



# Better Regulation of Nonprescription Medicines



WSMI

WORLD *self*-MEDICATION INDUSTRY





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## Executive summary

All too often around the world, 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 (through appropriate patient and consumer usage) and negatively impacts the international competitiveness of the nonprescription industry. Nonprescription medicines are in fact different from prescription medicines in some significant and under-appreciated ways.

Better regulation is a big issue in developed countries at the moment. The challenge for all countries is to recognise and reconcile the different objectives of regulation, and to avoid unintended consequences of the inappropriate application of prescription drug regulation to the nonprescription sector. Public health and consumer safety will not be compromised by more appropriate and proportionate regulation of nonprescription medicines. In fact, it is possible to promote responsible usage of these medicines while diminishing 'self-prescription,' the inadvertent and irrational use of prescription drugs without the intervention and supervision of a medical doctor – an all-too common practice in developing countries.

This booklet examines the underlying objectives of regulation of nonprescription products. These are commonly taken to mean over-the counter (OTC) or nonprescription medicines, but can also include traditional/herbal products and other products that have some form of medical or disease claim, including vitamins and minerals.



The purposes of  
regulation of  
nonprescription  
medicines

Section I

## How is the nonprescription sector different?

The main differences between nonprescription and prescription medicines are:

- 1 Nonprescription products are medicines with usually many years – often decades – of experience of safe usage.<sup>1</sup> Many nonprescription medicines are in use in a large number of countries around the world, and this experience should be taken into account in regulatory regimes. Furthermore, and to an increasing extent today, certain medicines that previously have been treated as prescription only are being examined now for potential 'switching' to nonprescription status. The substantial knowledge built up under prescription conditions of a medicine's quality, safety and efficacy profile can be carried over to nonprescription use. Overall, this means that nonprescription products do not need to be subject to the same extent of regulation as new prescription medicines at the point of registration (marketing authorization) or in ongoing usage.
- 2 Nonprescription medicines' chemical entities are commonly not protected by intellectual property patents on the basic molecule. Innovation and competition between manufacturers, which benefits patients, is based upon the development of new therapeutic claims for established products (plus the value conveyed by individual brands – see point 4). This innovation is costly, not least to small companies, leading to the need for data protection and marketing exclusivity for innovation rather than patent protection on a new chemical entity.
- 3 Doctors can play a very important part in encouraging and supporting self-care activities. But the fundamental difference between prescription medicines and nonprescription products is that the latter can be purchased and used by the consumer of the medicine without the necessary intervention of a medical doctor. This has far-reaching consequences for supporting the appropriate use of nonprescription products by consumers

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<sup>1</sup> Many regulatory regimes start with a premise of nonprescription status for all medicines, with prescription criteria specifically defined e.g. EU Medicines Directive 2001/83/EC (Article 71) advises that medicines shall only be prescription if they «are likely to present a danger if used without medical supervision», are frequently abused, contain novel substances (NCEs) or are parenteral products. All other medicines should be nonprescription.

and patients. Educating individuals in 'responsible' self-medication is appropriate; entirely different controls are necessary than those on doctor prescribing of prescription medicines. For nonprescription medicines there is therefore a special place for the provision of consumer information, and in making patients aware of product choices. For these products, labels, leaflets and consumer advertising have a special importance.

- 4 Marketplace competition and therefore consumer choice in the self-care sector is principally on the basis of the development of brands and the advertising of those brands by manufacturers, with manufacturers being free to develop a range of price offerings. The competitive marketplace provides choice for consumers and helps keep prices down. If the consumer does not wish to pay for a particular product, there are always alternatives in the nonprescription sector. Price competition rather than price control is effective, and advertising flexibility is essential, again emphasising that the market dynamics for the nonprescription sector are quite different to those of the prescription sector.
- 5 In today's information age, where the public is increasingly interested in healthcare matters and willing to play a more active role in its own healthcare, nonprescription medicines provide a tool for patients to practice 'self-care' (see Section II). Developing self-care also allows governments to move towards more patient-oriented and disease-preventive health services (see Section II), leading to improved public health standards. It is therefore in the interest of all that public health policies explicitly recognize and support self-care. Opportunities to encourage wider appropriate access to self-care products should also be considered, on a country-by country basis.

Taken together, these points illustrate the need for regulation to recognize the unique nature of the nonprescription sector. Nonprescription medicines are in some respects not very different to other consumer products, so it is always valid to question controls on the marketing of nonprescription products that would not be applied to other consumer products. This leads to the key question: what are the fundamental purposes of nonprescription product regulation?

## What are the fundamental purposes of nonprescription product regulation?

The purposes of nonprescription product regulation are threefold:

- 1 To ensure their quality, safety and efficacy.
- 2 To improve public health.
- 3 To encourage the competitiveness of the nonprescription industry.

The focus has traditionally been on the first of these – on medicines' quality, safety and efficacy – and there must be no compromise on this objective. But the other two purposes are important too, and tend to be overlooked, which is why they receive particular attention in this booklet.

### 1 Nonprescription medicines' quality, safety and efficacy

Medicines are substances used for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or for the modification of physical functions. Their quality, safety and efficacy must be the subject of high standards of regulation. This applies equally to drugs that are prescribed only by a doctor and to those that are available directly to patients and consumers as nonprescription products.

The underlying principles regulating nonprescription product quality safety and efficacy are therefore the same as for prescription drugs. Nevertheless, as mentioned above, nonprescription products usually have many years of experience in usage. Moreover, for those products which were in the past treated as prescription products but are now being considered for 'switching' from prescription to nonprescription status, the confidence in a product's quality, safety and efficacy profile that was proven during prescription usage can be carried over.

This knowledge and familiarity with the basic molecule has implications for the initial registration and marketing of a nonprescription product, for line extensions and for pharmacovigilance.<sup>2</sup> Regulations can often be simplified

without compromising public safety – see Section III: Appropriate regulation of nonprescription products.

In some other areas of regulation, nonprescription medicines and prescription drugs should be considered separately. Specifically, this applies to encouraging public health through promoting individual **self-care**, and to encouraging industrial development and international competitiveness in the nonprescription industry.

## 2 Improving public health

Around the world, in developing as well as developed countries, the emergence of chronic diseases – cancer, cardiovascular problems, diabetes etc – is being recorded. From a projected total of 58 million deaths from all causes worldwide in 2005, the WHO estimated that chronic diseases accounted for 35 million, which is double the number of deaths from all infectious diseases (including HIV/AIDS, tuberculosis and malaria).<sup>3</sup> Importantly, the contributing factors of these diseases are now well understood – obesity, insufficient exercise and tobacco smoking. Even more significantly, these factors are preventable, and the better use of nonprescription products can make a significant contribution. In most countries however, the focus of healthcare systems is on treating a disease after it appears, rather than on preventing it in the first place. A major future challenge therefore is to encourage people to take more care of themselves through self-care, improving individual lives and, collectively, public health.

