

**STANDARD TERMS AND CONDITIONS OF SALE - PHARMACEUTICAL AND  
VACCINE PRODUCTS DISTRIBUTED BY MERCK SHARP & DOHME LLC  
Effective April 1, 2025**

These Standard Terms and Conditions of Sale have been updated to reflect the following changes:

- Update Section 7 Remittances
- Update of Basis of Reimbursement in Section 16

# STANDARD TERMS AND CONDITIONS OF SALE - PHARMACEUTICAL AND VACCINE PRODUCTS DISTRIBUTED BY MERCK SHARP & DOHME LLC

Effective April 1, 2025

These Terms and Conditions may be updated at any time. The current version may be accessed at: [www.merck.com/termsandconditions](http://www.merck.com/termsandconditions), [www.merckorders.com](http://www.merckorders.com), or [www.merckvaccines.com](http://www.merckvaccines.com).

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These Standard Terms and Conditions of Sale govern all direct purchases and all returns of prescription pharmaceutical and vaccine products that are sold by Merck Sharp & Dohme LLC (“Merck”), a subsidiary of **Merck & Co., Inc.**, for itself and on behalf of its subsidiaries and/or affiliates (collectively, “Manufacturer”). Manufacturer has the unilateral right to modify these Standard Terms and Conditions of Sale at any time at its sole discretion. In the event of a conflict between these Standard Terms and Conditions of Sale and the terms of a product purchase agreement between Manufacturer and a Direct Purchasing Customer or a Client of a Direct Purchasing Customer, the terms of the product purchase agreement shall prevail, unless otherwise stated in such product purchase agreement.

## 1. DEFINITIONS

- A. **“Business Day(s)”** means Monday through Friday excluding weekends and holidays observed by Merck.
- B. **“Client of Direct Purchasing Customer”** means a licensed purchaser of Product from a Distributor.
- C. **“Depot Customer”** means a division, subsidiary, parent, affiliate, or related company under the common ownership and control of a Government Customer, Depot Vaccine Purchasing Customer, or Health Care Provider Vaccine Purchasing Customer and such Depot Customer meets the requirements of a Government Customer, Depot Vaccine Purchasing Customer, or Health Care Provider Vaccine Purchasing Customer as described in these Standard Terms and Conditions of Sale. These Terms and Conditions of Sale applicable to Government Customers, Depot Vaccine Purchasing Customers, and Health Care Provider Vaccine Purchasing Customers shall also apply to Depot Customers and such customers shall comply with these Standard Terms and Conditions of Sale, including but not limited to, The Storage and Handling Instructions for Transport of Refrigerated Vaccine Product or Frozen Vaccine Product from Depot Locations to Depot Customers in Section 21. A Depot Customer is not permitted to sell Product except to patients for administration of the Product at the Depot Customer facility.
- D. **“Depot Location”** means a facility that is under the control of a Government Customer, Depot Vaccine Purchasing Customer, or Health Care Provider Vaccine Purchasing Customer and stores Refrigerated Vaccine Product or Frozen Vaccine Product for distribution to a Depot Customer in accordance with the Storage and Handling Instructions for Transport of Refrigerated Vaccine Product or Frozen Vaccine Product from Depot Locations to Depot Customers in Section 21 of these Standard Terms and Conditions of Sale. A Depot Customer is not permitted to sell Product except to patients for administration of the Product at the Depot Customer facility.
- E. **“Depot Vaccine Purchasing Customer”** means a physician or physician group that owns or is employed by outpatient healthcare facilities or clinics, and that operates a Depot Location pursuant to a pharmacy license, as may be required by state law, for its outpatient use in order to depot Refrigerated Vaccine Product or Frozen Vaccine Product for distribution to Depot Customers in accordance with these Standard Terms and Conditions of Sale. A Depot Vaccine Purchasing Customer is eligible to purchase Refrigerated Vaccine Product or Frozen Vaccine Product directly from the Manufacturer or through a Merck Authorized Distributor for shipment to a Depot Location where such vaccine may be administered to patients or redistributed to Depot Customers. A Depot Vaccine Purchasing Customer, including its Depot Customers, is not permitted to sell Product except to patients for administration of the Product at the Depot Vaccine Purchasing Customer or Depot Customer facility.
- F. **“Distributor”** means a licensed wholesaler or physician distributor that has entered into, and has in effect, a Merck Authorized Distributor Agreement.
- G. **“Drop Shipment”** means any order sent to a Client of a Direct Purchasing Customer not legally or financially owned by the Direct Purchasing Customer, but where the invoice and payment for that particular order remains the responsibility of the Direct Purchasing Customer. Manufacturer determines which Products, if any, are eligible for Drop Shipment by Manufacturer to Client of a Direct Purchasing Customer.
- H. **“Frozen Vaccine Product”** means a Vaccine Product stored in frozen temperatures of between -50° C and -15°

C (-58° F and +5° F)

- I. **“Government Customer”** means a federal, state, local or tribal government entity. A Government Customer is eligible to purchase Refrigerated Vaccine Product or Frozen Vaccine Product directly from the Manufacturer or through a Merck Authorized Distributor for shipment to a Depot Location where such vaccine may be administered to patients or redistributed to Depot Customers. A Government Customer, including Depot Customer(s), is not permitted to sell Product except to patients for administration of the Product at the Government Customer or Depot Customer facility. Merck has a separate agreement with the Department of Veterans Affairs for Government Customers that are eligible to purchase off of the Federal Supply Schedule Contract (FSS Contract). Additional information about the terms of the FSS Contract may be made available upon request to the Merck National Service Center (section 10 of this document).
- J. **“Health Care Provider Vaccine Purchasing Customer”** means a physician who owns, is employed by, or has contracted with nonpayer outpatient health care facilities; or an advanced practice nurse, nurse midwife, or physician assistant, or a licensed naturopathic physician (ND) who is authorized pursuant to state law to purchase and administer vaccines, either alone or in tandem with a collaborating physician. A Health Care Provider Vaccine Purchasing Customer is eligible to purchase Refrigerated Vaccine Product or Frozen Vaccine Product directly from the Manufacturer or through a Merck Authorized Distributor for shipment to a Depot Location where such vaccine may be administered to patients or redistributed to Depot Customers. A Health Care Provider Vaccine Purchasing Customer, including its Depot Customer(s), is not permitted to sell Product except to patients for administration of the Product at the Health Care Provider Vaccine Purchasing Customer or Depot Customer facility.
- K. **“Manufacturer Reverse Distributor”** means a business that collects Products from Direct Purchasing Customer or Client of Direct Purchasing Customer and returns them to Manufacturer to destroy or destroys them on behalf of, and at the direction of, Manufacturer. Manufacturer Reverse Distributor is identified in Section 16. C. below.
- L. **“Product”** means a Pharmaceutical Product or Vaccine Product.
- M. **“Pharmaceutical Product”** means a prescription pharmaceutical product that Manufacturer sells in the Territory.
- N. **“Refrigerated Vaccine Product”** means a Vaccine Product stored in refrigerated temperatures of between 2-8°C (36-46°F) per the Manufacturer’s Prescribing Information.
- O. **“Territory”** means the 50 states of the United States and the District of Columbia.
- P. **“Vaccine Product”** means a vaccine that Manufacturer sells in the Territory.
- Q. **“Warehousing Retail Pharmacy Pharmaceutical Purchasing Customer”** means a retail pharmacy chain that has at least one warehouse and serves 50 or more wholly-owned stores.

