



The Japanese Rogue Internet Pharmacy Market

2013 Data and Top Rogue Internet Pharmacy Networks



Introduction

From the perspective of the average Japanese Internet user, the website bestkenko.com seems eminently reassuring: three Japanese physicians smile out at the Internet user, next to an image offering "100% assurance" of drug authenticity, effectiveness and delivery. The website, written entirely in flawless Japanese, offers assurances to "first time customers" that the website is completely legal, and offers — mostly, at least — pristine pictures of familiar Japanese medicines. The customer is told that the medicines have been approved for safety by the US Food and Drug Administration. The prices are in yen, and a page offers multiple testimonials, apparently from Japanese residents, as to their satisfaction regarding the medicines provided by bestkenko.com. To any Japanese Internet user, it would seem that bestkenko.com offers a fully legal, entirely safe, website selling prescription medicines, marrying the best of the Internet with online healthcare fully regulated for safety.

The truth, however, is starkly different.

In fact, bestkenko.com has no affiliation whatsoever with any Japanese physician or pharmacy, despite the marketing. The drugs are not, for the most part, approved for sale in Japan, and are not sold by any licensed pharmacy in Japan or any other location. Contrary to the website's assertions, the drugs are not approved by the US FDA drug safety authorities. The website, which replaced a rogue Internet pharmacy website recently shut down by LegitScript called bestkusuri.com, is registered to an Indian company that, via other websites, also supplies residents in the US with drugs from India, despite marketing itself as a "Canadian" pharmacy. Current or former website operators from the same network of websites hail from Singapore. The active ingredients contained in the medicines require a prescription in Japan (and in other countries) but are sold by BestKusuri without a prescription, pharmacy license or any physician intervention at all. In contrast to real pharmacies which must be licensed in a Japanese prefecture, and real physicians, which must adhere to a code of conduct and be licensed in Japan, the website bestkenko.com is akin to the *ronin* samurai of ancient Japan in that it operates without the normal level of oversight and safety controls designed to protect Japanese residents.

This study shows that such websites are by far the rule, not the exception, when it comes to Internet searches for prescription drugs in Japan. This is true more or less worldwide: in the US, for example, the National Association of Boards of Pharmacy has shown that roughly 95% - 97% of English-language websites facilitating the sale of prescription drugs operate illegally. As we show, this is also true for Japanese Internet searches.

Japan permits the importation of prescription drugs in exceedingly narrow circumstances. The exception is very limited, and is only written to permit a small degree of prescription drug importation,



and then only if the website does not advertise unapproved drugs via text or image to the customer. To fully comply with guidance issued by the Japanese Ministry of Health, Labor and Welfare, the merchant must be in a truly "passive" role for the exception to apply; otherwise, prescription drug importation is not allowed. As we show in this study, virtually none of the websites that sell prescription drugs into Japan adhere to the narrow nature of this exception, although most claim — inaccurately — that their websites are legal because "prescription drug importation is permitted in Japan."

Also of concern, as we show, these websites are not selling prescription drugs from legitimate, licensed pharmacies in the US or other countries, despite being marketed as if they are. The prescription drug importation exception in Japanese regulation presumably intended that the drugs would be imported from real, licensed pharmacies — for example, a licensed, safe pharmacy in the US that happens to fill a few orders from Japan. As we show, the reality is different, and far less than 1% of websites that facilitate the importation of drugs into Japan actually adhere to the exception and the guidance issued by the MHLW. Instead, the search results generally represent websites operated by organized networks also targeting other countries; at best, the drug source is undisclosed and unregulated.

This analysis first recaps the current state of Japanese laws and regulations pertaining to the online sale of drugs into Japan. Next, this paper provides data about Japanese-language websites selling prescription drugs into Japan based on 2,345 Japanese-language search results related to prescription drugs and pharmacy terms analyzed by LegitScript analysts. This paper estimates the percentage of those search results selling prescription drugs to Japanese residents (either online or offline), and of those, what proportion adhere to applicable Japanese drug safety laws and regulations.

This report then digs deeper into the data, looking at the organized criminal or affiliate marketing networks represented among the search results, and provides a summary of what is known about their activities and operations — not only from their Japan-focused activities, but from their other global activities. We estimate that 44% of illicit prescription drug sales into Japan are traceable back to three multi-national criminal networks illegally selling drugs worldwide, including into Japan.

