



nabp
National Association of Boards of Pharmacy
1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

November 21, 2012

John C. Horton
President, LegitScript
818 SW Third Ave., #353
Portland, Oregon 97204

Dear Mr Horton:

In this letter, the National Association of Boards of Pharmacy[®] (NABP[®]) is pleased to recognize LegitScript's international Internet pharmacy certification standards and classifications, as well as LegitScript's health care product classifications for products such as dietary supplements and psychoactive substances, both of which are attached.

NABP is the independent, international, and impartial association that supports its member boards of pharmacy in protecting the public health. Founded in 1904, NABP represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, eight Canadian Provinces, and New Zealand. As you know, pharmacies must adhere to applicable federal and state laws in the US and Canada, but are primarily regulated at the state level by the regulatory boards that constitute NABP membership. **On behalf of those regulatory boards, NABP endorses the use of LegitScript's classification and monitoring services by search engine advertising programs, Domain Name Registrars, registries, payment processing companies, social media companies, and other Internet platforms to ensure that Internet platforms operate in compliance with applicable healthcare laws and regulations, and are not utilized in furtherance of the illicit sale of unregulated healthcare products.**

Internet Pharmacy Web Site Certification and Classification

NABP is pleased to recognize LegitScript's standards for verifying and classifying Web sites that sell or facilitate the sale of prescription drugs, sometimes called "Internet pharmacies," "online pharmacies," or "Internet drug outlets." Those standards are attached to this letter. This includes the definition of "rogue Internet pharmacy" that has been developed by LegitScript in consultation with NABP to identify Web sites that are engaged in clear violation of applicable pharmacy and/or drug safety laws. NABP also endorses LegitScript's definition of "applicable laws" as including the laws and regulations of the jurisdiction where the website and/or its dispensing pharmacy operate or dispense from, as well as any jurisdiction where the Web site offers to facilitate the shipment of drugs to.

We note furthermore that NABP and LegitScript have harmonized the aforementioned standards as they pertain to the US (for NABP's e-Advertiser Approval program).

Health Care Product Classification Program

NABP is also pleased to recognize and endorse LegitScript's classification program for dietary supplements and psychoactive substances (sometimes called "designer drugs"). NABP recognizes that such products are sometimes offered for sale by various online and offline sales outlets including but not limited to pharmacies, and may be harmful to human or animal health if they contain active pharmaceutical ingredients or toxins, or are marketed with inaccurate claims as to safety and efficacy.

Domain Name Registrars and Registries

NABP supports LegitScript's efforts to work with domain name registrars and registries, the Internet Corporation for Assigned Names and Numbers (ICANN), the European Registry for Internet Domains (EURID), Nominet, and other similar organizations to effectuate the suspension of Web site domain names that facilitate the violation of applicable laws or regulations, and/or accepted standards of safety, related to the sale or dispensing of prescription drugs and other health care products.

NABP is aware that domain name registrars accredited by ICANN, in accordance with the Registrar Accreditation Agreement and the Uniform Dispute Resolution Policy, are required to maintain certain policies and procedures, including maintaining and enforcing Terms and Conditions prohibiting the registration or use of domain names for "an unlawful purpose," "in violation of any applicable laws or regulations," or in a way that would "infringe upon or violate the rights of any third party." (Uniform Dispute Resolution Policy, accessed at www.icann.org/en/help/dndr/udrp/policy on October 22, 2012.) Web sites that meet the criteria of being a "rogue" Internet pharmacy or drug outlet fall squarely within this definition.

With respect to the qualifier "applicable" in the above paragraph (citing ICANN's Uniform Dispute Resolution Policy), NABP notes that pharmacy and drug safety regulatory requirements in the US and most other countries are not intended to be adhered to only by dispensing pharmacies, entities, or individuals physically located within that country's jurisdiction. Rather, the laws and regulations of the destination where the prescription drugs are to be dispensed or sent to are equally applicable, and the entity dispensing prescription drugs is not exempt from adhering to the pharmacy and drug safety laws and regulations of a particular jurisdiction simply by virtue of being physically located outside of that jurisdiction. Similarly, the existence of a foreign pharmacy license does not, by itself, permit the dispensing pharmacy to dispense drugs into a jurisdiction where the pharmacy is not licensed or permitted to practice pharmacy under rules of reciprocity.