## 2. CATEGORIES OF DIRECT PURCHASING CUSTOMERS

- A. **“Direct Pharmaceutical Purchasing Customers”** means the following categories of customers that are eligible to purchase Pharmaceutical Products, with the exception of KEYTRUDA® (pembrolizumab) for Injection, ZINPLAVA™ (bezlotoxumab) Injection, WELIREG® (belzutifan), and WINREVAIR™ (sotatercept-csrk) directly from Manufacturer: Distributors, Warehousing Retail Pharmacy Pharmaceutical Purchasing Customers, and Government Customers.
- B. **“Direct Vaccine Purchasing Customers”** means the following categories of customers that are eligible to purchase Vaccine Products directly from Manufacturer: Distributors, Government Customers, and Health Care Provider Vaccine Purchasing Customers.
- C. **“Direct KEYTRUDA® (pembrolizumab) for Injection Purchasing Customers”** means a Distributor that has been approved by Manufacturer, in its sole discretion, to purchase KEYTRUDA directly from Manufacturer and that has entered into, and has in effect, a Specialty Distribution Agreement for KEYTRUDA.
- D. **“Direct ZINPLAVA™ (bezlotoxumab) Injection Purchasing Customers”** means a Distributor that has been approved by Manufacturer, in its sole discretion, to purchase ZINPLAVA directly from Manufacturer and that

has entered into, and has in effect, a Specialty Distribution Agreement for ZINPLAVA.

- E. “Direct WELIREG® (belzutifan) Limited Network of Specialty Distributors Direct Purchasing Customer”** means a Distributor that has been approved by Manufacturer, in its sole discretion, to purchase WELIREG directly from Manufacturer and that has entered into, and has in effect, a Specialty Distribution Agreement for WELIREG.
- F. “Direct WINREVAIR™ (sotatercept-csrk) Limited Network of Specialty Distributors Direct Purchasing Customer”** means a Distributor that has been approved by Manufacturer, in its sole discretion, to purchase WINREVAIR directly from Manufacturer and that has entered into, and has in effect, a Specialty Distribution Agreement for WINREVAIR.
- G. “Direct Purchasing Customers”** means Direct Pharmaceutical Purchasing Customers, Direct Vaccine Purchasing Customers, Direct KEYTRUDA® (pembrolizumab) for Injection Purchasing Customers, Direct ZINPLAVA™ (bezlotoxumab) for Injection Purchasing Customers, Direct WELIREG® (belzutifan) Limited Network of Specialty Distributors Direct Purchasing Customers, and Direct WINREVAIR™ (sotatercept-csrk) Limited Network of Specialty Distributors Direct Purchasing Customer collectively.

### 3. PURCHASING REQUIREMENTS

Customers are encouraged to purchase all Pharmaceutical Products and Vaccine Products directly from Manufacturer or indirectly from a Merck Authorized Distributor. Merck Authorized Distributors are listed at [www.merck.com](http://www.merck.com) and [www.merckvaccines.com](http://www.merckvaccines.com).

### 4. ORDERS

- A.** Manufacturer prefers orders to be placed electronically via Electronic Data Interchange (“EDI”), [www.merckorders.com](http://www.merckorders.com), or [www.merckvaccines.com](http://www.merckvaccines.com). To register for [www.merckorders.com](http://www.merckorders.com) or [www.merckvaccines.com](http://www.merckvaccines.com), click on “I need to Register” and follow the instructions. Only Direct Purchasing Customers with existing accounts may order through EDI or the Internet.
- B.** Direct Purchasing Customers may alternatively place orders with the Merck Order Management Center by telephone, fax, or mail, as set forth in Section 10 of these Standard Terms and Conditions of Sale.
- C. Obligations of Direct Purchasing Customer (Financial and Credit Position)**
  - i.** Direct Purchasing Customer must maintain an adequate financial condition satisfactory to Manufacturer and substantiate such condition with financial statements or as otherwise requested by Manufacturer. If, in Manufacturer's judgment, at any time before shipment of Product, the financial condition of the Direct Purchasing Customer becomes impaired or unsatisfactory to Manufacturer, Manufacturer may hold, deny, or require cash payment or appropriate security before shipment. These remedies shall be in addition to, and not instead of, other remedies available to Manufacturer under these Standard Terms and Conditions of Sale or by law.
  - ii.** Direct Purchasing Customers are responsible for paying, in full, all amounts that are applicable to Product purchases by the due date. No deductions, other than cash discount, if any, are permitted unless authorized by a prior credit memo or as otherwise expressly permitted herein. Direct Purchasing Customer shall reimburse Manufacturer for any cash discount taken but not earned. Manufacturer reserves the right to hold orders on accounts with past due balances until such items are resolved to Manufacturer's satisfaction.
- D. Miscellaneous Account Administration**
  - i.** All orders are subject to acceptance by Manufacturer.
  - ii.** Manufacturer reserves the right to cancel backorders after 30 days.
  - iii.** Manufacturer reserves the right to issue a check to Direct Purchasing Customers who do not use open credits on their accounts after 90 days.

