

EFFECTIVE SEPTEMBER 1, 2014

This document is Amedra Pharmaceuticals LLC ("Manufacturer") current policy for return of Manufacturer pharmaceutical product purchased directly from Manufacturer, or its Authorized Distributors of Record ("ADR") by entities licensed to dispense or distribute Manufacturer's products ("Customer"). This policy also applies to pharmaceutical products purchased by Manufacturer's ADR either from Manufacturer or from the Manufacturer's ADR.

Non Authorized wholesalers and distributors and customers whom purchase products from them are not eligible to return Manufacturer products for credit.

### ALL AMEDRA SALES ARE SUBJECT TO THIS POLICY

### **Return Goods Eligible for Reimbursement**

Any Manufacturer product eligible for return reimbursement must meet the following minimum criteria; 1) be directly purchased from Manufacturer or from an Manufacturer ADR with proof of purchase (supplied upon request) and 2) in the original Manufacturer packaging with label intact and fully readable including NDC, bar-code, valid Manufacturer lot number and expiration date.

Unless otherwise specified within this policy, the following products purchased in the United States are returnable by customers to Manufacturer for return goods credit:

- 1. Products within six (6) month prior to expiration and up to twelve (12) months past the product labeled expiration date
- 2. Products in the original Manufacturer container and have Manufacturer valid and readable lot number and expiration date
- 3. All products must have <u>both</u> a Return Goods Authorization ('RGA') and an accompanying debit memo with the following minimum information: NDC, Lot #, HDMA Debit Memo Template, Expiration Date, and Quantity

### **Damaged in Transit**

For product shipped directly by Manufacturer that is damaged in transit, subject to F.O.B. terms, or material shipped in error by Manufacturer, Customer must contact Manufacturer customer service department within ten (10) days at telephone number 1-888-894-6528.

### **Recall Product**

Product associated with a Manufacturer-initiated recall is eligible for return subject to specific terms of the recall notification and requested return actions. If a product recall occurs, only Manufacturer-authorized recalls will be honored for return of product for credit. Specific instructions for each recall shall be disseminated to the appropriate entities. To qualify for a credit or product replacement, the returned product must meet the criteria noted in the recall notification issued by Manufacturer.



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### **Return Goods Not Eligible for Reimbursement**

All products, other than those listed above, shall be deemed not returnable for return goods credit. Non-returnable products include, without limitation:

- 1. Returns submitted without an RGA.
- 2. When proof of purchase from Manufacturer or an ADR cannot be verified either by invoice supplied by returning entity or EDI 867 data from the ADR.
- 3. In-dated product (i.e., product with more than 6 months expiration dating remaining) unless otherwise stated in this policy.
- 4. Products dated more than 12 months beyond the expiration date noted on the package.
- 5. Products discontinued more than twelve (12) months.
- 6. Any partial or open containers wherein the original manufacturer seal (including tamper evident or other seals) is removed, broken or missing, unless specifically required by state law. If required by state law the Manufacturer shall follow the laws pertaining to partial credits for that particular state.
- 7. Any Repackaged products not bearing the original manufacturer label including, but not limited to, products in patient prescription packaging and third party repackaged items.
- 8. Product containing prescription or patient labels, stickers, label alterations or markings or remnants thereof.
- 9. Product in which the lot number and/or expiration date is invalid, missing, illegible, covered, and/or unreadable on original container.
- 10. Product stored out of compliance with the specifications or handled improperly.
- 11. Product that has been in a sacrifice, clearance, bankruptcy, or similar type sale.
- 12. Product sold on a "Non-Returnable" basis, marked as non-returnable, free goods, donated products, professional samples, for "clinical trials" or with similar or special labeling.
- 13. Product destroyed or damaged from causes such as fire, water, tornado, catastrophe etc., and product that has otherwise deteriorated due to conditions occurring after shipment and beyond the control of Manufacturer, such as improper storage or handling, heat, cold, smoke, etc.
- 14. Products not distributed by Manufacturer.
- 15. Counterfeit, re-imported, diverted or product obtained illegally, or from a distributor who is not a Manufacturer ADR or any product purchased or otherwise obtained in violation of any Federal, State, or local law or regulation.
- 16. Products destroyed by a Customer or ADR or any Third Party Processor for Customer or ADR.
- 17. Any product manufactured to customer specifications or any private labeled product.
- 18. Products sold to any government stockpile program.



