First steps for new customers

What do I need to consider?

(version 3.0)

ACS PharmaProtect GmbH

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Table of contents

1. Introduction 3
2. Required registrations and logins 3
3. ACS MAH System 5
4. Changes that must be notified to ACS 6
5. Important information on serialisation 7
6. ACS contact information 8
7. Information material 8

1. Introduction

As part of securPharm, ACS PharmaProtect GmbH is an integral element in Germany's protective shield to prevent falsified medicines from entering the legal supply chain.

securPharm e.V. was founded as a non-profit stakeholder organisation on 16 March 2012 with the aim of establishing a system for the authentication of medicines in accordance with the requirements of the Falsified Medicines Directive 2011/62/EU and the Delegated Regulation No. 2016/161 (EU).

ACS PharmaProtect GmbH was founded in parallel on 22 June 2012 as the operating company of the database system for the pharmaceutical industry in Germany. ACS PharmaProtect GmbH's shareholders are the pharmaceutical associations BAH, BPI, Pro Generika and vfa.

The core task of ACS PharmaProtect GmbH (ACS) as the operator of the database system of the pharmaceutical industry (ACS MAH System) is to provide the pack data for prescription medicines marketed in Germany that are necessary for verification in the end-to-end process. These data have to be uploaded into the ACS MAH System by the pharmaceutical companies. These guidelines are intended to provide pharmaceutical companies with an overview of the necessary "first steps" to upload product pack data into the ACS MAH System in order to ensure that medicines can be safely dispensed in Germany.

2. Required registrations and logins

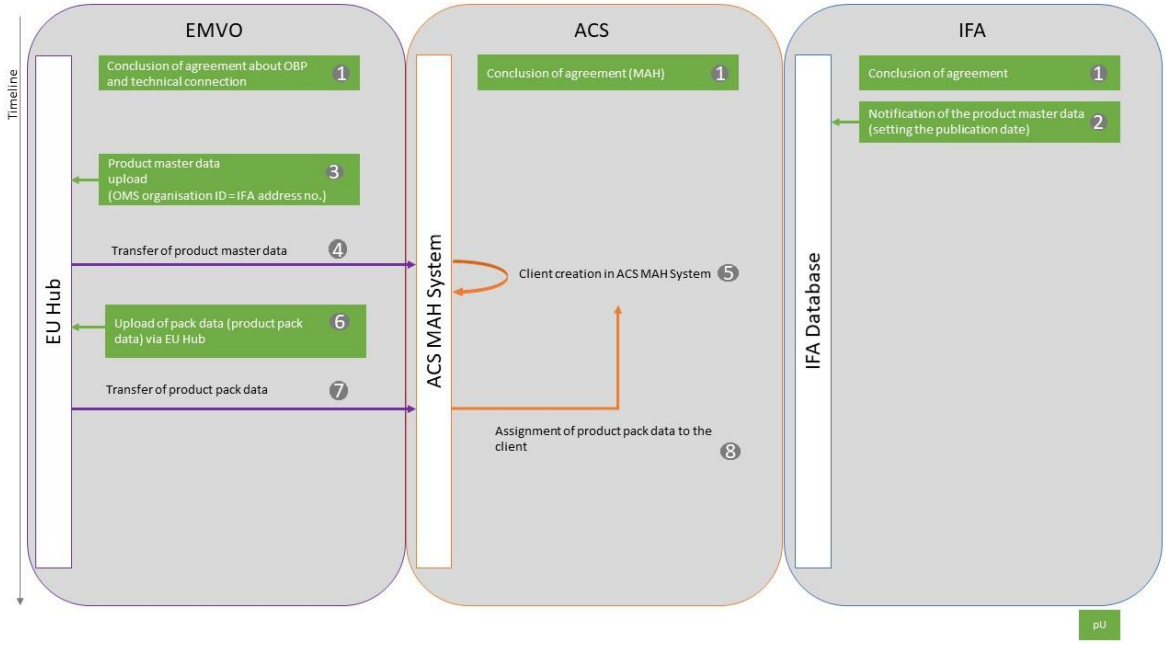


Figure 1: Uploading data to the ACS MAH System (timeline)

There are three prerequisites that need to be met in order to make your pack data available to the dispensing agencies and hence for to them to be uploaded:

Onboarding at EMVO(1); this step is a basic requirement for all pharmaceutical companies, including those in Germany, to ensure that the data are available in the European verification system (EU Hub) for verification in all affiliated Member States. Details about on-boarding at EMVO can be found at https://emvo-medicines.eu/pharmaceuticalcompanies/obp-portal/

On-boarding at EMVO consists of a contractual and a technical part. You need to complete both parts in order to upload your data (especially product master data) to the EU Hub.

