The Self-medication Collaborative Asian Regulator Expert Roundtable (Self-CARER)

The Self-medication Collaborative Asian Regulator Expert Roundtable (Self-CARER) is an international coalition of medicines regulatory authorities in the Asia Pacific region. It is a unique regulatory network in the sense that it deals with non-prescription medicines.

The Self-CARER members meet annually to devise coordinated and strategic plans to improve the effectiveness and efficiency of regulatory activities concerning self-care medicines in the region. Self-CARER is a non-binding forum devoted to fostering mutual public health and economic benefits in its member nations and regions through enhanced self-care medicine product regulation.

Background
The regulations applicable to pharmaceutical products in the Asia Pacific region, including over-the-counter (OTC) and traditional medicines, vary significantly between regulatory authorities. Currently, the majority of health and medical product regulators in this region focus their attention and resources primarily on issues related to prescription products rather than non-prescription medicines. In connection with the activities described in this article, the term “self-care medicines” is used instead of more specific terms such as “OTC” (Box 1).

Unlike prescription drugs, self-care medicines do not necessarily need to be used under the supervision and guidance of a medical professional. As such, considering the reasons for which a given medicine is designated as a self-care medicinal product, its review, registration, and post-approval regulation should be conducted within a framework that is optimized for this product category. (1) Success in this regard would increase the efficiency of self-care medicine product reviews and thus bring about needed improvements in public access to safe and efficacious non-prescription medicines throughout the Asia Pacific region.

To accomplish this goal, leaders of regulatory authorities in the region, with support from the corresponding industry association, (2) determined that greater international cooperation was necessary to identify mutually beneficial regulatory reforms, and that harmonization would then be integral to fully realizing the benefits of such reforms.

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Collaboration

The Self-CARER network

To promote regulatory cooperation and harmonization in the area of self-care medicines, the Self-medication Collaborative Asian Regulator Expert Roundtable (Self-CARER) was formed in 2014. Chaired by the Thai Food and Drug Administration, it is the first platform to materialize cooperative efforts and opinion exchange between Asia Pacific regulators focused on self-care medicine products. The members of Self-CARER meet annually to discuss initiatives and concerns related to improving self-care medicine regulation in the Asia Pacific region in a non-binding, mutually respectful environment.

Past efforts

To date, Self-CARER has focused its activities on three major areas with the goal of realizing overall improvements in self-care medicine product regulation: (1) streamlining product review and registration, (2) establishing a shared directory of active pharmaceutical ingredients (APIs) found in self-care medicines, and (3) simplifying the criteria governing the reclassification of prescription products to self-care medicine status.

Simplified registration

The safety and efficacy profiles of most APIs used in self-care medicines have been established through evidence generated over many years of appropriate use. In some regulatory environments the physicochemical, quality, purity, and potency attributes of self-care medicine APIs are standardized in the form of pharmacopoeias or drug monographs. This practice allows for more rapid and consistent review and classification of self-care medicine products in comparison to prescription products, which require full-scale reviews.

Despite the differences between prescription-only and self-care medicines, various regulatory authorities in the Asia Pacific region use the same procedure to review applications for new self-care medicine products and those for switching from prescription-only status. This suggests that there is room for improvement in the efficiency of product reviews by such regulators.

Box 1: What are “self-care medicines”?

In order to avoid misunderstanding over the meaning of over-the-counter (OTC) products, which can vary between regulatory authorities, the members of Self-CARER newly defined and adopted the term “self-care medicine” at the Self-CARER’s inaugural meeting. The new term refers to all OTC and off-the-shelf medicines usable by consumers to treat self-recognized minor injuries or illnesses. The members agreed to use this term in connection with all future Self-CARER activities and discussions.

In relation to this definition, WHO defines “self-medication” as “the selection and use of medicines by individuals to treat self-recognised illnesses or symptoms.”

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At previous Self-CARER meetings, the members discussed options for simplified product registration following two potential models: abbreviated registration or a monograph system. The Self-CARER members are currently in ongoing discussions with the goal of producing various ideas for ways to simplify or streamline product reviews and registration systems. These ideas will take the form of model operating procedures that will serve to aid regulators in converging on mutually agreed-upon best practices. Ideas proposed thus far have included reforms such as exempting certain types of data from application requirements for self-care medicines, allocating dedicated review staff to self-care products to simultaneously build expertise and increase efficiency, adopting a monograph system, or establishing a framework for receiving and utilizing reference data from pre-defined reference regulatory authorities.

**Ingredient directory**

In a departure from the status quo in which the different regulators each maintain their own databases, it has been proposed to establish a single database of APIs contained in self-care medicines. The primary advantages of such a shared repository include greater regulatory efficiency as well as mitigation of linguistic and cultural obstacles encountered through the use of the existing multiple parallel databases. However, although the members recognize the utility of a shared ingredient directory, various concerns remain such as how this initiative will be funded, what form of entity will be tasked with maintaining the database, and what types of content are most critical. Discussions between the members concerning potential solutions are currently ongoing.

**Reclassification criteria**

Another common issue recognized by the members of Self-CARER is that the criteria used to reclassify or "switch" prescription-only medications to self-care medicine or off-the-shelf status are an important area for discussion.

The most common factors considered by Asia Pacific regulators in such applications for reclassification include the safety profile of a medicine under its approved use, the severity and frequency of adverse drug reactions, the pharmacokinetic and pharmacodynamic properties of the APIs, product indication(s), route(s) of administration, extent of use, time on the market, and risks when the product is misused. Sharing of information regarding these criteria among the members of Self-CARER would both increase the speed of application reviews by each regulator as well as improve the consistency of the review results.

**Obstacles**

Self-CARER functions as a level field for discussions between the regulators of both developed and developing countries and regions on how to achieve greater effectiveness and efficiency in the regulation of self-care medicines. However, Self-CARER faces various challenges, such as:

- Lack of specific review/registration schemes for self-care medications, or of assigned dedicated review staff;
- Difficulty to achieve necessary legislation changes without disrupting routine operations;
- Scarce resources for necessary training of reviewers regarding evaluation processes and best practices for decision-making;
- Shortages of qualified review staff; and
- Lack of a shared model for how to simplify product review/registration procedures.
To overcome these obstacles, Self-CARER is currently considering working with each of its members as needed to develop basic model regulatory frameworks that are still similar enough to those of other Asia Pacific regulators to promote streamlining and harmonization across the region.

**Future goals**
In the years to come, Self-CARER plans to focus its efforts on overcoming its various challenges and bringing about both public health and economic benefits for its members. The network intends to prioritize policy adjustments that can increase regulatory efficiency by several means: creating a review scheme for self-care medicines that is separate from that used for prescription-only products, devising ways to further streamline review processes, and developing concrete plans to expand the safe and effective use of self-care medicines.

**References**