



GLOBAL PRODUCT PROTECTION EXCLUSIVE SOURCING AGREEMENT

Exclusive Sourcing Agreement (ESA)

The safety and integrity of AbbVie products for the patients we serve is our highest priority. AbbVie understands that the threat posed to public health and safety by counterfeit products is a very serious one. We regularly take action to keep counterfeit products out of the marketplace. Secondary market products are generally products purchased from any source other than from the original manufacturer and are commonly referred to as "secondary market," "gray market", or "diverted" products. It is often through the secondary market that counterfeit, adulterated, or improperly stored and handled products make their way into the distribution channel. When product comes from the secondary market, it is difficult to assure patients and health care professionals of the product's quality or safety or to provide product updates.

Through the exclusive sourcing initiative, AbbVie is working to prevent the introduction of unsafe product into the United States. As of July 1, 2004, U.S. wholesale distribution of AbbVie pharmaceutical products is permitted only through wholesalers/distributors that have agreed to source their entire product needs directly from AbbVie.

ESA Amendment for Vicodin-Class Products

The United States Drug Enforcement Administration (DEA) has stated that "rogue" Internet websites are the number one source of abused combination hydrocodone products. Our goal is to prevent the sale of our Vicodin-class products through these rogue Internet sites, while preserving the ability to fill and refill legitimate prescriptions, issued within the context of bona fide physician-patient relationships, using on-line technology.

Global Product Protection Exclusive Sourcing Agreement: Questions and Answer

Why has AbbVie initiated this agreement?

A: Discoveries of counterfeit product in the worldwide distribution channel have highlighted risks to patients, healthcare providers, and customers who have always recognized AbbVie as providing high-quality products. The safety and integrity of AbbVie products are of the highest priority and the threat posed to public health and safety by counterfeit products is taken very seriously. Accordingly, AbbVie has undertaken this initiative domestically to help prevent any unsafe products from being introduced into the supply chain.

Q: What is the geographic scope of the policy?

A: The scope of the agreement currently applies to entities within the 50 United States (excluding U.S. territories and Puerto Rico) and for specific countries outside the U.S. where ESA's have been implemented. We are monitoring international markets and will work closely with wholesalers/distributors and customers in taking further action, as appropriate, to ensure the integrity of AbbVie products and patient safety throughout the world.

Q: Have AbbVie's Terms and Conditions been changed to incorporate Exclusive Sourcing Agreement?

A: Yes. The Terms and Conditions of Sale of each of the Divisions/Business Units included have been changed appropriately to incorporate Wholesaler/Distributor adherence to this agreement.

Q: Can wholesalers/distributors buy from and sell to each other products that are manufactured by AbbVie?

A: No. If wholesalers/distributors buy AbbVie products from any source other than AbbVie, they are not in compliance with this agreement. Because of the need to ensure product integrity and patient safety, as well as a secure distribution channel, the policy does not allow trade between wholesalers/distributors. Where specifically stated, products shall be purchased from AbbVie solely for resale to end customers who are properly licensed entities by the states/countries in which they operate, for their own use or distribution to their own consumers/patients. Any change or alteration of this policy potentially creates a risk of unauthorized product entering secure distribution channels.

Q: How does the agreement impact international markets and U.S. wholesalers/distributors who have international branches?

A: The agreement currently applies to the U.S. market. We are monitoring international markets and will work closely with wholesalers/distributors and customers in taking further action, if needed, to ensure the safety of patients and the integrity of our products throughout the world.

Regarding U.S. wholesalers/distributors with international branches: The distribution agreement does not allow purchases or transfers of AbbVie's products across borders by U.S. wholesalers/distributors. The agreement relates to and governs U.S. trading practices of wholesalers/distributors purchasing products from AbbVie in the United States. Because product requirements vary across world regions (dosage strength, quantities, etc.) to meet unique local needs and/or regulations, products developed by international business units of AbbVie to meet those needs cannot be transferred to and used within the United States.

Q: What is AbbVie doing to reduce the supply of products currently moving into the secondary market?

A: AbbVie is committed to ensuring patient safety and the integrity of our products throughout the world. Business practices and policies are being evaluated and refined with priority placed on product integrity, to assure appropriate control of products in the marketplace. Immediate emphasis includes education in the marketplace about the risk and existence of counterfeit product and the importance of a secure channel to minimize risks in the secondary market.

In addition, AbbVie is working with government agencies around the world, and exploring product protection programs, including the application of special features for our product packaging and product tracing. We believe it is vital for our customers and patients to receive genuine products so they can use our products with confidence. We are also monitoring markets to ensure the safety of patients and the integrity of our products. We will continue to develop and implement actions to address the issue.

Q: What is AbbVie's agreement on auditing wholesalers/distributors?

A: As previously outlined, we reserve the right to enforce the commitments made in our notification letter of April 30, 2004 to U.S. wholesalers and distributors, by requiring within thirty (30) days after written request by AbbVie, that the wholesaler/distributor shall provide, or cause to be provided, as elected by AbbVie, (i) a certification of compliance from a senior officer or executive with financial oversight responsibility for the wholesaler/distributor, or (ii) the opportunity for an audit of the relevant books and records of the wholesaler/distributor. In addition, AbbVie reserves the right to cease shipments to the wholesaler/distributor if AbbVie in its sole discretion in good faith believes the wholesaler/distributor may not have complied with the agreement. There also are audit clauses in the ESAs for customers outside the U.S.

