

Reports of NGO observers to COP 2016

Contact Details

- 1) Name of organization  
World Self-Medication Industry, WSMI
- 2) Mailing Address  
Rue de Cossonay 5  
CH-1023 Crissier,  
Switzerland
- 3) Contact person responsible for the report  
First Name, Family name  
Dr Gerald Dziekan, Director-General
- 4) Telephone  
Please enter the full number (example: +41 123 456 7890)  
+41(0)794600725
- 5) Email:  
gdziekan@wsmi.org
- 6) website of Organization  
<http://www.wsmi.org>
- 7) Email:  
admin@wsmi.org

General Information

- 1) Please indicate if your organization would like to retain it's status as observer to the Conference of the Parties  
Yes
- 2) Does your organizations mission statement specifically refer to tobacco control?  
No
- 3) If yes, please specify:

4) Does your organization have regional branches to enhance activities in different regions or groups of countries?

Yes

5) If yes, please provide details:

The world Self-Medication Industry is a federation of regional and national associations, and manufacturers and distributors of nonprescription medicines, including Nicotine Replacement Therapy on all continents. WSMI has 4 regional member associations: (a) Association of the European Self-Medication Industry (AESGP) with 25 national association members, (b) Asia-Pacific Self-Medication Industry (APSMI) with 5 national association members, (c) Middle East Self-Medication Industry (MESMI) with 6 national association members, and (d) Industria Latinoamericana de Automedicacion Responsable (ILAR) with 6 national association members. In addition WSMI has 19 national association members and 18 company members.

6) Does your organization regularly convene meetings or conferences for its membership?

Yes

7) If yes, is tobacco control covered in these meetings?

Yes

8) If yes, please provide details:

WSMI organizes three international conferences per year (in Europe, USA and alternating Asia Pacific and Latin America). In addition WSMI regularly participates in national conferences and scientific meetings organized by its national member associations. At all such conferences and meetings the safety and value of over-the-counter medicines, including the value of Nicotine Replacement Therapy are regular topics and feature in presentations and podium discussions. Meetings are usually attended by national health administrators from Ministries of Health, medicines regulators, healthcare and public health professionals, academia and industry. WSMI and its members regularly make presentations mentioning FCTC developments in general, and tobacco dependence reduction in particular in many countries around the world. E.g. in October 2015 in meetings in Mexico and Colombia, smoking cessation, the safety and availability of NRT and its public health value have been the subject of several presentations. As a general point referenced in many of these presentations, WSMI's official collaboration plan with WHO encompasses work on the importance of disease prevention in reducing chronic disease, and health promotion, both areas linking strongly to disease risk reduction through smoking cessation.

Participation in WHO FCTC meetings and contributions to other tobacco control related events

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1) Please indicate the meetings organized by the Convention Secretariat at which your organization was represented (sessions of the Conference of the Parties, meetings of intersessional groups, NGO meetings, etc.):

Title and date

- Regional Meeting on Implementation of the WHO FCTC (18-21 March 2014, Budapest, Hungary)
- Sixth Session of the Conference of the Parties to the WHO FCTC, (13-18 October 2014, Moscow, Russia). WSMI has attended all six sessions of the CoP in the past.
- Informal consultative meeting of NGOs accredited as observers to the Conference of the Parties to the WHO Framework Convention on Tobacco Control (23 May 2013, Geneva, Switzerland)
- Regional Meeting on Implementation of the WHO FCTC (3-6 September 2013, Geneva, Switzerland)

2) Please list any other meetings or conferences with a focus on tobacco control attended by your organization:

Title and date

- UK Nicotine and Smoking Cessation Conference (UKNSCC), 11-12

June 2015; Johnson & Johnson, a WSMI member company was a key sponsor (and held a symposium), at the conference which remains the largest annually held smoking cessation conference

in the world. It has been a supporter and sponsor of this conference every year that it has been held.

- Johnson & Johnson routinely has delegates attending the global and European SRNT meetings, frequently presents scientific posters at such events and on occasion has sponsored the conferences or symposiums at them.
- Johnson & Johnson frequently attends and/or sponsors national tobacco control and smoking cessation meetings or conferences, for example the Annual Ottawa Conference on Smoking Cessation or previous Russian Health or Tobacco Forum meetings.

Your organization's activities to support implementation of the WHO FCTC:

Has your organization conducted any work/activity in relation to the following provisions of the WHO FCTC?

1) Article 5 (General obligations)?