- iv. Unless otherwise mutually agreed to by Manufacturer and Purchaser in writing, Manufacturer will determine the time, route, and carrier of all shipments. Orders will be subject to a service fee in an amount determined by Manufacturer when Direct Purchasing Customer requests expedited shipping, including overnight shipping.

#### **E. Order Maximums**

- i. If a Direct Purchasing Customer's order(s), within thirty (30) days for any individual Product, exceeds 110% of the Direct Purchasing Customer's established pattern of previous total monthly purchases for that Product, then Manufacturer reserves the right to reduce, defer, back-order, or decline such order(s).
- ii. To ensure adequate supply of a Product for all customers, Manufacturer reserves the right to reduce, defer, back-order, or decline such orders to a level below 110% of the Direct Purchasing Customer's established pattern of previous total monthly purchases for that Product.

### **5. PRICES**

- A. Orders will be invoiced at prices in effect at the time the order is received unless deferred shipment beyond the Merck standard shipping period is requested by the Direct Purchasing Customer. If the Direct Purchasing Customer requests deferred shipment, then the order will be invoiced at the price in effect at the time of shipment. The Merck standard shipping period may vary based on the category of Direct Purchasing Customer and Product purchased. Please contact the Merck Order Management Center at 800-MERCK-RX (800-637-2579) for further information regarding the Merck standard shipping period for your order.
- B. All prices are subject to change without notice. If Manufacturer changes the price of a Product, Manufacturer will not allow price adjustment for inventory on hand or enroute to Direct Purchasing Customer because of a price change.
- C. Manufacturer reserves the right to rebill a Direct Purchasing Customer if it determines the Direct Purchasing Customer was billed an incorrect price due to internal system errors.
- D. Please address all requests for price quotations to the Merck Order Management Center.

### **6. TAXES**

- A. Direct Purchasing Customers are responsible for paying any tax that is applicable to the sale of any Product as of the date of shipment of such Product, except for backordered Product. On backordered Product, the Direct Purchasing Customer will be responsible for Federal Excise Taxes that were applicable at the time the Product was ordered and all other taxes that were applicable at the time the Product was shipped.
- B. When product is returned to Manufacturer via Manufacturer Reverse Distributor, regardless of whether it is eligible for reimbursement, the Direct Purchasing Customer or Client of the Direct Purchasing Customer will be credited for the Federal Excise Tax paid.

### **7. REMITTANCES**

- A. Manufacturer accepts three (3) forms of payment: Electronic, Check, and Credit Card:
  - i. Manufacturer prefers Electronic Payment. Arrangements for establishing payment via Electronic Fund Transfer may be made by contacting the Merck Order Management Center at 800-MERCK-RX (800-637- 2579).
  - ii. Check Payment should be sent to the lock-box address indicated on the invoice. Payment is recognized when received at this lock-box address.
  - iii. Manufacturer accepts the following forms of Credit Card Payment: American Express, MasterCard, and VISA. Orders placed by credit card will be charged automatically on the applicable prompt payment discount due date. The amount charged will reflect a two percent (2%) prompt payment discount on

eligible Product purchases (Merck in its sole discretion will determine which Product purchases are eligible for the prompt payment discount and eligibility will be noted on the invoice).

## **B. Payment Terms**

Merck may designate alternative payment terms applicable to a specific Product upon written notice.

### **i. Pharmaceutical Product**

- a. Other than electronic payment: a two percent (2%) prompt payment discount may be earned on eligible Product purchases, if invoice paid within 30 days from date of invoice; net 31 days (Merck in its sole discretion will determine which Product purchases are eligible for the prompt payment discount and eligibility will be noted on the invoice).
- b. Electronic payment: a two percent (2%) prompt payment discount on eligible Product purchases if invoice paid within 35 days from date of invoice, net 36 days (Merck in its sole discretion will determine which Product purchases are eligible for the prompt payment discount and eligibility will be noted on the invoice).
- c. Government Purchasing Customers invoice payment terms are net 30 days.

### **ii. Vaccine Product**

#### **a. Distributors Vaccine Purchasing Customers**

1. Other than electronic payment, a two percent (2%) prompt payment discount may be earned on eligible Product purchases if invoice paid within 30 days from date of invoice; net 31 days (Merck in its sole discretion will determine which Product purchases are eligible for the prompt payment discount and eligibility will be noted on the invoice).
2. Electronic payment: two percent (2%) prompt payment discount on eligible Product purchases if invoice paid within 35 days from date of invoice, net 36 days (Merck in its sole discretion will determine which Product purchases are eligible for the prompt payment discount and eligibility will be noted on the invoice).

#### **b. Government Vaccine Purchasing Customers**

1. Federal government entity: invoice payment terms of net 30 days.
2. State, local, or tribal government entity: a two percent (2%) prompt payment discount may be earned on eligible Product purchases if invoice paid within 60 days from date of invoice; net 61 days (Merck in its sole discretion will determine which Product purchases are eligible for the prompt payment discount and eligibility will be noted on the invoice).

#### **c. Health Care Provider Vaccine Purchasing Customers**

A two percent (2%) prompt payment discount may be earned on eligible Product purchases if invoice paid within 60 days from date of invoice; net 61 days (Merck in its sole discretion will determine which Product purchases are eligible for the prompt payment discount and eligibility will be noted on the invoice).

## **8. CLAIMS FOR LOSS, SHORTAGE, BREAKAGE, LEAKAGE, OR OTHER DAMAGE IN SHIPMENTS FROM THE MANUFACTURER**

- A. Title to merchandise sold will pass to the Direct Purchasing Customer upon delivery to the carrier at the point of shipment. Orders are shipped freight prepaid (unless expedited delivery is requested). However, unless the Direct Purchasing Customer designates the carrier, Manufacturer retains the risk of loss, shortage, breakage, or leakage until the merchandise is delivered to the Direct Purchasing Customer by the carrier.
- B. Claims for loss, shortage, breakage, leakage, or other damage occurring in transit from the manufacturer must be submitted to the Merck Order Management Center at 800-MERCK-RX (800-637-2579) within thirty (30) days from date of shipment. The sole and exclusive remedy of the Direct Purchasing Customer for loss, shortage, breakage, leakage, or other damage occurring in transit is Manufacturer reimbursement for affected Products, in an amount equal to the original Manufacturer invoice price, and the opportunity to repurchase the affected Products at

the original Manufacturer invoice price. Alternatively, Manufacturer may, in its sole discretion, provide replacement Product. Direct Purchasing Customer agrees that no other remedy (including, but not limited to, incidental, consequential, or other damages of any kind) shall be available. Claims submitted beyond thirty (30) days from date of shipment may be considered for remedy at the Manufacturer's sole discretion.