This research is intended to underscore the fact that most search results for prescription drugs, and particularly those search results that in some way, whether online or offline, facilitate the sale or dispensing of prescription drugs to Japanese residents, operate illegally and many are tied to known multinational rogue Internet pharmacy or other criminal networks. In some cases, these networks are known to be tied to counterfeit and substandard drug sales. Japanese Internet users seeking to purchase drugs online should be aware of the risks.



Overview: Japanese Laws and Regulations

Like virtually all other countries worldwide, Japan laws create a regulated structure for the practice of medicine and pharmacy. While Japan's Pharmaceutical Affairs Law (PAL), Customs Law and Medical Act of course contain hundreds of provisions applicable to drug dispensing and pharmacy practice, among the most salient to this paper are the requirements that a pharmacy be duly licensed in a Japanese prefecture, that a prescribing physician be licensed in Japan, that the physician physically examine the patient before issuing a prescription, that a prescription be required for the dispensing of prescription drugs, and — with an exception discussed later in this section — that prescription drugs only be dispensed by a licensed pharmacy in Japan and, as a general principle, may not be imported directly into Japan.

Equally pertinent is a prohibition against Japanese Internet pharmacies. It is illegal to sell or dispense prescription drugs on the Internet.⁵

To all of this, however, there is an exception: the Japanese Ministry of Health, Labor and Welfare (MHLW) issued a guideline for regulating personal importation agencies. The MHLW guidance on this is found at http://www.mhlw.go.jp/kinkyu/diet/tuuchi/0828-4.html and is a narrow exception indeed: as shown in the graphic on the following page, which was obtained directly from the MHLW website (and, for the English version of this report, translated into English by LegitScript), any advertisement of unapproved drugs is not allowed, and agents cannot ship medicines to the customers, as doing so is considered as sales activity.

Additionally, Article 68 of Japan's Pharmaceutical Law prohibits the advertisement of unapproved drugs. A 100 mg Viagra tablet, for example, even if genuine, cannot be advertised, because only 50 mg and 25 mg dosages are approved in Japan. The seller of the drugs cannot advertise unapproved drugs to the general public — in Japanese, cannot *kibo wo tsunoru* (translated literally, cannot "stoke the hopes [interest]" of potential customers). The merchant can only be a facilitator or "agent" and cannot be the one physically distributing the drugs themselves. Rather, they must be a "passive third party" who merely provides a mechanism for the customer to contact the pharmacy or other

¹ Pharmaceutical Affairs Law Article 4: http://www.houko.com/00/01/S35/145.HTM#s2.

² Medical Act Article 17: http://law.e-gov.go.jp/htmldata/S23/S23HO201.html

³ Medical Act Article 20: http://www.houko.com/00/01/S23/201.HTM#s3-2

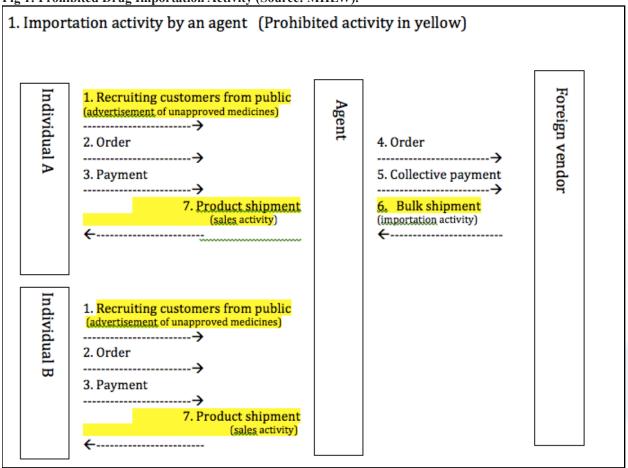
⁴ Pharmaceutical Affairs Law Article 49: http://www.houko.com/00/01/S35/145.HTM#s2

⁵ Pharmaceutical Affairs Law Enforcement Regulation Article 15: http://www.mhlw.go.jp/bunya/iyakuhin/ippanyou/pdf/shourei.pdf



entity supplying prescription drugs (and not the reverse). As is discussed later in this report, however, that very structure — the insertion of a third-party not responsible for drug authenticity or safe pharmacy practice -- into the transaction is precisely the model that international criminal networks utilize via affiliate marketing networks to conceal the origin of drugs and the identify of the supplier.

Fig 1: Prohibited Drug Importation Activity (Source: MHLW).



In summary, Japan's domestic laws and regulations pertaining to drug safety are, in many respects, like those of any other country, in that prescription drugs must be dispensed by a licensed pharmacy, prescribed by a licensed practitioner, must be approved for sale by Japanese drug safety regulators, and must, for prescription medicines, be dispensed pursuant to the issuance of a lawful prescription. Unlike other countries, however, there is a narrow exception that allows personal importation of limited amount of prescription drugs if a website does not advertise or market unapproved drugs directly to potential customers.



