



Our Struggle to Ensure Fair Play in Japan's OTC Pharma Market

– Also available online at:

<http://www.kenko.com/company/pr/archives/2010/03/> –

What's this about? Abuse of bureaucratic power

In June 2009, Japan's Ministry of Health, Labor & Welfare (MHLW) imposed new regulations on the sale of non-prescription pharmaceutical products – commonly known as “Over-The-Counter” or OTC products.

New regulations were required by revisions to the Pharmaceutical Affairs Law enacted by the Diet in June 2006. This replaced the Pharmaceutical Affairs Law of 1960, which was clearly outdated.

The revised law established basic principles for Ministry bureaucrats to follow in drafting detailed regulations (“ministerial ordinances”) to cover all aspects of the ¥628 billion OTC business. These ordinances were to be drawn up and phased-in over a three-year period up to June 2009.

The revised law, as enacted by the Diet, did not in any way restrict the online sale of OTC products.

In the process of drafting the ordinances, however, Ministry bureaucrats distorted the intent and principles of the revised law. This was done in a way that effectively barred online vendors and convenience stores from the OTC market from June 2009.

We allege that Ministry officials unreasonably favored incumbent business interests that have close ties to the bureaucracy.

For this reason, on May 25, 2009, Kenko.com and Wellnet Corporation sued the government in Tokyo District Court alleging that Ministry actions represent abuse of power and a violation of our constitutional rights.

The court is expected to announce its verdict on March 30th, 2010. Please check this site for updated information once the verdict is available.

On the following pages you will find an outline of this story.

For more information, please contact:

PR@kenko.com or 033584-4138

Chronology of the OTC Case

Date	Event	Comment
May '04-Dec '05	1960 law revision advisory council formed	No online sellers involved Almost no discussion of online sales "Face-to-face" principle discussed
June '06	"2009 Law" enacted	Category 1 side-effect warnings required No "face-to-face" principle No online sales restriction
Feb. '08-July '08	Ordinance research panel	No online sellers involved Online sales prohibition discussed
Sep. '08	Ordinance proposed	"Face-to-face" made mandatory Online sales limited to Cat. 3
Sep. '08-Oct '08	Public comment on proposed ordinance	Of 2,353 citizen comments, 97% (2,303) favor NO online sales restrictions
Feb. '09	Ordinance enacted	No change to proposal despite objections
May 25 '09	Kenko.com and Wellnet Corp. sue government	Allege abuse of bureaucratic power and violation of constitutional rights
June '09	New ordinance took effect	
Mar. '10	Court judgment due March 30	

2004: Need for Revision of 1960 Pharmaceutical Affairs Law

By 2004 it was clear that Japan's Pharmaceutical Affairs Law required revision. When the law was enacted in 1960, Japan had only pharmacies run by professional pharmacists. There were no equivalents to today's "drug stores" that sell OTC products even when the staff pharmacist is not present.

Obviously, there was no such thing as an online drug store in 1960. Nor did the law anticipate that new sales channels (such as convenience stores) would seek the ability to sell OTC. Kenko.com was able to begin OTC sales from 2002 because the 1960 Law did not prohibit it. But as a responsible vendor we welcomed the prospect of clear guidelines.

May 2004: Law Revision Advisory Council

In May 2004 the government formed an advisory council to consider revising the 1960 law. No online drugstores were invited to join this process. And there was almost no discussion of online sales. So when the advisory council made its report in December, 2005 there was no suggestion to restrict online sales.

June 2006: Diet passes Revised Pharmaceutical Affairs Law

New law established three categories for OTC products according to risk of side effects and potential for abuse. For Category 1 – "behind-the-counter" drugs that entail risk of side effects or abuse – the new law set the principle consumers must be warned – in writing – of any possible side effects. The new law did not mention online OTC sales and did nothing to restrict them. During a three-year phase-in period, Ministry officials were to draft ministerial ordinances to take effect in June 2009. These detailed regulations covering all aspects of OTC were supposed to be consistent with the principles of the law.

February 2008: Ministry forms “ordinance research panel” on OTC

To draft the required OTC regulations, the Ministry of Health, Labor & Welfare formed an ordinance research panel in February 2008. Again no online drugstores were invited to join.

Ministry bureaucrats did invite the Japan Association of Chain Drugstores (JACDS) to join. It is an “open secret” in the industry that JACDS effectively wrote the ordinances.

Consequently, the ordinances were slanted heavily in favor of JACDS members – drug chains that have a huge vested interest in keeping competitors out of the ¥628 billion OTC market.

September 2008: New OTC ordinance announced

While newspaper headlines said the ordinance opened OTC to convenience stores, in fact, the reverse was true. The requirement to have specially trained staff (“Registered Sellers”) in-store 24/7 cunningly but effectively barred convenience stores from OTC.

With online sales, the ordinance distorted the principle that consumers should be notified about side effects. The law requires written notification only for Category 1. The ordinance cleverly extended this to require “face-to-face” notification for all categories.

This enabled Ministry bureaucrats to claim online sales were not safe because there is no face-to-face communication involved.

Japan’s Three OTC Pharmaceutical Categories ...and Ostensible Sales Channels Under the Ministerial Ordinance of Feb. 2009

Products are classified according to risks of side effects or abuse.

