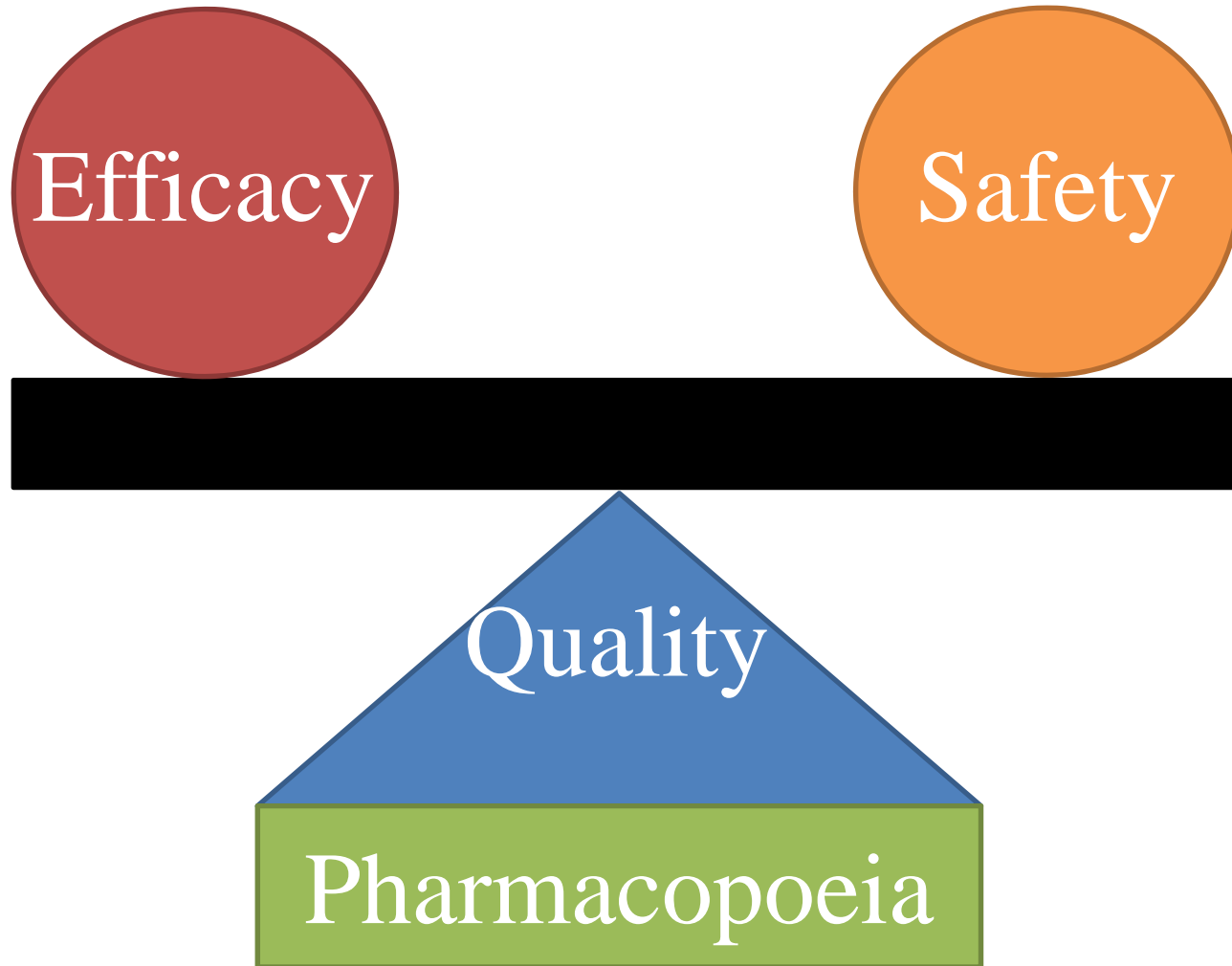


Japanese Pharmacopoeia and OTC medicines at the 130th Anniversary

Japan Self-Medication Industry
President
Tatsuo KUROKAWA, Ph.D.

Q. S. E. of Pharmaceuticals

- Role of Pharmacopoeia



From in the era of Alchemists

- Among others, quality and its assurance has been the first priority when people talk about drugs.



Pharmaceuticals vs. Commodities

- On the Foodstuff, Commodities, consumer can manage to judge whether they are good or bad from its flavor, color or other appearance.
- On the medicines, it is not so easy to be judged by consumer because it looks like just water or small tablet.
- Consumer rely on the pharmacy, pharmacist and OTC suppliers in confidence. Practically there is no other way for people.
- Basement is the confidence on the “good management of pharmaceutical manufacturers”. The JP is the reliable measure of the base.