Japanese Prescription Drug Search Result Landscape

If a Japanese-speaking Internet user attempts to search for information pertaining to prescription drugs online, what percentage of the results accord with Japanese legal requirements? To evaluate this question, LegitScript ran 50 queries in Japanese on Google and Bing for common prescription drug search terms. Our goal was to analyze all of the search results to determine how many of the websites represented businesses or people selling or facilitating the sale of prescription drugs (either online or offline), and of those, how many were acting lawfully and unlawfully.

As to our methodology, LegitScript notes that there are potentially thousands of prescription-drug related search terms that one could choose from as a starting point to make this assessment. For this study, we chose fifty terms that we think represent a spectrum of types of prescription medication and search terms. In an attempt to use a cross-section of search terms based on the type or medication and activity involved, we used three kinds of search terms. The first were prescription drugs with phrases such as "mail order," "import" and "personal importation" to reflect the keywords that are likely used by people who have some interest in purchasing medicine online. A second were prescription drugs with more general terms such as "buy" or "sale." These kind of keywords are likely to be used by people who are interested in the purchasing medicines, but not limited to online transactions. The other type of keywords are general terms, such as "birth control meds", "ED drugs," the active pharmaceutical ingredient such as "tadalafil" or a prescription medicine name such as "Clavit." These terms are more likely used by Internet users who are looking for information for prescription drugs, and these Internet users may or may not actually be intending to purchase the drugs online (or offline). Note that medicine names adopted as keywords are all approved in Japan, and medicines that are not approved in Japan, such as Kamagra, Xenical and Finpecia, are not used as keywords here.

The search terms that LegitScript utilized in our queries were:

Japanese search term	English translation
中絶薬 買う	abortion meds buy
処方薬 通販	prescription drug mail order
海外医薬品	foreign medicines
薬 個人輸入	medicine personal importation
血圧の薬 通販	blood pressure med mail order
避妊薬	birth control meds
アフターピル 通販	after pill mail order
ED薬	ED drug
アクトス 通販	Actos mail order



Japanese search term	English translation
アドエア 買う	Adoair purchase
アフターピル	after pill
アリセプト 買う	Aricept buy
アルサルミン 輸入	Ulcerimin importation
オルメテック 通販	Olmetec mail order
クラビット	Clavit
クラビット 通販サイト	Clavit mail order website
ザイザル 個人輸入	Xyzal personal importation
サインバルタ 買う	Cymbalta buy
シアリス	Cialis
ジプレキサ 通販	Zyprexa mail order
シルデナフィル	Sildenafil
ゾピクロン 個人輸入	Zopiclone personal importation
ゾロフト 販売	Zoloft sale
タダラフィル	Tadalafil
タダラフィル 販売	Tadalafil sale
タミフル 販売	Tamiful sale
チャンピックス	Champix
ディオバン 買う	Diovan buy
トラマール 通販	Tramal mail order
トリキュラー	Triquilar
ネキシウム 輸入	Nexium importation
ノルバスク 個人輸入	Norvast personal importation
ノルレボ ネット販売	Norlevo online sale
ノルレボ 輸入	Norlevo importation
バイアグラ	Viagra
バルデナフィル	Vardenafil
ピオグリタゾン 輸入	Pioglitazone importation
プラビックス 通販	Plavix mail order
フルナーゼ 個人輸入	Flunase personal importation
プレマリン 買う	Premarin buy
ブロプレス 個人輸入	Blopress personal importation
プロペシア	Propecia
ボルタレン 個人輸入	Voltaren personal importation
メトホルミン 個人輸入	Metformin personal importation
リピトール 通販	Lipitor mail order
ルミガン	Lumigan
レクサプロ 輸入代行	Lexapro importation agency



Japanese search term	English translation
レビトラ	Levitra
レミケード 個人輸入	Remicade personal importation
ロゼレム 輸入代行	Rozerem importation agency

From these 50 keyword search terms, we received 2,345 prescription drug-related search results. LegitScript reviewed the first two pages of search results, each of which typically contain 10 unpaid search results and between zero and ten sponsored search results, on both Bing and Google. (The expected number of unpaid search results was therefore 2,000, with the additional 345 constituting paid, or sponsored, search results.)

