

## **Guideline for the PZN transfer at IFA GmbH and a change of supplier in the ACS-MAH-System**

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### **Objective and scope**

This document describes the process steps that must be considered when an article is sold by Supplier A to Supplier B. If a new supplier, Supplier B, takes over item distribution, the article data in the IFA database can be transferred from Supplier A to Supplier B while keeping the existing PZN. The prerequisite for this is that no product change be made as part of the change of supplier. For example, if there is a change in trademark, an application for a new PZN must be filed.

For this purpose, Supplier B, who will acquire the product, must meet the basic prerequisites for marketing prescription-only drugs, among others in accordance with the Delegated Regulation (EU) 2016/161 and other legal regulations. This also includes that new Supplier B concludes a contract with ACS PharmaProtect GmbH (hereafter referred to as "ACS") and obtains access to the EU Hub via an On-boarding Partner (hereafter referred to as "OBP"). Furthermore, it must be taken into account that each article must be transferred at the EMVO. The so-called "OBP Guideline for Divestitures and Acquisitions" of the EMVO describes important aspects that are relevant for marketing authorisation holders in case of divestitures and acquisitions.

### **Implementation**

#### **1) IFA notification - Notification of the PZN transfer to IFA GmbH via modification order:**

An order for a PZN transfer can be issued by the former or future supplier (if the future supplier is not yet a contractual partner of IFA GmbH (hereafter referred to as "IFA"), he must first conclude an IFA supplier contract). For the order, the articles concerned must be entered in a file or in the form "Anlage C – Änderung von Artikeldaten" ("Appendix C – Product Changes"). If this concerns the entire product range, an indication will suffice that all articles of the former supplier must be transferred. The order is complete if a declaration of consent regarding the PZN transfer has been submitted to IFA by both the former and the future supplier. This declaration of consent must state that the undersigned company agrees with the new supplier being entered for the articles in question. With the PZN transfer, the former supplier's right to place orders with IFA regarding the articles concerned is also transferred to the new supplier. The supplier responsible in each case will receive an order confirmation following the processing of the modification order. The publication of an article modification in the IFA information services, and therefore also in physicians' and pharmacy software among others, depends on the IFA Publication calendar in consideration of notification deadlines for article modifications.

<https://www.ifaffm.de/de/ifa-fuer-anbieter/ifa-redaktionskalender.html>

## **2) Notification of a supplier change to ACS for the ACS-MAH-System:**

In principle, the IFA transmits the PZN subject to mandatory verification together with the associated master data including the 5-digit IFA supplier number (IFA ID) to ACS. This is typically done 10 business days before IFA's chosen date of publication. If a supplier imposed a blocking period for the IFA modification order, the corresponding data delivery will be done on the 5th business day prior to IFA's date of publication. Upon receipt by ACS, the data will be entered into the database of the ACS-MAH-System. The new supplier can use his access information to check in the ACS-MAH-System if the supplier change was already effected. As soon as the supplier change has been effected, the new supplier can view the information regarding the article via his access to the ACS-MAH-System. At that point, the former supplier no longer has this option. At the same time, the article is blocked for the further upload of pack data in the ACS-MAH-System and neither the former nor the new supplier can upload new pack and batch data to the ACS-MAH-System via the EU Hub.

As a result, the last upload of serial numbers for the former IFA ID to the EU Hub must take place before the "new" master data are entered into the ACS-MAH-System. Under normal circumstances, this would be up to 10 business days prior to the date of publication at IFA.

## **3) Update of the master data in the EU Hub:**

The prerequisite for uploading new pack and batch data under the new supplier is an update of the master data in the EU Hub including the IFA ID by the OBP in charge. Since these updated master data are reconciled with the IFA data in the ACS-MAH-System, this can be done no sooner than the change of supplier has been completed in the ACS-MAH-System. The 5-digit IFA ID is entered for the element "MAH ID". Detailed instructions are provided in the current "EMVS Master Data Guide" by the EMVO. Upon successful reconciliation of the master data in the ACS-MAH-System, the new pack and batch data will be unblocked and the item can be marketed by the new supplier.

The initial upload of serial numbers for the new IFA ID to the EU Hub can only be executed after the EMVO master data have been updated and successfully reconciled in the ACS-MAH-System.

### Important information

It must be taken into account that, following the PZN transfer in the ACS-MAH-System, the new supplier can also view the transactions/alerts for batches that were released by the former supplier and may still be in the market. These can no longer be viewed by the former supplier from the date the PZN is transferred. Therefore, we would like to point out that the associated responsibilities (e.g. notification of suspected falsifications, reporting, etc.) must be settled internally between the former and the new supplier.

### Example (without blocking period)

