accordance with this Cooperation Agreement, the Client is obligated to inform ACS immediately in writing. ACS will, if the Client requests so and if the third party is not an Authorised Third Party or a Subcontractor, reasonably support the Client in defending the claims at its own expense.

19.2.2 At its own expense and according to its own choice, ACS will either provide the Client with the required usage rights or modify the services to be rendered according to this Cooperation Agreement so they no longer violate the intellectual property rights of any third party and continue to meet the contractual arrangements in accordance with this Cooperation Agreement.

19.2.3 If the services to be rendered in accordance with this Cooperation Agreement are changed, ACS is obligated to perform all required conversions, rearrangement, adjustments of documentations, training measures, etc.

19.2.4 If ACS is not able to provide the Client with the required usage rights and to modify the services to be rendered by ACS in accordance with this Cooperation Agreement pursuant to Section 19.2.2, the Client is entitled to immediately terminate this Cooperation Agreement without notice. The Client's right to claim damages according to Section 28 remains unaffected.

19.2.5 Upon written proof, ACS is obligated to indemnify the Client against all legally established claims of any third party for the violation of intellectual property rights due to the services to be rendered by ACS in accordance with this Cooperation Agreement. ACS' duty of indemnity applies under the condition that the Client does not terminate the legal dispute with the third party either in court or out of court without the prior written consent of ACS.

20. Rights to data

20.1 The rights and access to the data are determined in accordance with the Legal Requirements.

20.2 The Client is only given access to the data of its Medicinal Products to be Verified. The Client bears the full responsibility for activities conducted in connection with access to the data. The Client also bears full responsibility for activities carried out by Authorised Third Parties and Subcontractors engaged by it in connection with access to the data.

20.3 ACS only grants access to the data in the ACS MAH System to the Competent Authority for the purpose of fulfilling Art. 39 of the Delegated Regulation, unless access must be granted due to the Falsified Medicines Directive, other provisions of the Delegated Regulation or due to other applicable law.

21. IT security

21.1 If one Party notices a Security Breach that could impact the other Party or the Data, it shall immediately inform the other Party and indicate the following:

21.1.1 Type of the Security Breach including the number of affected persons and the category as well as the number of relevant data records;

21.1.2 The consequences of the Security Breach;

21.1.3 Measures taken by the reporting Party in order to eliminate the Security Breach and to limit the consequences;

21.1.4 Measures taken by the reporting Party in order to avoid such Security Breaches in the future.

21.2 In the case that a Security Breach is reported, both Parties are obligated to take all appropriate steps to eliminate the Security Breach and to limit the consequences. Furthermore, both Parties are

obligated to take appropriate steps in order to avoid a reoccurrence of the Security Breach in the future.

22. Business continuity management and disaster recovery management

As of the Date of Effectiveness, ACS is obligated to have established appropriate and customary measures for business continuity management and disaster recovery management with regard to the ACS MAH System and to maintain these until this Cooperation Agreement is terminated.

23. Data security

23.1 The Data and other information about the Client's Pharmaceutical Packs, the Client's contact information as well as the contact information of Authorised Third Parties and the contract data may be used by ACS in their entirety, individually and as data packages from multiple individual data exclusively for the purpose of fulfilling this Cooperation Agreement. ACS is not allowed to use the data for other purposes, either paid or unpaid.

23.2 Immediately on the Date of Effectiveness and no later, ACS must obligate its bodies, agents and external consultants accordingly, if they have access to the data and other information pursuant to Section 23.1.

24. Protection of personal information

If, as part of the implementation of this Cooperation Agreement, the Parties intend to not process person-related information within the meaning of Art. 4 of the GDPR on the basis of Art. 6 (b) and/or (f) of the GDPR, the Parties shall take the required measures to comply with applicable EU law or that of the member states.

25. Amendments to this Cooperation Agreement

25.1 ACS is entitled to amend this Cooperation Agreement any time according to this Section 25. This does not apply to the fee. For fee adjustments, Section 8.3 shall apply exclusively.

25.1.1 Amendments to this Cooperation Agreement shall only become effective upon written notification of the Client, which must be made at least six weeks prior to the intended change.

25.1.2 If ACS amends this Cooperation Agreement, the Client has the right to terminate the Cooperation Agreement without observing a period of notice at the time the change becomes effective. ACS will point this fact out to the Client in the notification of the change.

25.1.3 The Client's right to an ordinary termination pursuant to Section 30.2.1 and to an extraordinary termination for important reasons pursuant to Section 30.2.2 remains unaffected.