Of these 2,345 search results, 1,553, or 66%, exist for the purpose of dispensing prescription drugs, either online or offline. ("Offline" dispensing refers to legally operating clinics physically located in Japan, for example.) The remainder were informational or fell into a neutral category — for example, informational medical pages, personal blogs or Internet user forums.

Strikingly, of these 1,553 search results, rogue Internet pharmacies that fail to comply with Japanese laws and regulations — including failing to comply with the personal prescription drug importation agent exception — accounted for 1,454 search results. Another 55 were clinics operating (insofar as we know) lawfully that do not dispense prescription drugs online, but merely advertise their location and the services they offer to walk-in patients. Drug manufacturers accounted for another 34 search results, and websites selling over-the-counter drugs only — some of them are still unlawful as of this writing, but in the process of being liberalized as per a Japanese Supreme Court decision — accounted for eight websites.

Among all of these results, only one website representing two separate search results might be considered to adhere to the passive personal importation exception because it did not show the unapproved drug names and prices on the top page; rather, customers must type part of the drug name for any information at all to be displayed. The two search results were from within a single domain name, avis-drug.com. Even if this website may technically follow the MHLW's guidelines, however, this website is potentially problematic because all customers have to do is type in one letter to see the advertisement of unapproved drugs. That is, once a potential customer type one letter into the search bar, the website shows a list of unapproved prescription drugs with prices without disclosing the origin of the medicines. For this reason, LegitScript emphasizes that we do not approve of or endorse the website, which ultimately is no safer than any of the rogue Internet pharmacies discussed on the following pages. Rather, we simply note that it arguably (but not necessarily) complies with the personal prescription drug importation exception.



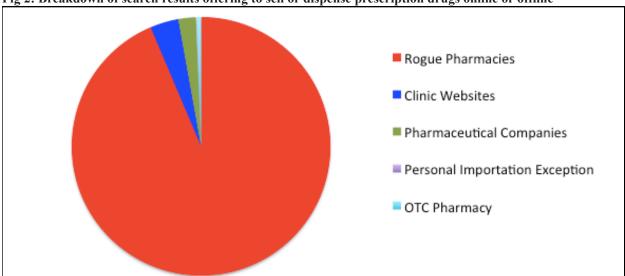


Fig 2: Breakdown of search results offering to sell or dispense prescription drugs online or offline

The results here are discouraging for patient safety: among 1,553 search results that facilitated the dispensing (online or offline) of prescription drugs, 93.6% blatantly fail to comply with Japanese drug safety regulations, and similarly fail to comply with the pharmacy licensure and prescription requirements that exist in Japanese laws. Only 0.1% might comply with the limited passive personal drug importation exception authorized by the MHLW — a single website representing two search results. And only 6.4% were legitimate clinics, drug companies or similar websites.

Here, it is worth providing a few examples of the 1,454 websites that LegitScript classified as rogue Internet pharmacies. Without exception, all of the websites sell or facilitate the sale of prescription-only medications without a prescription; advertise and sell unapproved drugs; market prescription drugs directly over the Internet to Japanese residents; and fail to maintain required pharmacy licenses. Three examples of websites that represent the group are:

• <u>kanpoudonya.com</u>. This domain name appeared as a search result for birth control pills (避妊薬).

Despite the domain name "Kanpou", which means "Chinese herbal medicine" in Japanese, this website advertises and sells not only dietary supplements and aphrodisiacs, but also prescription birth control pills and an abortion pill called RU486. Japan's MHLW specifically bans the personal importation of RUS486 because of safety issues.⁶

image follows on next page

⁶ mhlw.go.jp/houdou/2004/10/h1025-5.html



Fig 3: kanpoudonya.com, a typical rogue Internet pharmacy targeting Japan

・ sizen.co.jp. This website has a very professional look and the design, along with phrases such as "Beauty," "Body Care" and "Diet," show that it is geared toward women. Contrary to a nice and professional look, however, the website offers a wide variety of prescription drugs: anti-

depressant, birth control pills, diabetes medicines, as well as reductil, which is banned in most

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countries because of their dangerous side effects, including death.



Fig 4: sizen.co.jp, a rogue Internet pharmacy targeting Japan.

• $9 \le 7 \text{ N.meblog.biz}$. This website may appear to be a personal blog website at first sight.

However, the contents of the blog entries have only one purpose: to urge readers to purchase Tamiful via <u>bestkenko.com</u>, by describing online purchase as cheaper and not illegal. LegitScript therefore classifies the website as a rogue Internet pharmacy, since its sole purpose is to facilitate the illegal dispensing of prescription drugs.

