

2020

First steps for new customers

What you need to know

(Version 2.0)

With the kind support of

Informationsstelle für Arzneispezialitäten



1. Introduction

As part of securPharm, ACS PharmaProtect GmbH is an integral element in Germany's protective shield to prevent counterfeit 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 marketing authorisation holders. These guidelines are intended to provide marketing authorisation holders with an overview of the necessary "first steps" to upload pack data into the ACS MAH System in order to ensure that medicines can be safely dispensed in Germany.

2. Required registrations and logins

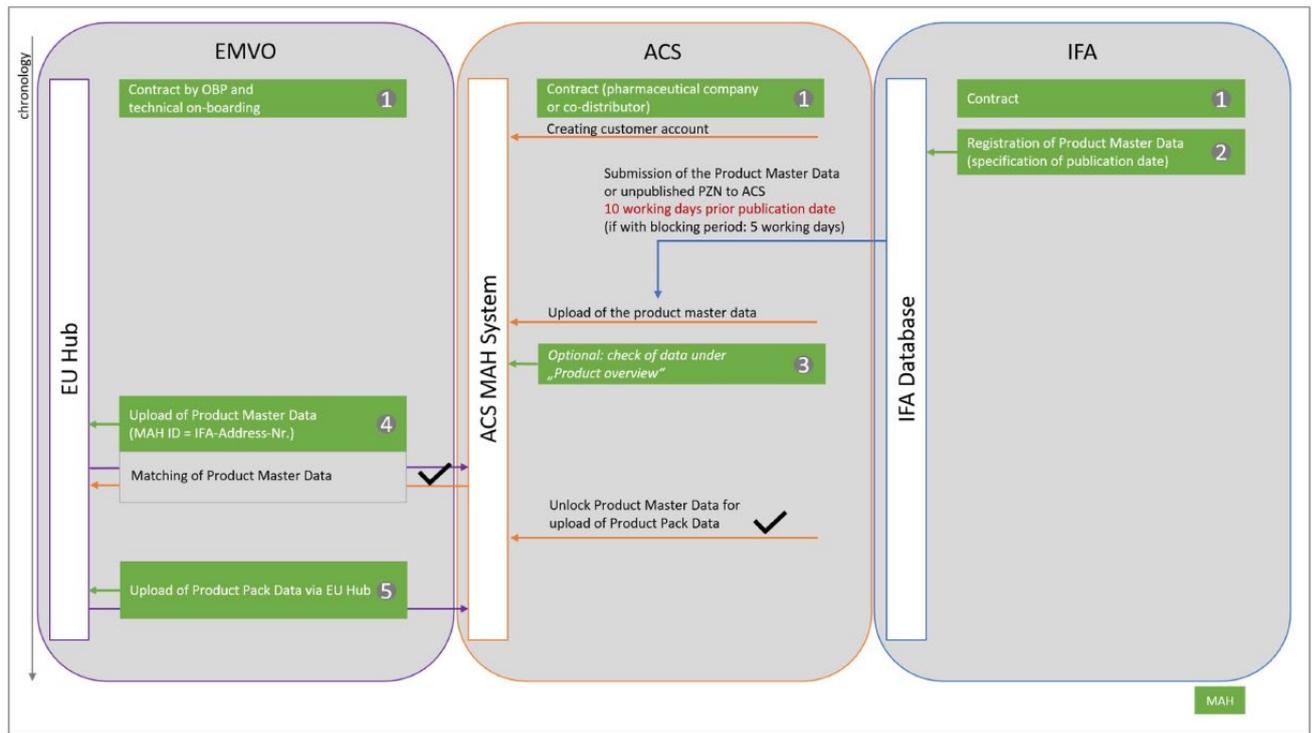


Figure 1: Uploading data into the ACS MAH system (timeline)

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

On-boarding at EMVO ① : This step is a basic requirement for all marketing authorisation holders, 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 when uploading via the EU Hub that for each medicine that is marketed in Germany, the IFA address number (max. 5 digits) must be entered as MAH-ID in the EU Hub master data.

Furthermore, the central pharmaceutical number (PZN) must be specified in the “National Code” field, which is mandatory for multi-market packs (MMP) and single market packs (SMP) when reporting product master data to the EU Hub (EMVO).