26. Changes to the functionalities of the ACS MAH System and the Web Interfaces

26.1 Changes to the functionalities of the ACS MAH System

26.1.1 Section 25 also applies to technical updates, changes and/or modifications of the functionalities of the ACS MAH System. For technical updates, changes and/or modifications to the ACS MAH System, which lead to changes in the functionalities of the ACS MAH System, Section 25.1.1 applies provided that a written notification must be made with an appropriate deadline depending on the situation and as long as they do not prevent the Client from meeting its legal obligations according to the Falsified Medicines Directive.

26.1.2 If the provision or installation of such updates, changes and/or modifications to the ACS MAH System involves a (temporary) access restriction or disruption to parts or all of the functionalities of the ACS MAH System and the Web Interfaces for the Client, ACS will inform the Client of this fact in writing beforehand and make all necessary efforts to avoid any restriction or disruption and to mitigate the impacts. Furthermore, ACS will undertake all reasonable efforts to conduct such updates, changes and/or modifications to the ACS MAH System as part of maintenance windows pursuant to Section 27.

26.2 After written notification of the Client with an appropriate deadline, ACS is entitled to change technical updates, changes and/or modifications of the functionalities of the Web Interfaces any time or to fully or partially discontinue the Web Interfaces. The Client has to ensure that Authorised Third Parties are informed about such technical updates, changes and/or modifications of the functionalities of the Web Interfaces.

27. Maintenance window

27.1 ACS is entitled to conduct maintenance work for centralised data centre infrastructures, specifically power supply, networks, switches, LAN, system management, firewalls and shared storage systems on six (6) dates per calendar year, on a *pro rata temporis* basis, if necessary. If maintenance work is conducted, it is done on the last Sunday of a given calendar month between 2:00 a.m. and 8:00 a.m. (CET or CEST). However, ACS will make an effort to keep the duration of maintenance work as short as possible.

27.2 ACS is obligated to inform the Client at least one week prior to the maintenance work pursuant to Section 27.1 in writing or via email of the start of the maintenance work, if this has an impact on the

contractually defined performance. The Client has to ensure that Authorised Third Parties are informed of the performance of such maintenance work.

27.3 Furthermore, to fend off immediately imminent threats, ACS is entitled to take the necessary emergency precautions, as long as these are threats that are unforeseen or unforeseen in their extent for the operational security of the ACS MAH System, other parts of the EMVS or the web interfaces.

28. Liability of the Parties

28.1 ACS is liable to the Client for any damage caused intentionally or through gross negligence by ACS, its bodies and agents.

28.2 For other damage than that pursuant to Section 28.1 of this Cooperation Agreement, ACS bears liability towards the Client that is limited to the damages typical for this type of contract and applicable at the time the contract was concluded.

28.3 Claims by the Client due to a guarantee given by ACS, due to injury to life, body, health and according to product liability law as well as due to mandatory liability regulations and for damage caused by violations of essential contractual duties by ACS, its bodies and agents remain unaffected. Essential contractual duties are those for which a violation jeopardises the contractual purpose of this Cooperation Agreement, because it takes away rights from the Client or limits those that must be granted to him by ACS according to the content and purpose of this Cooperation Agreement.

28.4 Other than that, liability by ACS towards the Client is excluded.

28.5 The liability restrictions pursuant to Sections 28.1 through 28.4 also apply accordingly to the Client, its bodies and agents as well as Authorised Third Parties.

29. Compliance

The Parties are obligated to comply with the laws and codes applicable to them in connection with the prevention of and fight against corruption, money laundering and terrorist funding.

30. Contractual term and termination

30.1 Contractual term

The term of this Cooperation Agreement begins on the Date of Effectiveness. This Cooperation Agreement is concluded for an indefinite period.

30.2 Termination

30.2.1 Ordinary termination

(a) The Client can ordinarily terminate this Cooperation Agreement at any time with a period of notice of three months to the end of the month.

(b) The right of ACS to an ordinary termination of this Cooperation Agreement is excluded.

30.2.2 Extraordinary termination

(a) Each Party is entitled to an extraordinary termination of this Cooperation Agreement for important reasons without notice.

(b) For each Party, an important reason is present specifically if a Party violates at least one key obligation according to this Cooperation Agreement and does not end the violation within 30 calendar days after being asked to do so in writing by the other Party.

(c) Furthermore, an important reason exists for ACS specifically in the following cases:

(a) Without prejudice to ACS's right pursuant to Section 30.2.2(b), an important reason is also given for ACS if the Client fails to pay a fee that is due and/or due default interest even after two additional grace periods set in writing by ACS. Any grace period pursuant to this Section must be at least 14 calendar days;

(b) The operation of the ACS MAH System is discontinued;

(c) The securPharm is dissolved;

(d) The ACS MAH System is no longer part of the EMVS; and

(e) Violation of the obligations under Section 6.4 by the Client.