The posts on the website suggest that an outbreak of avian influenza in China will result in a shortage of medicine in Japan when needed. This website has multiple links to bestkenko.com— a common strategy used by major rogue pharmacy networks. Through the BestKusuri (now doing business as BestKenko) affiliate marketing program, rogue Internet pharmacy networks create multiple websites with content designed to lure Internet users to the primary sales website such as bestkenko.com. As noted in the first section of this report, bestkenko.com advertises and sells various prescription drugs, and most of them are not approved in Japan.

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Fig 5: タミフル.meblog.biz, a rogue Internet pharmacy targeting Japan



Another finding worth noting is the relationship between the keywords and the search results. As mentioned above, three kinds of search terms were used: prescription drug name with phrases such as "mail order"; prescription drug with general terms such as "buy"; and general terms, such as "birth control meds" or API or medicine names. Not surprisingly, the first kind of keywords with "mail order" or "personal importation" showed the highest percentage of problematic results. For example, 100% of the results for "レクサプロ 輸入代行 (Lexapro importation agency)", 96% for "リピトール 通販 (Lipitor mail order)", 90% for "フルナーゼ個人輸入 (Flunase personal importation) were rogue Internet pharmacies. This is somewhat expected, because rogue Internet pharmacies target customers who are interested in "personal importation" or "mail order" of prescription medicines, and at the same time, Internet users who search using those terms may be interested in acquiring medication online. By contrast, when Internet users use only the prescription drug name, there are fewer problematic results, although still a majority overall. Our study shows 66% of the results for "バイアグラ (Viagra)", 50% for "チャンピックス (Champix)", 49% for "トリキュラー (Triquilar), and 40% results for "クラピット (Clavit)" were rogue Internet pharmacies. Even for a very general term such as "避妊薬 (birth control



meds)", rogue Internet pharmacies constituted 31% of the results. This is problematic because Internet users who perform searches with these terms may not intend to import those medicines, and are may only be looking for information. Despite that, they are exposed to multiple rogue Internet pharmacies.

Finally, out of all the 50 keywords used in this study, none returned solely non-problematic search results. Every single keyword returned multiple rogue pharmacy results.



Who is Behind Japanese Rogue Internet Pharmacy Search Results?

The global Internet pharmacy market can seem overwhelming in scope: LegitScript estimates that at any one time, there are at least 40,000 unique websites selling or facilitating the sale of prescription drugs on the Internet. Most of these are not written in Japanese, but a few thousand — we estimate somewhere in the 2,000 - 4,000 range in total — are written partially or solely in Japanese, targeting residents of Japan.

This seemingly overwhelming number of websites becomes more manageable, however, when viewed in the context of networks. In fact, LegitScript estimates, based on our data, that well over 90% (probably about 97%) of all Internet pharmacy websites are part of a "network" that may consist of anywhere from two websites to several thousand. Internet pharmacy websites should be considered part of the same network when most the money paid by the customer goes to the same central organization or coordinator of multiple websites.

Perhaps predictably, networks do not just stop at two or three separate Internet pharmacy websites. Rather, networks seeking to maximize their profit from illicit prescription drug sales want to deploy as many websites as possible to "fill up" the search results and drive out competitors and legitimate search results. In order to accomplish this goal, an illicit prescription drug distribution has two primary strategies it can employ: first, to register hundreds of domain names itself, and seek to market drugs on all of them, or second, operate an affiliate marketing program in which anyone can set up their own website selling prescription drugs in connection with the network, and receive a cut of the sales. Some networks employ a hybrid approach of both. In any case, this tends to push legitimate companies and websites out of the search results, since legitimate clinics and companies only tend to deploy one website for their company — not thousands.

In light of this, LegitScript sought to understand and analyze which networks are primarily represented among the illicit search results. We found that the top three networks accounted for 634, or 44%, of all rogue Internet pharmacies targeting Japan. Those three networks are:

- 1. BestKusuri (aka BestKenko).
- 2. Roy Union.
- 3. RxCash.biz.

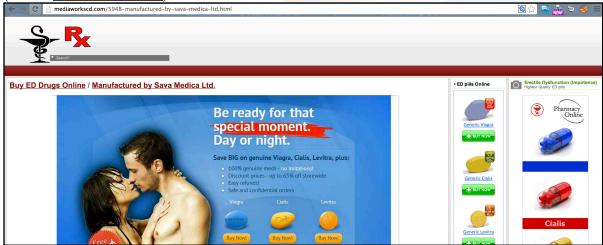
There are, of course, other rogue Internet pharmacy networks targeting Japan. In the remainder of this section, we provide a brief synopsis of each of the top three Internet pharmacy networks targeting Japan.