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<sup>2</sup> Pharmacovigilance is the science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long-term and short-term side effect of medicines, with a view to identifying new information about hazards associated with medicines and preventing harm to patients. Pharmacovigilance provides for risk control over the entire product life cycle.

<sup>3</sup> Preventing chronic diseases: a vital investment: WHO global report. 2005 WHO Geneva.

## What is self-care?

Self-care is the care taken by individuals towards their own health and wellbeing, including the care extended to their family members and others. In practice self-care includes the actions people take to stay fit and maintain good physical and mental health; meet social and psychological needs; prevent illness or accidents; avoid unnecessary risks; and use nonprescription products to treat minor ailments and reduce the risk of long-term conditions. Self-care involves:

- Healthy choices that encourage the maintenance of health (including psychological health) and the prevention of illness, including good nutrition and appropriate levels of physical activity.
- Avoidance of risk factors such as unsafe sex, tobacco smoking and environmental hazards.
- Self recognition of symptoms, and screening and assessing these in partnership with a healthcare professional when appropriate.
- The responsible use of all health products including prescription drugs and nonprescription products.

Although many governments have regulations which affect self-care activities, relatively few have a specific policy of encouraging self-care on the part of their citizens (see Box 1). But the opportunity is now being increasingly recognized even by emerging/developing countries such as China and Mexico, which see that the way to healthy populations is not simply through greater public healthcare expenditures but should include the contribution that self-care and self-medication can make.

## Box 1 Self-care in Britain – a formal government policy of the National Health Service (NHS)

Self-care has been identified in NHS plans as one of the key building blocks for a patient-centred health service:

“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). See:

<http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/SelfCare/fs/en>

The biggest challenge in future will not be to identify what individuals should be doing to maintain health and prevent disease, but to help people change their behaviors. One way to do this is to provide people with access to ‘tools’ for undertaking self-care – including responsible self-medication. Giving people greater opportunities to do more for themselves, including better access to nonprescription products, can be expected to lead to improvements in public health (Figure 1).

Figure 1 Nonprescription products are 'tools' for self-care



The opportunity therefore is for government departments and agencies to specifically encourage self-care in general and responsible self-medication in particular, in the interests of public health. Regulations regarding nonprescription products should thus be designed to encourage (and not discourage) self-care. The contrast with the appropriate use of prescription drugs is clear. The substantial opportunity to improve public health through encouraging responsible self-care and self-medication should therefore be an explicit objective. In Section II the substantial contribution that nonprescription products can make to public health is further described.

### 3 Encouraging international competitiveness in the nonprescription industry

Regulations may be viewed by medicines regulators as being primarily focused on issues of quality, safety and efficacy of medicines. This is essentially a control and restriction function, appropriate in the interest of public safety.

In addition however, regulations also have a powerful effect on the companies in an industry, and are thereby an instrument of a country's industrial policy. Regulations relating to the marketplace for nonprescription products – their labeling, advertising and promotion, availability and distribution in a market and the incentives for research – all have a powerful effect on companies' success or failure.

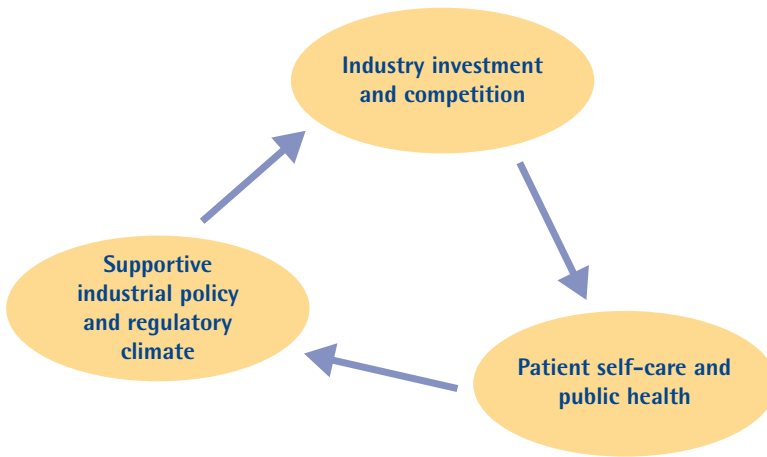
In general terms, a country's industrial policy includes any government regulation or law that affects the ongoing operation of a particular industry. A government's industrial policy often affects, or is even wholly determinant of, investment policy by companies in that industry.

Many countries have an industrial policy for the nonprescription sector which is supposedly intended to encourage industrial development. The industrial policy objectives may include the following:

- Encouraging competition between companies. This leads to more products being made available and to improvements in product brands – giving as a direct result more choice for patients and consumers.
- Supporting related economic activity. Self-care products feed distribution channels through wholesalers, retailers and pharmacies, providing income to these sectors. In this way the nonprescription sector indirectly supports employment and economic activity, and subsidizes healthcare services on a wider basis.
- Raising government tax revenues. A healthy self-care industry pays higher company taxes and deploys more employees whose own taxes and spending also benefit the community.

A positive industrial policy encouraging industrial development and investment leads to a positive 'virtuous spiral' (Figure 2). Healthy companies produce more and better choices to encourage self-care, supporting public health objectives.


**Figure 2** The virtuous spiral



However, many opportunities for better health are in fact being missed around the world. In section II the significant opportunity to encourage the use of nonprescription medicines for the benefit of public health as well as in the interests of industrial development are considered in more detail. This can be achieved by improving the regulatory climate – through appropriate regulation of nonprescription medicines (see section III) and through a reduction in unnecessary regulation (section IV).

## Conclusions of Section I

The nonprescription sector is different to the prescription sector in ways that are not always recognized. The broader effects of regulation should always be considered, and the often undervalued effects of regulation – on improving public health and on industrial policy – should receive more attention.



**The opportunity  
to make more use  
of nonprescription  
medicines**

**Section II**

## The benefits of nonprescription medicines

The health, social and economic benefits of responsible self-medication with nonprescription products is well known and extensively reported.<sup>4</sup> These benefits may be summarized as follows:

- 1 Direct health benefits for patients and consumers, helping with patient wellness and productivity and improved health behaviors in terms of prevention. Figure 1 illustrated how self-medication can support individuals' self-reliance and the practice of self-care and not least help those who suffer from chronic conditions control their symptoms.
- 2 Economic gains for employers in having employees attend work when they might otherwise have stayed at home. The economic benefit to industry in having consumers use their products is also significant – through government tax revenues, and industrial employment.
- 3 Cost savings to society when people are responsibly self-treating with appropriate nonprescription medicines, rather than unnecessarily visiting a doctor (who may feel obliged to provide a prescription drug). These cost savings come from reduced physician visits and better focused public medicines budgets. (e.g. based on a detailed analysis of seven European countries, total annual savings resulting from a move of 5% of prescribed medications to self medication exceed 16 billion Euros).<sup>5</sup>
- 4 Providing individuals who live in rural areas with basic health resources, particularly in developing countries.
- 5 Reducing the extent in which self-prescription with prescription medicines is practiced (e.g. in Mexico, between 1989 and 1999, self-prescription showed a 20% reduction thanks to increased availability of self-care medicines newly approved by the Mexican Ministry of Health).