The US Food and Drug Administration (FDA) has stated that the importation of prescription drugs directly to a patient in the US is a violation of federal law. There are similar prohibitions against the import of prescription drugs in other countries, including Canada. The sale of prescription drugs without requiring a valid prescription, or sale of prescription drugs into a jurisdiction where the dispensing entity cannot show a pharmacy license or licensure reciprocity, is likewise illegal.

Credit Card Companies and Acquiring Banks

NABP also endorses the use of LegitScript's monitoring process and classification standards by credit card companies, acquiring banks, and other payment processing companies, to help those companies ensure that their services are not used in furtherance of violating applicable laws and regulations pertaining to the practice of pharmacy or dispensing of drugs.

The recognitions contained in this letter continue to be predicated upon the understanding that LegitScript will not develop or encourage any business plan, advertising strategy or other business activity that would directly or indirectly encourage Internet users to use pharmacies or Web sites that sell or facilitate the sale of prescription drugs in violation of the aforementioned standards or in any way that would be considered unsafe or illegal. Additionally, NABP understands that, from time to time, NABP and/or LegitScript may wish to propose modifications or updates to the aforementioned standards or definition. Such modification will require the written agreement of NABP.

NABP is furthermore pleased that Internet pharmacies granted accreditation under NABP's Verified Internet Pharmacy Practice Sites^{CM} (VIPPS[®]) and Veterinary-Verified Internet Pharmacy Practice Sites^{CM} (Vet-VIPPS[®]) program will be granted expedited review toward approval as a legitimate Internet pharmacy by LegitScript.

NABP understands that LegitScript may seek to publicly refer to NABP's recognition of LegitScript standards and classifications. LegitScript may continue to note this recognition, including at *legitscript.com*, using phrases or statements that NABP has already approved. Please note that NABP must first approve, in writing, the use of its name or trademarks in association with any other publication.

NABP is pleased to support and recognize LegitScript's certification and classification program for Internet pharmacies and healthcare products, and support LegitScript's ongoing relationships with domain name registrars, registries, search engines, social media platforms, payment processing companies and other organizations, and your efforts to identify and suspend the domain names of Web sites engaged in unlawful or unsafe activity involving the sale of prescription drugs and other healthcare products over the Internet and/or deny such merchants' ability to process payments.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY



Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

LegitScript Internet Pharmacy Classification Standards

Defining Internet Pharmacies and Applicable Laws

A website is designated by LegitScript as an Internet pharmacy website if the website facilitates the sale or dispensing of a prescription drug or medical device, either via the website or by directing the Internet user to another website or pharmacy.

In determining legitimacy classifications, LegitScript applies the applicable laws to LegitScript International Internet Pharmacy Certification Standards. In this context, “applicable laws” refers to both the laws and regulations where the website operates *from* (e.g., dispenses or supplies medicines from) and the laws and regulations of any jurisdiction where the website offers to ship drugs *to*. Internet pharmacy websites *must* adhere to the laws and regulations in both sets of jurisdictions. (If an Internet pharmacy website is not fully legal in a particular jurisdiction, that area should be removed from the list of possible shipping destinations.)

Legitimate Internet Pharmacy Websites

Websites designated by LegitScript as legitimate are those that have been through the LegitScript certification process and are confirmed to meet LegitScript standards. Legitimate Internet pharmacy websites are monitored on an ongoing basis with quarterly reviews and are subject to a full re-review on at least an annual basis.

LegitScript international Internet pharmacy certification standards are:

LegitScript International Internet Pharmacy Certification Standards
Pharmacy Licensure The website must only facilitate the dispensing of drugs by pharmacies that are licensed or registered in good standing to operate a pharmacy or engage in the practice of pharmacy in all required jurisdictions. This includes the jurisdiction that the drugs are dispensed from and the jurisdiction where the drugs are offered to be shipped to, except where reciprocity exists or other legal authority does not require such licensure.
Controlled Substances Controlled substance laws vary by country. The dispensing pharmacy must be in compliance with all applicable laws and regulations for controlled substances. For example, any dispensing pharmacy, if dispensing controlled substances to US locations, must be registered with the US Drug Enforcement Administration (DEA) and must be in compliance with DEA rules and regulations.
Prior discipline The pharmacy, which may also include its pharmacists and any physician associated with the website, must not have been subject to significant recent and/or repeated disciplinary sanctions.
Pharmacy location All pharmacies that dispense drugs on behalf of the website must be domiciled in the jurisdiction where the website offers to ship drugs to, except where reciprocity exists, drug importation is expressly permitted as a matter of law, or other legal authority permits

or does not require the pharmacy to be domiciled in the jurisdiction.