Conclusion of contract with ACS PharmaProtect GmbH (Cooperation Agreement) ① : This step is necessary because pack-related data (serial numbers and expiry dates) for the necessary verification process are only stored in the particular National Medicines Verification Systems (NMVO) and not in the EU Hub. Since the National Medicines Verification Systems store these data for you in corresponding server environments, you need a contract for this as well.

ACS's contractual partners are marketing authorisation holders (Section 4 (18) of the German Medicinal Products Act – AMG).

In contrast to other National Medicines Verification Systems, the product master data that you report to IFA GmbH for the medicines affected by the EU Falsified Medicines Directive are automatically transferred to the ACS MAH System and matched with the data you report to the EU Hub.

Conclusion of contract with and notification of product master data to IFA GmbH (IFA) ①②:

This step is necessary to ensure that the pack-related data of your medicines affected by the EU Falsified Medicines Directive can be correctly transferred to the ACS MAH System.

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

After product master data have been reported to IFA GmbH and given a publication date, the relevant master data are automatically transferred to the ACS MAH System ②.

Once this process has taken place, you should access the report “Products Overview” (G371) in the ACS MAH System to check that your products have been transferred ③.

If the check is positive, you can now upload product master data via the EU Hub ④. Please ensure that the data record structure is correct. Once uploaded, data will be systematically synchronised between the EU Hub and the ACS MAH System. In this way, the data records are checked for consistency.

Finally, you must now upload the pack data via the EU Hub so that the products are ready for dispensing ⑤.

Please be sure to follow the sequence of the individual steps described, otherwise the pack data upload will not function properly.

Registration and active use of the ACS MAH System is not absolutely necessary for pack data to be uploaded. 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. The ACS MAH System offers helpful options, such as the ability to edit alerts and create 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 check processes and files internally, as well as to gain familiarity with the various functions of the ACS MAH System before using them in the production environment. Both the integration environment and the production environment are connected to the equivalent systems of the EU Hub. This means that any incorrect data in the integration environment has no influence on the way your products can be dispensed.

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

The web addresses for accessing the relevant system environment can be obtained with the temporary access details sent by post to the main contact named in Enclosure 3 of the Cooperation Agreement. Thanks to two-factor authentication, the use of personal certificates and certificates issued by the PKI service is mandatory for login to the ACS MAH System. This means that a certificate must be downloaded 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 30 4000 484 14).

The two system environments of the ACS MAH System are distinguished by different colours at login to provide you with better orientation. The login screen and status bar are orange for the integration environment, while they are blue for the production environment.

The rights of a first administrator are assigned to the main contact. You must set up two ACS MAH System administrators with different Email addresses before the ACS MAH System can be used. Temporary access data will expire and can no longer be used once the new accounts have been set up. You will receive detailed instructions for the initial login to the ACS MAH System together with the temporary access data.

4. Data upload / “IFA notification” by marketing authorisation holder since 9 February 2019

The prerequisite for performing checks in the ACS MAH System is the allocation of a central pharmaceutical number (PZN) by the information service provider IFA GmbH and the reporting of certain details to the IFA database. Furthermore, the notification and publication deadlines (14 days) must be observed in this connection.

Data for each PZN must be reported completely and correctly. This applies to the following data fields in particular with regard to the application of the Falsified Medicines Directive (FMD)

- *Verifizierung im Pflichtbetrieb ab Hochladedatum (Verification in mandatory operation from upload date)*
- *Verifizierung im Pflichtbetrieb ab Verfalldatum (Verification in mandatory operation from expiry date)*

By reporting an entry in the data field *Verification in mandatory operation from the upload date*, the marketing authorisation holder/supplier determines the general verification obligation for a particular PZN. Please enter the date of the first upload in this field.

By reporting an entry in the data field *Verification in mandatory operation from the expiry date*, the marketing authorisation holder/supplier determines the expiry date from which the verification obligation applies to the PZN concerned.

In this context, it is recommended to check and, where necessary, correct the entry for the data field *Duration (shelf life of an article from production in months)* for each PZN.

The complete and correct entries for the two data fields *Verification in mandatory operation from upload date* and *Verification in mandatory operation from expiry date* are the prerequisite for

- Identifying goods subject to verification,
- Dispensing inventory goods that were released before 9 February 2019 and identifying them as such,
- Supplying patients safely with pharmaceuticals.

If suppliers' notifications fail to appear, the logic procedures in the system have reacted in the same way as indicated by the notification since 9 February 2019. Incomplete or incorrect notifications can prevent a pack from being dispensed, even though it could actually be dispensed.