- C. Loss, shortage, breakage, leakage, or other damage claims must also be accompanied by freight bill with notation by the carrier of the loss, shortage, breakage, or damage, or accompanied by the carrier's concealed loss or damage report where the loss is of a concealed nature. Where loss, shortage, breakage, leakage, or other damage has occurred in transit from the manufacturer, Direct Purchasing Customer agrees to cooperate fully with Manufacturer in the Manufacturer's effort to establish a claim against the carrier. Claims submitted by the Direct Purchasing Customer without appropriate documentation will be denied.
- D. If Product is delivered damaged to the Direct Purchasing Customer, Direct Purchasing Customer should accept the shipment and call the Merck Order Management Center at 800-MERCK-RX (800-637-2579) upon receipt, for instructions. Reimbursement may be delayed if Direct Purchasing Customer does not follow this process by not taking receipt of damaged Product.
  - i. For any order placed by the Client of a Direct Purchasing Customer through a Distributor that is delivered damaged, the Client of a Direct Purchasing Customer should contact the Distributor upon delivery for instructions.

## 9. OTHER CLAIMS

- A. Direct Purchasing Customers and Clients of Direct Purchasing Customers that receive Product that has not been subject to breakage, leakage, or other damage occurring in transit, but that otherwise appears to be defective ("Defective Product"), should contact the Merck National Service Center immediately at 800-672-6372. The Merck National Service Center will provide instructions on how to return Defective Product and will arrange for Product replacement. Direct Purchasing Customers and Clients of Direct Purchasing Customers that fail to follow this process (for example, by returning Defective Product with expired Product) shall not be eligible for replacement or reimbursement for the Defective Product. The sole and exclusive remedy of the Direct Purchasing Customer for Defective Product is Product replacement or reimbursement as described in Section 16.D.ii. Direct Purchasing Customer agrees that no other remedy (including, but not limited to, incidental, consequential, or other damages of any kind) shall be available.
- B. VACCINES ONLY: Other claims, should be brought to the attention of the Manufacturer by calling the Merck Vaccine Customer Center at 877-VAX-MERCK (877-829-6372).
- C. All claims involving discounts, pricing, credits, returns, or account receivable issues must be received by Merck Order Management Center within one (1) year of the date of shipment for the purchase in question. Unauthorized deductions taken by Direct Purchasing Customer from Direct Purchasing Customer payments, including, but not limited to, those made after this deadline, will be denied. Noncompliance could jeopardize the fulfillment of future orders.

## 10. CORRESPONDENCE

All Direct Purchasing Customer communication relative to <b>order fulfillment</b> should be directed to:	<b><u>All other</u></b> correspondence should be directed to:
Merck Order Management Center Mail Stop UG4C-24 351 North Sumneytown Pike North Wales, PA 19454 Phone: 800-MERCK-RX (800-637-2579) Fax: 215-652-6700	Merck National Service Center 3900 Paramount Parkway Morrisville, NC 27560 Phone: 800-NSC-MERCK (800-672-6372) Fax: 215-616-5677

## 11. DROP SHIPMENTS

### A. Pharmaceutical Products

- i. Pharmaceutical Products are generally not available for Drop Shipment.

- ii. If supply is low, Manufacturer may prohibit or restrict routine replenishment orders to Direct Purchasing Customers. If this occurs, Manufacturer may allow Drop Shipments to the Clients of a Direct Purchasing Customer on behalf of the Direct Purchasing Customer, billing the Direct Purchasing Customer at the prices in effect when such Drop Shipments are ordered.
- iii. Manufacturer reserves the right to limit the fulfillment of Drop Shipment orders.
- iv. It is the sole responsibility of the Direct Purchasing Customer to ensure that the Client of the Direct Purchasing Customer is fully licensed to receive Pharmaceutical Products.

#### **B. Vaccine Products**

- i. Vaccine Products are generally not available for Drop Shipment.
- ii. Frozen Vaccine Product may be eligible for Drop Shipment by Manufacturer to Clients of Direct Purchasing Customer, at Manufacturer's election.
- iii. If supply is low, Manufacturer may prohibit or restrict routine replenishment orders to Direct Purchasing Customers. If this occurs, Manufacturer may allow Drop Shipments to the Clients of Direct Purchasing Customer on behalf of the Direct Purchasing Customer, billing the Direct Purchasing Customer at the prices in effect when such Drop Shipments are ordered.
- iv. Manufacturer reserves the right to limit the fulfillment of Drop Shipment orders.
- v. It is the sole responsibility of the Direct Purchasing Customer to ensure that the Client of the Direct Purchasing Customer is fully licensed to receive vaccine products.

### **12. DATED PRODUCTS**

All Products carry expiration dates, which may be greater than or less than one year from the date of Product shipment. Products shall not be used after the expiration date printed on the Product label.

### **13. FORMULAE**

The formulae shown in the Merck Catalog are those in use at the time of publication. Manufacturer reserves the right to make changes without notice whenever advances in medical science or therapeutic knowledge justify such action. Such changes and those made necessary by revisions of the USP–NF standards make it necessary that customers be cautioned to rely on the label statements appearing on the package rather than the Merck Catalog information.

### **14. LIABILITY**

- A.** Manufacturer will assume the pharmacist's defense and possible judgment liability that might result against the pharmacist in connection with a lawsuit arising solely out of the dispensing (excluding immunization or administration by a pharmacist or anyone on pharmacist's behalf) of a Product if the following conditions are met:
  - i. A physician prescribed a Product or a drug product by generic name or other brand name, and the pharmacist properly filled the prescription with a Product; and
  - ii. The pharmacist cooperates fully in the defense of any lawsuit.
- B.** Manufacturer will NOT assume the pharmacist's defense and possible judgment liability if any of the following conditions apply:
  - i. The lawsuit alleges negligence on the part of the pharmacist (including, without limitation, a claim that the pharmacist provided or failed to provide oral or written information or warnings about the Product, or if the pharmacist misrepresented or extended our warranty to the patient/customer);



- ii. The pharmacist dispensed another manufacturer's product in filling a prescription written for a Product; or
- iii. The lawsuit could not be brought against Manufacturer directly because of the National Childhood Vaccine Injury act of 1986, as amended.