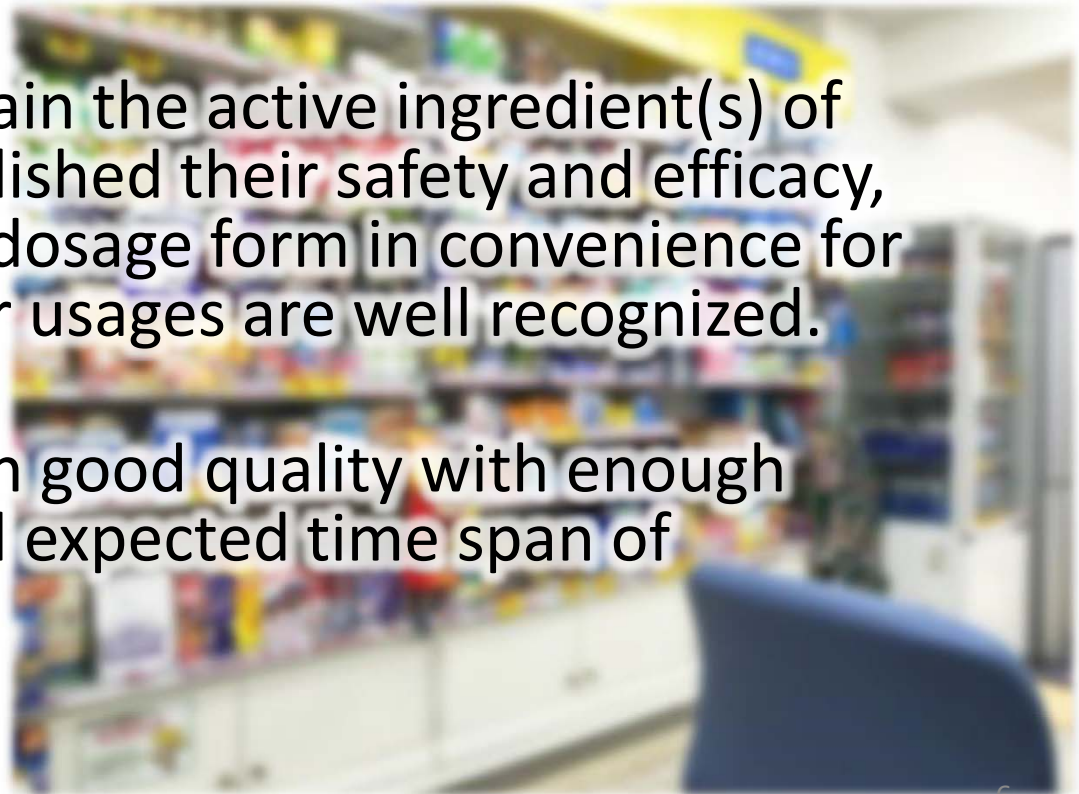
Globalization and Japanese Pharmacopoeia

- Recent bursting purchase of OTC medicines by visitors is found in Japanese market.
- OTC medicines in Japan have been lauded for their quality and reliability, thanks to Japanese Pharmacopoeia.
- Based on the native feature of medicines, every national health regulatory authority assesses the Q. S. E. of proposed medicines.
- Pharmacopoeia is the basement of quality control of medicines. It's not easy to establish own national pharmacopoeia. It requires many resources.



Feature of OTC medicines

- OTC medicines are acquired by consumers at the pharmacies or drugstores without prescription with the supports by pharmacists or other stakeholders, and used by consumers at their decision.
- OTC medicines contain the active ingredient(s) of which are well established their safety and efficacy, are produced in the dosage form in convenience for consumers, and their usages are well recognized.
- OTC medicines are in good quality with enough stability in home and expected time span of distribution.



OTC medicines and Pharmacopoeia

- Consumers are NOT responsible to test or triage the OTC medicines by themselves.
- Supporting scheme for the quality of OTC medicines, including the recipe, stable quality, and packaging to protect the contents.
- National standards of distinguishing measure for the API, Excipients, and Final Preparation, and also testing methods are defined in the Pharmacopoeia.

National Formulary 2nd Ed.



Amazon.co.jp

More than 100 compounded medicines, and crude herbal medicines are defined in 1955.

The National Formulary were integrated into the Japanese Pharmacopoeia.

Ingredients of OTC medicines are mostly defined in JP.

*:2016年3月
(使用上の注意改訂)

使用前にこの説明文書を必ずお読み下さい。
また、必要な時に読めるよう大切に保管して下さい。

09

解熱鎮痛薬

第1類医薬品

日本薬局方 ロキソプロフェンナトリウム錠

痛みに速く効く

頭痛・生理痛 **ロキソニンS**

要指導医薬品

この添付文書は本剤とともに保管し、服用の際には、よくお読みください。

日本薬局方 エバステル錠

アレルギー専用鼻炎薬 **エバステルAL**

アレルギー性鼻炎の症状は、花粉やハウスダストなどを吸い込んだときに、アレルギー誘発物質（ヒスタミン等）が体のなかで放出される。その放出を元から抑える。エバステルALは、1日1回、個々の生活習慣や生活環境に合わせた使い方がしやすいのが現状です。エバステルALは、この※花粉などの季節性の効果的です。

sato セルフメディケーションをサポートします
HEALTHCARE INNOVATION

要指導
医薬品

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日本薬局方 ペミロラストカリウム点眼液

アールPガード点眼液

花粉などによる目のアレルギー症状に

ノアールPガード点眼液は…

- 抗アレルギー剤「ペミロラストカリウム」を配合した「目のアレルギー症状の緩和」に効果を発揮する目薬です。
花粉シーズン中の症状軽減を目的とした場合、症状があらわれていなくても花粉飛散開始の1～2週間前からの使用をおすすめします。

相談すること

Lots of Newly Rx-to-OTC Switched medicines are defined in Japanese Pharmacopoeia

OTC medicines are
essentials for healthy life.
JP is a key-element for
the QA of medicines.

Thank you for
your cooperation and supports
on Self-Medication.

Thank you for your attention

Congratulations to Japanese Pharmacopoeia
130th Anniversary

JSMI T.KUROKAWA