1. The BestKusuri (aka Best Kenko) network. BestKusuri (now doing business as BestKenko) websites accounted for 419 out of the 2,345 search results. To put this in perspective, compare this number to the fact that all clinic websites and all pharmaceutical companies' websites combined only reached 89 in number. In other words, BestKusuri's websites alone outweigh the number of legitimate websites in total in Japanese prescription drug-related search results by nearly a factor of five.

LegitScript has conducted independent research into the BestKusuri network. Our investigation indicates that current or former website operators, linked to a company called Pagerise, are based in Singapore. The network has some relationship with a drug supplier in India (Sava Medica) that distributes unapproved medicines around the world via other non-compliant Internet pharmacy websites. After LegitScript shut down the original flagship website, bestkusuri.com, individuals connected to Singapore-based Pagerise contacted the domain name registrar requesting that the website be released; after this was refused, the network launched a replacement website, bestkenko.com, which is now registered to Deepak Shinde of India, ultimately connected to Sava Global, an enterprise that ships unapproved drugs around the world without legally required pharmacy licenses or requiring a prescription. For example, http://mediaworkscd.com/5948-manufactured-by-sava-medica-ltd.html markets various drugs as "manufacturered by Sava Medica Ltd."; the website directs English-speaking users to rxcvs.org, a rogue Internet pharmacy that falsely implies it is affiliated with the popular US pharmacy chain CVS, but instead is part of a Russian organized crime network commonly known as Rx-Partners.

<u>Fig 6</u>: A Russian organized criminal network affiliate identifying the drugs as coming from Sava Medica (source: <u>mediaworkscd.com</u>)



⁷ http://blog.legitscript.com/2012/10/bestkusuri-com-japanese-rogue-pharmacy-linked-to-singapore-internet-firms/



ヒアルロン酸

Claiming to list 856 products on the top page, <u>bestkenko.com</u> markets a wide variety of prescription medicines, both "brand medicines" and "generic medicines." Nearly all the "generic" versions are unapproved medicines in Japan. This network also has some websites that sell prescription animal medicines without requiring a prescription, such as <u>petkusuri.com</u>; these medicines, likewise, are not sourced from licensed pharmacies in Japan.

BestKusuri's strategy of utilizing many domain names, and also the wide variety of products they carry, makes BestKusuri websites throughout the results for nearly all the keywords used for conducting searches. In other words, whatever terms Japanese citizens use for Internet search, whether it's birth control pill, blood pressure meds or Cialis, it is virtually certain that they will probably see some BestKusuri websites in their search results.

It is important to emphasize the extent to which the BestKusuri criminal network fails to comply with Japanese (or other countries' laws): it does not come close to complying with the personal prescription drug importation exception; the drugs are sold without a prescription or any requirement of medical supervision, and there is no assurance of supply chain security for patients or animal owners.

Fig 7: Rogue Internet pharmacy bestkenko.com www.bestkenko.com/categories/高血圧・糖尿病/ C S Google お薬解説プログ マイ・アカウント 注文履歴 カートの中身を見る FAX 注文 検索 アドバンスト・サーチ | 検索ヒント o.com 正規品100%保証 ご希望の方へ 商品数:856点 口コミ:17,064件 ホーム | 初めてのお客様へ | お買い物手順 | お客様の声 | ポイントシステム | お友達紹介 | よくある質問 | お問い合わせ | アフィリエイト ホーム > 高血圧・糖尿病 **お客様の声 ✓全国送料無料 ✓手数料·商品税無料 並び替え: 売れている順 高血圧・糖尿病 / 処方箋·診断書不要 日 中身が解らない 包 商品名記載無し Valsartan Tablets alzogr-80 くすりカテゴリー ナイトライフ 作年2月と比べても ノルパスク5ma グルコバイジェネリック リピトール10mg ディオバンジェネリック 育毛・ヘアケア 明らかな増毛に 80mg 50mg 満足しています。 ダイエット ¥4,780 ¥2,580 ¥4,500 ¥2,250 ¥5,800 ¥3,280 **** **** ピル・避妊薬 □ 比較 □ 比較 □ 比較 □ 比較 お薬の比較のな 低用量ビル カートに入れる <u>カートに入れる</u> カートに入れる <u>カートに入れる</u> アフターピル ○ ED薬の比較 ○ ダイエット楽の比較 アンチエイジング ○ 育毛薬の比較 美容・スキンケア まつ毛育毛剤 ○ 避妊ピルの比較