**C. Direct Purchasing Customers that administer Vaccine Products to patients warrant that they will:**

- i. Take all appropriate steps to assure that all Vaccine Products purchased from Manufacturer shall be administered to each patient on the basis of an individualized medical judgment by a licensed, authorized health care professional; or
- ii. Take all appropriate steps to provide to such patient (or to the patient's parent or guardian) meaningful and complete warnings relating to the risks and benefits of vaccination with the Vaccine Product, in form and language understandable to such patient, parent, or guardian.

## **15. WARRANTY**

Manufacturer warrants that, at the time of shipping, Products will, in all material respects, have been manufactured in conformance with current good manufacturing practices as set forth in Title 21 of the Code of Federal Regulations effective at the time of manufacture, and will not be manufactured, sold or shipped in violation of any applicable federal, state, or local laws or regulations in any material respect. This warranty is in lieu of all other warranties, express or implied, and all other warranties, including but not limited to the implied warranties of merchantability and fitness for a particular purpose.

## **16. PRODUCT FOR RETURN ("RETURN POLICY")**

### **A. General**

- i. All returns must comply with federal and state laws and regulations, including, but not limited to, the Prescription Drug Marketing Act.
- ii. Direct Purchasing Customers are not permitted to accept return of expired Product from Clients of Direct Purchasing Customers and must instruct Clients of Direct Purchasing Customers to make their returns directly to the Manufacturer, via Manufacturer Reverse Distributor.
- iii. Manufacturer representatives are not permitted to pick up merchandise for return. Manufacturer representatives may provide information about this Return Policy; however, the ultimate decision and responsibility for selecting the items and making the return rest with the Direct Purchasing Customer or Client of Direct Purchasing Customer.
- iv. All Product identified for return by Direct Purchasing Customer or Client of Direct Purchasing Customer must be returned to Manufacturer, via Manufacturer Reverse Distributor for destruction by Manufacturer or its authorized agent. Direct Purchasing Customers or Clients of Direct Purchasing Customers may not destroy Product.

### **B. Qualification for Reimbursement**

- i. In order to be eligible for Reimbursement, returned Products must be returned in their original containers bearing the original label. The original outer packaging is not required providing the product is in a sealed container.
- ii. The period for which Manufacturer will accept Products for reimbursement (the "Product Returns Window") is measured as follows:
  - a. Pharmaceutical Products purchased by Direct Purchasing Customers and Vaccine Products purchased by Distributors are eligible for reimbursement if they are **received** by the Manufacturer Reverse Distributor, Inc. 180 days before the Product expiration date to 1 year after the Product expiration date.
  - b. Vaccine Products purchased by Government Customers or Health Care Provider Vaccine

- Purchasing Customers are eligible for reimbursement if they are **received** by the Manufacturer Reverse Distributor on the Product expiration date to 1 year after the Product expiration date.
- c. Manufacturer recommends returning parties not return Product before the first day of the Product Returns Window and not later than 15 Business Days before the end of the applicable Product Returns Window.
  - d. Product **received** by Manufacturer Reverse Distributor outside of the applicable Product Returns Window will be accepted for destruction only.

**iii.** The following will **not** be eligible for reimbursement:

- a. Products labeled, marked, or sold as nonreturnable;
- b. Products returned in damaged condition (broken vials, broken tablets);
- c. Opened liquids, vials, granules, ophthalmics, cartridges, and activated injectables, except as provided in Section 16.E.;
- d. Partially dispensed lotions, ointments, tubes, creams, gels, ampoules, and syringes except as provided in Section 16.E.;
- e. Products that have been involved in a fire or obtained in a sacrifice or bankruptcy sale;
- f. Products labeled as samples or free goods or repackaged Products;
- g. Product that is not in its original container or not bearing its original label. If Product is contained within an outer packaging, the original outer packaging is not required providing the product is in a sealed container;
- h. Product that Manufacturer determines, in its sole discretion, is otherwise adulterated or misbranded;
- i. Products returned by other than a Direct Purchasing Customer, Client of a Direct Purchasing Customer, or reverse distributor;
- j. Product illegally imported into the Territory;
- k. Counterfeit goods and/or diverted product; or
- l. Product in which the lot number and/or expiration date is missing, illegible, covered, and/or unreadable on original container.

**C. Returning Party Instructions**

- a. Return Products are to be sent by the returning party to Manufacturer Reverse Distributor, PharmaLink, at the following address:

PharmaLink  
Receiving Department PLI-MRK  
8285 Bryan Dairy Road, #160  
Largo, FL 33777

- i. All returns require a Return Authorization (“RA”). RA’s are created at the following website: [www.pharmalinkinc.net/MReturns/Login.aspx](http://www.pharmalinkinc.net/MReturns/Login.aspx). In order to create an RA, an account is required which can be created on the website. Failure to return Products within 60 days of the RA creation may delay processing and reimbursement or may make the Product ineligible for reimbursement at Manufacturer’s sole discretion.
- ii. Shipments spanning multiple containers must have each carton clearly numbered (e.g., 1 of 10, 2 of 10).
- iii. The returning party will pay transportation charges. Manufacturer will not pay or give credit for transportation, service, handling, or processing fees.
- iv. If a reverse distributor returns Product for multiple customers (e.g., multiple Direct Purchasing Customers or multiple Clients of Direct Purchasing Customers) in a single container, the returned Product and accompanying Return forms must be segregated by customer, to enable the Manufacturer Reverse Distributor to calculate proper reimbursement to each Direct Purchasing Customer or Client of a Direct Purchasing Customer.