Taken together these benefits to society as a whole are significant, but this is given added force when self-care health products are not able to make their optimal contribution to the health care system.

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<sup>4</sup> WSMI: Guiding Principles in Self-Medication, 1999; Creating a Framework for the Self-Care Consumer, 2002. <http://www.wsmi.org/publications.htm>

<sup>5</sup> AESGP: The Economic and Public Health Value of Self-Medication, 2004. <http://www.aesgp.be/ephv/2004study.pdf>

## Building an environment that improves the opportunities for people to manage their own health through the responsible use of safe and effective nonprescription products

Despite the clear benefits of nonprescription products, they have yet to contribute their full value to health care, for a variety of reasons. Statistically, people around the world get the same everyday health problems such as colds, digestive complaints and headaches, and respond in the same way. About fifty percent do nothing or treat symptoms with home remedies such as salt water gargles, ice packs or hot water bottles. Roughly one quarter visit a doctor or treat themselves with a prescription drug obtained earlier for the same condition. Only one quarter turn to nonprescription medicines. This provides not only a simple illustration of how much potential self-care products have, but also shows the essentially conservative attitude most people have towards medicines.<sup>6</sup>

The international variation in the classification of substances as nonprescription medicines is significant. The AESGP/WSMI ingredients tables<sup>7</sup> present a comparison of the legal classification status of around 200 ingredients widely used in nonprescription medicines around the world, showing where ingredients have been safely used in responsible self-medication. A simple review reveals that the availability of many ingredients varies widely. Of the more than 200 ingredients available in some form without a prescription, only 6 out of 25 countries list more than 50% of them as nonprescription. Furthermore, 6 out of 25 country markets have less than 30% of ingredients available without a prescription.

The significance of the need for self-care to make a stronger contribution to health care may be best appreciated by considering some specific therapy areas. Boxes 2-4 illustrate the significant examples of smoking cessation, calcium supplementation for osteoporosis and obesity.

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<sup>6</sup> Responsible Self-care and Self-medication: A Worldwide Review of Consumer Surveys. WSMI 2006.

<sup>7</sup> <http://www.wsmi.org/otc.htm>

<sup>8</sup> <http://www.who.int/tobacco/framework/en/>  
<http://www.who.int/entity/tobacco/framework/download/en/index.html>

## Box 2 Smoking cessation

Tobacco is the second major cause of death in the world. Half of the people that smoke today will eventually be killed by it (WHO). Quit rates vary – for example in Europe, only 21% of smokers manage to quit each year, while every day 80,000-100,000 young people around the world become addicted to tobacco. Yet only just over one-third (37%) of smokers have ever used the nonprescription treatment NRT (Nicotine Replacement Therapy).

### Helping people to quit

144 countries are party to the WHO Framework Convention on Tobacco Control (FCTC) which in article 14 supports commitment to demand reduction measures including facilitating access for pharmaceutical treatment of tobacco dependence. Yet despite the massive impact of smoking on public health, the accessibility of NRT varies greatly according to country – from being available in pharmacies, grocery stores, via specialist stop smoking clinics, practice nurses and GPs (e.g. UK), through to not even being registered as a nonprescription medicine. Countries vary in their reimbursement of NRT, cigarette tax levels, government health campaigns, bans on tobacco promotion, support from doctors, and in other ways. All these areas present opportunities to help people quit.

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<sup>9</sup> Generally meaning a Body Mass Index (BMI) >25 for adults

<sup>10</sup> Generally meaning a Body Mass Index (BMI) >30 for adults

### Box 3 Osteoporosis

Osteoporosis is a condition characterized by low mineral density and deterioration of bone tissue, which leads to increased bone fragility and susceptibility to fracture. Loss of bone mass is asymptomatic and symptoms only become overt once a fracture has occurred. The clinically most important of the fragility fractures is the hip fracture but vertebral fractures and wrist fractures substantially contribute to the overall morbidity.

Osteoporosis occurs most commonly in post-menopausal women, who often lack sufficient dietary calcium to meet daily requirements. Those at risk of osteoporosis should maintain an adequate intake of calcium and Vitamin D, and any deficiency should be corrected by increasing dietary intake or taking supplements.

The challenge in the case of osteoporosis is not the availability of dietary supplements, but the lack of awareness and management of osteoporosis risk. According to the National Osteoporosis Foundation (NOF) of the USA, close to 30 million women are at risk of developing osteoporosis, rising to 40 million by 2020, with more than 1.5 million fractures each year in the USA. If self-care was better understood and more widely practised, major diseases such as osteoporosis could be significantly reduced.

## Box 4 Obesity

Obesity is one of the greatest public health challenges of the 21st century. Its prevalence has tripled in many countries in the WHO European Region since the 1980s, and the numbers of those affected continue to rise at an alarming rate, particularly among children. In 2005, globally, approximately 1.6 billion adults (age 15+) were overweight and at least 400 million adults were obese.

The two key pillars in the fight against the escalating obesity epidemic are healthy diets and physical activity. However, experience has shown that they are not enough. Treatment options must therefore also be supported, and amongst these there are clinically proven medicinal products. Prescription and nonprescription products are recognized as efficient and beneficial tools when used in conjunction with dietary therapy and physical activity.

Weight loss is a nonprescription category. The U.S. Food and Drug Administration (FDA) has recently recognized this by approving a safe, weight loss nonprescription medicine for overweight adults. This will provide many more Americans with access to a safe and effective treatment option that, in conjunction with a healthy diet and exercise, will help them address their critical health issues. The nonprescription medicine orlistat has also been approved in Asia Pacific markets including Australia, New Zealand, Thailand, Singapore, Philippines and China. The WHO has set a goal of reversing the current obesity trend by 2015 at the latest. If this ambitious goal is to be reached, then all the right efforts need to be made. Safe and readily available approved nonprescription weight loss medicines could have a significant impact on the potential to reach that goal.

From these examples it can be seen that self-care can play a much stronger role in health care if there is greater access to relevant medicines, familiarity with treatment options, and more tools are provided to consumers to help them manage their own health.

