



# THE STORY OF SELF-CARE AND SELF-MEDICATION

*40 years of progress, 1970-2010*

# Who is responsible for my health?

*Throughout human history the dominant paradigm of healthcare was individual self-care in the family and local community. Treatment involved self-treatment with locally-produced preparations of generally uncertain efficacy. People themselves were responsible for their own health, and that of their families, as self-sufficiency was obligatory and almost universal. The opportunities and needs for improvement were great.*

*Starting in the 19<sup>th</sup> Century and carrying on through the 20<sup>th</sup> Century, health care was revolutionized by scientific and medical discoveries, technological advances in diagnostics, surgery and medicines, and the development of the healthcare professions. Patients gratefully placed themselves into the hands of the doctors and took the effective newly-developed medicines they prescribed. The role model of the patient as a largely passive recipient of public services was complemented by the mystique of the expert healing physician. At the low point of self-care – around the 1960's in the West – self-care and self-medication were regarded as unnecessary and potentially even unhealthy practices. This paternalistic approach to medicine, supported by health systems designed to treat sickness (rather than to prevent disease) remains a familiar aspect of healthcare in many countries to this day.*

*Circumstances and societies are ever-changing, however. The paternalistic approach to medicine is expensive when applied to entire populations, especially in ageing countries. People around the world are better educated and want more information, choice and control over their lives – not least in the area of health. Chronic “lifestyle” conditions such as cardiovascular disease, cancer and diabetes are taking over from infectious diseases as the primary cause*

*of death and disability in most countries. These chronic non-communicable diseases are significant in that they are substantially preventable through better self-care – by individuals avoiding risk factors such as smoking and obesity. The healthcare professions retain an important role but a purely paternalistic approach and health systems that only provide “sickness services” are less well-attuned to the 21<sup>st</sup> Century's health challenges and needs.*

*As a result, over the past 40 years there has been a push-back against the paternalistic model of health, towards a more person-centric approach involving self-care and responsible self-medication with nonprescription (or over-the-counter, OTC) medicines. Definitions of health have broadened to include concepts of wellness. A patient's needs and rights have become central considerations and run through many of today's initiatives in health – in medical ethics, patient autonomy and “person or patient-centred medicine”. But along with patient's rights comes responsibilities. There has been a growing realisation that personal self-care and self-medication in the community should be the starting point of healthcare, and is in fact the foundation for people to manage life-long health. Initiatives in “community healthcare”, “health promotion” and the switching of medicines from prescription to nonprescription status are examples of the new approach.*

*However, being ultimately based on individuals looking after themselves, there is no natural “champion” for the self-care movement as a whole. Self-care activities are central to many healthcare programmes, but the elements – for example good hygiene, appropriate levels of nutrition and physical activity, risk avoidance and responsible use of nonprescription medicines – are diverse.*



*To support self-care and responsible self-medication with nonprescription medicines, many countries and regions formed manufacturers and distributors associations during the last century. In a globalising world, in 1970 the World Self-Medication Industry (WSMI) was also created to convey the social and economic value of self-care and responsible self-medication to global audiences. Working with the World Health Organisation and other Intergovernmental Organisations, WSMI aims to demonstrate the importance of people (and not just patients) taking more responsibility for their own self-care and self-medication with nonprescription medicines.*

*Nonprescription medicines are “tools” of self-care, supporting health awareness and healthy practices. Today, responsible self-medication with nonprescription medicines is increasingly being recognised as the first line of treatment and as a foundation of public health and healthcare systems. This is not only through helping to educate and motivate people to treat their own minor ailments and conserve scarce healthcare resources, allowing the medical profession to focus on the most needy cases. In addition, and importantly, motivated people are much more likely to undertake other positive self-care behaviours, and thereby help tackle the chronic disease future of most countries.*

*Today’s answer to the question “Who is responsible for my health?” is that it is all of us individually*

Christopher B. Combe - Chairman, WSMI

*that have a large measure of personal responsibility – as it always used to be, throughout human history. But help and support is available, with healthcare professionals, with access to modern knowledge and education, and with technology support such as nonprescription medicines. As expressed by the World Health Organisation:*

*“Social control of health technology can greatly facilitate the development of effective self-care practice. Appropriate technology, which is socially and culturally acceptable, should be used by individuals, families and communities. For this to happen, people must be in control of the technology that is made available for their use.”*

Ref: Self-care in the Context of Primary Health Care. WHO SEARO 2009

*This booklet provides some highlights of the rebalancing towards a self-care world over the last 40 years. The dramatic increase in activity during this period is apparent, illustrated by examples of self-care related initiatives by the World Health Organisation (WHO) and other Intergovernmental Organisations, by the broader availability of nonprescription medicines supporting people in self-care, and by the activities of the World Self-Medication Industry (WSMI) since its establishment in 1970.*

*Thank you for your interest.*

David E. Webber - Director General, WSMI

**Self-care** is what people do for themselves to establish and maintain health, prevent and deal with illness. It is a broad concept covering hygiene, nutrition, life-style, physical activity, avoiding risks (e.g. smoking, obesity) and responsible self-medication with nonprescription medicines (OTCs).

**Self-medication** is one part of self-care and is the responsible selection and use of nonprescription medicines by people to treat self-recognised illnesses or symptoms.

## The 1970's & 1980's – Momentum for self-care: social forces for change

*«... It appears that the public have taken health care into their own hands and in some areas of the world are actively pursuing increased access to health knowledge, skills, and technology.» Professor Lowell S. Levin, Yale University School of Medicine, USA (1980).*

Throughout the 1970s and 1980s, some important developments on the global scene set the stage for a more patient-centred healthcare, supportive of self-care.

In 1975, the first international symposium on the role of the individual in primary care was held at the European Regional Offices of the WHO and brought together 29 scholars from around the world. In the book based on the symposium entitled "Self-Care", a number of important aspects were already apparent:

*"Self-care practices are nearly universal among patients [...] perhaps 75 percent or more of health care is undertaken without professional intervention. [...] without self-care any system of health care would be swamped [...] The most crucial limitations in self-care functioning stem from the motivation, knowledge, custom and competence of the individual." (L S Levin et al. Self-Care. Lay Initiatives in Health. Croom Helm. London, 1977).*

In 1977, the World Health Assembly adopted the resolution calling for "health for all" by the year 2000 and, in 1978, the Declaration of Alma-Ata, building on the recognition of health as a fundamental social goal, set a new direction for health policy by emphasizing people's involvement, cooperation between sectors of society and primary health care as its foundation:

*"Health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease*

*or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal [...] The people have the right and duty to participate individually and collectively in the planning and implementation of their health care" (Declaration of Alma-Ata, 1978).*

In 1981, The World Medical Association stressed the responsibility of people for their own health in a "Declaration on the Rights of the Patient":

*"Every person has the right to health education that will assist him/her in making informed choices about personal health and about the available health services. The education should include information about healthy lifestyles and about methods of prevention and early detection of illnesses. The personal responsibility of everybody for his/her own health should be stressed. Physicians have an obligation to participate actively in educational efforts". (Declaration on the Rights of the Patient, WMA 1981, revised 2005).*

The first WHO Conference on Health Promotion took place in 1986 in Ottawa (Canada) and launched "the Ottawa Charter for Health Promotion", which emphasized the central role of individuals and communities in contributing to health:

*"Health promotion is the process of enabling people to increase control over and to improve their health". (Ottawa Charter for Health Promotion, WHO 1986).*





The Government of Canada, host of the first conference on Health Promotion, also published an important health policy document in 1986 in which self-care was identified as one of the three key mechanisms for health promotion:

*“Health promotion [...] means creating environments conducive to health, in which people are better able to take care of themselves, and to offer each other support in solving and managing collective health problems” (Achieving Health for All: A Framework for Health Promotion. Health Canada, 1986).*

The World Federation of Proprietary Medicine Manufacturers Association (WFPMMA), now renamed the World Self-Medication Industry (WSMI), was created in 1970. The founding members were The Proprietary Association of the USA (now the Consumer Healthcare Products Association – CHPA), the Proprietary Association of Canada (now Consumer Health Products Canada – CHP Canada) and the AESGP (“Association Européenne des Spécialités Grand-Public”), the Proprietary Association of Europe. WSMI’s first General Assembly was held in London, in 1971, in conjunction with the 8th Annual Meeting of the AESGP. WSMI achieved “official relations” status with the WHO in 1977, seven years after its creation.