#### **D. Manufacturer Administration of Reimbursement**

- i.** Only those Products that conform to the foregoing requirements will be accepted for reimbursement. The credit memorandum, if applicable, will list each Product accepted for return and the amount of reimbursement. Products not accepted for reimbursement will not be returned to the returning party but will be destroyed.
- ii.** Basis of Reimbursement:
  - a.** For all JANUVIA<sup>®</sup>, JANUMET<sup>®</sup>, and JANUMET XR<sup>®</sup> Products:
    - 1.** Direct Purchasing Customers:  
The basis for determining reimbursement, if applicable, will be the lowest price available to the Direct Purchasing Customer three (3) months before the date that the Manufacturer Reverse Distributor receives the return. Manufacturer reserves the right to adjust or eliminate the amount of reimbursement at Manufacturer's sole discretion.
    - 2.** Clients of Direct Purchasing Customers:  
The basis for determining reimbursement, if applicable, will be the lowest price available (excluding any markup or fees from any third parties) to the Client of Direct Purchasing Customer three (3) months before the date that the Manufacturer Reverse Distributor receives the return. An alternative basis for determining the reimbursement price will be the lowest contract price (excluding any markup or fees from any third parties) available to the Client of Direct Purchasing Customer for the returned Product within three (3) months prior to the date that the Manufacturer Reverse Distributor receives the return, if Manufacturer can identify the contract(s) accessible by the Client of Direct Purchasing Customer. Manufacturer reserves the right to adjust or eliminate the amount of reimbursement at Manufacturer's sole discretion.
  - b.** For all other Products:
    - 1.** Direct Purchasing Customers:  
The basis for determining reimbursement, if applicable, will be the lowest price available to the Direct Purchasing Customer 24 months before the date that the Manufacturer Reverse Distributor receives the return (if pricing history is less than 24 months, Manufacturer will apply the earliest pricing available). An alternative basis for determining the reimbursement price will be the Manufacturer's invoice for the returned Product if furnished by the Direct Purchasing Customer. Manufacturer reserves the right to adjust or eliminate the amount of reimbursement at Manufacturer's sole discretion.
    - 2.** Clients of Direct Purchasing Customers:  
The basis for determining reimbursement, if applicable, will be the lowest price available (excluding any markup or fees from any third parties) to the Client of Direct Purchasing Customer 24 months before the date that the Manufacturer Reverse Distributor receives the return (if pricing history is less than 24 months, Manufacturer will apply the earliest pricing available). An alternative basis for determining the reimbursement price will be the lowest contract price (excluding any markup or fees from any third parties) available to the Client of Direct Purchasing Customer for the returned Product within 24 months prior to the date that the Manufacturer Reverse Distributor receives the return, if Manufacturer can identify the contract(s) accessible by the Client of Direct Purchasing Customer. Manufacturer reserves the right to adjust or eliminate the amount of reimbursement at Manufacturer's sole discretion.
  - c.** No credit will be issued for transportation/shipping, service, handling, distribution or processing fees.
- iii.** For Products in tablet form, reimbursement will be given based on the number of actual tablets returned, not to exceed the number of tablets that were packaged in the original container.

iv. The form of reimbursement is generally as follows:

- a. If the returning party is a Direct Purchasing Customer and the returned Products were purchased directly from Manufacturer, then reimbursement for returned Products will be issued in the form of a credit memo on the Manufacturer account, which may be applied against any purchase.
- b. If the returning party is not a Direct Purchasing Customer or the returned Products were not purchased directly from Manufacturer, then Manufacturer's preferred form of reimbursement will be a credit memo through the returning party's designated Distributor; however, Manufacturer, in its sole discretion, may provide reimbursement via a check to the returning party.
- c. Manufacturer will not provide reimbursement for Product to a reverse distributor, but will instead provide reimbursement to the Direct Purchasing Customer or Client of the Direct Purchasing Customer on behalf of whom the Product is returned to the reverse distributor.
- d. Manufacturer will not provide information to a reverse distributor regarding reimbursement provided to a Direct Purchasing Customer or Client of the Direct Purchasing Customer.

**E. Returned Product from North Carolina, Mississippi, or Georgia**

- i. Product purchased by a Direct Purchasing Customer or Client of a Direct Purchasing Customer located in Georgia, Mississippi, or North Carolina shall be subject to the Return Policy set forth elsewhere in these Standard Terms and Conditions of Sale, except that:
  - a. Partial package returns of liquids, vials, granules, ophthalmics, cartridges, and activated injectables, dispensed lotions, ointments, tubes, creams, gels, ampoules, and syringes shall be eligible for reimbursement. The basis for reimbursement shall be the percentage of Product returned based on the following best estimate:
    1. nearly full or full equates to 100% credit;
    2. half and up to three quarters full equates to 75% credit;
    3. one-quarter and up to half full equates to 50% credit;
    4. less than one-quarter full equates to 20% credit; and
    5. almost empty equates to 0% credit.
  - b. Reimbursement for returned Product will be issued within sixty (60) days from the date that the Manufacturer Reverse Distributor receives the Product and all necessary return documentation. If the returned Product is not eligible for reimbursement, Manufacturer will notify the returning party in writing, within thirty (30) days of the receipt of the return, of Manufacturer's intent not to issue reimbursement.
- ii. In order to be eligible for the returns exceptions detailed in Section 16.E.i, above, Product purchased by a Direct Purchasing Customer or Client of a Direct Purchasing Customer located in North Carolina, Mississippi, or Georgia must be returned in a separate container(s) from any other Product and accompanying Return Forms must be segregated. The container and associated paperwork must clearly be labeled as a product return from Georgia, Mississippi, or North Carolina. If the returning party fails to properly segregate and label returns from Georgia, Mississippi, or North Carolina, then the exceptions detailed in Section 16.E.i shall not apply.

**17. SUPPLEMENTAL RETURN PROGRAMS**

Certain Product that is not eligible for return under the Return Policy in Section 16 may be eligible for return pursuant to one of the following of Manufacturer's supplemental return programs:

- A. Supplemental Return Program for eligible Vaccine Products for Direct Vaccine Purchasing Customers and Clients of Direct Vaccine Purchasing Customers - Further information regarding the Supplemental Return Program is available by calling the Merck Vaccine Customer Center at 877-VAX-MERCK (877-829-6372).

- B. Supplemental Return Program for Oncology Products - Further information regarding the Supplemental Return Program for Oncology Products is available by calling C3i Solutions at 800-611-7397.
- C. Supplemental Replacement Program for WINREVAIR (sotatercept-csrk) – Further information regarding the Supplemental Replacement Program for WINREVAIR is available by calling 800-672-6372.