## Conclusions of Section II

The clear benefits of nonprescription products present significant opportunities for countries to improve public health, to empower individuals in nonprescription use with regard to their personal health, and to encourage industrial development. The means to do this through positive and appropriate regulation of nonprescription medicines is discussed in section III.



**Appropriate regulation  
of nonprescription  
medicines**

**Section III**

Experience in many countries has shown that regulations introduced for medicines in general (prescription and nonprescription) can result in unintended and negative consequences for the nonprescription sector. This is because, as explained above, the nonprescription medicines marketplace is in fact quite different to that of prescription medicines.

Thus for policy makers to achieve desirable ends in the nonprescription sector – for example encouraging responsible self-care by patients or supporting innovation, industrial development and international competitiveness – regulations need to be considered with nonprescription medicines market dynamics specifically in mind. Appropriate regulation also requires a distinction between the initial registration of a nonprescription medicine and encouragement of ongoing use.

## General conditions of good medicines – and nonprescription medicines – regulation

The regulatory system for medicines in general – including nonprescription medicines – should be based on:

- Transparency (legislation and detailed guidelines should be publicly available and easily accessible).
- Accountability (the Regulatory Authority should operate openly, with public oversight of expenditure and operation).
- Proportionality (conditions to place products on the market should be proportionate to the risks associated with the product).
- Efficiency in the use of resources (the regulatory framework should be capable of protecting public health, without expensive over-regulation).
- Simplification (undue complexity should be avoided in the registration process), with, where appropriate, choice and flexibility.

Harmonization between countries' regulatory agencies is, on first principle, a positive development. However, there sometimes seems to be an almost instinctive process by which regulation always tends to go in the direction of imposing increasingly restrictive standards. The worst possible harmoniza-

tion scenario would be one in which the tightest legislation from different countries is used on different subjects. This would likely fail in the goals of supporting innovation, industrial development and international competitiveness and encouraging self-care – and would probably yield little benefit for the protection of human health and safety.

For the regulation of nonprescription medicines specifically, consideration should also be given to questions such as:

- **Is this regulation necessary for the nonprescription sector? Does the intended regulation really apply to nonprescription medicines given the different market dynamics of this sector?** If not, the explicit exclusion of nonprescription medicines from the scope of intended regulation should be considered. An example from China of unintended consequences of regulations intended for prescription medicines inappropriately catching nonprescription brands is shown in Box 5.
- **Have representatives of patient groups or the nonprescription medicines industry been consulted regarding the proposed regulation?** This could help avoid subsequent embarrassment through unintended consequences of inappropriately-designed legislation, and time spent later in making changes. Early and informal contacts are useful. The result of lack of consultation by government authorities and a policy reversal is illustrated by the introduction and subsequent withdrawal of price controls on nonprescription medicines in South Africa (Box 6).
- **Could the need for regulation be met by self-regulation, e.g. through the greater use of codes of practice in addition to regulation?** In the UK for example this means a greater use of self-certification procedures by industry, based on mutually agreed codes of practice. Government retains safeguards in the form of guidance documents, inspections and audit procedures, complaints procedures and the ability to remove privileges in the case of breaches. The evolution of the regulator's role from 'administrative audit' (checking every detail in application forms) to 'compliance audit' (holding the industry accountable to the rules) and moreover to 'health promoter' (enhancing individual and public health) presents an opportunity for all stakeholders.

- Has a regulatory impact analysis been conducted? Is public health and industrial development enhanced? What is the expected overall benefit to public health – is the net benefit sufficient when factoring in negative impact on public usage or on innovation or competitiveness? In other words, is the regulation 'proportionate' to its desired outcome?

### Box 5 "Schedule 24" and nonprescription brand names in China

Without prior consultation, the Chinese State Food and Drug Administration (SFDA) in March 2006 issued a Regulation for Drug Insert Sheet and Label (Schedule 24), applying to both prescription and nonprescription medicines. One important feature was that product brand names would be restricted to half the font size of the generic name (international nonproprietary name or INN) on labels, effective from June 1, 2006.

No distinction was made between prescription and nonprescription medicines in the regulation. The nonprescription medicines industry's concern was that focus on generic name rather than on trade or brand name would reduce the incentive for brand investment and development, to the detriment of patients as well as companies. This would over time hurt the development of the nonprescription pharmaceutical industry in China.

Over the following nine months a massive effort on the part of individual companies, trade associations and WSMI highlighted the importance of the brand in the nonprescription sector to the SFDA. Letters, meetings, conferences and trade and political delegations all presented the case for the likely damage to the nonprescription sector from Schedule 24.

It was never the purpose of Schedule 24 to catch the nonprescription industry but having introduced general regulation that did not separate the generic prescription sector from the nonprescription sector; it was seen as politically difficult to make this distinction after the event. A great deal of effort could have been avoided if the differences between the prescription and nonprescription sectors had been considered at the outset.

## Box 6 South African pricing regulations

Without prior consultation, in the Government Gazette of 16 January 2004 the Minister of Health of South Africa published draft regulations proposing a series of draconian changes to the free pricing and pricing structure of all medicines including nonprescription medicines, to come into effect between May and August 2004.

In response, the local industry association SMASA (Self-Medication Manufacturers' Association of South Africa) commissioned economic consultancy work and made a submission to the Pricing Committee on the proposed legislation in March 2004. SMASA requested the South African Minister of Health to exempt nonprescription medicines (medicines under 'schedule 0') from the proposed regulations. The basis for the exclusion was that, in the nonprescription sector, market-based price competition works better than price controls and creates greater choice for consumers. Further, the burden on regulators would not be repaid by any savings to consumers – market-based competition in the nonprescription medicines sector leads to profit margins that are narrow and yearly price increases generally at no more than the rate of inflation.

Based on the evidence, the South African Registrar of Medicines, on the recommendation of the Government's Pricing Committee, in July 2004 confirmed the exclusion of 'Schedule 0' (nonprescription) medicines from the new regulations.

In July 2007, SMASA commissioned a further independent study which confirmed that market forces had indeed been effective in 2005 and 2006 in restraining price increases. The ongoing exemption of schedule 0 medicines is therefore justified.

The common element in both the Chinese and South African examples – and in other similar examples – is that a great deal of effort, and no little embarrassment, could have been avoided if the differences between prescription and nonprescription medicines had been considered before the new regulations were announced.

## Regulatory impact assessments

Regulatory impact assessments (RIA) are a formal review of the anticipated impact of a regulation on the key stakeholders – on public health, improvement in public safety, and on economic impact on industry (e.g. through the cost of compliance). The objective is to show (preferably with economic data in support) that the public health gains are worth the costs to those having to comply. However, too much regulation makes little difference to public health but simply adds costs to those having to comply – often healthcare professionals and industry. Some countries such as Australia, Canada and the UK – and generally the European Union – develop RIAs, but they are not always analytically sufficiently incisive or are not taken into consideration in the subsequent legislative steps.