One of WSMI’s early objectives was to press for worldwide regulatory classification of medicinal products into two classes: prescription and nonprescription. To this day WSMI supports responsible use of nonprescription medicines and the appropriate enforcement of national regulations to

combat self-prescription (the use of prescription medicines without obtaining a prescription). The industry supports re-classification (or “switch”) of prescription medicines to nonprescription status where there is adequate evidence to support the safe and effective use of such products without requiring the intervention of a physician.

In the 1970s and 1980s the conditions generally considered as suitable for people to treat themselves without the intervention of a doctor were quite limited. They included mild to moderate pain, coughs and colds, constipation and minor skin problems such as cuts and bruises, for which a limited range of medicines were available for self-medication. A new era of access to modern, effective medicines was heralded in the early 1980s, when medicines which had previously only been available on prescription began to be switched to nonprescription status. Among the first products switched to nonprescription status was ibuprofen for the treatment of pain, in the UK (1983) and the US (1984). In Canada, hydrocortisone became available without a prescription in 1986.

Consumer information is an extremely important component of responsible self-medication. A statement of WSMI Policy on Consumer Information and the Role of Labelling was formally approved and released by the WSMI Board of Directors at the Fifth General Assembly in October 1979 in Australia. The policy emphasizes that the role of labeling is “to provide all information necessary to enable an individual without medical training to use the medicine appropriately”.

*"Responsible self-medication can mean better health for people all over the world"*

*Hiroshi Nakajima, WHO D.G.  
WSMI General Assembly, Rome, Italy (1989).*



*WFPMM (now WSMI) Board Members Baden-Baden, Germany 1970 Front from left: P.A. Visseur (Switzerland), W.G. Hollis (UK), D.L. Bryant (USA), A.M. Sanderson (Canada) Rear from left: D. Callewaert (Belgium), C.E. Rhyne (USA), J.D. Cope (USA), H.W. Bach (Germany).*



**1970** - Creation of the World Federation of Proprietary Medicine Manufacturers (WFPMM – now WSMI). Founding members: the European Proprietary Association (now AESGP), the Proprietary Association of USA (CHPA) and the Proprietary Association of Canada (CHP Canada).

**1971** - WSMI's 1<sup>st</sup> General Assembly, in London, England.

- The Self-Medication Manufacturers' Association of South Africa (SMASA) and the Japanese Self-Medication Industry join WSMI.

**1972** - WSMI's 2<sup>nd</sup> General Assembly in Tokyo, Japan.

- The Australian Self-Medication Industry (ASMI) joins WSMI.

**1973** - The American Hospital Association issues 'A Patient's Bill of Rights' (revised 1992 & 2008), which lists rights along with patient responsibilities that can help a person be a more active partner in his or her healthcare.

**1974** - WSMI's 3<sup>rd</sup> General Assembly in White Sulphur Springs, West Virginia, USA.

**1975** - The first international symposium to give particular attention to the role of individuals and families in the primary health care process took place in Copenhagen, Denmark. It brings together scientists, physicians, health administrators and educators; one output was the book *"SELF-CARE. Lay Initiatives in Health"* by Levin, Katz & Holst (1977).

**1977** - The World Self-Medication Industry receives official relations status with the World Health Organization.

- The World Health Assembly adopts the resolution calling for *"Health for All"* by the year 2000 and the first WHO Essential Medicines List containing a number of nonprescription medicines is published.

1976

1980s

1981

1983

*The US switches antihistamines (allergy treatments) and nasal decongestants.*

*Ibuprofen (for pain) becomes nonprescription in the UK (1983) and the US (1984).*

*Benzoyl peroxide (acne treatment) is switched in Canada.*

*Loperamide (anti-diarrhoeal) becomes available without a prescription in the UK.*

*Antihistamines and nasal decongestants are switched in the Europe and around the world throughout the 1980s.*

## Key dates

-WSMI's 4<sup>th</sup> General Assembly takes place in Geneva, Switzerland.

**1978** - The UNICEF/WHO International Conference on Primary Health Care, Alma-Ata, Kazakhstan produces the *"Declaration of Alma-Ata"*.

**1979** - WSMI's 5<sup>th</sup> General Assembly in Sydney, Australia is attended by some 550 delegates from 27 countries. Membership has grown to a total of 26 national and regional associations.

**1981** - The World Medical Association's *"Declaration on the Rights of the Patient"*.

- WSMI's 6<sup>th</sup> General Assembly in Ottawa, Canada.

**1984** - WSMI's 7<sup>th</sup> General Assembly in Tokyo, Japan.

**1986** - First WHO Conference on Health Promotion in Ot-

tawa. The "Ottawa Charter for Health Promotion" calls for action to achieve "Health for All" by the year 2000 and beyond.

- Health Canada publishes: *"Achieving Health for All, a Framework for Health Promotion"*.

- WSMI's 8<sup>th</sup> General Assembly in Washington DC, USA.

**1988** - Second WHO International Conference on Health Promotion in Adelaide, South Australia. *"Adelaide's recommendations on Healthy Public Policy"* gives specific attention to the harmful use of tobacco and passive smoking.

- The Chinese Nonprescription Medicines Association (CNMA) joins WSMI.

**1989** - WSMI's 9<sup>th</sup> General Assembly in Rome, Italy.

1986

*Loperamide is switched in Canada as well as hydrocortisone (for allergic dermatitis).*

1987

*Hydrocortisone is switched in the UK. Tioconazole (for fungal infections of the skin) and loperamide are switched to nonprescription status in Australia. Tioconazole will be switched in Canada in 1995.*

1988

*Chewing tablets containing 2mg or less of nicotine per tablet (tobacco dependence) are switched in Australia.*

1989

*Ibuprofen becomes available without a prescription in Canada.*

## The 1990's – Guiding principles in self-medication

*«The first key to developing a drug policy which includes self-medication is to draw a distinction between those products which require more active involvement by a doctor or other qualified health professional for safe and effective use - prescription medicines, and those products which are safe and effective for use by consumers on the basis of their marketing authorization and labeling - nonprescription medicines.» - WSMI, 1998*

By the 1990s, there was an increasing recognition in many parts of the world that people were managing or treating a large proportion of their ailments without always consulting a health professional. In 1998, WSMI and the International Pharmaceutical Federation (FIP) worked together in a WHO Consultative Group on the role of the pharmacist in self-care and self-medication. The report of the group acknowledged the increasing importance of self-care and responsible self-medication and laid the groundwork for a common global understanding of self-care, self-medication and responsible self-medication:

*“The increase in self-care is due to a number of factors. These factors include: socioeconomic factors; lifestyle; ready access to drugs; the increased potential to manage certain illnesses through self-care; public health and environmental factors; greater availability of medicinal products; and demographic and epidemiological factors.”*

*“Responsible self-medication is the practice whereby individuals treat their ailments and conditions with medicines which are approved and available without prescription, and which are safe and effective when used as directed. Responsible self-medication requires that:*

- 1. Medicines used are of proven safety, quality and efficacy and*
- 2. Medicines used are those indicated for conditions that are self-recognizable and for some chronic or recurrent*

*conditions (following initial medical diagnosis). In all cases, these medicines should be specifically designed for the purpose, and will require appropriate dose and dosage forms. Such products should be supported by information, which describes: how to take or use the medicines; effects and possible side-effects; how the effects of the medicine should be monitored; possible interactions; precautions and warnings; duration of use; and when to seek professional advice.” (Report of the WHO Consultative Group on the Role of the Pharmacist in Self-Care and Self-Medication (The Hague, Netherlands, 26-28 August 1998).*

The close collaboration of the WSMI and FIP led to a joint statement in 1999:

*“Nowadays people are keen to accept more personal responsibility for their health status and to obtain as much sound information as possible from expert sources in order to help them make appropriate decisions in health care [...] Pharmacists have a key role to play in providing them with assistance, advice and information about medicines available for self-medication.” (WSMI-FIP joint statement, 1999)*

Within this positive environment, governments around the world became increasingly interested in working with nonprescription products manufacturers, health professionals, patients, consumers and others towards



*25 Years of WSMI.  
WSMI Board meeting in Buenos Aires, Argentina (1995).*



*Hiroshi Nakajima, WHO D.G.  
WSMI General Assembly in Toronto, Canada (1996).*



a wider availability of safe and effective nonprescription products for use in responsible self-medication.

