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# A GLOBAL VIEW OF SELF-CARE WITHIN HEALTH POLICY

## A blueprint for responsible self-medication

*Mr Anthony Jamison, Chairman, World Self-Medication Industry (WSMI) and President, Roche Consumer Health Worldwide*

*Dr Brundtland*

*Dr Bangemann*

*Dr Milton*

*Distinguished guests*

*Friends and colleagues,*

*It gives me great pleasure to extend a very warm welcome to you all on behalf of WSMI, the World Self-Medication Industry, and our European association, AESGP. We are indeed fortunate to be holding our meeting in this wonderful city of Berlin.*

*In June 1963, when President Kennedy delivered his now-famous speech in the shadow of the Berlin Wall, his theme was personal freedom. He identified with the quest for freedom for which the people of Berlin had become renowned. Although at a different level, this desire among people is now manifest in the healthcare sector. People want to have the freedom to make informed healthcare choices – in this information age they want to be the leader of their own healthcare team.*

The last joint assembly of WSMI and AESGP was held in Rome in 1989, the same year that the Berlin wall was finally dismantled.

In the 10 years since then, we have seen a strong development of our industry and its associations, and we will see much evidence of this during our meeting.

These assemblies are important mainly as a forum for the exchange of ideas and opinions between the OTC industry, government agencies, regulatory bodies and healthcare professionals. However, they are also important in identifying opportunities for synergy and progress.

The Brandenburg gate is a great symbol of unity for the German people. Let it also symbolise our unity of purpose during this conference, as we explore what our role in healthcare policy should be, on the eve of the new millennium. Based upon a discussion of the social and economic questions later this morning, this afternoon's session will look at widening the boundaries of self-medication. We will see that self-care can become an increasingly important element of healthcare policy, and that there are compelling reasons for creating a more harmonised world market environment for OTCs.

Tomorrow, during the panel discussion, these developments will be put into the perspective of a more informed population, with a desire for additional knowledge about healthcare options and treatments. This desire is being fed by an explosion of information, driven mainly by the Internet. This, in turn, is generating an accelerating pace of change, including the development of e-commerce, which should give us cause to reconsider current thinking and policies.

On Saturday, we are holding a Regulators' Forum which will enable representatives of the regulatory authorities to discuss the messages from our meeting, hopefully with a positive and productive outcome for the future regulatory environment.

Let me explain where we now stand in the development of responsible self-medication and point out where important advances have been made, and where further progress is needed. I propose to do this in the context of the eight guiding principles we advocate as the basis for

individuals to realise their full potential in self-care and responsible self-medication.

**A philosophy of individual participation and empowerment is vital in responsible self-medication.**

The first principle is that a philosophy of individual participation and empowerment is vital in responsible self-medication; these themes are echoed in statements by WHO, key regulators and many others.

People are demanding greater independence and responsibility in their healthcare. They are more assertive, more questioning and more concerned about their options. They want to exercise greater judgement in informed and responsible self-medication, and our federation will continue to lobby for the removal of obstacles which prevent individuals from realising their full potential in terms of self-care.

**The social and economic value of self-medication must be recognised.**

Our second principle is that the social and economic value of self-medication must be recognised.

The economic value is clear. By encouraging additional responsible self-medication, governments are addressing the problem of spiralling healthcare costs. The social value is realised when the public resources that were treating minor ailments are re-directed towards more serious illnesses with a larger impact on individuals and on overall public health, and there is growing support for self-medication from many social security institutions around the world.

**The first step in developing a regulatory framework is to draw a clear distinction between prescription and non-prescription medicines.**

The third principle concerns the basic regulatory environment.

The first step in developing a regulatory framework is to draw a clear distinction between prescription and non-prescription medicines. Fortunately, the approaches used in the more developed regulatory systems, such as US, EU and Japan, are similar. The most common approach, which is strongly supported by our industry, is to define the criteria for prescription-only medicines and then to classify the remainder as non-prescription. This approach works very well but requires an adequate enforcement mechanism to be effective. Such an enforcement mechanism is missing in a large number of countries, and we

need to work together to overcome the problems and dangers to public health created by wrongful self-medication using products classified as prescription-only, especially as these medicines frequently come with no consumer information indicating their correct use.

Classification as prescription-only or OTC can be part of the market authorisation or registration process. An alternative or complementary method of classification uses category or ingredient monographs, combined with adequate quality controls. However, it is difficult to understand the lengthy registration process in many countries, even for products with well-established ingredients. We need much faster access to markets for our products. We propose that more countries recognise a US or EU registration as sufficient for their purposes. Alternatively, perhaps the US system, with monographs for well-established ingredients alleviating the need for individual market authorisations, could be adopted in a wider, even global context. Within EU, efforts must be intensified to harmonise the regulatory environment for OTC medicines - free circulation of OTCs is long overdue. Our EU proposals are clearly outlined in the AESGP publication "Deregulation 2001" which is contained in your conference folders.