Those cited below are examples of the many products in each category

	Conventional Drugstores	Convenience Stores	Online Sales
Category 1			
Sleeping pills	O	X	X
Strong pain relievers			
Category 2			
Aspirin	O	O	X
Herbal remedies			
Pregnancy tests			
Category 3			
Vitamins, Iodine	O	O	O
Hydrogen peroxide			

The ordinance seems to allow convenience stores to sell OTC Categories 2 & 3. But the requirement to have a “Registered Seller” in-store at all times makes it impossible in practice. Although not pharmacists, Registered Sellers must pass a demanding exam to prove they are competent to explain side-effect risks to consumers. For convenience stores that depend heavily on part-timers working shifts around-the-clock, having a Registered Seller in-store 24/7 is obviously difficult.

September-October 2008: Public reacts against ban of online sales

According to protocol, the Ministry was required to solicit public comment on the new ordinance. The public response was emphatic. Of 2,353 citizen comments received, 2,303 – 97% – opposed the government’s move to ban online OTC sales.

December 2008: online safety concerns are manufactured

Just as public opinion came out strongly in favor of online OTC sales, an exclusive story was fed to the Yomiuri newspaper.

This concerned a tragic case in 2006 where a 19-year-old man tried to kill himself with sleeping pills. The story claimed online OTC sales were unsafe because the man bought 24 boxes of sleeping pills from an online drugstore.

What the story did not say was that young man also bought six boxes of sleeping pills from two brick-and-mortar drug stores. Clearly, an orchestrated PR campaign was at work.

February 2009: New ordinance enacted

Despite vocal opposition from consumers and affected businesses, the Ministry enacted the ordinances as proposed, without any significant revisions. The Ministry's failed to reconcile the interests of all parties concerned, and instead favored the interest of one group of businesses.

May 25, 2009: Kenko.com sues government

All online OTC vendors were outraged by the government's high-handed actions. But only two decided to mount a legal challenge.

On May 25, 2009 Kenko.com and Wellnet Corporation sued the government in Tokyo District Court, alleging abuse of bureaucratic power and violation of their constitutional rights.

June 2009: Ordinance takes effect**March 30, 2010: Verdict expected in lawsuit****Online OTC Quick Facts**

- Annual OTC in Japan are estimated at ¥628 billion
- Online sales account for about 1% of total OTC sales, but growth has been rapid in recent years – approximately 20% annually.
- At least 500 companies had entered the online OTC market before June 2009
- Most are privately owned, small- or medium-size pharmacies. Many work through online shopping malls such as Rakuten Ichiba and Yahoo! Shopping.
- For basic information on OTC and online pharmacies in other countries, see:
 - http://en.wikipedia.org/wiki/Over-the-counter_drug
 - http://en.wikipedia.org/wiki/Online_pharmacy

What is at stake in the OTC Struggle?

Two major issues are at stake. The narrow issue is serving the interests of consumers in OTC. The wider issue is governance in Japan and fairness in the regulation of business.

Serving the interests of consumers

Online OTC sales offer Japanese consumers enhanced accessibility, selection, information, competition and, above all, safety.

Limited shelf space in conventional drug stores means that:

- Only the most common needs are catered for; many consumer needs are unmet.
- No room for consumer information at point-of-sale – just tiny notices on each box.
- Major manufacturers dominate scarce shelf space preventing market-entry by new players – particularly imports.
- Rural residents, and those facing mobility challenges, are disadvantaged.
- No information for foreign residents in their own languages

At Kenko.com our online shelf space is unlimited. So we now stock 3,791 OTC products in a range that includes 120,000 product variants (“SKUs”) – more than 10 times the average chain drug store inventory. This allows us to:

- Meet even rare consumer needs;
- Meet the needs of remote consumers, quickly and economically;
- Offer a level playing-field to existing brands and new market entrants alike.

Unlimited online shelf space means unlimited information space. So Kenko.com offers:

- Full information on side effects – in fact, consumers must acknowledge warnings before orders are processed;
- Details on each product that help consumers choose the one best suited to their needs;
- Foreign-language info. Our new English beta-test site demystifies drug-store shopping for foreign residents. We plan to offer Chinese, too.

Online means greater safety and consultation without embarrassment:

- If you pay cash at a conventional drug store there is no record of your purchase. So in the event of a recall the store cannot find you.
- At Kenko.com, we need every customer’s name and address because we must deliver. That means we can find customers in the event of a recall. It also means we can limit the sale of items that could be abused.
- To order OTC products, customers must first confirm they are not at risk of side effects.
- Asking a pharmacist face-to-face about personal needs and concerns can be acutely embarrassing. At Kenko.com we make it easy.

The Big Picture: fair regulation and governance in Japan

One of Japan’s e-commerce pioneers, Hiroshi Mikitani, Chairman & CEO of Rakuten Inc., frames the issue this way:

“This is not just a pharmaceutical affairs issue. If we allow regulations such as these to be imposed, it will leave the door open for similar regulations to be imposed one after another. This will be the source of great problems for Japan’s future.”

Japan’s future in the global economy depends on our ability to evolve competitive strength in emerging sectors like e-commerce. We will surely fail at this task if our domestic market is artificially manipulated in a non-transparent way to favor incumbents over innovation and powerful vested interests over consumer interests. So while the narrow issue at stake is OTC pharmaceuticals, in reality this is a battle for Japan’s future.

##