WSMI took a global role in promoting responsible use of nonprescription medicines, encouraging high standards for their quality, safety, efficacy and rationale use, and ensuring that self-medication takes place within a safe and responsible framework. During the 1990s, WSMI undertook a wide review of consumer surveys around the world, and reported in a 1997 paper that “consumers in virtually every part of the world trust OTC medicines and use them conservatively, carefully and safely”. Some key findings of the review included:

1. People throughout the world suffer common health problems and their symptoms at roughly the same frequency;
2. People generally respond in the same way to these problems – letting the condition run its course about half the time, turning to nonprescription medications about a quarter of the time;
3. People are cautious and careful when they do turn to nonprescription medicines – most people in all of the countries surveyed read the label completely before taking a nonprescription medicine the first time;
4. People are overwhelmingly satisfied with the nonprescription medicines they use – to the point where many believe that nonprescription medicines are just as effective for some problems as prescription drugs ;

5. People are not prompted to an over-usage of nonprescription medicines as a result of advertising.

Interestingly, the significant problem of people treating themselves with prescription drugs (in countries where enforcement of the prescription requirement is insufficient), is reduced by wider availability of nonprescription medicines. A study in Mexico showed a 20% decrease in the degree of self-prescription in the 10 years between 1989 and 1999. This was attributed to the significant number of switches authorized by the Mexican Ministry of Health between 1995 and 1998.

An important WSMI initiative during this period was the publication of the brochure “Guiding Principles in Self-Medication”, which discussed the elements of a healthcare policy supportive of responsible self-medication. The objective was to ensure that products designed for self-medication are used safely and effectively and that there is a clear distinction between products which require more active involvement by a doctor or other qualified health professional for safe and effective use. Mechanisms can be put in place to reclassify or switch ingredients to nonprescription status when they are shown to be safe and effective for direct consumer use. Finally, usable consumer information is crucial, as well as appropriate pricing and distribution systems. Widely used by WSMI member associations worldwide, this booklet has been reviewed and updated in a second version entitled “Creating a Framework for the Self-Care consumer”, which was published in 2002.

*Joint WSMI-FIP statement being signed by WSMI D.G. Jerome Reinstein in presence of FIP President Peter Kielgast (centre) and WSMI Chairman Anthony Jamison (1999).*



*WSMI General Assembly, Berlin, Germany (1999). From left: AESGP D.G. H.Cranz, WSMI Chairman A. Jamison, WHO D.G. G.H. Bruntland, European Commissioner M. Bangemann, Chairman of the Council of the World Medical Association A. Milton and AESGP President G. Summerer.*



The UK is a leading country for switching ingredients to nonprescription status. Switches in the 1990s included products such as clotrimazole (for fungal infections) in 1992, acyclovir (for cold sores) in 1993 and beclomethasone (a hayfever treatment) in 1994. Many of these switches, considered controversial at the time, are today well-established and recognized as allowing people to self-treat successfully and take more responsibility for their own healthcare. Clotrimazole was also switched in 1992 in Canada as was nicotine gum (tobacco cessation). Ketoconazole (shampoos only-dandruff) was switched in Canada in 1994 and the non-sedating antihistamine cetirizine in 1995. Nicotine Replacement Therapy (NRT, for treatment of tobacco addiction) became nonprescription in the US in 1996, the same year as the WHO initiated discussions on what was to become the Framework Convention on Tobacco Control (FCTC). Fexofenidine (non-sedating antihistamine) was approved directly as a nonprescription medicine in 1997 in Canada.

which present a global comparison of the legal status of selected ingredients available without a prescription. A recent review found that out of 224 ingredients available today in some form without a prescription, only 5 out of 36 countries listed more than 50% of them as nonprescription medicines. This indicates the extent of the opportunity for the greater use of nonprescription medicines in many countries.

WSMI and the European association AESGP initiated in 1999 the "Nonprescription Ingredients Classification Tables",

1992

1993

1994

1995

1990

1991

*Nicotine gum (smoking cessation) is switched in Canada. Clotrimazole and miconazole nitrate (vaginal antifungals) are switched in Canada. Clotrimazole is also switched in the UK, followed by Germany towards the end of 1994.*

*Aciclovir (for cold sores) and cetirizine and loratadine (antihistamines) are switched in the UK.*

*Beclomethasone (for hayfever) is switched in the UK. Ketoconazole in topical preparations (for fungal infections of the skin) is switched in Australia and Canada. Loratadine is switched in Australia. Ibuprofen combination products switched in Canada.*

*Fluconazole (for vaginal thrush) becomes available without prescription in the UK. Famotidine and ranitidine (stomach acid relief) become nonprescription in the US and Australia, as do cimetidine and nizatidine in Australia. Cetirizine non-sedating antihistamine is switched in Canada, followed by Australia in 1997. Nizatidine (for migraine) is switched in the US in 1996 and cetirizine in 2007.*

## Key dates

**1990** - WSMI counts 35 country member associations.

**1991** - WSMI's 10<sup>th</sup> General Assembly in Seoul, Korea.

**1993** - WSMI's 11<sup>th</sup> General Assembly in Acapulco, Mexico, where the theme is *"Globalization of the self-medication market: challenges and opportunities"*. This is the first major WSMI meeting in Latin America.

- 1<sup>st</sup> WSMI Asia-Pacific Regional Conference, Jakarta, Indonesia.

**1995** - WSMI celebrates 25 years of existence with an international meeting in Buenos Aires, hosted by Argentinian member CAPEMVeL which joined in 1992.

- 2<sup>nd</sup> WSMI Asia-Pacific Regional Conference, in Bangkok, Thailand.

- AESGP publishes the first "Economic and Legal Framework for Non-Prescription Medicines" guide book describing the rules and regulations relating to nonprescription medicines in European

countries. By 2010 the 16<sup>th</sup> edition has grown to include many WSMI member countries from around the world.

**95/6** - The idea for an international instrument for tobacco control is proposed in May 1995 at the WHO's 48<sup>th</sup> World Health Assembly (WHA). The following year the WHA initiates the development of a WHO Framework Convention on Tobacco Control (FCTC) and negotiations begin in 1999. WSMI is substantially involved.

**1996** - WSMI's 12<sup>th</sup> General Assembly in Toronto, Canada.

**1997** - WSMI publishes its first global review of consumer surveys: *"Health Care, Self-Care and Self-Medication: 14 National Surveys Reveal Many Similarities in Consumer Practices"*.

**1998** - WSMI and FIP collaborate at the 4th WHO Consultative Group on the Role of the Pharmacist in

1996



*Nicotine patches and gum are approved for nonprescription status in the USA. Triamcinolone acetonide (mouth ulcers) switched in Australia. Famotidine (heartburn prevention) is switched in Canada.*

1997



*Cromolyn sodium (allergy) becomes nonprescription in the US and Canada. Loperamide/simethicone (antidiarrheal/antigas) becomes available without prescription in the US. 500mg tranexamic acid tablets (menorrhagia) becomes nonprescription in Sweden. Ranitidine (heartburn prevention) is switched in Canada as well as nicotine transdermal patches (smoking cessation). The non-sedating anti-histamine fexofenidine as well as antifungals butenafine and oxiconazole are approved directly nonprescription in Canada.*



self-care and self-medication in The Hague, Netherlands. The output is a written report which acknowledges the growing role of self-care in healthcare provision and defines a common understanding for the terms “self-care”, “self-medication” and “responsible self-medication”.