30.2.3 General information on termination

(a) In the case of a termination, ACS is not obligated with regard to its continued performance duty according to Section 30.2.3(d) to refund a fee paid in accordance with Section 8 to the Client. If the continued performance duty of ACS pursuant to Section 30.2.3(d) ceases at a point in time when the Client has already paid a fee, ACS is obligated to refund the fee on a pro rata temporis basis, unless a termination was effected by ACS pursuant to Section 30.2.2(b) or Section 30.2.2(c)(i). A refund of the fee pursuant to Section 8.1 remains excluded, except in cases prescribed by mandatory law.

(b) Each Party is obligated to return any accessories, documentations and information that belong to the other Party after the termination of the contract without delay. Any potential rights of retention are excluded.

(c) Any potential claims of the Parties that arose before a termination of this Cooperation Agreement became effective remain unaffected by the termination.

(d) At the time the termination becomes effective, the Client's right to upload Data through the EU Hub into the ACS MAH System ends. Services by ACS pursuant to Section 4.1 are rendered even after the termination becomes effective, specifically until

(a) All Medicinal Products to be Verified for which the Client has uploaded Data through the EU Hub to the ACS MAH System have been dispensed to the public;

(b) The Client has recalled all Medicinal Products to be Verified and for which the Client has uploaded Data through the EU Hub to the ACS MAH System;

(c) The Marketing Authorisations for all Medicinal Products to be Verified and for which the Client has uploaded Data to the ACS MAH System were transferred to another Marketing Authorisation holder; or

(d) Other processes have been concluded that free the Client from all of its responsibilities in accordance with the Legal Requirements with regard to all Medicinal Products to be Verified and for which the Client has uploaded Data to the ACS MAH System.

(e) To become effective, each termination according to this Cooperation Agreement requires the written form pursuant to Section 34 of this Cooperation Agreement.

31. Transfer of rights and obligations

31.1 ACS is entitled to transfer to any third party individual rights and obligations or their entirety in accordance with this Cooperation Agreement without the consent of the Client.

31.1.1 ACS is obligated to inform the Client in writing at the earliest possible time, however, at least six week before any transfer pursuant to Section 31.1 regarding the fact of the upcoming transfer as well as the identity and address of the legal entity to which the transfer will be made.

31.1.2 Sections 25.1.2 and 25.1.3 apply accordingly.

31.2 The Client is entitled to transfer individual rights and obligations or their entirety to a third party in accordance with this Cooperation Agreement. If the third party is not yet a client of ACS at the time of the planned transfer pursuant to sentence 1 of this Section 31.2, the Client is only entitled to make the transfer upon prior written consent of ACS and after payment of a transfer fee by the third party to ACS. ACS may only deny its consent in accordance with sentence 2 for factual reasons.

32. Hierarchy

32.1 If there are contradictions within this Cooperation Agreement and in case the contradiction is sufficient, what first applies are

32.1.1 The provisions in the Confidentiality Agreement pursuant to Enclosure 1,

32.1.2 Then, the provisions stipulated in the main part of this Cooperation Agreement,

32.1.3 Then, the provisions stipulated in Enclosure 2,

32.1.4 Then, the provisions stipulated in Enclosure 4,

32.1.5 Then the provisions stipulated in Enclosure 5, and

32.1.6 Finally the provisions stipulated in Enclosure 3.

32.2 All enclosures become effective with the signing of the main part of this Cooperation Agreement unless agreed otherwise.

33. Place of jurisdiction and applicable law

33.1 Exclusive venue for all disputes arising from or in connection with this Cooperation Agreement or its effectiveness (including claims arising from tort) between the Parties, for which there is no other exclusive jurisdiction, is Berlin, Germany.

33.2 The law of the Federal Republic of Germany shall apply to the exclusion of the terms of private international law.

34. Form requirements

To become effective, any modifications and additions to this Cooperation Agreement (including its enclosures) must be signed by hand, with a qualified electronic signature or with a simple electronic signature using “Adobe Acrobat Sign” and can be submitted to the other Party by letter (postal mail, courier), fax or email. This also applies to a modification or elimination of this written form requirement.

35. Miscellaneous

35.1 This Cooperation Agreement contains all agreements made between the Parties regarding the subject of this Cooperation Agreement. No supplementary agreements were made.

35.2 ACS is entitled to render its services in accordance with this Cooperation Agreement at its headquarters or another place within the European Union.

35.3 The application of general terms and conditions of the parties outside of this Cooperation Agreement is excluded, specifically also if one of the Parties references its own general terms and conditions and if the other Party does not expressly object to their inclusion.