About the notification variants:

Variant 1

Request the current EAD file (EAD verification) via the IFA GmbH website. Subsequently, please enter the verification information in columns N “Verifiz Pflicht ab Verfall” (“Verification obligation as from expiry”) and O “Verifiz Pflicht ab Hochlade” (“Verification obligation from upload”), save the file and then transfer it to IFA GmbH (ifa@ifaffm.de).

The EAD file can be accessed here: <http://www.ifaffm.de/de/ifa-fuer-anbieter/anforderung-aktuell-ead-datei.html>

Variant 2

Complete the order cover sheet + Annex C (Changes to article data)

Auftragsdeckblatt



Hinweise zum Ausfüllen des Formulars:
 - Bitte füllen Sie das Formular elektronisch aus (nicht handschriftlich).
 - Bitte füllen Sie das Formular vollständig aus und fügen Sie die entsprechenden Anlagen (A, B1, B2, C und/oder D) bei.
 - Versand per E-Mail an ifa@ifaffm.de.

IFA GmbH
Hamburger Allee 26 – 28
60486 Frankfurt am Main

Neukunde

Kunden-Nr.

Auftraggeber

Ansprechpartner/in

Frau Herr

Titel

Vorname

Name

Straße/Postfach

Anlage C - Änderungen von Artikeldaten



Hinweise zum Ausfüllen des Formulars:
 - Bitte füllen Sie das Formular elektronisch aus (nicht handschriftlich).
 - Bitte fügen Sie diesem Formular ein Auftragsdeckblatt bei.

Tipp: Bei mehreren Ergänzungen/Änderungen an einer PZN innerhalb eines Auftrages wird nur der Preis für eine Änderung berechnet.

Auftraggeber

Veröffentlichung zum * 01. oder 15. eines Monats
*unbedingt Datum angeben

Neukunde Kunden-Nr.

ohne Sperrfrist mit Sperrfrist

			Neue Preise
PZN	<input type="text" value="12345684"/>	PZN Nachfolger <input type="text"/>	KHAEP <input type="text"/>
Produktname	<input type="text" value="Tripapolon Forte"/>		APU <input type="text"/>
Darreichungsform	<input type="text" value="KAPSELN"/> Menge und Einheit <input type="text" value="20"/>		AEP <input type="text"/>
Art der Änderung			AVP inkl. MwSt. <input type="text"/>
			UVP inkl. MwSt. <input type="text"/>

This can be accessed here <http://www.ifaffm.de/de/ifa-fuer-anbieter/ifa-formulare-dateien.html>

Please enter the text “Verifizierung im Pflichtbetrieb ab Verfalldatum MMJJJJ und Verifizierung im Pflichtbetrieb ab Hochladedatum TT.MM.JJJJ” (“Verification in mandatory operation from expiry date MMYYYY and Verification in mandatory operation from upload date DD.MM.YYYY”) under “Art der Änderung” (“Type of change”).

Note on the field “Art der Änderung” (“Type of change”): in the case of Verification in mandatory operation from expiry date, the expiry date of the first batch going to the verification facility must be indicated (note format MMYYYY). For Verification in mandatory operation from upload date, the first upload date of the relevant PZN must be entered (note format DD.MM.YYYY).

The product master data for your PZNs will be transferred to the ACS MAH System after the IFA publishes the notification. The presence of the product master data in the ACS MAH System is a prerequisite for uploading the corresponding serial numbers.

5. ACS contact information

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

Email: info@pharmaprotect.de

Further contact options will be available to you once the contract 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).