- 3<sup>rd</sup> WSMI Asia-Pacific Regional Conference in Kuala Lumpur, Malaysia. “Responsible self-medication: recognizing its role in total healthcare”.

**1999** - A joint statement is produced by WSMI and FIP entitled “Responsible Self-Medication”.

- WSMI’s 13<sup>th</sup> General Assembly in Berlin, Germany, where the theme is “Self-Care, a vital element of health policy in the information age”.
- The International Alliance of Patients’ Organisations (IAPO) is officially created to represent patients of all nationalities across all disease areas and promote patient-centred healthcare around the world.

- WSMI’s publication “Guiding Principles in Self-Medication” is launched during the 13<sup>th</sup> WSMI General Assembly in Berlin, with a workshop on the topic of “switching”.

- WSMI & AESGP publish the first “Nonprescription Ingredients Classification Tables”, a worldwide comparison of the nonprescription status of a selection of ingredients.

*The WHO Consultation on Selected Medicinal Plants, July 1996, Munich, Germany, with substantial representation from WSMI and WSMI member organisations.*



**1998**



*Domperidone (nausea) and mebeverine (irritable bowel syndrome) is switched in the UK. Nizatidine (heartburn relief) switched in Canada.*

*In Mexico, 31 ingredients are switched to nonprescription status, based on an international comparison.*

**1999**



*Terbinafine hydrochloride (antifungal) becomes nonprescription in the US. Amorolfine (for fungal nail infection) is switched in Australia. Beclomethasone aqueous nasal sprays becomes nonprescription in Australia. Minoxidil (male pattern baldness) is switched to nonprescription in Canada.*







## 2000-2005 – The benefits of responsible self-medication

*«Research shows that supporting self-care can improve health outcomes, increase patient satisfaction and help in deploying the biggest collaborative resource available to the NHS and social care – patients and the public. Helping people self-care represents an exciting opportunity and challenge for the NHS and social care services to empower patients to take more control over their lives». UK Department of Health. «Self-care – A real choice» (2005)*

By the year 2000, stakeholders in health had acquired a deeper understanding of the potential benefits arising from self-medication. The social and economic benefits of self-care and self-medication have since then been widely reported but an early summary of the potential benefits arising from self-medication can be found in the WHO Guidelines for the Regulatory Assessment of Medicinal Products for Use in Self-Medication:

*“The social and economic benefits of self-medication reflect the fact that it is voluntarily chosen by consumers for conditions where it seems preferable to them. It will usually be selected for use in symptoms and conditions which the user regards as sufficiently troublesome to need medicinal treatment but not to justify consulting a physician. Only if the condition fails to respond, persists or becomes more severe will professional medical help be sought. Accordingly, good self-medication should offer the individual consumer:*

- Efficacy: i.e. the product does what it is claimed to do;
- Reliability and safety: the individual will often choose a product which experience has shown to be suitable. The scope and duration of self-medication can be kept within safe limits by appropriate selection of approved indications, labelling texts, dosage strengths and forms, and package sizes;
- Product safety when used as recommended in the instructions;
- Acceptable risk, even when used for a longer duration, at a higher dose, or somewhat differently than recommended in the instructions;
- Wider availability of medicines;
- Greater choice of treatment;
- Direct, rapid access to treatment;
- An active role in his or her own health care;
- Self-reliance in preventing or relieving minor symptoms or conditions;
- Educational opportunities on specific health issues (i.e. stop-smoking aids and products to treat heartburn);
- Convenience;
- Economy, particularly since medical consultations will be reduced or avoided;
- At the community level, good self-medication can also provide benefits such as saving scarce medical resources from being wasted on minor conditions, lowering the costs of community-funded health care programmes (including prescription reimbursement systems), and reducing absenteeism from work due to minor symptoms.

*Guidelines for the Regulatory Assessment of Medicinal Products for Use in Self-Medication. (WHO Geneva 2000)*

Published in 2000, the “Guidelines for the Regulatory Assessment of Medicinal Products for Use in Self-Medication” was a key reference point for regulatory authorities and other stakeholders looking at medicines for nonprescription use. It mapped out general principles such as the criteria for nonprescription status and the characteristics of self-medication, including potential benefits and risks. Specific issues were considered relating to the regulatory assessment of products for self-medication, such as the active ingredient, dosage form and strength, route of administration, labeling, packaging and advertising, as well as the types of pharmacological, toxicological, clinical and other evidence normally required.

Improving the information around medicines and promoting rationale use of medicines is another important role of WSMI. The “Medicines Labelling Group” brought together consumer advocates and industry leaders with the common objective of improving the labeling of nonprescription medicines through a “performance-based” approach. A joint project of AFAMELA (the Mexican country association) and COFEPRIS (The Mexican Regulatory Agency) was undertaken which consisted of training industry and regulatory personnel in the writing and evaluation of performance-based labeling.

A “Reclassification Alliance” was established between government, industry, pharmacists and other parties

WSMI Board meeting in Rome, Italy (2001).



in the UK in 2001 to review the issues and opportunities for switching more medicines from prescription to nonprescription. Self-care more broadly gained new momentum with the publication of the “Wanless Report” in the UK in 2002. This independent review commissioned by the government introduced self-care as a crucial element of an effective, publicly-funded health system, showing that for every £100 spent on encouraging self-care, around £150 worth of benefits could be delivered in return. In 2005 the UK Department of Health followed this up with the publication “Self-Care, A Real Choice”, setting out the support for self-care:

*“Research shows that supporting self-care can improve health outcomes, increase patient satisfaction and help in deploying the biggest collaborative resource available to the NHS and social care – patients and the public. Helping people self-care represents an exciting opportunity and challenge for the NHS and social care services to empower patients to take more control over their lives.”*

In 2003 the World Health Assembly adopted the WHO Framework Convention on Tobacco Control (FCTC), the world’s first global public health treaty. The treaty entered into force in February 2005 and has since become one of the most widely embraced treaties in UN history, with 168 country parties as of 2010. The Convention represents a milestone for the promotion of public health and provides new legal dimensions for international health cooperation. “Article 14” covers demand reduction measures including

the treatment of tobacco dependence with medicines such as Nicotine Replacement Therapy (NRT).

In 2004, the WHO adopted the Global Strategy on Diet, Physical Activity and Health to fight heart disease, stroke, diabetes, cancer and obesity related conditions. In 2005, The WHO publication “Preventing Chronic Diseases” (2005) raised awareness of the rising incidence of noncommunicable diseases around the world and advocated for their prevention and control:

*“The impact of chronic diseases in many low and middle income countries is steadily growing. It is vital that the increasing importance of chronic disease is anticipated, understood and acted upon urgently. This requires a new approach by national leaders who are in a position to strengthen chronic disease prevention and control efforts, and by the international public health community.”*

In 2005 WHO and WSMI worked together on a booklet entitled “Avoiding Heart Attacks and Strokes. Don’t be a victim. Protect yourself.” The purpose was to produce a consumer’s guide to preventing cardiovascular disease, with simple explanations of the diseases and practical advice.

During the first decade of the 21<sup>st</sup> century, Governments became more aware of the emerging epidemic of chronic disease and the financial burden imposed on health systems. Countries such as Australia, the UK, the US and others began

*The International Council of Nurses' monograph "Tobacco Control and Smoking Cessation: The Role of the Nurse" (2003).*



*The Middle-East Self-Medication Industry's meeting in Dubai, UAE (2004).*



*The WSMI Website launched in 2004. (www.wsmi.org)*

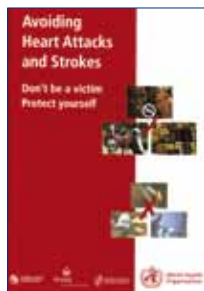


to explore the prospects for switching more medicines intended for chronic conditions, with – where necessary – initial support to patients from a healthcare professional in a “collaborative care” setting.