Validity of prescription

The pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined below, issued by a person authorized to prescribe under applicable laws. The pharmacy must not distribute or offer to distribute prescriptions or prescription drugs solely on the basis of an online questionnaire or consultation without a pre-existing patient-prescriber relationship that has included a face to face physical examination, except as explicitly permitted under applicable telemedicine laws or regulations.

*Definition: A **valid prescription** is one issued pursuant to a legitimate patient-prescriber relationship, which requires the following to have been established: a) The patient has a legitimate medical complaint; b) A face-to-face physical examination adequate to establish the legitimacy of the medical complaint has been performed by the prescribing practitioner, or through a telemedicine practice approved by the appropriate practitioner board; and c) A logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.*

This requirement may be waived upon a showing that the prescribing and dispensing of the drug, as well as the location of the patient, all occur or exist within a jurisdiction that has expressly authorized, by statute, regulation or other applicable law, prescribing based on an online questionnaire or consultation without a pre-existing patient-prescriber relationship that has included a face-to-face physical examination.

Legal compliance

The website and any dispensing pharmacy must comply with all provisions of applicable laws. For the US, this includes but is not limited to state laws and regulations, the Federal Food, Drug, and Cosmetic Act and the Federal Controlled Substances Act, and the website must not facilitate the dispensing of, or offer to facilitate the dispensing of, medications that have not been approved by the US Food and Drug Administration (FDA). For countries other than the United States, the website and any dispensing pharmacy must adhere to all applicable pharmacy licensure, drug safety and supply chain laws and regulations.

Privacy

Websites must adhere to all privacy laws and regulations in the jurisdictions where the website offers to ship drugs from and to.

For any website offering to facilitate the dispensing of drugs to the US, if the pharmacy website transmits information that would be considered Protected Health Information (PHI) under the HIPAA Privacy Rule (45 CFR 164), the information must be transmitted in accordance with HIPAA requirements, including the use of Secure-Socket Layer or equivalent technology for the transmission of PHI, and the pharmacy must display its privacy policy that accords with the requirements of the HIPAA Privacy Rule.

Patient services

The website must display an accurate street address for the dispensing pharmacy or pharmacies. The pharmacy must provide on the website an accurate, readily accessible and responsive phone number or secure mechanism via the website, allowing patients to contact or consult with a pharmacist regarding complaints or concerns or in the event of a possible adverse event involving their medication.

This requirement may be modified to permit the listing of a pharmacy's corporate headquarters, but only in cases in which the pharmacy business has multiple dispensing

pharmacies, or in cases in which the corporate headquarters' address is listed with the applicable government agency that licenses and regulates the pharmacy.
Website transparency Neither the website nor the pharmacy may engage in practices or extend offers that may deceive or defraud patients in any way, including but not limited to, any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.
Domain name registration The domain name registration information of the website must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy. Pharmacy websites utilizing anonymous domain name registration services will not be eligible for approval.
Affiliated websites The pharmacy, website, pharmacy staff, any associated medical personnel, domain name registrant, and any person or entity that exercises control over, or participates in, the pharmacy business must not be affiliated with or control any other website or group of websites that violates these standards.

Unapproved and Unverified Internet Pharmacy Websites

Most Internet pharmacies that do not comply with LegitScript international Internet pharmacy certification standards are “rogue.” However, a failure to comply with LegitScript’s Internet pharmacy certification standards does not necessarily mean that the website is a rogue Internet pharmacy. Some are classified as “unverified” or “unapproved” but not “rogue.”

“Unverified” Internet pharmacies are those that, based on a brief, initial review, appear likely to comply with LegitScript requirements but have not been subject to the LegitScript certification process, or appear likely to be easily able to comply with our standards with minimum adjustments. “Unverified” is a neutral descriptor.