35.4 If one provision of this Cooperation Agreement or a provision that was incorporated later is completely or partly invalid or impracticable for other reasons than those mentioned in Sections 305 to 310 of the German Civil Code (*Bügerliches Gesetzbuch*), or if this Cooperation Agreement turned out to contain a loophole, the other provisions shall remain unaffected. The Parties are aware of the jurisprudence of the German Federal Court of Justice on severability clauses, based on which they merely reverse the burden of proof. However, the Parties are obligated to replace the invalid or impracticable provision with a valid and practicable one, which comes closest to the originally agreed upon clause and therefore waive Section 139 of the German Civil Code (*Bügerliches Gesetzbuch*). The same applies if the regulatory gap becomes apparent during the implementation of the Cooperation Agreement.

35.5 This Cooperation Agreement does not entitle either Party to represent the other in legal transactions. The Parties are separate and independent companies.

35.6 Due to reasons for perpetuation of evidence, each Party is obligated to sign two copies of this Cooperation Agreement. Each Party shall receive one of the two signed copies of this Cooperation Agreement.

35.7 Any potential translations of this Cooperation Agreement are exclusively made for the Client’s information and are not legally binding. Only the German version of this Cooperation Agreement is legally binding.

For ACS PharmaProtect GmbH

Berlin,

Signature

_____

Dr. Markus Gerigk

For_____

Place, Date

Signature

_____

Name in block letters

Place, Date

Signature

_____

Name in block letters

Enclosure 1
Confidentiality Agreement

As of: 09 May 2022

between

_____
[Company name]

_____
[Street]

_____
[City, Postcode]

_____ ("**Client**")
[Country]

and

ACS PharmaProtect GmbH,
represented by its management,
Taubenstraße 20, 10117 Berlin, Germany ("**ACS**")

1. Preamble

The Parties have concluded the Cooperation Agreement, part of which is this Confidentiality Agreement.

2. Confidentiality obligations

Each Party is obligated to keep the Confidential Information of the disclosing Party strictly confidential and to only make it accessible, disclose it and use it in accordance with this Confidentiality Agreement. Specifically, the recipient of Confidential Information is

2.1 Obligated with regard to the protection of Confidential Information of the disclosing Party to apply at least the standard it applies to the protection of its own Confidential Information, however, never a standard that is below that of a proper businessperson in the pharmaceutical industry, including the use of appropriate and current IT hardware and software security measures, access restrictions and controls including organizational and legal measures for the protection of the Confidential Information of the disclosing Party;

2.2 Only authorised to disclose or make available Confidential Information of the disclosing Party towards its bodies and employees to the extent that this is required for the implementation of the Cooperation Agreement and/or the legal obligations pursuant to the Falsified Medicines Directive, the Delegated Regulation or the corresponding national laws; in this case, the bodies and employees of the recipient must be obligated in writing to meet confidentiality and non-usage requirements prior to disclosing or making available the Confidential Information of the other Party, e.g. in a service or work contract or any other agreements, and these requirements must appropriately ensure protection of the Confidential Information of the disclosing Party;

2.3 Authorised to disclose or make available Confidential Information of the disclosing Party towards

2.3.1 External consultants of the recipient only to the extent that they are legally and/or professionally obligated to maintain confidentiality;

2.3.2 Authorised Third Parties, Subcontractors or other third parties, including Affiliated Companies, but only entitled according to Section 2.2 of this Enclosure 1; and

2.4 Obligated to limit copies of Confidential Information of the disclosing Party to the required number for the implementation of this Cooperation Agreement.

3. Use of Confidential Information

Each Party is obligated to only use the Confidential Information of the other Party that was or is disclosed or made accessible to it for the purposes of this Cooperation Agreement and not for other purposes.

4. Return and destruction

4.1 At the written request (main part of the Cooperation Agreement, Section 34) of the disclosing Party, the recipient is obligated, based on its own choice, to either return all Confidential Information of the disclosing Party within 14 calendar days upon receipt of the request or to destroy it. With the exception of statutory storage obligations, the recipient is specifically not entitled to retain copies of the Confidential Information of the disclosing Party (regardless of its form) contrary to this Section 4.1 of this Enclosure 1.

4.2 The return and/or destruction of the Confidential Information of the disclosing Party as per the contract must be confirmed to the disclosing Party upon its request by the recipient in writing without delay (main part of the Cooperation Agreement, Section 34).

5. Mandatory disclosure

5.1 If the recipient is forced to disclose or make accessible the Confidential Information of the disclosing Party due to a court order, an official decision or a comparable order ("**Order**"), the recipient is obligated to inform the disclosing Party of this fact in writing without delay (main part of the Cooperation Agreement, Section 34) in order to enable the disclosing Party to take legal measures to protect its Confidential Information.