An example of regulation with doubtful 'proportionality' is the EU requirement for the name of a medicinal product to be expressed in Braille format on the packaging. This proposal was not in the original Commission's proposal and was introduced at a much later stage of the legislative procedure and thus did not undergo any RIA. This presents a significant design and manufacturing cost to industry. Although the objective of helping the blind and partially sighted is very worthy, in reality the number of people helped is likely to be very small. Only a minority of those affected can actually read Braille, and pharmacists or shop assistants were already used to providing the necessary assistance to them.

## The particular features of nonprescription medicines and their relevance to regulation

As detailed in Section I, the main differences between nonprescription medicines and prescription medicines are:

- 1 Nonprescription medicines are commonly chemical entities with many years of international experience in usage (some originally as prescription drugs). The confidence in a product's quality, safety and efficacy profile obtained either through many years of consumer usage or through

prescription usage in a given country or abroad can often be applied to nonprescription medicines use.

From a regulatory perspective it is therefore unnecessary to duplicate or 'reinvent the wheel' in every country when it comes to applying some regulatory requirements. There are rarely physiological differences between individuals living in developed and developing countries which justify restricting the availability of non-prescription products. The ideal regulatory framework should make the major regulatory activities required for the self-medication market to function in a manner that is as transparent, time efficient and least burdensome as possible. The major regulatory activities are:

- (New) registration/marketing authorization applications for medicinal products containing well-established active ingredients (including combinations).
  - (New) registration/marketing authorization applications for a non-prescription product containing an active ingredient previously only approved for prescription use.
  - Abridged ('line-extension') applications based on an existing, national, marketing authorization.
  - Maintenance/renewal of existing national registrations/marketing authorizations.
- 2 Nonprescription medicines' chemical entities are commonly not protected by intellectual property patents on the basic molecule. Innovation and competition between manufacturers, which benefits patients, is based upon the development of new therapeutic claims for established products and not on new chemical entities (plus the value conveyed by individual brands – see point 4). This innovation is costly, not least to small companies.

From a regulatory perspective this feature of the nonprescription medicines market points to the need for data protection and marketing exclusivity for innovation rather than patent protection. A minimum of 3 years of data protection or market exclusivity is appropriate for innovators granted approval for novel indications on existing self-care products,

and for the switch of a product from prescription to nonprescription status.

In the USA the Hatch-Waxman Act specifies a three-year data exclusivity period for submissions requiring clinical trials, which would include new indications for existing products. Similar rules are in effect in Japan. The European Union Directive 2004/27/EC specifies that where an application is made for a new indication for a well-established substance, a period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies are carried out in relation to the new indication.

- 3 Doctors can play a very important part in encouraging and supporting self-care activities. But the fundamental difference between nonprescription medicines and prescription drugs is that the former can be purchased and used without the necessary intermediary of a doctor – one is dealing directly with the consumer of the product. This places emphasis on the patient and consumer being able to make an informed choice regarding the use of a self-care product.

From a regulatory perspective, this feature of the nonprescription market indicates the need to recognize and facilitate the many ways in which product information can be provided to the consumer. This includes in particular the product labeling and advertising.

- 4 Marketplace competition and therefore consumer choice in the self-care sector is principally based on the development of brands, and the advertising of those brands by manufacturers, with manufacturers being free to develop a range of price offerings. This competition provides choice for consumers and helps keep prices down. If the consumer does not wish to pay for a particular product, there are always alternatives in the nonprescription sector. Pricing freedom is common in many markets and the fact that price increases tend to occur around the rate of inflation is testimony to the effectiveness of competition.

From a regulatory perspective the removal of price controls has a number of benefits – not least the reduction of the administrative burden for regulators. More generally the development of self-care brands should not be discouraged (see Box 5), which includes allowing the same trade name for different forms of nonprescription medicines ('umbrella brands') and for medicines moved from prescription to nonprescription status. Further, regulations protecting a brand against copying or 'passing off' (where a company misrepresents its products as being the products of another, usually the brand leader), should be properly enforced.

- 5 Self-care in general needs support in the minds of public and healthcare professionals. As illustrated in Section II, there is widespread opportunity to encourage appropriate use of self-care products, around the world to support responsible self-care.

From a regulatory perspective, public health policies should therefore explicitly recognize the importance of self-care, and public health promotion by government should encourage self-care. Opportunities to encourage wider appropriate access to self-care products should be considered, on a country-by-country basis.

## The ideal regulatory framework for nonprescription medicines

### Classification


The two-class system for classifying medicines as prescription or nonprescription is almost universal. Defining and listing criteria under which a product must be limited to prescription status, and where a product will have nonprescription status, is crucial to the two-class system since it governs legitimate public availability to medicines and information for correct use. A common philosophy underlying classification rules – in the EU and North America for example – is that all medicines are available without a prescription unless they meet the criteria making their supply subject to medical prescription.

While the two-class system is at the heart of most countries' regulatory systems, there are further sub-divisions, and the exact boundaries and terminologies vary. For example, there may be sub-classifications based on distribution availability e.g. pharmacist assist ('behind the counter'), pharmacy self-selection or general sale through any retail outlet. Or special rules may apply according to the nature of the medicine (e.g. homeopathic remedies, herbal medicines or nutritional supplements).

Despite these complications and variations in country terminology, there is usually a well-understood set of categories of medicines that cover the majority of the nonprescription sector. Proposed medicines regulations can therefore specifically exclude the nonprescription category if the target purpose of the regulation is inappropriate for nonprescription medicines.

### Registration/marketing authorization for nonprescription medicines

Classification can be treated as part of the market authorization or registration process, or as a separate process. A basic consideration when classifying and authorizing a product is the mechanism for authorization itself. While an individual product license or individual registration with a full dossier of



information might be thought of as the primary mechanism, in fact regulatory authorities use a number of other methods.

For many, if not most, nonprescription medicines, the U.S. FDA uses a Monograph system based on a review of ingredients by class (antacids, internal analgesics, etc.) rather than individual product registrations. The Monograph system, established through a process known as the 'OTC Drug Review', looks at nonprescription medicines which are 'Generally Recognized As Safe and Effective' by qualified experts, and thus do not require an individual product authorization or registration to be marketed. Instead, they can be sold by meeting the terms of the Monograph for that class of ingredients, including references to other FDA requirements, such as current Good Manufacturing Practice regulations, which cover quality requirements.