Yes

2) If yes, please provide details:

WSMI and its members support the "guiding principles" of the FCTC as well as the "general obligations", in particular article 5.3 and are independent from the tobacco industry. All

its members are committed to the improvement of global health in line with WSMI's mission "to foster a favorable environment

for the wider availability and practice of self-care through the responsible use of safe and effective consumer healthcare

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products". WSMI members are dedicated to research, manufacture and distribute nonprescription medicines. They do not sell or supply any tobacco-related products or services to the tobacco industry.  
WSMI recently conducted a survey among its members assessing any link, collaboration or cooperation between our members and the tobacco industry and its subsidiaries. I am pleased to report, that none of our members has reported any link or collaboration with the tobacco industry.  
Furthermore, as you know FCTC CoP6 in October 2014 reached an initial decision on Electronic Nicotine Delivery Systems (ENDS) calling for their regulation and including medicinal licensing as one possible framework under which this can be achieved. This opens the future possibility of ENDS manufacturers seeking membership in WSMI, including those which are partly or fully owned by the tobacco industry or which may be linked to the tobacco industry.  
As a response, the WSMI Board has agreed to review its statutes, and to include a paragraph which allows refusing membership in WSMI of ENDS producers linked with the tobacco industry. This demonstrates WSMI's commitment to public health and to supporting initiatives to control tobacco dependencies.

3) Article 6 (Price and tax measures to reduce demand for tobacco)?  
Yes

4) If yes, please provide details:  
WSMI members have routinely called for taxation to be used as a national tobacco control measure around the world, acknowledging it is a critical element of a holistic tobacco control strategy. In the past, WSMI members have worked with other organizations to generate the data to support the case for tobacco tax increases (e.g. by supplying data on NRT uptake associated to effective tobacco taxation measures) and have also coordinated smoking cessation campaigns to occur at the time tobacco tax increases are implemented, thus supporting quitting associated to taxation.

5) Article 8 (Protection from exposure to tobacco smoke)?  
Yes

6) If yes, please provide details:  
WSMI and its members are keen to make their contribution to a smoke-free world.  
Generally speaking, nonprescription smoking cessation therapy provides an alternative to smoking to those who want to quit, by allowing to manage the nicotine level in the body without needing to smoke. This contributes to limiting the exposure to second-hand smoke, as soon as they decide to stop smoking using an NRT product.  
"The Global Smoke-free worksite Challenge" launched as a "Clinton Global Initiative Commitment to Action" aims at furthering the development of smoke free worksite policies and smoke free legislation around the world. It is a collaboration

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between Johnson & Johnson (a WSMI member), the American Cancer Society, the Global Business Coalition on Health, the Mayo Clinic, the Campaign for Tobacco-Free Kids, and the United States Department of Health & Human Services.

7) Article 9 (Regulation of the contents of tobacco product) and/or Article 10 (Regulation of tobacco product disclosures)?  
No

8) If yes, please provide details:

9) Article 11 (Packaging and labelling of tobacco products)?  
Yes

10) If yes, please provide details:  
WSMI members have routinely engaged in the tobacco control debate, including on areas such as plain or standardised packaging as well as the use of pack warnings, notably calling for the use of a combination of “why-to-quit messages” and “how-to-quit messages” in order to support demand for quitting as well as quitting advice.

11) Article 12 (Education, communication, training and public awareness)?  
Yes

12) If yes, please provide details:  
WSMI routinely disseminates information (reports, publications, meetings etc) on the FCTC and the CoP to its members around the world. This is done through regular WSMI conferences and meetings and through the WSMI website, by email or by post as appropriate. It is our experience that these communications are further widely circulated by our members within their countries. This includes information on tobacco control and tobacco cessation measures to a wide range of stakeholders, such as officials from national Ministries of Health, regulatory officials, health professionals, academia and industry.  
As an example, WSMI regularly provides links to the FCTC Convention News to its members as well as the general public through the WSMI website.  
In addition WSMI works closely at the global level with representative bodies of the healthcare professionals, such as the World Medical Association (WMA), the International Pharmaceutical Federation (FIP) and the International Council of Nurses (ICN), on a range of subjects including the management of tobacco dependence. This helps propagate important messages to key players in health delivery. Johnson & Johnson was a founding member of a multi-stakeholder initiative named “The Global Dialogue on Effective Stop Smoking Campaigns”. Whilst the initiative has now concluded the resources developed (notably the Campaign Toolkit) remain available and accessible to all.