This means that people often go to the doctor when first presenting symptoms of a condition, but once the doctor has established a diagnosis, people can recognize the symptoms when they recur and can treat the condition themselves with a nonprescription medicine. An AESGP report supported by the European Commission entitled “Development of an information policy for medicinal products” (2002) described this evolution.

In this time period, the Asia Pacific Region started to become a greater focus for WSMI activities, reflecting the emergence of the region in global terms. WSMI commenced a series of conferences and programmes in China with the support of the Japanese Self-Medication Industry, one of the very earliest and most active members of WSMI.

*The WHO Booklet “Avoiding Heart Attacks and Strokes, don't be a victim, protect yourself” (2005).*



*“Public Health depends to a significant extent on the ability of individuals to take care of themselves and each other... Self-medication and the social support in illness and for the prevention of illness represents a great alternative for healthcare... We need to see significant progress in self-care”.*

*Dr Jong-Wook Lee, WHO D.G. Address to WSMI, WSMI General Assembly, Geneva, Switzerland (2005).*



*SFDA Commissioner Shao Mingli. International Forum on Promoting Self-Medication, Beijing, China (2005).*



## Key dates

**2000** - The WHO publishes "Guidelines for the Regulatory Assessment of Medicinal Products for Use in Self-Medication".

- First WSMI Latin American Regional Conference in Rio de Janeiro, Brazil, where the theme is «Recognizing and Developing the Role of Responsible Self-Medication in Latin America».

- World leaders at the United Nations in New York adopt the "United Nations Millennium Declaration", committing nations to a set of eight "Millennium Development Goals" to be achieved by 2015 that include healthcare development.

- 4<sup>th</sup> Asia-Pacific Regional Conference in Sydney, Australia, where the theme is "Harmony for Health; who wins in self-medication?"

Medicines regulators agree on the "Sydney Declaration", laying the foundations for a more rational and clearly defined self-medication sector in the Asia-Pacific region.

- WSMI gains official observer status at the World Intellectual Property Organisation (WIPO) and the Codex Alimentarius Commission.

**2001** - The UK "Reclassification Alliance" is established between government, industry, pharmacists and other parties in the UK to review the issues and opportunities for switching more medicines from prescription to nonprescription.

- Foundation of a regional association for Latin America – Industria Latinoamericana de Auto-medificacion Responsable (ILAR), designed to help harmonize classification, switching, advertising and distribution of nonprescription medicines in the region.

**2002** - WSMI counts 50 member associations around the world.

- The Wanless Report, an independent review commissioned by the UK government, introduces self-care as a crucial element of an effective, publicly-funded health system.

- WSMI publishes "Creating a framework for the self-care consumer".

- 1<sup>st</sup> WSMI/ILAR Latin American Conference, Cancun, Mexico.

- WSMI's 14<sup>th</sup> General Assembly and 5th Asia Pacific Regional Conference in Tokyo, Japan has the theme "Beyond the Conventional Boundary of Self-Medication, Shared Vision, Common Understandings".

- WSMI offices move from London to near Geneva, Switzerland, headquarters of the WHO. The new WSMI office is co-located with the World Medical Association (WMA).

**2003** - The World Health Assembly adopts the WHO Framework Convention on Tobacco Control. The WHO "FCTC" will enter into force on 27 February 2005. It becomes one of the most widely embraced treaties in the history of the United Nations and as of January 2010 has 168 parties.

- The International Council of Nurses (ICN) publishes a monograph on "Tobacco Control and Smoking Cessation", sponsored by WSMI.
- A joint statement is produced by WSMI and ICN entitled: «Role of Nurses in Self-Medication». A fact sheet «Growing Trend in Self Care» is published by ICN in 2005 as part of the Council's «Informed Patient Project».
- The World Medical Association (WMA) publishes the "Medical Ethics Manual" considering questions such as the "patient-physician" relationship and the "centrality of the patient". The WMA Declaration of Helsinki (1964, latest revision 2008) promotes ethical principles for medical research

involving human subjects with the primary objective to protect their health and rights.

**2004** - The 6<sup>th</sup> WSMI Asia-Pacific Regional Conference in Beijing, China has the theme "From the past to the future, public health regulatory and industrial opportunities in responsible self-medication."

- Creation of the Middle-East Self-Medication Industry (MESMI), covering Saudi Arabia, Oman, the United Arab Emirates, Bahrain, Qatar and Kuwait. The First MESMI board meeting takes place on 12 May 2004.
- The WHO adopts the Global Strategy on Diet, Physical Activity and Health to help fight heart disease, stroke, diabetes, cancer and obesity-related conditions. The strategy encourages people to be more physically active and eat healthier diets.
- AESGP publishes "The Economic and Public Health Value of Self-Medication", a ground-

2000



*Docosanol (cold sore/fever blister) becomes available without prescription in the US. Meclizine (prevention and treatment of nausea) and cimetidine (treatment of heartburn) are switched in Canada.*

2001



*Emergency contraception levonorgestrol becomes available without a prescription in the UK. Australia will follow in 2004, the Netherlands in 2005, India (2005), Canada (2005), USA (2006), and Spain (2009). Triamcinolone acetonide for the short term prophylaxis or treatment of seasonal allergic rhinitis in adults and children 12 years and over switched in Australia.*

2002



*The antihistamine loratadine is switched in the US. Fluticasone (hay fever and allergy) switched in the UK.*

2003



*All NRT products are switched from pharmacy-only to general-sale status in Norway. Paracetamol- and ibuprofen-based analgesics, nasal decongestant sprays, antacids and expectorants also become general sales. Omeprazole switched for the relief of reflux-like symptoms such as heartburn in the UK and the US.*





breaking analysis of the potential in Europe for self-medication.

- WSMI launches a new website. The objective is to provide a source of reliable information on self-care and responsible self-medication.
- WSMI receives consultative status with the Economic and Social Council (ECOSOC), the United Nations central coordination body.

**2005** - The UK Department of Health publishes "Self-Care, A Real Choice", setting out support for self-care.

- The US FDA declares it needs to be more proactive in recommending switches that could result in further consumer empowerment in healthcare, with a goal to increase switches.
- Launch by WHO of the Commission on Social Determinants of Health, taking leadership for a process to increase equity in health and which starts to look at broader environmental aspects of healthy living.

- WHO report on "Preventing Chronic Diseases, a Vital Investment".

- Launch of the WHO and WSMI Booklet «Avoiding Heart Attacks and Strokes. Don't be a victim - Protect yourself».

- WSMI's 15<sup>th</sup> General Assembly in Geneva, Switzerland, with the theme "Working together for self-care: the world's vision".

- WSMI presents at a Government-Industry Round Table in China on why self-care and responsible self-medication is so important to healthcare in China.

- 2<sup>nd</sup> WSMI/ILAR Latin American Conference in Sao Paulo, Brazil where the theme is "Responsible self-medication in Latin America: The way forward to self-care".

- The 4<sup>th</sup> Pan American Conference for Drug Regulatory Harmonization (PANDRH) led by Argentina, Brazil, Costa Rica, Guatemala, Mexico and ILAR approves harmonized classification criteria and recommends their inclusion in all Pan American Health Organization (PAHO) member states.

2004



2005



*Orlistat (weight loss) available without prescription in Australia. Singapore, Malaysia, New-Zealand, Thailand and the Philippines will follow shortly as well as China (2005), the USA (2007) and the European Union (2009). Cholesterol-lowering simvastatin becomes available without prescription in the UK. Fluconazole in single-dose oral preparations containing 150 mg or less of fluconazole for the treatment of vaginal candidiasis is switched in Australia.*

*Antibiotic chloramphenicol eye drops (acute bacterial conjunctivitis) switched in the UK. Vitamin K becomes available without a prescription in Canada. Between 2004 and 2005, the Chinese SFDA classifies 4542 drugs as nonprescription including 3548 Chinese herb-formulated medicines and 994 chemical medicines.*

## 2006-2010 and the future – A globalizing world. Prevention of disease through self-care and responsible self-medication.