5.2 With the exception of prior written permission by the disclosing Party, the recipient is only allowed to disclose or make available the Confidential Information of the disclosing Party immediately before the end of the deadline set in the Order.

5.3 Any disclosure or provision of access pursuant to Section 5.1 of this Enclosure 1 may only occur to the extent in accordance with the Order.

5.4 Each Party declares that at the time pursuant to Section 8.1 of this Enclosure 1 no injunction was imposed against them.

6. Liability

Pursuant to Section 28 of the main part of the Cooperation Agreement, the Parties shall be liable for violations of this Confidentiality Agreement.

7. Continued validity

The confidentiality obligations and the duty pursuant to Section 3 of this Enclosure 1 continue to be valid even after the Cooperation Agreement is terminated.

8. Term and termination

8.1 The term of this Confidentiality Agreement begins with the Date of Effectiveness.

8.2 As part of this Cooperation Agreement, a separate termination of this Confidentiality Agreement is excluded. A termination or other discontinuation of the main part of this Cooperation Agreement also ends this Confidentiality Agreement, effective at the same time.

9. Miscellaneous

9.1. All definitions in accordance with the main part of this Cooperation Agreement also apply to this Confidentiality Agreement.

9.2. Sections 33 to 35 of the main part of the Cooperation Agreement apply to this Confidentiality Agreement accordingly.

Enclosure 2
Fee and payment terms

As of: 09 May 2022

Pursuant to Sections 8.1 and 8.2 of the Cooperation Agreement, the fee for the contractual use of the functionalities of the ACS MAH System consist of a fee to be paid at the time the Cooperation Agreement is concluded and of the annual fee.

1. Fee payable at the time the Cooperation Agreement is concluded (initial set-up fee)

The fee to be paid by the Client in accordance with Section 8.1 of the Cooperation Agreement at the time the Cooperation Agreement is concluded is EUR 30,000.00.

2. Annual fee

ACS determines the amount of the annual fee to be paid by the Client pursuant to Section 8.2 of the Cooperation Agreement in accordance with Section 2.1 of this Enclosure 2. For Affiliated Companies, Section 2.2 of this Enclosure 2 applies additionally.

2.1 ACS determines the annual fee as follows:

2.1.1 The calculation of the annual fee is based on two parameters:

(a) the number of Pharmaceutical Packs of Medicinal Products to be Verified uploaded into the ACS MAH System for the Client via the EU Hub in a calendar year ("**Number of Packages**"), and

(b) the net ex-factory sales of Medicinal Products to be Verified of the Client (**"Product Turnover"**), whereby in the outpatient sector, the net ex-factory Product Turnover is calculated based on the uniform sales prices pursuant to Section 78 of the German Medicinal Products Act (*Arzneimittelgesetz*) (sales price of the pharmaceutical entrepreneur, ApU)) without discounts; the determination of the Product Turnover is based on charged information obtained by ACS from IQVIA.

2.1.2 The amount of the annual fee is derived from adding the relevant amounts for the Number of Packages and the Product Turnover in accordance with Sections 2.5.1 and 2.5.2 pursuant to this Enclosure 2.

In deviation from Section 2.1.1 and sentence 1 of this Section 2.1.2, the annual fee exclusively corresponds to the amount relevant for the Product Turnover according to Clause 2.4.2 of this Enclosure 2, if the Product Turnover of the Client is less than € 100,000.00 p.a., since in this case the consideration of the Number of Packages shall be omitted.

2.1.3 If the date of the first upload of Data for the Client into the EU Hub does not fall on a day in January of a calendar year, the Client owes the annual fee on a *pro rata temporis* basis relating to the month in which the date of the first upload of Data for the Client into the EU Hub falls.

2.1.4 ACS determines the annual fee owed by the Client for the previous year after the end of each calendar year, however, no later than during the first quarter following the end of each calendar year.

a) The Number of Packages and the Product Turnover used by ACS will be communicated to the Client in writing with the invoice.

Within one month upon receipt of the invoice, the Client is entitled to provide proof of the incorrectness of the Number of Packages and/or the Product Turnover ACS based its calculation on.

(i) If the Client provides proof of the incorrectness and if the number of Pharmaceutical Packs actually placed on the market and/or the actual turnover deviates from the Number of Packages and/or the Product Turnover ACS based its calculation on in such a way that the annual fee to be paid by the Client for the previous year would change, ACS is obligated to calculate the annual fee owed by the Client for the previous year based on the information submitted by the Client on the actual number of packages actually marketed and/or the actual product turnover.

(ii) ACS is entitled to provide proof of the incorrectness of the Client's reported actual number of packages and the actual turnover.

b) If the determination of the annual fee owed for the previous year shows that the Client

(i) Overpaid for the advance payment pursuant to 2.3, the invoice amount of the first invoice for the current calendar year will be reduced accordingly. The reduction will be shown separately in the invoice.