クリンダマイシンジェル

アルダクトン

ノルバスク10mg

16



2. Roy Union rogue Internet pharmacy network. Roy Union is a rogue Internet pharmacy network that appears to be operating out of China. The websites accounted for 183 of the websites in our search results. This is less than half of those that were related to BestKusuri/BestKenko, but still more than double the number of all the legitimate clinic and pharmaceutical company websites combined. Roy Union has about ten rogue Internet pharmacy websites that are the network's "flagship" Internet pharmacy websites, plus hundreds of other affiliate marketing websites. A few of the flagship Internet pharmacy websites are <u>osakado.com</u>, <u>jisapp.com</u>, <u>orandaya.com</u> and <u>m-hk.com</u>. Despite using misleading website names, such as orandaya.com ("Orandaya" translates to "Holland store") or osakado.com ("Osakado" translates to "Osaka store"), Roy Union Limited is not located in either Holland or in Osaka, Japan. Rather, the company claims to be registered in Hong Kong, and claims to ship medicines from Hong Kong, Singapore, the US, Thailand and other places. However, there is no evidence that the drugs are actually from licensed pharmacies any of these locations (or, for example, from the US at all). The websites in this network carry products that run the gamut from erectile dysfunction drugs, anti-depressants, birth control pills and diabetes medicines to cancer drugs, HIV drugs and even psychoactive high (designer drug) products. The network also has rogue animal Internet pharmacies, such as usapara.com. No prescription is required for any of these drugs, which include many drugs not approved for sale in Japan. China is a known source of many counterfeit, dangerous medications, as also discussed in example #3 below (RxCash.biz).

image appears on the following page





Fig 8: Rogue Internet pharmacy osakado.com, one of the flagship websites in the Roy Union network

3. **RxCash.biz**. RxCash.biz is a multi-national criminal enterprise headquartered in Israel that targets the US, European Union nations, Japan and other regions including the Middle East. The network is primarily operated by an individual from the country of Georgia who now resides in Israel. RxCash.biz websites worldwide have consistently sold prescription drugs, including controlled substances, without a prescription. The drugs are unapproved and in some cases are reputed to be counterfeits. Examples of websites in this network include <u>i-kusuri.ip</u> and <u>kenkostore.org</u>.

RxCash.biz websites accounted for 32 in the search results. Globally, however, RxCash.biz is much larger in scope, with over 2,000 websites targeting the US, Canada, EU countries, the Middle East, and other countries. LegitScript has confirmed more than 50 Japanese language websites under this network, illustrating the network's diversification: while Japan is not the only or the primary focus of this international criminal network, it is nevertheless an important focus. RxCash.biz websites sell various prescription drugs including erectile dysfunction drugs and diabetes drugs, as well as dietary supplements and aphrodisiacs. Despite their Japanese-language websites being written in impeccable Japanese, with images of Japanese citizens implying that the websites are somehow linked to Japan,



ツゲイン・ジェル2%

RxCash supplies drugs from a variety of sources, including China. Some of the products are sourced by this network come from Kunming Dali, a major counterfeit drug supplier in China that has been identified as selling products tainted with sibutramine, a controlled substance linked to heart failure that is banned in most countries. LegitScript stands by our designation of RxCash as an organized criminal network and is aware of cases in the US in which individuals reportedly have been sickened or otherwise been harmed from drugs sold by this criminal network.

Fig 9: kenkostore.org, an affiliate of the RxCash.biz rogue Internet pharmacy network Q C S Google kenkostore.org Kenko Store.org 受付: 月~金 10時~21時 電話注文・カスタマーサポート専用フリーダイアル 0066-33-800639 又は 0120-958-144 ホーム ご注文方法 価格表 よくある質問 マイ・アカウント マイ・カート お問い合わせ メール注文 本日のお勧め商品 男性向け 受付:月~金 10~21時 シアリスオーラルゼリー ビットリア 電話注文 カスタマーサポート専用フリーダイアル 0066-33-800639 または 0120-958-144 シアリス・プロ バイアグラ・プロ バイアグラ・スーパーアクティブ カスタマーサポートにご連絡頂く前に、必ずお読み下さい。 こちらをクリック > シアリス・スーパーアクティブ バイアグラ 4フレーバー(味) ハーバル・バイアグラ 銀行振込みがお得っ!! 銀行 ジェネグラ シートタイプEDセット 銀行振込みでお支払いのお客様には、もれなく10%増量サービス!! ご注文より3日以内のお振込みで、さらに5%増量サービス!! パイアグラ ジェネリック・バイアグラ ☆★☆合計で15%増量サービス獲得のチャンスッ☆★☆ ジェネリック・バイアグラ 50mg パイアグラ・ソフトタブ (さらに便利♪お近くの干郵便局干からもお振込み頂(けるようになりました。) ※増量対象外商品につきましては、予めご了承下さい。 バイアグラ オーラルゼリー(カマグラ) シアリス ジェネリック・シアリス ジェネリック・プロペシフ (フィナステリド) 180錠 1mg バイアグラ 12錠 100mg シアリス・ソフト レビトラ 16\$2 100m 育毛製品 ジェネリック・プロペシア(フィナステリ ¥11770 詳細を見る ¥13930 詳細を見る ¥18250 詳細を見る 詳細を見る ¥11770 詳細を見る ¥22570 詳細を見る ミントップ 2% ミントップ 5% ツゲイン 2% 女性用パイアグラ 15錠 100mg ジェネリック・ダイフルカン 15 150mg ジェネリック・パイアグラ 15錠 100mg ツゲイン 5%



