



## **AMAG PHARMACEUTICALS, INC. / COVIS PHARMA US, INC. RETURNED GOODS AND PRODUCT REPLACEMENT POLICY (As of April 19, 2021)**

This Returned Goods and Product Replacement Policy (the “Policy”) sets forth the policy and procedures that AMAG Pharmaceuticals, Inc./Covis Pharma GmbH (“AMAG/Covis”) follows in the United States regarding returns and replacements of the Products set forth below.

**This Policy is subject to change at any time and without notice.**

### **I. DEFINITIONS**

- “Product” shall mean Feraheme® (ferumoxytol injection).
- “Direct Customer” shall mean a pharmaceutical distributor, wholesaler, specialty pharmacy or similar entity with which AMAG/Covis has entered into an agreement to distribute Product on behalf of AMAG/Covis or to purchase Product directly from AMAG/Covis.
- “Indirect Customer” shall mean doctors, pharmacies, hospitals, and clinics who do not directly purchase the Products from AMAG/Covis. For purposes of clarity, patients are not Indirect Customers.
- “Customer” shall mean Direct Customer and/or Indirect Customer.
- “Out-of-Date” shall mean three (3) months prior to and six (6) months beyond the expiration date on the Product package or label.
- “In-Date” shall mean the period prior to the Out-of-Date period.
- “Shipping Error” shall mean a) wrong Product or package size sent through no error of distributor or b) Product quantity shipped in excess of the amount set forth on the applicable purchase order.

### **II. RETURNED GOODS**

#### **A. ELIGIBILITY CRITERIA**

##### **1. Returnable Products**

Subject to Section II, B below, AMAG/Covis will accept Product returns for credit ONLY to the extent the Direct Customer’s request to return Product relates to the following (“Valid Returns”):

- Out-of-Date Product in original, unopened containers;
- Product damaged during transition to the common carrier, provided AMAG/Covis is notified within thirty business days of receipt;
- Product received as a result of a Shipping Error, provided AMAG/Covis is notified within five (5) business days of receipt. Product shall be segregated and protected from all other inventory until resolution of shipment discrepancy; or
- When required by state law.



## 2. Non-returnable Products

AMAG/Covis reserves the right to destroy, without credit or refund, any returns of Product that fall under any of the following categories:

1. Product returned after the Out-of-Date period;
2. Product sold or distributed on a non-returnable basis, including, without limitation, Product that is expressly marked (a) “Non-Returnable,” (b) “Professional Sample,” (c) “Professional Package,” (d) “Clinical Trial,” or other donated or free Products or other similar special label;
3. Repackaged Product;
4. Product that is adulterated, misbranded, or counterfeit, as determined by AMAG/Covis in its sole discretion;
5. Partially-filled containers;
6. Unexpired Product returned for the purpose of reducing inventory;
7. Product damaged by improper storage;
8. Product involved or purchased in a fire sale, bankruptcy or sacrifice sale;
9. Product damaged by fire, flood, or Act of God;
10. Product for which original proof of purchase cannot be established;
11. Product destroyed by Direct Customer, Indirect Customer, or non-contracted 3rd party return processor;
12. Product obtained illegally or via diversion, including imports from countries outside the U.S., or in violation of AMAG/Covis policy; and
13. Non-approved returns or Product returned other than in accordance with this Policy, including failure to obtain authorization in accordance with the below section entitled “Shipment for Returns.”

AMAG/Covis reserves the right to verify the original purchase documents as proof that the Product being returned has been procured directly from AMAG/Covis and to verify the purchase price (net of applicable discounts, credits, or rebates) prior to authorizing a credit or refund in accordance with this Policy.

### **B. CREDIT FOR RETURNED PRODUCT**

Credit will be issued for Valid Returns. The credit will be determined based on the quantity of product returned and the amount actually paid by the customer for that Product and Lot. There will be no exchange of Products. No credit will be given for service, storage, handling, or processing fees associated with a return. Credits for Valid Returns Products are valid for one (1) year from the date of issuance.

### **C. RETURNS PROCESS AND SHIPMENT**

Valid Return Product must be returned in its original container.