(ii) Underpaid for the advance payment pursuant to 2.3, the invoice amount of the first invoice for the current calendar year will be increased accordingly. The increase will be shown separately in the invoice.

2.1.5 If the Client is no longer a contractual partner of ACS during the current calendar year and a proceeding according to Section 2.1.4b) is not possible, the Client shall receive a separate invoice for advance payments that were too high or too low no later than the last day of the

first calendar quarter of the current calendar years. Any potential overpayment will be reimbursed to the Client simultaneously with billing by ACS.

2.2 Affiliated Companies shall be granted, upon request, a Group Rebate on the annual fee in accordance with this Section 2.2, provided that the conditions set forth in this Section 2.2 are met.

2.2.1 A request for the granting of a Group Rebate may only be submitted by the Entitled Group Company by 30 September of a year with effect for the current calendar year. The request must be submitted in written form (Section 34 of the main part of the Cooperation Agreement) and must contain the following information:

a) The confirmation that solely the Entitled Group Company is authorised to submit the request;

b) The Affiliated Companies to be included with their full company name and address and with the ACS contract number;

c) Proof that the companies to be included are affiliates of the Entitled Group Company (e.g., copies of financial statements); and

d) Bank details of a Group company or the Entitled Group Company to which ACS will reimburse, in full discharge of liabilities with regard to the Group, the amounts, if any, resulting from the Group Rebate.

2.2.2 A request for a Group Rebate shall be deemed to have been made for an indefinite period of time unless the Entitled Group Company notifies ACS in writing (Section 34 of the main part of the Cooperation Agreement) of a change by 30 September of any year (subject to the changes pursuant to Section 2.2.4f) of this Enclosure 2).

2.2.3 Upon submission of the request for a Group Rebate, a fee in the amount of € 10,000 shall be paid, which shall be invoiced separately to the Entitled Group Company within the invoice regarding the advance payment following the request. For each additional calendar year for which the request for the Group Rebate is valid, a fee in the amount of € 5,000 shall be payable, which shall be invoiced separately to the Entitled Group Company in the first invoice regarding the advance payment of each calendar year. The fees are due 30 calendar days after the respective invoice date.

2.2.4 The granting of a Group Rebate is subject to the following conditions:

a) In accordance with Section 2.1, ACS determines for each Group Company and the Entitled Group Company the annual fee owed in each case for the previous year and sends them each their invoice separately, i.e. ACS first settles its accounts with each Group Company and the Entitled Group Company as if no request for a Group Rebate involving the Client had been made.

b) No later than within the second calendar quarter following the end of each calendar year, ACS calculates a hypothetical annual fee of the Group for the prior calendar year by adding the respective Package Numbers and Product Turnovers of the Group.

c) If the hypothetical annual fee pursuant to letter b) above is lower than the sum of the annual fees owed by the Group, the Entitled Group Ccompany will receive the difference shown on a refund invoice no later than on 30 June of the current calendar year. A difference will be transferred by ACS to the account specified in the request pursuant to clause 2.2.1 at the same time as the invoice is issued in accordance with this letter c), whereby the payment is in full discharge of liabilities with regard to the Group. Any internal settlement within the Group shall be the responsibility of the company belonging to the Group that is the holder of the account.

d) The Package Numbers and Product Turnovers used by ACS to calculate the Group Rebate will be provided to the Entitled Group Company in the refund invoice.

e) The Entitled Group Company is entitled to raise objections to the invoice in accordance with letter c) of this Section 2.2.4 within one month of receipt of the invoice and is obligated to substantiate any objections. In the event of justified objections, ACS shall be obligated to recalculate the Group Rebate on the basis of the facts submitted and to grant the Group Rebate calculated in this way to the Group. ACS is entitled to prove the incorrectness of the facts submitted by the Entitled Group Company.

f) If a company that was named in the request for the granting of a Group Rebate pursuant to Section 2.2.1 of this Enclosure 2 loses its status as an Affiliated Company of the Entitled Group Company in the course of a calendar year, the Entitled Group Company is obligated to notify ACS thereof in writing without undue delay (Section 34 of the main part of the Cooperation Agreement). ACS will only consider the exited company in the context of the calculation of the Group Rebate on a pro rata basis, with cut-off dates being 31 March, 30 June, 30 September, 31 December, depending on which of the cut-off dates follows the receipt of the complete written notification.