Q: How does AbbVie communicate the status of U.S. wholesalers/distributors?

A: AbbVie provides a listing of wholesalers/distributors approved to purchase AbbVie products: [Exclusive Sourcing Agreement Members List](#). Regular updates are made to this listing

Q: Where should potential violations to the Exclusive Sourcing Agreement be reported?

A: AbbVie Global Product Protection

Q: Where should suspicions or leads on counterfeit, diverted or stolen AbbVie product be reported?

A: AbbVie Global Product Protection

Exclusive Sourcing Agreement: Question and Answers Regarding Amendment for Vicodin Class Products

Q: Why has AbbVie initiated this amendment?

A: The DEA has stated that "rogue" Internet Web sites are the number one source of abused combination hydrocodone products. According to the DEA, such sites commonly offer drugs for sale outside the context of a legitimate doctor-patient relationship and without the benefit of a valid prescription for a scheduled product. The safety and integrity of AbbVie products are of the highest priority and AbbVie takes the threat posed to public health and safety by illicit Internet purchases very seriously. Accordingly, we are undertaking this initiative to prevent the sale of our Vicodin-class products (e.g. Vicodin IR, Vicoprofen and any future hydrocodone bitartrate/acetaminophen products) through such rogue Internet sites, while preserving the ability to fill and re-fill legitimate prescriptions, issued within the context of bona fide physician-patient relationships, using on-line technology.

Q: Can the 30-day deadline be extended?

A: The threat of illicit Internet purchases to public health and safety is serious and therefore dictates that we maintain the amendment's effective date of 30 days beyond the date the ESA amendment letter was issued. A wholesaler/distributor's agreement to comply with the ESA amendment letter is required no later than 30 days after the ESA amendment letter is issued, which is the deadline for signature and return of the original notification via certified mail to AbbVie. Only those wholesalers/distributors in compliance with this ESA amendment will be approved to purchase Vicodin-class products from AbbVie.

Q: What happens if a wholesaler/distributor does not meet the 30-day deadline?

A: Unless AbbVie receives the signed ESA amendment for Vicodin-class products by the 30-day deadline, a wholesaler/distributor will lose its status as a wholesaler/distributor for AbbVie's Vicodin-class products, and shipments of such products by AbbVie to the wholesaler/distributor will cease effective as of that date.

Q: What products of AbbVie are included in this ESA amendment?

A: Vicodin-class products are addressed in this ESA amendment. "Vicodin-class" is defined to include Vicodin IR, Vicoprofen, and any future hydrocodone bitartrate/acetaminophen products.

Q: What happens if a wholesaler or distributor elects not to sign the ESA amendment for Vicodin-class products?

A: Any wholesaler or distributor who elects not to sign the ESA amendment for Vicodin-class products will not be eligible to purchase Vicodin-class products

Q: How does AbbVie communicate the status of wholesalers/distributors vis-à-vis this amendment?

A: AbbVie provides a listing of wholesalers/distributors approved to purchase Vicodin-class products at: /ESAlist. Regular updates are made to this listing.

Q: Does the ESA amendment replace the terms of the original ESA?

A: No. The terms regarding Vicodin-class products are in addition to, and do not replace, the current terms of the ESA. The ESA is amended only to the extent set forth in the amendment, and all the current terms of the ESA remain the same and are not affected by this amendment.

Q: How do the terms of the ESA amendment for Vicodin-class product differ from AbbVie's other pharmaceutical products?

A: The terms of the ESA amendment for Vicodin-class products differs from the original ESA for AbbVie pharmaceutical products in 2 ways. The ESA amendment for Vicodin-class products states that: (i) when selling to customers in the United States who are predominantly Internet pharmacies, these pharmacies must be VIPPS accredited. A predominant Internet pharmacy is defined as generating greater than 50 percent of their sales dollars via Internet transactions and (ii) wholesalers and distributors who sign the ESA amendment for Vicodin-class product are certifying that they have designed and implemented prospective suspicious order monitoring or similar programs to identify and report to the DEA suspicious orders of controlled substances.

Q: What does VIPPS stand for?

A: VIPPS stands for Verified Internet Pharmacy Practice Sites, and is an accreditation awarded by the National Association of Boards of Pharmacy ("NABP") to US-based online pharmacy Web sites based in the United States that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection. A link to the Web site is attached below: <http://www.nabp.net/programs/consumer-protection/buying-medicine-online/recommended-sites>.

Q: What do prospective suspicious ordering programs need to include?

A: Such programs shall comply with DEA regulations requiring identification and reporting of suspicious orders including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Programs shall include controls reasonably sufficient to prevent resale of Vicodin-class products to entities that dispense product via illegitimate Internet Web sites.

Q: Where should potential violations to the ESA be reported?

A: AbbVie Global Product Protection

Q: Where should suspicion or leads on counterfeit, diverted, or stolen AbbVie product be reported?

A: AbbVie Global Product Protection

Education or other volunteer efforts in your communities