Please note that all marketing authorisation holders (MAHs) of the on-boarding partner (OBP) must be registered as active for the particular EU markets in which you distribute products.

Please note that, when uploading via the EU Hub, the IFA address number (max. 5 digits) must be entered as MAH ID or OMS Organisation ID in the master data of the EU Hub for each medicine that is placed on the market in Germany.

Furthermore, the pharmaceutical central number (PZN) must be indicated in the "National Code" field of the notification of the product master data in the EU Hub (EMVO).

You can find more information on the individual data fields relating to uploads via the EU Hub at https://emvo-medicines.eu/knowledge-database/, for example in the "EMVS Master Data Guide" document.

After a product master data upload **(3)** via the EU Hub, they are forwarded to the ACS MAH System **(4)** and your products can be viewed in the ACS MAH System using the "Products Overview" report (G371), provided a cooperation agreement has been concluded with ACS and you have thus been granted access to the ACS MAH System.

A client account is created when you upload your first master data **(5)**. Each MAH registered with EMVO has an individual account in the ACS MAH System in order to be able to correctly assign products, among other things.

Once you have successfully uploaded product master data, you can then also upload product-pack data via the EU Hub **(6)**. Please ensure that the data record structure is correct. You can also find information on this in the "EMVS Master Data Guide" document. Product pack data relevant to the German ACS MAH System will be forwarded as soon as the upload has been completed **(7)**. These will be assigned to your account **(8)**.

Conclusion of agreement with ACS PharmaProtect GmbH (cooperation agreement) (1); this step is necessary because complete pack-related data for the necessary verification process are only stored in the particular national verification systems (NMVO) and not in the EU Hub. An agreement is necessary since the national verification systems store the pack data in corresponding server environments. ACS's contractual partners are pharmaceutical companies (Section 4 (18) of the German Medicinal Products Act – AMG). The contractual requirement is determined in an obligation-based legitimacy check, which is repeated at regular intervals or on an ad hoc basis.

Conclusion of agreement with and reporting of product master data to (1); IFA GmbH is the central issuing authority for the pharmaceutical central number (PZN), which is, among other things, a component of the unique identifier (embedded in the product code formats PPN and

NTIN) and must be specified as a mandatory “national code” for multi-market packs (MMPs) and single market packs (SMPs) when reporting product master data in the EU Hub (EMVO).

If you have any further questions regarding IFA reporting, please contact IFA support directly at ifa@ifaffm.de.

The product is released for the ERP systems as a result of the notification of the product master data and a selected publication date **(2)**.

Login to and active use of the ACS MAH System are not necessary for pack data upload. The pack data required for verification are processed and made available after the above prerequisites have been met, even if you do not create any users in the ACS MAH System. However, the ACS MAH System offers you helpful additional options, such as the ability to edit alerts and use reports.

3. ACS MAH System

The ACS MAH System consists of two system environments: the integration environment and the production environment.

The integration environment can be used, for example, to test processes in advance, to check transactions for validity or to familiarise yourself with the various features of the ACS MAH System. Both the integration environment and the production environment are connected to the equivalent system of the EU Hub. This separation of environments means that faulty data or processes in the integration environment have no influence on the actual ability of your products to be dispensed.

The production environment is also what is known as the live environment, serving the actual business purpose. There is an interface to the EU Hub and to the pharmacy server, to which the dispensing and verification points are connected. Errors in this production system can actually prevent a pack or an entire batch from being dispensed and lead to notifiable alerts.

You will receive the web addresses for access to the production environment portal with the temporary access data sent by post to the administrators you have specified. We will gladly send you the access data for the integration environment on request to info@pharmaprotect.de. Owing to two-factor authentication, the use of personal certificates issued by a PKI service is mandatory for logging in to the ACS MAH System. This means that a certificate must be downloaded and installed before the ACS MAH System can actually be accessed.

For this reason, please contact our ACS customer support before logging in to the ACS MAH System in order to obtain the download link for the required certificate (phone: +49 (0)30 4000 484 14 | support@pharmaprotect.de).

For better orientation, the two environments of the ACS MAH System can be distinguished by their appearance when you log in. The login screen and footer are orange for the integration environment, while they are blue for the production environment.