Manufacturer reserves the right to modify or cancel any of the foregoing supplemental return programs at any time.

## **18. DISASTER RELIEF VACCINE RETURN PROGRAM AND DISASTER RELIEF RETURN PROGRAM FOR ONCOLOGY PRODUCTS**

Certain uninsured Products that spoil due to a FEMA-Declared Major Disaster may be eligible for return pursuant to Manufacturer's Disaster Relief Vaccine Return Program or Manufacturer's Disaster Relief Return Program for Oncology Products. Further information regarding the Disaster Relief Vaccine Return Program is available at [www.merck.com/disaster\\_relief](http://www.merck.com/disaster_relief) or by calling the Merck Vaccine Customer Center at 877-VAX-MERCK (877-829-6372). Further information regarding the Disaster Relief Return Program for Oncology Products is available by calling C3i Solutions at 800-681-7022. Manufacturer reserves the right to modify or cancel the Disaster Relief Vaccine Return Program or Disaster Relief Return Program for Oncology Products at any time.

## **19. PRODUCT RECALLS**

Direct Purchasing Customers agree to fully cooperate in implementing any recall or withdrawal of Product deemed necessary by Manufacturer. Manufacturer will notify Direct Purchasing Customers in the event of a Product recall or withdrawal and will provide instructions on how to assist in returning all affected Product and communicating with Clients of Direct Purchasing Customers regarding the recall or withdrawal. Manufacturer, in its sole discretion, shall determine what, if any, recall services are required and shall make such determination on a recall-by-recall basis.

Manufacturer shall compensate Distributors for expenses incurred for recall services directly related to Distributor's inventory of the recalled Product and dissemination of recall information to Clients of Direct Purchasing Customers, to the extent requested by Manufacturer's recall notice. The amount of such compensation shall be determined by Manufacturer, in its sole discretion. Distributors requesting reimbursement for recall activities must submit their request, on the Merck Recall Reimbursement Form, within 60 days after the date on which Manufacturer sends Distributor the Merck Recall Reimbursement Form, but in any event no later than one year after Manufacturer's recall notice. The Merck Recall Reimbursement Form may be obtained by contacting 1-800-MERCKRX.

## **20. STORAGE AND HANDLING**

- A. Direct Purchasing Customers taking physical possession of Products are fully responsible for complying with all applicable federal, state, and local laws and regulations relating to the storage, handling, and distribution of such Products, including, without limitation, any laws applicable to the distribution of controlled substances. Furthermore, Direct Purchasing Customer represents and warrants that it has and will maintain at all times the proper license or licenses required to receive, handle, and store Product, including, but not limited to, licenses that may be required to distribute Refrigerated Vaccine Product or Frozen Vaccine Product from Depot Locations to Depot Customers.
- B. Direct Purchasing Customers shall thoroughly review the documentation provided within the shipment upon receipt.
  - i. When the shipment includes a packing slip specifying a date on or by which the product must be received (noted on the slip as the "Product Must Be Received On or By" date), Direct Purchasing Customer shall immediately contact the Merck Order Management Center at 800-MERCKRX (800-637-2579) if Product is received after this date.
    - a. Receiving Instructions (Shipping Time Insert Instructions) are available at [www.merckorders.com](http://www.merckorders.com).
  - ii. When the shipment includes a temperature recording device, Direct Purchasing Customer shall follow the instructions accompanying the device to determine if the appropriate temperature was maintained

during shipping and handling and shall report all temperature excursions to Manufacturer.

- a. Receiving Instructions (including those for the temperature recording device) are available at [www.merckorders.com](http://www.merckorders.com). Temperature recording devices shall be returned as instructed in the shipping documents. Do not discard a temperature recording device unless instructed to do so.
  - iii. Direct Purchasing Customers must not reuse the Manufacturer's thermal shipping containers for shipments to their customers.
  - iv. Identified deviations, including, but not limited to, late delivery or temperature excursions, may require the Manufacturer and the Direct Purchasing Customer to collaboratively investigate and identify the root cause. Direct Purchasing Customers shall cooperate with Manufacturer and perform such investigations as requested by Manufacturer.
  - v. Failure to comply with the terms and conditions of this Section 20. is a violation of the Standard Terms and Conditions of Sale. Manufacturer, in its sole discretion, may remediate such violation, including, but not limited to, by temporarily or permanently suspending the shipment of Products to the location(s) that failed to comply with these requirements.
- C. Direct Purchasing Customers shall take such precautions as are necessary to prevent Product from falling into the hands of those who may not lawfully possess or handle Product, and shall fully comply with all applicable local, state, and federal laws and regulations.
- D. Direct Purchasing Customers shall immediately report in writing to Manufacturer any in-transit loss or shortage of Product, including controlled substances.
- E. Direct Purchasing Customers shall report in writing to Manufacturer, subject to applicable federal and state laws and regulations, any administrative, civil, or criminal action by local, state or federal authorities against Direct Purchasing Customers, its officers, or employees, regarding alleged violations of the Controlled Substance Act of 1970, as amended or other comparable legislation, and shall provide Manufacturer with complete information concerning the disposition of such action.
- F. Direct Purchasing Customers warrant and agree not to stock any counterfeit goods, diverted Product, Product that is illegally imported into the Territory, expired Product, or Product that has been used, opened, repackaged, or otherwise tampered with.
- G. Direct Purchasing Customers shall take precautions during receiving, storage, and packing for distribution to prevent product in glass containers (e.g., vials, syringes) from falling or dropping. If product packaged in glass containers is handled roughly or dropped from a distance greater than six (6) inches, it must be discarded and must not be distributed to Clients of Direct Purchasing Customers or dispensed/administered to patients.
- H. Eligibility to purchase any Product considered to be a controlled substance shall be limited to those Direct Purchasing Customers that have (i) completed Manufacturer's Controlled Substances Handling and Suspicious Order Monitoring Questionnaire (the "Questionnaire"), including an revised or updated version thereof that Manufacturer may issue from time to time in its sole discretion, or (ii) submitted such other responsive documentation of Direct Purchasing Customer's controlled substance compliance program that is otherwise acceptable to Manufacturer, in its sole discretion. Notwithstanding anything to the contrary in these Standard Terms and Conditions of Sale, Manufacturer shall have the right to refuse to sell controlled substances to any Direct Purchasing Customer or to place reasonable restrictions on Direct Purchasing Customer's purchases of controlled substances if (i) Manufacturer reasonably determines, in its sole discretion, the Direct Purchasing Customer has provided an incomplete, inaccurate, deficient, or otherwise unsatisfactory response or information in the Questionnaire or other related documentation, or (ii) Manufacturer reasonably determines, in its sole discretion, that the Direct Purchasing Customer is handling, storing, or distributing controlled substances in a manner that is not compliant with applicable law or that otherwise creates the appearance of non-compliance, until such time as Manufacturer is able to investigate the matter and make a final determination, or (iii) Manufacturer reasonably determines, in its sole discretion, that Direct Customer is not compliant with any applicable EDI requirements in Direct Customer's Merck Authorized Distributor Agreement, irrespective of any grace periods that may have been extended to Direct Customer, in Manufacturer's sole discretion.