A somewhat similar approach underlies the way in which the Australian Therapeutic Goods Administration (TGA) handles registration of certain types of low-risk healthcare products including sunscreens, vitamin and mineral products, and complementary medicines. For these eligible medicines, a company may use the TGA's Electronic Lodgement Facility (ELF) where it submits only limited information about the product and a signed declaration of the company's compliance with required standards. It may then, via this self-assessment approach, proceed to market the product. The system is extremely time- and resource-efficient for industry and government, and consumers benefit from more rapid availability. As a quality assurance check, the TGA routinely audits a broadly representative sample of products that have gained entry through the ELF system.

Finally, authorities can choose to rely on the approval of another specified regulatory authority as the basis for registering a product in their own country. Many countries also accept registration in the country of origin (as evidenced by the WHO Pharmaceutical Product Certification Scheme) as sufficient for importation, especially where regulatory authority resources are limited.

## Effect of simplified approval processes for non-prescription medicines on Regulatory Authority efficiency

Since non-prescription medicines are typically based on well-established ingredients, it is reasonable for Regulatory Authorities to base their assessment of most such products purely on quality standards, rather than on all aspects of quality, safety and efficacy as required for New Chemical Entities.

In Europe, a 'bibliographic application' where appropriate scientific literature replaces the results of pre-clinical tests or clinical trials, is sufficient for well-established medicines. A simplified registration procedure – so called 'traditional-use registration' – is also made possible for certain herbal medicinal products which fulfil a number of set criteria (of which demonstration of long-standing use and experience).


In the US, the assessment target for new chemical entities is 12 months, versus no pre-marketing assessment (and thus little regulatory authority resource requirement) for monographed OTC products.

Simplified approval processes for non-prescription medicines thus enable Regulatory Authorities to free resources to focus on new prescription medicines and on other important public health initiatives (e.g., anti-counterfeiting measures).

## Prescription to nonprescription switch

As medical science and experience with newer medicines evolve, mechanisms need to be in place to allow companies to apply for the reclassification or 'switch' of ingredients from prescription to nonprescription status if they are shown to be safe and effective for direct consumer use. This is typically referred to as prescription-to-nonprescription switch, or simply "switch".

Prescription-to-nonprescription switch has received a good deal of attention in many countries, particularly where switches have occurred for new classes of medicines or for new or expanded indications not previously available on a nonprescription basis. These switches have been based on solid evidence.



The WSMI and the Association of the European Self-Medication Industry (AESGP) web sites – [www.wsmi.org](http://www.wsmi.org) and [www.aesgp.be](http://www.aesgp.be) – include comparisons of approximately 200 ingredients as to their legal classification status in 37 countries. Where available as nonprescription medicines, many of these ingredients were switched to that status over the past generation.

With the extensive and data-driven nature of the prescription-to-nonprescription switch process in those countries that have led in this trend, WSMI encourages other authorities to consider these countries' decisions and safe market experience as an element in favor of switching such suitable products to nonprescription status in their own countries. For example, in 1998 after extensive discussions with AFAMELA and others, the Mexican health authorities decided on the prescription-to-nonprescription switch of 31 ingredients. (AFAMELA is the WSMI member association in Mexico.). The international comparison of the prescription or nonprescription status of the ingredients was the main element in the decision.

One final aspect of prescription-to-nonprescription switch is the need to consider research incentives and the ability to protect confidential, company-generated data for those firms who conduct research to first initiate a switch. Recognizing that regulatory environments differ, WSMI encourages systems that include an appropriate period of data protection in order to encourage innovation in new self-medication treatments.

## **Nonprescription medicines safety considerations and pharmacovigilance**

Those countries that have led the world in switching prescription products to nonprescription status have been very thorough throughout the entire process, keeping consumer safety as the highest priority. While no product – medicine or otherwise – is completely safe, regulatory authorities in these countries have demanded applicants to submit appropriate evidence of a wide margin of safety, along with convincing evidence of efficacy, before transferring the product to nonprescription status. The safety profile has typically been established and documented through years of experience and an extensive number of uses as a prescription medicine.

Figure 3 Benefits and risks of responsible self-medication

- Incorrect self-diagnosis
- Delay in treatment of serious conditions
- Drug misuse



- Improved access to effective medicines
  - Lower costs
  - Increased efficiencies in health care system
  - Greater consumer autonomy
  - Improved consumer education
  - Reduction in self prescription
- Not to forget:
- Medical errors in Rx writing or dispensing
  - Overtreatment/ unnecessary procedures
  - Helps address undertreatment of the 'invisible undiagnosed'

The underlying philosophy which is now being more explicitly stated in some countries is of a 'proportionate approach to risk'

Where a specific ingredient is to be assessed as a nonprescription medicine, the European Commission's "Guideline on Changing the Classification for the Supply of a Medicinal Product for Human Use" provides a useful tool<sup>11</sup>.

## Consumer and patient information

Good nonprescription medicines labeling (labels and/or leaflets), specially designed for consumers, is a fundamental requirement in responsible self-medication. By definition, the information consumers need to use nonprescription medicines correctly and without professional supervision must be on the label or in the leaflet which comes with the product. For nonprescription medicines the aim is that the information on the label is presented in such a way that consumers can:

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<sup>11</sup> January 2006 version. Parts 1 and 2 scheduled to be updated.  
[http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/switchguide\\_160106.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/switchguide_160106.pdf).

- Choose an appropriate medicine on their own.
- Use the medicine safely and effectively.
- Readily find the information they need, understand it and act on it appropriately.
- Access further information if they want to know more about the medicine.

In short, labeling for nonprescription medicines should include:

- The name of the product (brand name or names).
- What the product will do – its purpose or use.
- The active ingredient(s) in the product (by established name, the name from an authoritative pharmacopeia, or international nonproprietary name (INN), for example).
- When not to take the product, including necessary relevant warnings for safe use by consumers; limits on use, if any; common side effects, if any; drug interactions, if any; or circumstances which may require a health professional's advice before taking the medicine.
- Directions on how to use the medicine, including how long to continue using it.
- Non-medicinal components of the product (excipients).
- The name and location of the manufacturer, distributor, or packager.
- Other necessary information, such as a telephone 'hot line'; special storage instructions, if any; a batch or lot number; an expiration date if the product's stability deteriorates over time; or references to special packaging (such as child-resistant packaging), if any.

All this information should be provided in a language that consumers really understand, avoiding medical or scientific terms. However, the rules for labeling should not seek to be over-prescriptive as this can work against the primary objective of consumers being able to choose and use a medicine effectively on their own.