Email: support@pharmaprotect.de

Phone: +49 30 4000 484 14

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

Email: info@pharmaprotect.de

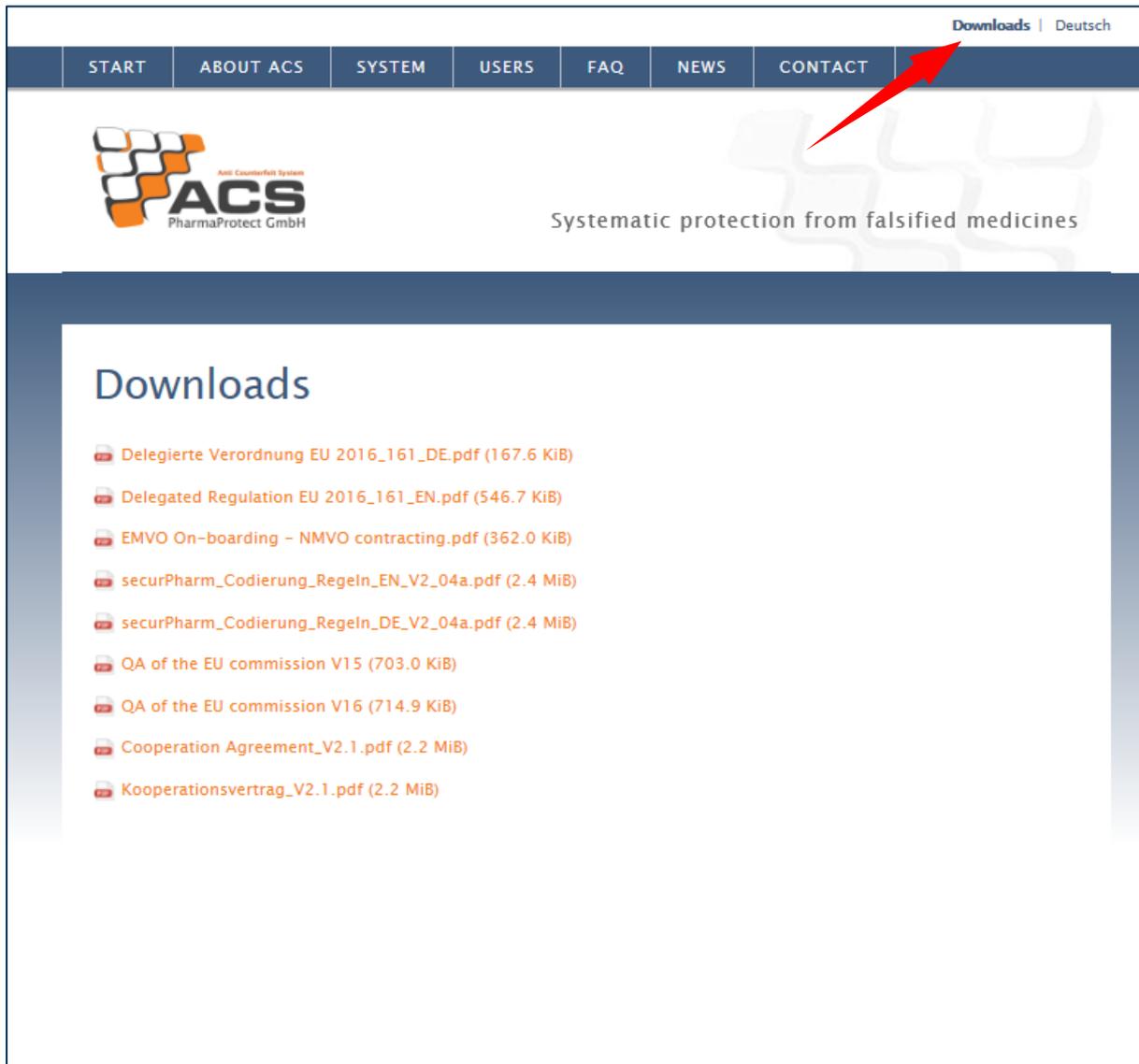
Phone: +49 30 4000 484 00

Contact for questions about your invoices

Email: rechnungswesen@pharmaprotect.de

6. Information material

You can access further information material under “Downloads” on our website at <https://www.pharmaprotect.de/en>.



The screenshot shows the website's navigation menu with 'Downloads' highlighted by a red arrow. The main content area is titled 'Downloads' and lists several PDF documents with their file names and sizes.

File Name	Size
Delegierte Verordnung EU 2016_161_DE.pdf	167.6 KiB
Delegated Regulation EU 2016_161_EN.pdf	546.7 KiB
EMVO On-boarding – NMVO contracting.pdf	362.0 KiB
securPharm_Codierung_Regeln_EN_V2_04a.pdf	2.4 MiB
securPharm_Codierung_Regeln_DE_V2_04a.pdf	2.4 MiB
QA of the EU commission V15	703.0 KiB
QA of the EU commission V16	714.9 KiB
Cooperation Agreement_V2.1.pdf	2.2 MiB
Kooperationsvertrag_V2.1.pdf	2.2 MiB