

## AMAG PHARMACEUTICALS, INC.

### RETURNED GOODS AND PRODUCT REPLACEMENT POLICY

(Effective As of August 18, 2022)

This Returned Goods and Product Replacement Policy (the “Policy”) sets forth the policy and procedures that AMAG Pharmaceuticals, Inc. (“AMAG”) 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 has entered into an agreement to distribute Product on behalf of AMAG or to purchase Product directly from AMAG.
- “Indirect Customer” shall mean doctors, pharmacies, hospitals, and clinics who do not directly purchase Product from AMAG. For purposes of clarity, patients are not Indirect Customers.
- “Customer” shall mean a Direct Customer and/or an 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- “Out-of-Date” shall mean three (3) months prior to and six (6) months beyond the expiration date on the Product package or label.
- “In-Date” shall mean the period prior to the Out-of-Date period.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. RETURN POLICY

AMAG will accept Product returns only for purchases made by Direct Customers subject to the terms and conditions of this Policy. Unless otherwise agreed to by AMAG in writing, Product purchases by Indirect Customers and Product that is otherwise not obtained directly from AMAG must be returned directly to

the distributor or wholesaler from which such Product was acquired. Such Product returns will be governed by the agreement with the applicable distributor/wholesaler.

## **B. ELIGIBILITY CRITERIA**

### 1. Returnable Products

Subject to Section II.B. below, AMAG will accept Product returns for credit only to the extent a 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- Out-of-Date Product in original, unopened containers;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 (30) calendar 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 reserves the right to destroy, without credit or refund, any returns of Product that fall under any of the following categories:

- Product returned after the Out-of-Date period;
- 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;
- Repackaged Product;
- Product that is adulterated, misbranded, or counterfeit, as determined by AMAG in its sole discretion;
- Partially-filled containers;
- Unexpired Product returned for the purpose of reducing inventory;
- Product damaged by improper storage;
- Product involved or purchased in a fire sale, bankruptcy or sacrifice sale;
- Product damaged by fire, flood, or act of God;
- Product for which original proof of purchase cannot be established;
- Product destroyed by Direct Customer, Indirect Customer, or non-contracted third party return processor;

- Product obtained illegally or via diversion, including imports from countries outside the U.S., or in violation of AMAG policy; and
- Non-approved returns or Product returned other than in accordance with this Policy, including failure to obtain Return Merchandise Authorization as set forth herein.

AMAG reserves the right to verify the original purchase documents as proof that the Product being returned has been procured directly from AMAG 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.

### **C. CREDIT FOR RETURNED PRODUCT**

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

### **D. 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 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 in accordance with this Policy. To obtain an RMA request form, please contact the Quality Assurance Department at: [complaints@covispharma.com](mailto:complaints@covispharma.com). Direct Customer shall not return Product prior to receipt of an RMA from AMAG. AMAG 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 in its sole discretion.

Shipments should be carefully inspected by Direct Customer upon arrival for Product damage. Any Product damage must be reported to AMAG's Quality Assurance Department at

[complaints@covispharma.com](mailto:complaints@covispharma.com) within thirty (30) calendar days of receipt of Product in accordance with the terms of this Policy.

Shipments having a Shipping Error must be noted on the freight bill at time of delivery. AMAG's Quality Assurance Department must be notified at [complaints@covispharma.com](mailto:complaints@covispharma.com) within five (5) calendar days of receipt of Product in accordance with the terms of this Policy.

### **III. PRODUCT REPLACEMENT**

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

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

1. Customers may request a replacement for Product unusable due to:
  - Patient presentation issues, e.g., patient becomes ill after preparation but prior to administration
  - Theft
2. Product will not be eligible for replacement if:
  - Product has been reimbursed by a third party payor;
  - Product has been mishandled (e.g., vials broken or dropped by HCP);
  - Patient refuses treatment subsequent to preparation of product for administration;
  - Patient reschedules or misses appointment;
  - Product was obtained illegally or via diversion, including imports from countries outside the U.S., or in violation of AMAG policy;
  - Product has been involved in a fire, flood, natural disaster, or obtained in a sacrifice or bankruptcy sale;
  - Product has been adulterated, misbranded, or counterfeit, as determined by AMAG in its sole discretion;
  - Product has been repackaged; or
  - Product was shipped to offices for use by patients enrolled in or part of AMAG free drug programs (i.e., Patient Assistance Programs) or is a Product sample or was intended for use in a clinical trial.

#### **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. Customers must send a completed, signed Product Replacement Request Form (attached hereto) to AMAG's Quality Assurance Department at: [complaints@covispharma.com](mailto:complaints@covispharma.com).
2. Proof of purchase copy must accompany all requests for replacement.
3. A copy of the medical license referenced in the Product Replacement Request Form must accompany all requests for replacement.

Upon receipt, AMAG's Quality Assurance Department will determine if the request is in compliance with the requirements for Product replacement. If a request is denied, AMAG's/Covis Quality Assurance Department will provide the Customer with a Denial Letter outlining the reason for denial.

AMAG retains the right to discontinue this provision of the Policy for any healthcare provider, pharmacist, and/or their staff who AMAG 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's sole discretion, AMAG will accept returns of or provide replacement Product for: (a) recalled Product, or (b) Product subject to complaints related to identity, strength, quality, or purity.

In the event of a Product recall or return under this Section IV, AMAG will notify Customer of the procedures to effect the orderly removal of the product from Customer's inventory.

**AMAG PHARMACEUTICALS**  
**PRODUCT REPLACEMENT REQUEST**

(Effective As of August 18, 2022)

The following form must be completed by the health care provider or pharmacy (“Customer”) and emailed to [complaints@covispharma.com](mailto:complaints@covispharma.com) with the following attachments:

- Copy of Proof of Purchase showing the date and quantity of the Product purchase
- Copy of Pharmacy or Medical License with expiration date

**Please note this form has two pages, both of which must be completed in their entirety to initiate a replacement shipment. Please ensure the last page is signed.**

**PRODUCT INFORMATION:**

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

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

Current condition of the product:

\_\_\_\_\_

Explanation of Circumstances (describe the replacement request etc.):

\_\_\_\_\_

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

If you circled “N”, reason for non-return: \_\_\_\_\_

AMAG 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:**

Organization Name and Address (for replacement shipment purposes):

\_\_\_\_\_

\_\_\_\_\_

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

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

Purchase Order Number of Feraheme product: \_\_\_\_\_

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

\_\_\_\_\_

**AMAG PHARMACEUTICALS**  
**PRODUCT REPLACEMENT REQUEST**

(Effective As of August 18, 2022)

**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 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 reserves the right to modify or revoke this program at any time without notice.

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

Printed Name: \_\_\_\_\_

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: \_\_\_\_\_

Printed Name of Pharmacist/Provider: \_\_\_\_\_

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