If in the course of a calendar year a company acquires the status of an Affiliated Company of the Entitled Group Company, the Entitled Group Company may request ACS in written form (Section 34 of the main part of the Cooperation Agreement) to subsequently include a company in the request for the granting of a Group Rebate by providing the information in accordance with Section 2.2.1b) and c) of this Enclosure 2. If necessary, the Group Rebate shall be calculated on a pro-rata basis, the cut-off dates being 1 January, 1 April, 1 July, 1 October, depending on which of the cut-off dates follows receipt of the complete written notification.

2.3 Advance payments of the annual fee owed by the Client will be invoiced to the Client by ACS quarterly as of 31 March, 30 June, 30 September and 31 December in equal instalments.

2.3.1 For the amount of advance payments,

a) The Number of Packages of the respective calendar year, *pro rata temporis* basis, if necessary, pursuant to Section 2.1.4a),

b) The Product Turnover of the respective previous calendar year, in accordance with the fee-based information obtained by ACS from IQVIA,

shall be relevant. In the year in which the Client first becomes a Client of ACS, ACS shall be entitled to determine the amount of the advance payments at its reasonable discretion.

However, if the Client is able to provide credible facts that the Number of Packages and/or the Product Turnover during the current calendar year deviates so much from the previous Number of Packages and/or the Product Turnover that the fee to be paid by the Client would decrease compared to the calendar year in question, ACS is obligated to take that fact into account appropriately for the amount of the advance payments.

Any group affiliation of the Client has no influence on the amount of the advance payments.

2.3.2 If the amount of the advance payments cannot be calculated pursuant to Section 2.3.1, the amount shall be based on the average number of packages and the average turnover of comparable companies.

2.3.3 In deviation from Section 2.3, if the sum of the advance payments for a calendar year is less than 10,000.00 €, the Client shall receive an invoice for a one-time advance payment as of the last day of the first calendar quarter of a contract year.

2.4 The information, which is provided to ACS by IQVIA for a fee, is based on:

2.4.1 In the outpatient sector the turnover calculated with uniform sales prices by the Client pursuant to Section 78 of the German Medicinal Products Act (*Arzneimittelgesetz*) (sales price of the pharmaceutical entrepreneur, ApU)

as well as

2.4.2 The projected net revenue in the hospital market according to the assessed price (in Euro) of the smallest institutional package of Medicinal Products to be Verified or alternatively the largest original pack of Medicinal Products to be Verified. The assessed price is the weighted wholesale price (gross price minus discounts), which is determined from a survey of panel hospitals.

2.5 The following amounts result from the Number of Packages and Product Turnover determined pursuant to Section 2.1:

2.5.1 Number of Packages			
Number of packages per year			
Level	from	to	Fee in EUR per year
9	> 31,623,000	∞	47,500.00
8	> 10,000,000	31,623,000	38,000.00
7	> 3,162,300	10,000,000	30,000.00
6	> 1,000,000	3,162,300	25,000.00
5	> 316,230	1,000,000	16,000.00
4	> 100,000	316,230	11,000.00
3	> 31,623	100,000	6,500.00
2	> 10,000	31,623	3,000.00
1	0	10,000	1,300.00

2.5.2 Product Turnover			
Product Turnover in EUR per year			
Level	from	to	Fee in EUR per year
S	> 1,778,000,000.00	∞	140,000.00
R	> 1,000,000,000.00	1,778,000,000.00	115,000.00
Q	> 562,300,000.00	1,000,000,000.00	98,500.00
P	> 316,200,000.00	562,300,000.00	87,500.00
O	> 177,800,000.00	316,200,000.00	74,500.00
N	> 100,000,000.00	177,800,000.00	60,000.00
M	> 56,230,000.00	100,000,000.00	46,500.00
L	> 31,620,000.00	56,230,000.00	34,500.00
K	> 17,780,000.00	31,620,000.00	25,000.00
J	> 10,000,000.00	17,780.000.00	17,500.00
I	> 5,623,000.00	10,000,000.00	12,000.00
H	> 3,162,000.00	5,623,000.00	8,000.00
G	> 1,778,000.00	3,162,000.00	5,500.00
F	> 1,000,000.00	1,778,000.00	3,500.00
E	> 562,000.00	1,000,000.00	2,300.00
D	> 316,200.00	562,000.00	1,500.00
C	> 177,800.00	316,200.00	950.00
B	> 100,000.00	177,800.00	600.00
A	0	100,000.00	500.00

3. General

3.1 Any rebates, discounts or other price reductions are not taken into consideration during the determination of the Product Turnover.

3.2 All invoices from ACS are exclusively sent out electronically (email). ACS is under no obligation to use any potential invoice portals of the Client.

3.3 The Client is obligated to pay for any costs associated with the paying of invoice amounts, e.g. wire transfers.

3.4 The Client can modify his own client data for billing, e.g. the billing address, at any time. ACS is obligated to consider the changes during billing, if the modifications have been received by ACS at least 60 calendar days prior.