Transportation costs for Valid Returns must in all cases be prepaid by the Direct Customer, except when Valid Return Products are returned by the Direct Customer due to Shipping Error. It is the Direct Customer’s responsibility to package securely all Valid Return Products so as to prevent any damage during transit. Delivery of broken, wet, or leaking shipping containers may be refused by AMAG/Covis and returned to Direct Customer at Direct Customer’s expense. Valid Return Products lost in transit by Direct Customer’s transit carrier are the responsibility of the Direct Customer.



Direct Customer shall submit a request for a Return Merchandise Authorization (“RMA”) together with satisfactory supporting documentation to AMAG/Covis in accordance with this Policy. Direct Customer shall not return Product prior to receipt of an RMA from AMAG/Covis. AMAG/Covis will issue a credit memo to Direct Customer reflecting the value of the Valid Return Product deemed to have been satisfactorily returned under a valid RMA and in compliance with this Policy, which value shall be determined by AMAG/Covis in its sole discretion.

To obtain an RMA, contact:

**Quality Assurance Department Email:**  
**[complaints@covispharma.com](mailto:complaints@covispharma.com)**

#### **D. INDIRECT CUSTOMER RETURNS**

Unless directed otherwise by AMAG/Covis, Product which is not obtained directly from AMAG/Covis must be returned directly to the distributors and/or wholesalers from whom such Product was acquired. Such Product returns will be governed by individual distributor/wholesaler policy.

#### **E. OTHER PRODUCT SHIPMENT MATTERS**

Shipments should be carefully inspected by Direct Customer upon arrival for Product damage. Any Product damage must be reported to AMAG/Covis’s Quality Assurance Department at [complaints@covispharma.com](mailto:complaints@covispharma.com) within thirty (30) calendar days of receipt and shall be handled in accordance with the applicable procurement agreement under which the Product was obtained.

Shipments having a shortage or overage due to an error on the part of AMAG/Covis must be noted on the freight bill at time of delivery. AMAG/Covis must be notified within five (5) calendar days of receipt of such shortage or overage in accordance with the terms of this Policy.

For handling of Product damages, shortages, or overages, please contact AMAG/Covis Quality Assurance Department at [complaints@covispharma.com](mailto:complaints@covispharma.com).

Shipments involving Product damaged during transit should be handled in accordance with the risk of loss provisions contained in the applicable procurement agreement.



### III. PRODUCT REPLACEMENT

**AMAG/Covis makes no guarantee that compliance by Indirect Customer with this Policy will result in a replacement of the Product.**

#### A. ELIGIBILITY CRITERIA

Indirect Customers may request a replacement for Product unusable due to:

- Broken vials whereby the vial was received intact but then damaged or broken prior to administration;
- Patient presentation issues, e.g., patient becomes ill after preparation but prior to administration;
- Infusion complications;
- Product involved in an AMAG/Covis documented Product Complaint (see Section IV, below);
- Refusal by patient subsequent to preparation of product for administration.

#### Non-replaceable Products

No Product will be replaced if:

1. Product has been reimbursed by a third party payor;
2. Product is not listed in this Policy;
3. Product obtained illegally or via diversion, including imports from countries outside the U.S., or in violation of AMAG/Covis policy;
4. Product involved in a fire, flood, natural disaster, or obtained in a sacrifice or bankruptcy, sale except for Product returned by a patient and satisfying the requirements of Section III, A, which shall be an allowable return;
5. Product is adulterated, misbranded, or counterfeit, as determined by AMAG/Covis in its sole discretion;
6. Product has been repackaged; or
7. Products shipped to offices for use by patients enrolled in or part of AMAG/Covis free drug programs (i.e., Patient Assistance Programs); Product samples; and Clinical Trial Products.

#### B. REPLACEMENT PROCESS AND SHIPMENT

Product shall be processed for replacement exclusively by AMAG/Covis in its sole discretion. No credits or refunds will be issued for Product requested to be replaced.

To request a replacement:

1. Indirect Customers may request a Product Replacement Form from [complaints@covispharma.com](mailto:complaints@covispharma.com). The Indirect Customer must send a completed, signed Product Replacement Request Form to Quality Assurance Department: [complaints@covispharma.com](mailto:complaints@covispharma.com).
2. Proof of purchase must accompany all requests for replacement Product.