## **21. STORAGE AND HANDLING INSTRUCTIONS FOR TRANSPORT OF REFRIGERATED VACCINE PRODUCT OR FROZEN VACCINE PRODUCT FROM DEPOT LOCATIONS TO DEPOT CUSTOMERS**

These instructions apply to the storage and distribution of Refrigerated Vaccine Product or Frozen Vaccine Product from Depot Locations to Depot Customers only. These storage and handling instructions do not apply to **BCG VACCINE (TICE® strain)**. Please contact the Merck National Service Center at 1-800-672-6372, Monday through Friday, from 8 a.m. to 7 p.m. (ET), for information regarding this product.

- A.** If it is necessary to transport Refrigerated Vaccine Product or Frozen Vaccine Product to a Depot Location, Refrigerated Vaccine Product must be maintained at a temperature range of 2-8°C (36-46°F), and Frozen Vaccine Product must be maintained at a temperature range between -50° C and -15° C (-58° F and +5° F), while in storage and in transit to Depot Customers. Do not use dry ice as it may subject Vaccine Product to temperatures colder than -58° F (-50° C).
- B.** If the Refrigerated Vaccine Product or Frozen Vaccine Product must be transported from a Depot Location to a Depot Customer, Depot Location personnel should consider including a temperature recording device to monitor that an appropriate temperature of 2-8°C (36-46°F) for Refrigerated Vaccine Product, or between -50° C and -15° C (-58° F and +5° F) for Frozen Vaccine Product, is maintained during transit. If used, the temperature monitor should be placed next to the vaccine and should not come in contact with gel packs.
- C.** Do not place Refrigerated Vaccine Product or Frozen Vaccine Product in an area where the temperature cannot be regulated, for example, inside the trunk of the vehicle or left unattended inside a vehicle. Avoid placing the container in direct sunlight, or directly in line with any heating or cooling source. Staff should be instructed to deliver the vaccine directly to the appropriate personnel as soon as possible for proper storage as described in the Manufacturer's Prescribing Information.
- D.** If you have any questions about a Manufacturer Product or these instructions, please call the Merck National Service Center at 1-800-672-6372, Monday through Friday, from 8 a.m. to 7 p.m. (ET).

## **22. CHARGEBACK POLICY FOR DISTRIBUTORS**

Policies and procedures specific to chargebacks are set forth in Appendix A as part of these Standard Terms and Conditions and are available on request.

## **23. FORCE MAJEURE**

Neither Manufacturer nor Direct Purchasing Customer shall be liable for delay or failure of performance occasioned by causes beyond its control, including, but not limited to, acts of God or the public enemy, civil unrest, riots, acts of terrorism, declared or undeclared wars, fires, floods, unusually severe weather, earthquakes, or volcanoes ("Force Majeure Event"). If either party is affected by a Force Majeure Event, the affected party shall give the other written notice, which shall cause, without penalty to either party, all obligations under these Standard Terms and Conditions of Sale to be immediately suspended for a period of sixty (60) days.

## **24. COMPLIANCE WITH LAW**

Direct Purchasing Customers and Clients of a Direct Purchasing Customer shall comply with all federal, state, local, and other applicable laws and regulations including, but not limited to, the provisions at 42 C.F.R. § 1001.952(h)(1) relating to the reporting of discounts. Direct Purchasing Customers and Clients of a Direct Purchasing Customers agree, to the extent required under applicable federal or state laws, to accurately report to private and governmental third-party payors and others the net effective price, and any other information that must be disclosed under applicable law, for each Product purchased.

## **25. AGREEMENT, ORDER OF PRECEDENCE, AND MODIFICATION**

An order of Product from Manufacturer by a Direct Purchasing Customer signifies Direct Purchasing Customer's agreement to be bound by these Standard Terms and Conditions of Sale. The terms herein take precedence over any conflicting or inconsistent terms contained in any other quotation, purchase order, acknowledgement, invoice, or other document issued by anyone other than Manufacturer except as otherwise provided expressly herein. Any terms or

conditions proposed by any party other than Manufacturer that are inconsistent with, or in addition to, these Standard Terms and Conditions of Sale shall be void and of no effect unless Manufacturer agrees to such terms and conditions in writing signed by Manufacturer. No additional terms are implied by usage of trade, by course of dealing, or by course of performance. Notwithstanding anything to the contrary in this Section, Manufacturer has the unilateral right to modify these Standard Terms and Conditions of Sale at any time at its sole discretion.

## **26. SEVERABILITY**

If any provision or clause of these Standard Terms and Conditions of Sale conflicts with the governing law or if any court of competent jurisdiction holds invalid any provision or clause of the Standard Terms and Conditions of Sale, then such provision shall be deemed modified to reflect as nearly as possible the parties' intent. The remainder of the Standard Terms and Conditions of Sale shall remain in full force and effect.

## **27. GOVERNING LAW AND JURISDICTION**

The law of the Commonwealth of Pennsylvania, exclusive of its choice of law rules and the Convention for the International Sale of Goods (if otherwise applicable), shall govern these Standard Terms and Conditions of Sale. Direct Purchasing Customer (or Client of a Direct Purchasing Customer) agrees to submit to the jurisdiction of any competent federal or state court sitting in Pennsylvania.