**A mechanism is required to allow the reclassification of ingredients and indications from prescription to non-prescription status.**

Our fourth principle concerns OTC switching. With a distinction between prescription and non-prescription medicines in place, and as medical science advances and experience with newer medicines evolves, there needs to be a mechanism to allow the reclassification of ingredients and indications from prescription to non-prescription status.

Within our industry, we greatly appreciate the actions of many countries in switching products and indications from prescription to OTC. We also appreciate the recent adoption of switch guidelines within the EU. In fact, significant progress has been made since we met in Rome 10 years ago. For example, since then, 36 ingredients have been switched in the US, and 41 in the UK. In 1997, independent research in Latin America identified opportunities for the re-classification of medicines, and this concluded that two-thirds of the prescription-only medicines which were being purchased without a prescription, could have been moved into the prescription-free category. This would have the advantage not only of recognising the self-medication reality for these products but also of enabling label texts to be written for the consumer. Additionally, the task of regulating the remaining prescription-only medicines would thus be significantly reduced.

It was on a similar basis, following an international comparison of the status of the ingredients in other markets, that last year the Mexican Health Ministry switched 39 ingredients from prescription-only to OTC.

There are many countries, like Mexico prior to these switches, where the present classification of medicines needs to be reviewed in the light of new information and experience. Even within EU, several countries could learn from the switching experiences in other markets, including other neighbouring member states.

WHO is currently developing guidelines for both classification and switching of medicines, and has given us the opportunity to review and discuss the draft text. This is a document that has the potential to become a very useful basis for communicating the basic requirements for an appropriate system to authorities around the world – in particular in developing countries.

Our fifth and sixth principles concern consumer information.

**The OTC industry must provide an effective consumer information system in which appropriate product information is available in a timely manner.**

**Different forms of communication fulfil distinct and important roles.**

Effective communication with the consumer is a fundamental to our industry and much of our expertise is in this area.

While we are delighted that there is now wide recognition that different forms of communication have distinct roles, this point is still not universally accepted.

One of the most effective ways for government to encourage the ever-increasing trend of consumers towards greater independence in healthcare is to allow the OTC industry to provide an appropriate and effective consumer information system whereby product information is communicated in an appropriate manner.

Firstly, this requires the means to satisfy the individual's wish to be informed about the indications suitable for self-medication and the products available. The only cost-effective way to communicate this to a wide audience is through mass-media advertising.

To be effective, media advertising must be simple: to be efficient, it must have memorability. It is thus entirely inappropriate to include in media advertising the detailed product information the consumer nevertheless requires. To do so would render the advertising ineffective, especially when considered in the context of competing messages from manufacturers in other categories. Instead, we advocate including in all media advertising the instruction to read the label and, where appropriate, to seek the advice of a health professional.

Secondly, an appropriate communication system requires the means to satisfy the consumer's wish for detailed production information. The right place for this is the product labelling; either on the outer packaging (where the information is important prior to purchase) or on the package insert or leaflet. It is also important that

this information, which includes warnings, contra-indications and side effects as well as appropriate dosage instructions, is written in language which is in line with people's understanding and expectations.

Over recent years, it has been encouraging to see more and more countries move from a primarily government-led control system for OTC advertising to a self-regulatory control system which is supervised by government institutions. We strongly advocate the self-regulatory approach: it improves the quality of the control mechanism while at the same time reducing a costly administrative burden for government.

Finally, on the subject of consumer communication, I would like to mention brand names. Brand names are the principal assets in our business, and they provide consumers with important reassurances concerning quality and reliability. By line-extending an established brand, effective competition is enabled through a more rapid penetration of the market and this can be done without risk of confusion. This is also very relevant for products which switch from prescription to OTC. Forcing companies to invent a new brand name confuses both health professionals and consumers alike. Nevertheless, we are experiencing restrictions in quite a few countries around the world, including several in Europe and we hope that this conference will contribute to a re-think concerning these restrictions.