3. Upon receipt, Quality Assurance Department will determine if the request is in compliance with the Requirements.
4. If denied, Quality Assurance Department will provide Indirect Customer with a Denial Letter outlining the reason for denial.
5. AMAG/Covis retains the right to discontinue this provision of the Policy for any healthcare provider, pharmacist, and/or their staff who AMAG/Covis determines, in its sole discretion, has misused this provision of the Policy and/or misrepresented the reason for requesting replacement Product.

#### **IV. RECALLS AND PRODUCT COMPLAINTS**

At AMAG/Covis's sole discretion, AMAG/Covis will accept returns of or provide replacement product for: (a) recalled Product, (b) Product complaints related to the identity, strength, quality, or purity of a distributed Product, or (c) Product returned at the direction of AMAG/Covis.

In the event of a Product recall or a return for Product complaints or at the direction of AMAG/Covis, AMAG/Covis will notify all Direct Customers of the requisite procedures to effect the orderly removal of the product from Direct Customer's inventory.



## AMAG PHARMACEUTICALS / COVIS PHARMA PRODUCT REPLACEMENT REQUEST

(as of April 8, 2021)

To be completed by the health care provider or pharmacy (“Customer”) and emailed to complaints@covispharma.com.

**Please note this form has two pages, both of which must be completed in their entirety to initiate a replacement shipment. This form must also be signed.**

### PRODUCT INFORMATION:

Product Name: \_\_\_\_\_ Dosage/Strength: \_\_\_\_\_

NDC: \_\_\_\_\_ Lot Number/Expiration Date: \_\_\_\_\_

Current condition of the product:

\_\_\_\_\_  
\_\_\_\_\_

Will the Product be returned to AMAG/Covis? Y N (please circle one)

If “NO”, reason for non-return: \_\_\_\_\_

AMAG/Covis will determine replacement eligibility for unreturned Product on a case by case basis. Please note, more information regarding unreturned Product may be requested.

If “NO”, complete and sign section “IF NOT RETURNING THE PRODUCT”, below.

### PHARMACY or PROVIDER INFORMATION:

Name and Address: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Contact Phone and Email: \_\_\_\_\_

Rx Number of Product to be replaced (this number will be in the Purchase Order field of the replacement shipment for easy identification and administration to the patient whose Product is the subject of this Replacement): \_\_\_\_\_

Pharmacy or Medical License and Expiration Date (required for shipping replacement Product):

\_\_\_\_\_

Explanation of Circumstances (describe damage, loss etc.): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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# AMAG PHARMACEUTICALS / COVIS PHARMA PRODUCT REPLACEMENT REQUEST

(as of April 8, 2021)

### PHARMACY OR PROVIDER DECLARATION:

I verify that the information provided on this request is complete and accurate. The Product was rendered unusable for the reason listed above which satisfies one or more of the Product Replacement Requirements. Additionally, I understand that AMAG/Covis reserves the right to conduct periodic audits of the records, excluding patient-identifiable data (unless the auditor enters into an appropriate agreement with the facility to protect an individual’s medical privacy), of all entities receiving replacement returns. I accept that reasonable notice will be granted and audits will be conducted during regular business hours. I represent and warrant that this facility has obtained all applicable authorizations, consents, and notices necessary to comply with all federal and state laws and regulations relating in any way to medical and/or health privacy, including, but not limited to, the HIPAA Privacy Rule, codified at 45 C.F.R. Parts 160 and 164, as amended from time to time. I understand that AMAG/Covis reserves the right to modify or revoke this program at any time without notice.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### IF NOT RETURNING THE PRODUCT:

I, \_\_\_\_\_, hereby certify that the information provided herein is accurate and that \_\_\_\_\_ (quantity) of \_\_\_\_\_ (Product) was destroyed in accordance with all applicable laws and regulations on destruction of medical waste.

Pharmacy or Provider Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### FOR INTERNAL USE ONLY:

PC # (if applicable): \_\_\_\_\_  
Date Request Received: \_\_\_\_\_  
Date Replacement Sent: \_\_\_\_\_  
Tracking Number: \_\_\_\_\_