*«Today, self-care is becoming understood as increasingly important, not least for managing chronic non-communicable diseases, a major challenge for all health systems.» - Dr Carissa Etienne, WHO, Assistant Director-General, Health Systems and Services (2008)*

In recent years the societal impacts of ageing populations and chronic "lifestyle" conditions such as cardiovascular disease, cancer and diabetes has become clearer. As stated in WHO's 2008-2013 Action plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases (WHO 2008):

*"Today, noncommunicable diseases (NCDs), mainly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes represent a leading threat to human health and development. These four diseases are the world's biggest killers, causing an estimated 35 million deaths each year – 60% of all deaths globally – with 80% in low- and middle-income countries. These diseases are preventable. Up to 80% of heart disease, stroke, and type 2 diabetes and over a third of cancers could be prevented by eliminating shared risk factors, mainly tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol." (WHO 2008)*

Thus chronic non-communicable diseases are particularly significant in that they are substantially preventable through better self-care – by individuals avoiding risks such as smoking and obesity, and taking better care of themselves. In today's paradigm nonprescription medicines are the "tools" of self-care, supporting health awareness and healthy practices. Responsible self-medication with nonprescription medicines is increasingly being recognised as the first line of treatment and as a foundation of public health and healthcare systems. This is not only

through helping to educate and motivate people to treat their own minor ailments and conserve scarce healthcare resources. In addition, and importantly, motivated people are much more likely to undertake other positive self-care behaviours, and thereby help prevent the chronic disease future of most countries. The period 2006-2010 has witnessed a consolidation in the global understanding of this concept of responsible self-medication.

In 2006 the WSMI Board adopted the "WSMI Declaration on Self-Care and Self-Medication" which summarized many of the themes and concepts of self-care and self-medication (see p.31). It stated that a country which fully encouraged self-care – through building healthier settings, making healthy choices easier for individuals, and empowering individuals to adopt healthy behaviors - can expect to have a healthier population. The WSMI Declaration was followed by similar declarations in Bali Indonesia and Mexico City Mexico in 2006, in Bogota Colombia in 2007 and in Cartagena Colombia in 2009.

Similarly, on the occasion of its second global patients congress in 2006, the International Alliance of Patients' Organizations (IAPO) launched a declaration on patient-centred healthcare. According to IAPO, five principles are required for patient-centered healthcare. The principles are: respect, choice and empowerment, patient involvement in health policy, access and support, and information. The IAPO declaration commences with the statement:

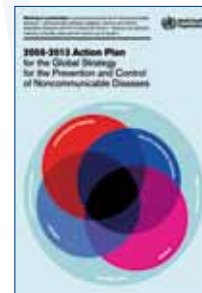
*Self-Medication Executive Forum, Bali, Indonesia (2006). Signature of the Declaration on Self-Care and Self-Medication.*

*Bottom picture from left: Motohito Nishizawa, M.D., JSMI; David Webber, D.G. WSMI and Anthony Sunarjo, President GP Farmasi, Indonesia.*

*The International Council of Nurses “Responsible Self-Medication, Nursing Perspectives”.*

*WSMI meeting hosted by the Thai FDA, with pharmacist and industry representatives (2009).*

*WHO’s Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases (2008).*



*“Health systems in all world regions are under pressure and cannot cope if they continue to focus on diseases rather than patients; they require the involvement of individual patients who adhere to their treatments, make behavioural changes and self-manage”.*

*(IAPO’s Declaration on Patient-Centred Healthcare, February 2006)*

Subsequently a communication of the European Commission stated that:

*“...non-prescription medicines...play an important role since they offer economic as well as social benefits. Self-medication empowers patients to treat or prevent short term or chronic illnesses which they consider not requiring the consultation of a physician or which may be treated by the people after an initial medical diagnosis. Consequently, access and availability of these medical products require particular attention.” (Communication of the European Commission on “Safe, Innovative and Accessible Medicines: a renewed vision for the Pharmaceutical Sector” of 10 December 2008)*

Research undertaken during the period has reinforced the importance of self-medication. The Swedish Institute for Health Economics showed that the benefits of switching more ingredients to self-medication status clearly outweighed possible drawbacks. Nonprescription status provides net beneficial health effects for the population. A switch cuts the number of medical visits and prescriptions, resulting in

lower healthcare costs; according to the studies available, medical visits may drop by 15-24 per cent and prescriptions by anything between 6 and 70 per cent.

In Australia a review of the impact of nonprescription NRT concluded:

*“We estimate that 68,750 successful quitters and premature deaths have been prevented in the 10 years or 6,875 per annum since NRT was switched in Australia. This should be viewed against the mortality of nearly 20,000 smokers per annum today” (R. Bittoun, Brain & Mind Research Institute, University of Sydney)*

Since the mid-1970s, the U.S. Food and Drug Administration (FDA) has switched over 80 ingredients, dosages, or indications from prescription to nonprescription status, making them more widely available to consumers. The success of prescription to nonprescription switch has stemmed from industry and FDA working in partnership to evaluate the specific merits of each potential switch. They work together to make a scientifically documented, data-driven decision that serves and protects consumers. Prescription to nonprescription switch has a strong track record of providing new safe and effective options for a variety of diseases and conditions, advancing the quality of healthcare for all. Coupled with the decades of usage of some of the original nonprescription medicines, there is now a substantial base of safe and effective products available to patients and consumers.

*WSMI Symposium on “Self-Care in Healthcare Systems” at the WHO Congress on Traditional Medicines, Beijing, China (2008). From left: WSMI D.G. David Webber, Outgoing WSMI Chairman Hans Regenauer, WHO D.G. Dr Margaret Chan, AESGP D.G. Hubertus Kranz, WSMI Chairman-elect Christopher Combe.*



*WSMI Chairman Chris Combe featured in a Chinese Self-Medication Magazine (2009).*



*The September 2006 issue of the WMA journal which features the WMA-WSMI joint discussion paper on “The Future of Self-Care and its Implications for Physicians”.*



In the last decade the interface between government policy, economics, development and health has become more prominent. Health ministries, specialized UN agencies and non-governmental organizations – those that have been traditionally involved in this area – have now been joined by new actors, such as public-private partnerships, academic institutions, foundations, philanthropic organizations and the private sector. These actors are all shaping and contributing to the global health arena.

WSMI is pleased to play its part in global health. In January 2010, WSMI's official relations with WHO were renewed for a three-year period. As the year 2010 marks the 40<sup>th</sup>

anniversary of the association, WSMI takes particular pride in receiving this recognition of successful support to the World Health Organization. Self-care and responsible self-medication will undoubtedly continue to play a stronger role in public health as people are given more knowledge, support and tools to help them manage their own health.

## Key dates

**2006** - First session of the WHO FCTC Conference of the Parties, Geneva, Switzerland. WSMI is accredited as observer.

- The International Council of Nurses (ICN) produces the booklet *"Responsible Self-Medication: Nursing Perspectives"*. WSMI contributes to the monograph through an educational grant.
- IAPO's 2<sup>nd</sup> Global Patient Congress takes place in Barcelona, Spain. Launch of IAPO's Declaration on Patient-Centered Healthcare.
- WHO Conference *"Combating Counterfeit Drugs: Building Effective International Collaboration"* in Rome, Italy. The "Rome Declaration" calls for the setting-up of an International Medical Products Anticounterfeiting Taskforce (IMPACT).
- A WSMI "Declaration" on Self-Care and Self-Medication is approved by the WSMI Board and is followed by a similar declaration in Bali, Indonesia.
- A "Mexico City Declaration" (2006), "Bogota Declaration" (2007) and "Cartagena Declaration" (2009) are developed during "Round Tables" on the Role of Self-Care in Healthcare, attended by industry representatives, health professionals, regulators and academia.
- The World Medical Association's General Assembly in Pilanesberg, South Africa, adopts the WMA Statement on the Physician's Role in Obesity re-

commending that physicians encourage the development of life skills that contribute to a healthy lifestyle in all persons and to better public knowledge of healthy diets, exercise and the dangers of smoking and excess alcohol consumption.