## Advertising of nonprescription medicines

In contrast to labeling, advertising – as a lower involvement, less targeted communication medium – is ill-suited to carrying detailed information. Recognizing these limitations, advertising must focus on what it can do: attract the viewer, listener, or reader's attention and communicate the availability of a product. With this background in mind, WSMI believes that government policies which regulate advertising should, first of all, rest on two basic standards:

- Claims must be truthful: objective claims made in advertisements should be supported by adequate substantiation.
- Advertising should not be misleading: this may seem the same as saying an advertisement must be truthful, but in fact the focus is different. The US Federal Trade Commission approaches this aspect from the 'deception' perspective – deception being material representations, omissions, or practices likely to mislead consumers acting reasonably under the circumstances. Japanese authorities approach the concept through a prohibition on implicit or exaggerated statements regarding indications or effects of drugs.

A variety of mechanisms – both governmental and self-regulatory – can be used by governments to ensure that nonprescription drug advertisements are truthful and non-misleading. Where they can be applied effectively, WSMI strongly favors self-regulatory or co-regulatory methods and government post-publication enforcement (i.e., taking action against violations rather than governments pre-clearing or pre-vetting advertisements). Where adequate mechanisms to enforce such systems are not present, WSMI encourages their adoption, and is available for advice on their creation.

The United Kingdom, the Netherlands, Australia, and Canada are examples of self-regulatory or co-regulatory systems (i.e., a system where an industry or self-regulatory body acts on behalf of the government in pre-clearing, enforcing or controlling advertising standards). Argentina, Mexico, Japan, Germany, and the U.S. are examples of post-publication control, including both governmental and self-regulatory components. In the latter three countries, governments and other parties have ample enforcement tools against infringing advertisements.

In contrast to self-regulatory approaches (pre-clearance or post-publication control) and post-publication measures by government, pre-clearance by government is likely to be more costly and more prone to delays. Experiences in Australia and Canada with increased reliance on co-regulatory mechanisms serve as an example of a shift from government pre-clearance to self-regulation.

Regardless of the system or systems chosen, WSMI requires its member associations either to introduce their own Codes of Advertising Practice or, where such codes already exist, to periodically examine them as to their continued appropriateness. WSMI does not believe that a single code applicable to all parts of the world would be appropriate, given the wide variety of advertising control systems in place and the need to ensure that national codes reflect cultural diversity in relation to healthcare generally and the use of medicines specifically.

## **Nonprescription medicines' trademarks and brands**

The importance of branding to the nonprescription medicines sector has been described above, and the danger of catching the nonprescription sector by regulations concerning brands was illustrated in Box 5. Beyond basic checks on similarities between new and established products, there is no case for regulating brand names.

Umbrella branding helps patients to identify trusted products, and is therefore of particular importance in the development of a well-defined nonprescription medicines sector. The use of umbrella trade names is acceptable provided the products are appropriately labeled and sufficient consumer information is made available. The use of the same brand is also highly appropriate in the area of healthcare products as long as the products are identified by simple 'product descriptors', e.g. Brand Name<sup>®</sup> hayfever, Brand Name<sup>®</sup> cough night, Brand Name<sup>®</sup> cough day, Brand Name<sup>®</sup> anti-fungal cream.

## Pricing of nonprescription medicines


The pricing of nonprescription medicines, or at least those which are not reimbursed by national social security or health insurance coverage programs, is not subject to price controls in most countries around the world. The European Commission has stated on several occasions that the positive experience with free pricing for manufacturers of nonprescription medicines should be taken into account, and has therefore recommended to all European Union Member States that they remove price controls for non-reimbursed medicines. Given the high level of competition among nonprescription medicine manufacturers, consumers have been well-served through a free market in which manufacturers set prices based on supply and demand. Mexico can be taken as an example of this, where from September 2005 to August 2006 prices of non-prescription increased 4.89%, close to the increase in the General Index of Prices (4%).

While recognizing that many governments have some form of price control or cost-containment measures in place for reimbursed medicines (be they prescription or nonprescription), WSMI urges governments to allow manufacturers to set their own prices for nonprescription medicines which are not reimbursed based on market conditions.

## Visibility and the retail environment

With practices of the pharmaceutical industry, community pharmacists and others having evolved over many years, retail distribution patterns for nonprescription medicines vary significantly from country to country. In most instances, such distribution patterns have been translated into national legislation. These patterns range from limiting the sale of all nonprescription medicines solely to pharmacies or drugstores, to allowing all nonprescription medicines to be sold in any retail outlet with self-selection off store shelves by consumers. Where pharmacists are few, some countries have developed specialized non-pharmacy outlets, such as drug seller shops and traditional Chinese medicine shops in Asia.

Countries that allow consumers to self-select nonprescription medicines directly from store shelves include the United States, Finland, Norway, and Sweden. Canada, Mexico, Australia, Argentina, Germany, Hong Kong, Malay-



sia, the Netherlands, Singapore, Switzerland and the United Kingdom allow self-selection of the majority of products with some being available only directly from a pharmacist. The US is most notable for the extent in which open self-selection of nonprescription products occurs in retail outlets.

A study undertaken in the United Kingdom showed that consumers welcome the opportunity to self-select approved nonprescription medicines, as opposed to the product being handed to them by the pharmacist. Three out of four British consumers in the study felt that re-configured pharmacies with easier access to nonprescription medicines was a good idea, half because it would save their own time or that of their doctor, and the remainder because it offered greater freedom of choice.


A number of countries and individual pharmacies have introduced changes in recent years to either increase the visibility of nonprescription medicines, or access to them. Giving consumers more control and power over their own health care and current economic trends have been among the forces behind these changes. Good presentation and visibility of nonprescription medicines not only informs consumers of the range of products available but can also encourage them to seek information and advice from pharmacists or other health professionals.

While WSMI believes examining ways to improve the visibility of nonprescription medicines and access to them is in the public interest, WSMI also recognizes that an attempt to harmonize retail distribution patterns among countries would not be practical.

## Conclusion of Section III

In summary, key points for successful nonprescription market development are:

- Use of simplified or abridged applications (defined as not requiring clinical trial data) for all products containing established nonprescription ingredients.
- Clearly defined processes for switching products from prescription to nonprescription status, including supporting incentives for submitting switch applications.
- Differentiation between prescription and nonprescription product labeling.
- The use of umbrella branding, e.g. the use of indications in product names.
- Allowing companies to set their own prices on the basis that the consumer has a choice.
- Freedom to communicate to patients and consumers by advertising. Advertising self-control and post-publication control systems have been found to work more efficiently than state-controlled and independent pre-publication control systems.
- Visibility and appropriate presentation of nonprescription medicines on shelves.



Addressing existing  
over-regulation

Section IV

In developed countries there is a widespread and growing concern that the current regulatory burden is a significant impediment to innovation and industrial development. All too often have regulations been introduced with a worthwhile purpose in mind but ended up having unintended and sometimes damaging consequences that could have been avoided. This applies particularly to the blanket application of medicines regulation which – although appropriate for prescription medicines – negatively affects the nonprescription medicines sector.