4. Special services

4.1 If the Client commissions ACS with the provision of additional services, e.g. additional training seminars or consulting services, these shall be billed to the Client based on the amount of time worked per started work hour and based on the ACS price list effective at the time.

4.2 The Client's use of ACS support will be billed to the Client based on the amount of time worked per started hour and based on the ACS price list effective at the time, if the time spent exceeds 2 hours in a given month and is not covered by ACS' warranty services.

Enclosure 3

Form for Client information

As of: 09 May 2022

1.	**General Client information**
Company name incl. corporate form	
Department/Division	
Address	
Postal code and city	
Country	
Sales tax ID no. (*USt-IdNr.*)	
Tax ID no. (*St.-Nr.*; only for companies in Germany)	

2.	Contacts
Main contact	**Name:**
	Email:
Deputy contact	**Name:**
	Email:
3.	**Administrators**
First Administrator	**Name*1:**
	Email*2:
	Address, incl. postal code, city and country (if different from 1.):
Second Administrator	**Name*1:**
	Email:
	Address, incl. postal code, city and country (if different from 1.):

*1 Recipient of temporary access information sent by regular mail.
*2 Recipient of system news for the ACS MAH System.

4.	Billing information
Email address for invoices	
Billing contact (e.g. for questions regarding payment processes)	**Name:**
	Email:
Required billing information	
Invoice language	☐ **DE** ☐ **EN**
5.	**Billing recipient information (if different from 1.)**
Company name incl. corporate form	
Department/Division	
Address	
Postal code and city	
Country	

6.	Information concerning a remote billing address (if different from 1. or 4.)
Company name incl. corporate form	
Department/Division	
Address	
Postal code and city	
Country	
7.	**Information regarding ACS PharmaProtect GmbH**
Address	ACS PharmaProtect GmbH, Taubenstraße 20, 10117 Berlin, Germany
Website	https://www.pharmaprotect.de
Contact for general inquiries and changes	**Email:** info@pharmaprotect.de
Contact for technical inquiries	**Email:** support@pharmaprotect.de
Contact for accounting issues	**Email:** rechnungswesen@pharmaprotect.de

Enclosure 4

Response Times and Processing Times

As of: 22 October 2019

1. The following Response Times and Processing Times apply.
2. Definition of error categories: see main part of the Cooperation Agreement.
3. Response Times

Error category	Response Time within core hours (Mo - Fr 8:00 a.m. to 7:00 p.m.):	Response Time outside of core hours
Critical and essential error (error categories 1 + 2)	within 60 minutes	within 120 minutes
Non-essential error (error categories 3 + 4)	within 60 minutes	within 120 minutes as of the start of the next core period.

4. Processing Times

If errors do not already result in a reduction of the defined availabilities, the following maximum Processing Times apply for these errors:

4.1 Production environment, within core hours (Mo - Fr 8:00 a.m. to 7:00 p.m.):

Error category	Processing Time
1	within 8 hours upon receipt of notification
2	within 20 hours upon receipt of notification
3 + 4	within 2 business days upon receipt of notification

4.2 Production environment, outside of core hours

Error category	Processing Time
1	within 16 hours upon receipt of notification
2	within 2 business days upon receipt of notification
3 + 4	within 2 business days upon receipt of notification

Enclosure 5
Availability

As of: 5 December 2018

Performance	Expected availability	Survey period (expected availability)	Minimum availability	Survey period (minimum availability)	Measuring period
EU Hub interface					
Verification of Pack-related Data	99.0%	per year	98.0%	per month	24/7
Provision and editing of Pack-related Data	99.0%	per year	98.0%	per month	24/7
Pharmacy Server interface					
Verification of Pharmaceutical Packs without status change	99.5%	per year	98.5%	per month	24/7
Dispensation of a Pharmaceutical Pack with integrated verification with status change	99.5%	per year	98.5%	per month	24/7
Recall of a dispensed Pharmaceutical Pack as part of defined rules.	99.5%	per year	98.5%	per month	24/7

The calculation basis for availability of the individual services are the agreed upon measuring times during the survey period shown in the table.

The availability of the individual services is considered fulfilled when the service in question is available at the service transfer point to the functional extent agreed upon. The service transfer point is the internet access router at the data centre of Arvato Systems.

ACS is obligated to inform the Client about the type and duration of any availability shortfall for each individual service in writing and without delay as soon as ACS becomes aware of it.

The time between a defect becoming known pursuant to Section 19.1.2 at ACS, e.g. through information by the Client, and before it is successfully eliminated is considered one continuous time period of non-availability. The Client is entitled to prove a deviating time period.