- WSMI and the World Medical Association (WMA) produce a joint paper entitled *"A Discussion Paper on the Future of Self-Care and its Implications for Physicians"*.
- First general meeting of the WHO IMPACT (International Medicinal Products Anti-Counterfeiting Task Force) in Bonn, Germany. WSMI is represented on the Working Groups on Technology, Communications, and Regulation.

**2007** - WSMI produces the booklet *"Better Regulation of Nonprescription medicines"* which spells out the regulatory conditions needed to optimize the use of nonprescription medicines.

- The Adam Smith Institute (UK) publishes a paper entitled *"Self-Care – Essentials of 21<sup>st</sup> Century Healthcare Reform"*.
- AESGP publishes "The Regulatory Framework for Food Supplements in Europe", the companion volume to the "Economic and Legal Framework for Non-Prescription Medicines."
- WSMI produces an update of the 1997 Review of Consumer Surveys: *"Responsible Self-Care and*





*Self-Medication: a Worldwide Review of Consumer Surveys”.*

**2008** - WHO's Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases is developed. This provides a roadmap to establish and strengthen initiatives for the surveillance, prevention and management of non-communicable diseases. WSMI provides input to the strategy.

- The Swedish Institute for Health Economics (IHE) publishes “Economic benefits of switching medicinal products to OTC status”.

- WSMI produces the booklet *“Advertising of Nonprescription Medicines to the Public; a Significant Contributor to Healthcare”*.

- WSMI is invited by the WHO to organise a Symposium at the WHO Congress on Traditional Medicines in Beijing China. This results in WSMI's 16<sup>th</sup> General Assembly & 7<sup>th</sup> Asia-Pacific Re-

gional Conference, and WSMI Symposia entitled *“Self-Care in Healthcare Systems”* and *“Medicines – Traditional, Alternative and Complementary” (together with the FIP)*.

- The Chinese self-care industry launches a self-medication magazine.

- European Commission on “Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector”.

**2009** - WHO regional consultation on “Self-care in the Context of Primary Health Care” in Bangkok, Thailand.

- In the UK a Ministerial Industry Strategy Group (MISG) provides a strategic discussion forum for stakeholders in health including the nonprescription association the Proprietary Association of Great Britain (PAGB).

2006

2007

2008

*Sumatriptan (for migraine), amorphine and penciclovir (for cold sores) are switched in the UK. Ketotifen (antihistamine eye drops) switched in the US. Nicotine lozenge (smoking cessation) and clobetasone butyrate (topical corticosteroid) are switched in Canada.*

*Orlistat (weight loss aid) becomes available without a prescription in the US. Cetirizine (antihistamine, hives relief) available without a prescription in the US.*

*Calciproliol (psoriasis) recommended for nonprescription use in Germany. Azithromycin (antibiotic for Chlamydia), naproxen (for period pain) and diclofenac (for pain relief and cold and flu symptoms) switched in the UK. Canada will follow with naproxen and diclofenac in 2009. Pantoprazole (relief of heartburn and other symptoms of gastro-oesophageal reflux disease) switched in Australia.*

## Key dates

- WSMI is invited to present at the Thai Food and Drug Administration on "Global Experiences in Medicines Reclassification" and participates in a forum at the International Chamber of Commerce exploring the opportunity to create a separate nonprescription association in the country.
- The WHO 17<sup>th</sup> Expert Committee on the Selection and Use of Essential Medicines recommends that Nicotine Replacement Therapy should be included into the 16<sup>th</sup> list of Essential Medicines
- WSMI research on self-care and self-medication in the French Speaking Countries of North Africa highlights the opportunity for a stronger responsible self-medication sector.
- 3<sup>rd</sup> WSMI/ILAR/ANDI Latin American Conference in Cartagena de Indias, Colombia with the theme "I Am Responsible For My Health. Recognizing the value of Self-Care and responsible Self-Medication in Latin America".
- WSMI Brochure "Prescription to Nonprescription Medicines Switch".
- 1<sup>st</sup> United Arab Emirates Health Advertising Conference. WSMI chairs a session on "future strategies for medical advertising: regulations development" and presents on "health education on medicinal products".

**2010** - WSMI's official relations with WHO are renewed for a three-year period.

- WSMI contributes to the drafting of the FCTC Article 14 Guidelines on the treatment of tobacco dependence.
- WSMI 8<sup>th</sup> Asia-Pacific Regional Conference in Chinese Taipei with the theme "The changing landscape of self-medication".

### 2009

1. Orlistat becomes the first ever nonprescription product to be granted a pan-European-Union Centralised approval, covering all 27 EU Member States.

2. Lansoprazole (acid reducer to treat frequent heartburn) switched in US. Fluconazole is switched in Canada.

3. Positive recommendation in Germany for nonprescription availability of sumatriptan (treatment of acute migraine attacks).

4. Pantoprazole approved as nonprescription in the 27 European Union member states.

5. Proton-pump inhibitor rabeprazole (10 mg) approved for nonprescription status in Australia.

6. Tamsulosin (treatment of lower urinary tract symptoms) approved for switch in the UK. Antivirals zanamivir and oseltamivir available from the pharmacy in Norway.

### 2010

*Domperidone (for stomach problems) is switched to nonprescription status in the UK.*

## WSMI Publications

*WSMI and member associations have produced a wide range of publications of interest to those involved in healthcare policy on the subject of responsible self-medication, self-care and nonprescription medicines. These publications are available from WSMI through [admin@wsmi.org](mailto:admin@wsmi.org).*



### **SWITCH. Prescription to Nonprescription Switch (2009)**

Switching more products to nonprescription status increases access to safe and effective medicines which patients can use without always having to go to

a healthcare professional, giving people the tools to take better care of themselves through self-care. After a worldwide historical review, the booklet describes the public health aims and benefits of switches and the central question of the indications, or conditions, that are likely to be considered for self-medication in the future. Following sections review the necessary country conditions for switching and address some of the key switch-related regulatory issues.



### **Advertising of nonprescription medicines to the public, a significant contributor to healthcare (2008)**

Nonprescription medicines are medicines which are approved as safe and effective for use without a doctor's prescription.

As no healthcare professional is necessarily involved in their use, advertising directly to the public is essential. The booklet is structured in three sections. The first and second sections review the nature and benefits of nonprescription medicines' advertising. The third section discusses the appropriate regulation of nonprescription medicines' advertising based on a review of various countries' experiences.



### **Better regulation of nonprescription medicines (2007)**

All too often in developing countries, regulation of nonprescription medicines is not clearly distinguished from that of prescription medicines. This lack of distinction places limits

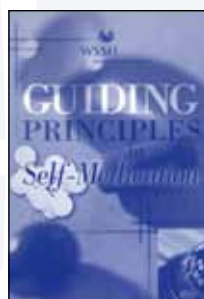
on achieving an optimal level of public health. Starting with clarifying the distinctions between prescription and nonprescription medicines, and the purposes of regulation, the booklet then summarizes the specific benefits of greater use of nonprescription medicines.

Appropriate and best practice in regulation of nonprescription medicines is then discussed in detail, and finally some material is presented on addressing existing over-regulation.