Analysis and Conclusion

This study had a limited number of objectives: first, to assess the "cleanliness" or "dirtiness" of the Japanese search space, based on fifty prescription drug-related queries. Second, of those search results that facilitate the online sale of prescription drugs — called "Internet pharmacies" in the vernacular, even though neither the websites, website operators nor drug suppliers are typically licensed pharmacies — we looked at what organizations are behind the search results to give qualitative texture to our results.

The results are not encouraging. First, as noted, the 66% of the 2,345 search results were for websites or businesses either selling or promoting the sale or dispensing of prescription or OTC drugs, either online or offline. Of these, only 6.4% were legitimate or potentially legitimate — under the current state of affairs of Japanese laws and regulations, by definition, nearly all of these were the websites of "offline" businesses such as walk-in clinics or pharmaceutical companies, not websites actually selling prescription drugs online. By contrast, about 93.6% of the remaining search results (that is, of the two-thirds of the overall search results) were operating out of compliance with Japanese laws and regulations. Only a single website, representing two distinct search results might arguably be considered to adhere the passive personal importation exception.

As to the question of who is behind those illicit search results, we found that 29% of the total number of search results, or 44% of the search results representing websites of businesses selling drugs online or offline, were represented by three organized rogue Internet pharmacy networks: BestKusuri (now doing business as BestKenko), Roy Union operating out of China, and the RxCash.biz criminal network, which focuses on many countries including Japan and is a major global public health threat. All of these networks, in their marketing, make use of the passive personal importation exception that exists in Japanese policy by including in their marketing techniques public statements that they comply with Japanese legal requirements. None actually do.

Moreover, our research showed that Japanese citizens are being exposed to dangerous rogue pharmacy websites merely by conducting Internet searches using simple prescription drug terms such as "トリキュラー (Triquilar)", or even with very general terms such as "避妊薬 (birth control meds)".

Additionally, we note that virtually none of the websites that facilitate the sale of prescription drugs via the Internet adhere to MHLW's guidance. Given this, it is not unreasonable to be concerned, given the way that these Internet pharmacy websites market themselves, that Internet users in Japan may believe that they are acquiring drugs from a licensed pharmacy in another country selling, as is often claimed to the the case, legitimate prescription drugs that are approved by the US Food and Drug Administration. Emphatically, that is not the case.



To drive this point home, it is important for the public to be aware that the websites that are selling drugs to Japanese residents are not legitimate, licensed pharmacies in another country that happen to make a few (or a lot) of sales to Japanese residents, but are otherwise nothing more than a friendly neighborhood pharmacy or a trusted chain drug store selling drugs approved by the US FDA or another drug safety agency. Rather, these are multi-national criminal networks operating outside of any regulatory safety controls, not unlike *ronin samuari* of ancient Japan who served no master and existed within no recognized social structure: 44% of the websites that represent entities selling prescription drugs (online or offline) were tied to three networks selling unapproved drugs, not only to Japan but other countries as well. These networks are BestKusuri/BestKenko of India and potentially Singapore; Roy Union of China, and RxCash of Israel. Although not analyzed in this report, the remainder of the websites selling prescription drugs are also part of smaller networks engaged in identical sorts of illicit activity, not only toward Japan but other countries as well. For this reason, LegitScript urges extreme caution on members of the Japanese Internet-using public who consider purchasing drugs online.

LegitScript appreciates the opportunity to have conducted this research and would be pleased to answer any questions that may arise.