4. Changes that must be notified to ACS

We would ask you to notify ACS of the following changes in good time in order to enable smooth cooperation and data processing:

Change of contact persons; the contacts named by you (main contact and deputy) will be informed about ACS news and events. The main contact you designate will also receive system messages from the ACS MAH System. The contact in the accounting department serves as an interface for queries on all matters relating to invoices.

Changes to company name and address; this is relevant in order to record your identity correctly and to be able to send correctly issued invoices and documents.

Change in co-distribution relationships; this is relevant to ensure that only authorised persons in the ACS MAH System can view your data.

PZN transfers (complete or partial); these are relevant as they may lead to changes to contractual situations. They must be evaluated by ACS and contractually followed up. Please also observe the EMVO requirements relating to these processes.

Termination of the contractual relationship; please inform us in good time if you plan to terminate the agreement due to a sale or the discontinuation of the line of business.

5. Important information on serialisation

We recommend that you observe the following additional information that must be observed with regard to serialisation:

Securpharm Coding Rules; this guide contains all the information to be considered regarding serialisation information on packs for the German market. The coding rules are updated at regular intervals and are valid in their most recent version.

EMVO Master Data Guideline; EMVO's guidelines regarding the technical requirements and specifications to be met for their upload processes to the EU Hub.

Delegated Regulation No. 2016/161 (EU); valid legal text of the delegated regulation based on the provisions of the Falsified Medicines Directive 2011/62/EU.

Falsified Medicines Directive 2011/62/EU; valid legal text concerning the Falsified Medicines Directive (FMD).

FAQs (Frequently Asked Questions) of the EU Commission; the EU Commission publishes interpretations and clarifications of the Delegated Regulation 2016/161 (EU) at regular intervals. The FAQs have a quasi-legally binding character.

6. ACS contact information

Please do not hesitate to contact us if you have any further questions

E-mail: info@pharmaprotect.de

Further contact options will be available to you once the agreement has been concluded. Please get in touch with the appropriate contact for the following topics to ensure that your request is assigned correctly.

Contact for technical queries concerning the ACS MAH System: Alert management, master and pack data, reporting, access (e.g. certificates, passwords, users/roles), EU Hub (e.g. for questions regarding the OBP/MAH interface to the EU Hub, questions regarding EMVO feedback).

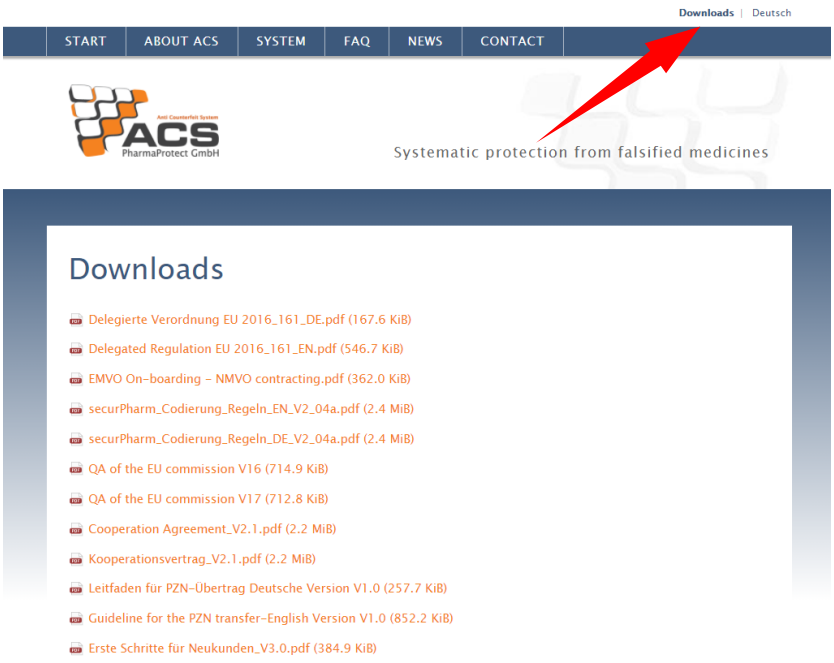
E-mail: support@pharmaprotect.de
Phone: +49 (0)30 4000 484 14

Contact for administrative queries regarding connection to the ACS MAH System, contracts, company master data and contact data changes and events

E-mail: info@pharmaprotect.de
Phone: +49 (0)30 4000 484 00

Contact for questions about your invoices

E-mail: rechnungswesen@pharmaprotect.de

7. Information material

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