### **Responsible Self-Care and Self-Medication, a Worldwide Review of Consumer Surveys (2007 update)**

This review of consumer surveys carried out over the past 10 years around the world confirms that nonprescription medicines are used cautiously and responsibly and that they help to educate people on the practice of healthy living habits and self-care. It summarizes the striking similarities among people around the world. Feeling unwell and suffering from ailments is a very common experience. People around the world tend to treat these conditions in much the same conservative way, about a quarter of the time turning to nonprescription medicines. People are becoming more confident that they have a role to play in their own healthcare and they believe that a modern healthcare system should offer increasing opportunities to access such medicines.



### **Guiding Principles in Self-Medication (1999)**

Every day people throughout take actions with respect to their health - they practice self-care. In some instances they do so through self-medication. How can governments further promote public health and ensure that products designed for self-medication are safe and effective? This publication discusses elements of a number of government policies for promoting better health through responsible self-medication.



### **Creating a Framework for the Self-Care Consumer (2002)**

This publication provides a brief description of the evidence underpinning responsible self-medication and covers examples of WSMI policy positions and illustrations of self-medication approaches taken by governments.

## WSMI General Assemblies & Conferences

GENERAL ASSEMBLIES		
1.	<b>London, UK</b>	November 29-30, 1971
2.	<b>Tokyo, Japan</b>	October 9-11, 1972
3.	<b>White Sulphur Springs, WV, USA</b>	May 12-15, 1974
4.	<b>Geneva, Switzerland</b>	March 21-23, 1977
5.	<b>Sydney, Australia</b>	October 23-25, 1979
6.	<b>Ottawa, Canada</b>	October 11-14, 1981
7.	<b>Tokyo, Japan</b>	November 11-13, 1984
8.	<b>Washington, DC, USA</b>	September 21-23, 1986
9.	<b>Rome, Italy</b>	June 4-7, 1989
10.	<b>Seoul, Korea</b>	October 16-18, 1991
11.	<b>Acapulco, Mexico</b>	October 27-30, 1993
12.	<b>Toronto, Canada</b>	October 28-31, 1996
13.	<b>Berlin, Germany</b>	June 9-12, 1999
14.	<b>Tokyo, Japan</b>	November 12-16, 2002
15.	<b>Geneva, Switzerland</b>	June 1-3, 2005
16.	<b>Beijing, China</b>	November 7-9, 2008
ASIA PACIFIC REGIONAL CONFERENCES		
<b>1<sup>st</sup> Asia Pacific Regional Conference</b>	Jakarta, Indonesia – 1993	
<b>2<sup>nd</sup> Asia Pacific Regional Conference</b>	Bangkok, Thailand – 1995	
<b>3<sup>rd</sup> Asia Pacific Regional Conference</b>	Kuala Lumpur, Malaysia – March 2-3, 1998	
<b>4<sup>th</sup> Asia Pacific Regional Conference</b>	Sydney, Australia – November 21-24, 2000	
<b>5<sup>th</sup> Asia Pacific Regional Conference</b>	Tokyo, Japan – November 12-16, 2002	
<b>6<sup>th</sup> Asia Pacific Regional Conference</b>	Beijing, China – October 26-29, 2004	



*Preliminary program of the 3rd WSMI/ILAR/ANDI Latin American Conference. "I Am Responsible For My Health. Recognizing the value of Self-Care and responsible Self-Medication in Latin America". Cartagena de Indias, Colombia (2009).*

*WSMI Beijing, China (2004) Conference Flyer.*



**7<sup>th</sup> Asia Pacific Regional Conference**

Beijing, China – November 7-9, 2008

**8<sup>th</sup> Asia Pacific Regional Conference**

Chinese Taipei – November 5-7 2010

## LATIN AMERICA REGIONAL CONFERENCES

**WSMI Latin America Regional Conference**

Rio de Janeiro, Brazil – March 30-31, 2000

**1<sup>st</sup> WSMI ILAR Latin America Regional Conference**

Cancún, Mexico – October 17-18, 2002

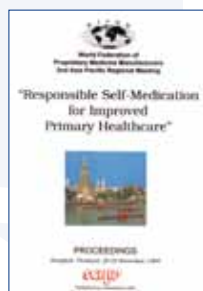
**2<sup>nd</sup> WSMI ILAR Latin America Regional Conference**

Sao Paulo, Brazil – October 26-28, 2005

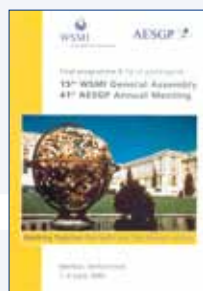
**3<sup>rd</sup> WSMI ILAR Latin America Regional Conference**

Cartagena, Colombia – October 22-23, 2009

*Proceedings of the 3<sup>rd</sup> Asia Pacific Regional Conference. "Responsible Self-Medication for Improved Primary Healthcare" Kuala Lumpur, Malaysia (1998).*



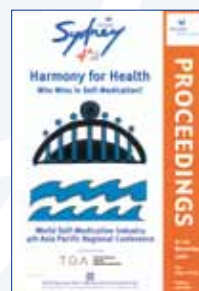
*Programme of the WSMI 15<sup>th</sup> General Assembly, Geneva, Switzerland (2005).*



*Invitation to WSMI Symposia and other events at the WHO congress on Traditional Medicines, Beijing (China) 2008.*



*Proceedings of the 4<sup>th</sup> WSMI Asia Pacific Regional Conference. "Harmony for Health, who Wins in Self-Medication?" Sydney, Australia (2000).*







# WSMI

WORLD *self*-MEDICATION INDUSTRY

## WSMI DECLARATION ON SELF-CARE AND SELF-MEDICATION

2006

### The WSMI Board declares that

- 1. Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity<sup>1</sup>. The healthcare system and healthcare professionals cannot bring about this state of health in the community alone; to achieve this requires the full involvement of individuals looking after themselves through self-care.*
- 2. Self-care includes healthy living behaviours such as avoiding health risks, adequate physical exercise, proper nutrition, maintenance of mental well-being, and taking medicines (prescription and over-the-counter) responsibly and appropriately. Self-care products are useful for individuals wishing to take preventive care and to treat a large number of ailments either under the direct supervision of a healthcare professional or on their own. All of these elements can contribute in a major way to individual wellness and collective public health, underpinned by the support of healthcare professionals.*
- 3. The determinants of good health and the causes of disease are now better understood than ever before and the contribution that can be made by self-care is today well understood and can be put into practice.*
- 4. People have the right and duty to participate individually and collectively in the planning and implementation of their health care<sup>2</sup>. Individuals thus have a responsibility towards as well as a right to their own health, and healthcare professionals are well placed to work with them to support and encourage individual health behaviours.*
- 5. With the epidemiological transition from predominance of communicable diseases to non-communicable diseases and disorders, self-care is particularly important. This evolution in disease profile will require healthcare services to reorient away from a focus on providing "sickness services" and towards prevention and management services. Self-care - including self-medication - will in fact constitute not only the reality but also a fundamental component of future healthcare. In fact, the use of self-care products is already a widely practiced component of self-care.*
- 6. Responsible use of self-care products involves using the right product for the right indication at the right time and in the right way. This includes both self-medication using self-care products for treating common health problems and the use of self-care products to help reduce the risk of disease. Self-care products are especially designed and labeled for use by the consumer and approved as safe and effective for such use. Self-medication is a widely practised component of self-care. The challenge and opportunity for government authorities, healthcare professionals and providers of self-medication products is to have an appropriate framework in place for responsible self-medication.*
- 7. A country which fully encourages self-care can expect to have a healthier population and be able to redeploy scarce resources to priority areas. The opportunity is to develop self-care as a fundamental core asset in health, not just as a support mechanism. Even (and perhaps especially) in the most resource-poor settings, self-care should play a major role.*
- 8. The strong relationship between the health of a country's population and the country's economic performance is now better understood. Investing in health should be seen as an excellent investment, with dividends in the short and long term.*

<sup>1</sup> WHO Constitution, first principle (see <http://www.who.int/about/definition/en/>)

<sup>2</sup> Declaration of the Alma-Ata International Conference on Primary Health Care, USSR, 6-12 September 1978



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