



日本OTC医薬品協会

Japan Self-Medication Industry



10th WSMI AP Regional Conference & 2nd APSMI General Assembly Meeting

Session 6: Communication, Education, and Partnership in Self-Care

“ OTC Advertising Regulation in Japan ”

広告宣伝

广告

Advertisement

การโฆษณา

광고 선전

廣告



“ OTC Advertising Regulation in Japan”

Legal Framework for Advertising Control in Japan

The legal framework to prevent medicines from posing a risk to public health and hygiene is based on **Pharmaceutical Affairs Law**.

The stipulation of the legal framework are explained in the ‘**Standards for Appropriate Advertisements of Pharmaceuticals**’ (SAAP).



“ OTC Advertising Regulation in Japan”

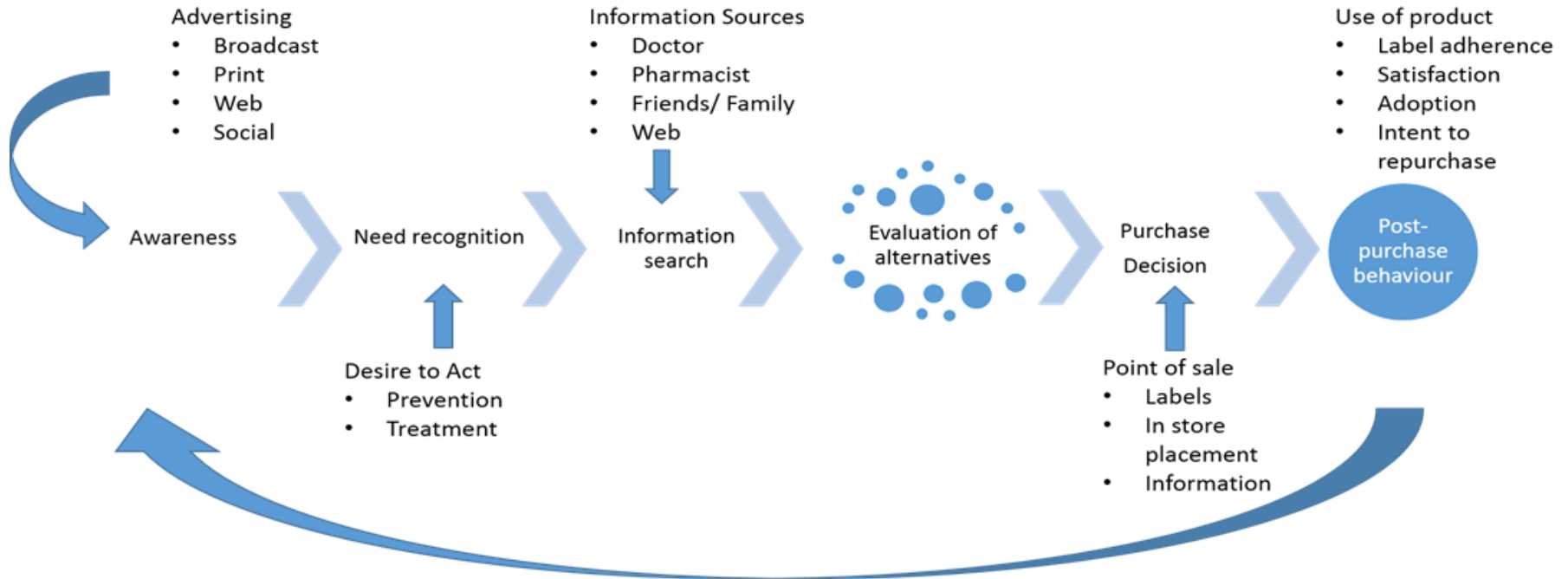
Article 4 (5) in PAL on the definition of OTC medicines

[4] Pharmacist Intervention Required medicines (PIRM) are specially designated by the Minister for Health, Labour and Welfare, which are specially intervened by the pharmacist to the consumer for the offering of information and instruction based on the pharmaceutical care. PIRM are aimed to be utilized by consumer with its selection supported with the information through the pharmacist and other related medical and/or pharmaceutical officials, and those are not harsh to human bodies in its indications and effects.

[5] OTC medicines (other than PIRM) are aimed to be utilized by consumer with its selection supported with the information through the pharmacist and other related medical and/or pharmaceutical officials, and those are not harsh to human bodies in its indications and effects.

“ OTC Advertising Regulation in Japan”

The Consumer Decision-making Process.



Advertisement is an essential factor which contribute to the Consumer Decision-making.

If there were no advertisement, it would be very hard for consumer to find out sufficient OTCs.



“ OTC Advertising Regulation in Japan”

Only three articles in PAL :

Article 66 <No false/exaggerated statements>

1. No person shall, explicitly or implicitly, advertise, describe or circulate false or exaggerated statements regarding the name, manufacturing process, indications or effects, or properties of medicines, quasi-drugs, cosmetics or medical devices.
2. It shall be construed as falling under the preceding paragraph to advertise, describe or circulate such statements as lead to the false impression that a physician or other person has certified the indications or effects, or properties of medicines, quasi-drugs, cosmetics or medical devices.
3. Statements or diagrams suggesting criminal abortion or any obscene statements or diagrams shall not be used in connection with medicines, quasi-drugs, cosmetics or medical devices.

Article 67 <No Ads for General Public on designated medicines>

With regard to the advertisements of medicines specified by cabinet order which are intended for use in the cure of cancer or other designated diseases laid down by cabinet order and for which use not under the direction of physicians or dentists is likely to be extremely dangerous, appropriate measures (such as restriction of the advertising means to ordinary people other than those involved in medical and pharmaceutical affairs) for maintaining the appropriate use of such medicines may be provided by cabinet order.

Article 68 <No Ads for non-approved products>

No person shall advertise the name, manufacturing process, indications or effects, or properties of either medicines or medical devices which have not yet been approved.



“ OTC Advertising Regulation in Japan”

Based on the Pharmaceutical Affairs Law,
No pre-approval system for Advertisement.

Voluntarily Review system supported by Industry
‘Advertising Review Board’ (ARB)

the Board consists of four independent experts representing consumers and professionals, and it holds meetings every two months to review the OTC advertisements carried in the major media channels: television, radio, newspapers and magazines.



“ OTC Advertising Regulation in Japan”

Since April 2014,

‘Advertising Review Board’ (ARB)

was supported by the

Japan Federal Self-Medication Industries. (JFSMI)

JFSMI is a federation of 5 OTC related associations including JSMI.

All reports of ARB are posted on the Web site of JFSMI for the public.

JFSMI works together with all stakeholders including national and local regulators.



“ OTC Advertising Regulation in Japan”

“ OTC Advertising Regulation in Japan”

広告宣伝

广告

Advertisement

광고 선전

廣告

Thank you for your contribution for
rational use of OTCs