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- 19. Forms-only returns (i.e. the physical product must be received by Manufacturer to receive credit).
- 20. Adrenaclick auto-injector in the two-pack configuration may not be returned for credit except for expired and sealed original packaging of unsold inventory from either the Manufacturer ADR or retail pharmacy Customers whom purchased product from the Manufacturer ADR. Adrenaclick auto-injector in the two-pack configuration returned prior to product expiration date will not be credited. Adrenaclick auto-injector in the single pack configuration is not eligible for credit.

#### **Reimbursement for Returned Product**

Credit will be issued at Manufacturer's discretion based on one of the following depending upon how the product was purchased:

- 1. The Manufacturer Wholesale Acquisition Cost (WAC) Price in effect at the time the first unit of such lot was sold by Manufacturer to any direct purchasing account, less 10%, or;
- 2. the Manufacturer Contract Price in effect at the time the first unit of such lot was sold by Manufacturer to the Customer, less 10%.

Manufacturer will not pay for nor reimburse Customers for any charges or deductions for administrative, processing, handling, or freight charges associated with the return of product to Manufacturer. Credit or reimbursement will not be issued for product destroyed by Customers or third parties.

Customers are prohibited from deducting based on debit memo amounts without the prior written approval from Manufacturer. Debit memos are often estimated and not considered accurate or valid by Manufacturer until final approval has been secured and therefore shall not be deducted from future payments to Manufacturer either directly from the customer of through their ADR.

### **Procedure for Returning Product**

All returns must include a Returns Goods Authorization ('RGA'). Returns will not be processed without a RGA. To obtain an RGA refer to the contact information below.

All returns must also include a debit memo with the following minimum information: NDC, Lot #, HDMA – Debit Memo Template, Expiration Date, and Quantity.

All products eligible for return and consideration for reimbursement must be returned to Manufacturer's approved RGP at the following address and in accordance with such RGP's procedures:

Amedra Pharmaceuticals LLC C/O Dohmen Life Science Services 4580 S Mendenhall Road Memphis, TN 38141-6700

Returns Contact Information: 1-877-622-2341 (telephone), 1-414-434-6965 (fax)

AmedraCustomerService@ddnnet.com



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All returns shall be made in compliance with all applicable Federal and State laws and regulations.

Product returned outside this Return Goods Policy will not be returned to the Customer and no credit will be issued.

### **Special Instructions**

- 1. Product must have been purchased from a Manufacturer ADR to be considered valid for credit with accompanying proof of purchase required when requested.
- 2. Manufacturer reserves the sole right to determine whether items qualify for returns and credit. Manufacturer's determination of physical count of any returns product will be final. Reimbursement for return goods is subject to verification by Manufacturer or its agent to determine if product is within Manufacturer's Commercial Return Goods Policy guidelines.
- 3. By returning product, you authorize Manufacturer as your agent to destroy, without payment or any other recourse, any returned product. Products not eligible for return and reimbursement that are sent to Manufacturer's RGP will be destroyed and no reimbursement or credit will be issued for product unless state or local law require otherwise.
- 4. Unless expressly permitted by the Manufacturer, Manufacturer will not be responsible for product destroyed by any Returns Good Processor (RGP), with the exception of Manufacturer's processor of record and proof of destruction will not be accepted in lieu of.
- 5. Products ineligible for return should NOT be shipped to Manufacturer's RGP of record.
- 6. This publication of this policy on the Manufacturers website shall supersede and/or serve as notice of termination of any previous agreement or policy, whether written oral, or established through course of dealing between Manufacturer and any customer with respect to the subject matter thereof.

### **Quality Concerns**

If you have received a product that may have a potential quality issue or be implicated in an Adverse Event please contact the Manufacturer for further instruction at 1-888-894-6528, Select Option 1.

This Return Goods Policy is subject to change at any time and without prior notice to other parties