**Consumers' best interests are served by a free market in which manufacturers determine their own prices without government controls.**

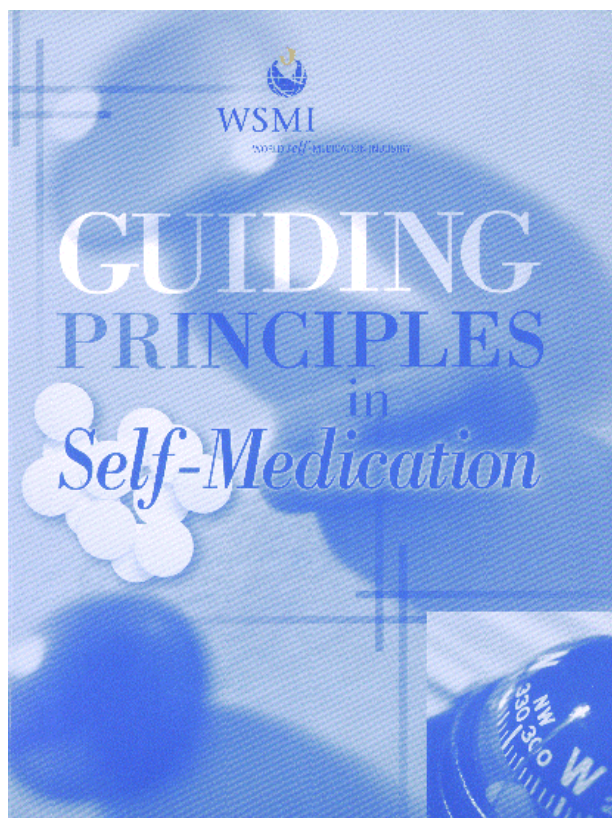
Given the highly competitive environment for non-prescription medicines, our seventh principle advocates that consumers' best interests are served by a free market in which manufacturers determine their own prices without government controls. This is supported by the fact that, where such freedom exists, price increases of OTCs have mostly been in line with, or lower than, inflation.

**Consumers' best interests are served by increased visibility for OTC medicines.**

Our eighth and last guiding principle concerns visibility and accessibility. Our industry does not advocate changes to existing distribution systems, even though these vary considerably around the world.

Instead, we advocate better visibility for our non-prescription medicines in the existing outlets on the basis that this provides consumers with more information on the range of products available and enables consumers to read the outer packaging. It is interesting to note that experiences in self-selection in pharmacies in Sweden and Finland stimulated a dialogue between consumers and

pharmacists, resulting in improved knowledge regarding self-medication products and their appropriate use.



To enable you all to gain a deeper understanding, and stimulate discussion on what I have outlined, we have published a booklet entitled "Guiding Principles in Self-Medication" We believe that this publication is an important contribution to the debate on how responsible self-medication can help promote public health goals. It is available in the foyer and I hope you will all take a copy home with you after our Assembly.

Of course, for our Federation, the regulatory agenda is vital, but is certainly not our only activity. We have increased our efforts in partnership building with all major healthcare stakeholders; not only with regulatory authorities but also with health professionals, notably with pharmacists and doctors.

Our relationship with the WHO is particularly important to us and we are delighted and honoured that Dr Brundtland is participating in our conference. We wish to build further on our strong relationship with WHO and be recognised as an NGO which can add value and make a difference to the outcome of WHO activities and programmes. Our WSMI Director General, Dr Reinstein, has been appointed a member of WHO's Policy Advisory Committee for the Tobacco Free Initiative. As you will be aware, this was one of the two top-level projects introduced by Dr Brundtland when she took office last year. This is the first time one of our industry representatives

has full membership of a WHO committee (rather than observer status) and heralds the new spirit of the partnership approach WHO wishes to develop with its key NGOs.

Later today, on behalf of WSMI, I will be signing a charter of collaboration with Mr Peter Kielgast, the President of the International Pharmacists Federation (FIP), and during this morning's session you will have the opportunity to hear the Chairman of the World Medical Association, Dr Anders Milton. The positive and growing partnership with both these federations has resulted in a better understanding of the need to actively support responsible self-medication, for example, through improved presentation and visibility of OTC medicines in pharmacies, and through advice from doctors on the possibilities offered by new self-medication products.

### Conclusion

Ladies and Gentlemen, together with regulatory authorities, doctors, pharmacists and consumer organisations, we must work in harmony to further define the parameters for responsible self-medication. Human nature is such that we are frequently prevented from seeing that what is accepted as today's unorthodoxy often becomes tomorrow's convention. We must all be prepared to adapt to meet the rapid changes in people's expectations heralded by the new information age. In this way, we can give individuals the freedom they seek to realise their full potential in terms of self-medication. Such an era promises benefits to our industry, to government and to health professionals and, most important of all, to the consumers we all serve, and for whom the whole system exists.

### Introduction Dr Bangemann

My colleagues need no reminding that this is the last time you address our Assembly as a representative of the European Commission. This is the end of an era in Brussels which has been of the utmost importance for our industry, not only in Europe but also worldwide. Also, it was under your responsibility Dr Bangemann that key European Directives were adopted on pharmaceutical advertising, on classification of medicines and on labelling. Furthermore, the creation of the new European marketing authorisation system with the new European Medicines Evaluation Agency as its centrepiece would not have been possible without your commitment. Thanks to your activities, Dr Bangemann, we have today a strong, stable framework for our industry on which we can build for the future. We greatly appreciate your joining us today.