It has also been observed that there tends to be a diminishing return on regulation, with too much additional regulation yielding rather limited additional benefit. Regulators have a natural tendency to creating new regulations, but ultimately the costs are borne by the patient or consumer. Today, dealing with bureaucracy consumes a large amount of time and resources in all countries. The World Bank estimates that, on average, from 5% (in Europe & Central Asia) to 10% (in Latin America) of senior management time is spent solely on dealing with the requirements of government regulation<sup>12</sup>. In a further study the World Bank found that the administrative cost of complying with regulations is three times higher for businesses in poor countries than for those in rich ones<sup>13</sup>.

The situation is aggravated by the fact that once regulation has been introduced, interpretation in use can lead to over-intellectualization or regulatory 'creep' (where rules are unclear and become more complicated in their elaboration).

Of course it must be acknowledged that regulators have to achieve a tricky balance – rules and standards to protect consumers must be sufficient but not so costly as to discourage innovation and halt progress. However, the fundamental issue raised in this section is that there tend to be few formal processes by which newly introduced or established regulations are subsequently reviewed. Often there is no discussion between stakeholders of potentially unnecessary established regulation, and few countries have formal systems of post-regulatory implementation review. This automatically leads to too little rationalization or simplification of redundant or unnecessary regulation.

## Tackling unnecessary regulation

Recognizing the problem of over-regulation, the European Commission in October 2005 launched its overall 'Better Regulation' initiative. This led in January 2007 to a European Commission 'Action Programme for Reducing Administrative Burdens in the European Union' in 13 priority areas, including pharmaceuticals. The Commission, with the help of the EU member states, is measuring administrative burdens related to legislation in order to draw up appropriate reduction proposals. Member states should measure and reduce the administration burdens of purely national legislation. The program commenced in May 2007 and aims to provide an assessment of administrative costs by November 2008. This will contribute to a proposed 25% reduction target of administrative burdens on businesses by 2012.

In addition, the European Commission has launched a project plan for a 'Transatlantic Administrative Simplification Workshop' which will aim at identifying opportunities for administrative simplification through EU-US cooperation. The conditions are that these issues for simplification do not entail changes in either the EU or US legislation and do not reduce public health protection. Agreement on the issues to be addressed should be reached by end 2007 and by June 2008, a roadmap for implementation should be made public jointly by the European Commission and US FDA.

On the legislative level, the European Commission is also proposing simplifications at EU level in the areas of pharmacovigilance and variations to a marketing authorization. Moreover, several individual countries have acted on the call for better regulation by looking at their national administrative burdens. The most widely reported action was the BROMI initiative in the United Kingdom (see Box 7), but other countries had already adopted pragmatic requirements for the handling of variation such as the simple 'do-and-tell' principle for minor variations in Germany and Austria.

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<sup>12</sup> World Bank Group: Enterprise Surveys: Bureaucracy.

<sup>13</sup> International Finance Corporation and World Bank, *Doing Business in 2005: Removing Obstacles to Growth*, Oxford University Press, September 2005; and World Bank, *World Development Report 2005: A Better Investment Climate for Everyone*, Oxford University Press, September 2004.

## Box 7 Better Regulation of OTC Medicines Initiative (BROMI)

BROMI was established by the British government in 2005 to reduce red tape surrounding regulation of OTC (nonprescription) medicines. Led by the Medicines and Healthcare products Regulatory Agency (MHRA), BROMI includes representatives of the UK OTC trade association PAGB, the National Pharmacy Association, the Department of Health and the Cabinet Office.

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BROMI has initially identified some simple but useful ways to reduce red tape.

- 1 Changes to product packaging. BROMI has agreed to the proposal of self-certification by the manufacturer of non-statutory information (such as extra information for patients) underpinned by a Code of Practice.
- 2 Variations to registrations/marketing authorizations. BROMI has agreed to streamline the processing of national variation applications, particularly simple changes, such as a change of address. Self-certification by a company will replace a lengthy process of approval by the MHRA. Some 6,000 variations each year would be simplified by this measure.
- 3 Self-certification of minor changes to nonprescription medicines' labeling and patient information leaflets. A list of 25 changes to labels and leaflets was deemed appropriate for self-certification by companies. "The changes have been selected for self-certification because of the low overall risk posed in terms of public health when other safeguards are in place", said BROMI, noting the changes accounted for more than a third of applications received by the MHRA for this type of work.

As a result of these changes, the authorities gain in having a reduced workload, transferring responsibility to the marketing authorization holder, based on a defined and agreed 'Code of Practice'. The authorities do not lose control or enforcement ability, however. Instead of approving every change, the MHRA will operate a quality audit system based on random and targeted sampling of self-certified changes, plus a new transparent complaints procedure.

In the United Kingdom an exercise aimed at measuring administrative burdens (excluding normal business costs) carried out in 2005-2006 identified 90 Department of Health regulations as suitable for administrative simplification. The regulations and standards that were considered (by the UK government itself) to be most burdensome included those for medicines registration/marketing authorization and the granting of product licences. The potential savings run to many millions of pounds.

Such initiatives are not confined to Europe – for example, Canada is developing a regulations 'renewal project' that is risk-based and has a reduction target of 20% of the current paper burden.

## Codes of practice

As mentioned in Box 6, the use of mutually agreed and transparent 'codes of practice' present an opportunity to reduce the administrative workload of governments and industry. Codes of practice for self-regulation have been used successfully for many years in areas such as approval of advertising and labels.

No significant controls relating to public safety are lost – firstly, the areas involved with self-regulation/self certification can be clearly defined. Operating practices are then agreed in the code of practice. The authorities can operate a sampling/audit approach and complaints procedure, and retain penalties for any transgressions. Overall the gain is to reduce administrative burdens all round, which also helps free the authorities to focus on higher priority areas of public health.

## Conclusion of Section IV

In developed countries there is a widespread and growing concern that the current regulatory burden is a significant impediment to innovation, industrial development and international competitiveness. However, the European Commission and a number of European countries are starting to review current, established, nonprescription medicines legislation with a view to reducing the regulatory burden on industry – and on themselves. The opportunity for self-regulation by industry, with appropriate checks and balances by government, is receiving renewed support. Such ideas for better regulation can also be useful to emerging and developing countries.



## The World Self-Medication Industry

W.S.M.I

C.I.B. • Immeuble A • "Keynes"  
13, Chemin du Levant  
01210 Ferney-Voltaire • France

Tel: + 33 (0) 4 50 28 47 28

Fax: + 33 (0) 4 50 28 40 24

E-mail: [admin@wsmi.org](mailto:admin@wsmi.org)

[www.wsmi.org](http://www.wsmi.org)

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