“Unapproved” Internet pharmacies are those for which LegitScript has verified some lack of compliance with LegitScript’s international Internet pharmacy certification standards or applicable laws or regulations. For example, if the lack of compliance is minor or appears unintentional, a website may be designated as “unapproved” but not “rogue.” Some unapproved Internet pharmacies are additionally designated as “rogue” based on the criteria below.

Rogue Internet Pharmacy Website Criteria

The literal definition of “rogue” in this context is “operating outside normal or desirable controls.” (See, e.g., thefreedictionary.com/rogue.) Because the practice of pharmacy and the sale of drugs should be, and are normally, regulated for safety, websites that facilitate the sale of drugs in a way that is not subject to sufficient regulatory oversight, or that reasonably appears to constitute knowing or intentional violation of applicable laws, may be considered “rogue.”

LegitScript often recommends that domain name registrars, Internet service providers, payment facilitators and other third-party platforms consider disabling services to websites designated as “rogue” Internet pharmacies upon direct verification by LegitScript that the website is not legally compliant.

An Internet pharmacy (as defined above) is rogue if it qualifies as unapproved, and:

- The sale, prescribing or dispensing of prescription or other drugs reasonably appears to intentionally or knowingly violate, facilitate the violation of, or offer to facilitate the violation of applicable laws or regulations, defined as the laws and regulations where the drugs are dispensed from or where they are offered to be shipped to;
- Does not adhere to accepted standards of medical and/or pharmacy practice, including standards of safety; and/or
- Engages in fraudulent or deceptive business practices.

The most common scenarios in which an unapproved website is additionally designated as a rogue Internet pharmacy are if one or more of the following three scenarios are true:

- The website sells prescription drugs without a valid prescription (as the term “valid prescription” is defined in LegitScript’s international Internet pharmacy certification standards), except where expressly permitted or authorized by applicable laws.
- The website sells unapproved drugs, which includes but is not limited to drugs that are considered unapproved under applicable law by virtue of being shipped or dispensed outside of authorized drug supply chains.
- The website facilitates the sale of drugs by pharmacies or non-pharmacy entities that do not have pharmacy licenses required under applicable laws.

LegitScript Healthcare Product Classification Scheme for dietary supplements and psychoactive substances

Approved drugs. Products that are approved as a medicine or medical device in the country or countries where they are primarily marketed. For example, Viagra, GC MI Paste, Alprazolam and Rimadyl would all be Approved Drugs in the US. Sildenafil citrate and Kamagra, by contrast, would not be approved drugs. The definition is:

A product is an approved drug if it has been formally approved by a jurisdiction's drug safety/approval authority (e.g., the US FDA or Health Canada) as a drug where it is marketed, and is not widely marketed in jurisdictions where it is not an approved drug.

Per se problematic products. These are dietary and bodybuilding supplements, psychoactive highs, and other products that LegitScript recommends not be used or marketed under any circumstances. The definition is as follows:

A product's legitimacy is *per se* problematic if the product is not an approved drug and:

- The product has been reliably confirmed as being tainted with toxins, unsafe for human consumption or containing active pharmaceutical ingredients; or,
- The product name intrinsically implies safety or efficacy to treat or cure a medical condition, but the product is not approved as a medicine; or,
- The product is used or marketed for experiencing the same or similar effects as those caused by a controlled substance.

Context-dependent healthcare products. These are non-drug products that do not meet the criteria of *per se* problematic products and are not intrinsically harmful, but are or have been marketed in a way that falsely suggests safety and efficacy to treat or cure a medical condition. The definition is as follows:

A product's legitimacy is context-dependent if the product is not an approved drug and is not *per se* problematic and:

The product is or has been marketed in a way implying that the product is safe or effective to treat, prevent or cure a medical condition, despite not being approved as a drug by the FDA (or applicable drug safety authority).

Neutral healthcare products. These are non-drug dietary and bodybuilding supplements that do not meet any of the criteria above. This classification is not a product endorsement, but is merely a neutral designation. The proposed definition is:

A product's legitimacy is neutral if it is neither *per se problematic* nor *context-dependent* nor an *approved drug*.