13) Article 13 (Tobacco advertising, promotion and sponsorship)?  
No

14) If yes, please provide details:

15) Article 14 (Demand reduction measures concerning tobacco dependence and cessation)?  
Yes

16) If yes, please provide details:  
FCTC articles 6-8 and 11-13 provide the foundation and context to our principal area of activity that is described in Article

14, the development of demand reduction measures concerning tobacco dependence and cessation. While our specific focus of activity as described below is on facilitating accessibility and availability of pharmaceutical products for the reduction of tobacco dependence under article 14, the broader positive environment of tobacco control is of substantial importance and is also emphasized in our work. Availability of proven safe and effective aids to reduce tobacco consumption is an important factor in increasing the number of smokers who successfully quit smoking and thus leading to the reduction of smoking prevalence. Our members are the principal source of medicines, especially of NRT, and have developed a range of presentation forms to facilitate usage, including gums, patches, inhalers, tablets, lozenges and sprays. As a generic substance NRT is available from a range of branded and generic suppliers. Companies develop brands to achieve consumer recognition and loyalty. Overall, competition between branded NRT and generics helps driving widespread availability and encourages price competition. WSMI has supported the inclusion of nonprescription nicotine replacement therapy (NRT) on the WHO Model List of Essential Medicines. Inclusion of NRT is intended to help motivate countries to discharge their duty under Article 14 and implement measures for the management of tobacco dependence. However, the simple existence of medicine is not enough to guarantee access or availability and our member companies have worked with regulatory authorities to stimulate a favorable environment for tobacco control and with patients and healthcare professionals in providing the necessary resources and support, at the national, regional and global levels. They also work to ensure registration of medicines within countries. NRT is now widely available. Smoking cessation is of course possible without pharmacological assistance, but the evidence clearly demonstrates that the use of NRT significantly increases quit rates. WSMI provides advocacy and support for promoting optimum access and availability of nicotine replacement therapy (NRT) in all countries. WSMI members also recognize the importance of partnering with civil society and public health officials worldwide to help implement the FCTC. Working within these partnerships, our

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members are able to bring significant infrastructure and resources to tobacco control efforts at the local, national and global levels.

Worth highlighting is a campaign in the UK that has been coordinated by our UK member association, the Proprietary Association of Great Britain. This campaign involved all NRT companies and included commissioning and launching in June 2015 an independent report titled "Will Smoking Meet its Match?", and holding a media and a multi-stakeholder roundtable event which led to the development of agreed common

policy principles for stop smoking services.

In addition to association activities, individual companies in

WSMI membership promote international dialogue and the sharing

of best practices in tobacco control. Manufacturers and suppliers of NRT also provide a range of information tools to further support smokers in their efforts to quit, such as quit

lines, web pages which can be personalized to increase the odds of successful quit efforts, and training.

In particular:

- The member companies GlaxoSmithKline (GSK) and Johnson & Johnson (J&J) routinely support and attend conferences dedicated to the advancement of the science and policy of smoking cessation.
- GSK continues to be a sponsor of the Smoke Free Partnership (SFP). The Smoke Free Partnership is a partnership between Cancer Research UK, the European Heart Network and Action on Smoking and Health UK. Their aim is to promote tobacco control

advocacy and policy research at EU and national levels in collaboration with other EU health organizations and EU tobacco control networks.

- Johnson & Johnson Russia, in association with the Health and

Development Fund, smoking cessation experts and the Ministry of Health, in mid-2015 supported the development and launch of

"Let's Quit Smoking" which is the first social program in Russia using social media to support people quitting smoking -

a simple and free system for providing information and behavioural support to mobile devices using SMS messaging.

- Through a Public Private Partnership Johnson & Johnson in late 2015 has signed a Memorandum of Understanding with the Ministry of Health in Malaysia where 23% of the population smokes. The "M Quit services" program will help people quit smoking. The MOH is targeting at least 130,000 people quitting

smoking every year. The partnership includes training HCPs and pharmacists to support cessation, setting up quitting clinics,

establishing a national quitline and developing support systems (including digital platforms) for quitters.

- In the UK in 2015, Johnson & Johnson developed and widely disseminated data and case studies that highlight how to optimize smoking cessation service delivery models in primary care settings in order to reduce GP appointments, emergency admissions and costs at primary care level. J&J also developed

and provided access to models that support local services to understand their local tobacco control burden and to support appropriate commissioning of services.

17) Article 15 (Illicit trade in tobacco products)?  
No

18) If yes, please provide details:

19) Article 16 (Sales to and by minors)?  
Yes

20) If yes, please provide details:  
WSMI members have routinely engaged in policy debate on under-age sales of tobacco and non-tobacco nicotine products, including e-cigarettes, and have engaged in multiple national consultation processes advocating in favour of sales restrictions to minors as a tobacco control and public health measure.

21) Article 17 (Provision of support for economically viable alternative activities) and/or Article 18 (Protection of the environment and the health of persons)?  
No

22) If yes, please provide details:

23) Article 19 (Liability)?  
No

24) If yes, please provide details:

25) Article 20 (Research, surveillance and exchange of information)?

Yes

26) If yes, please provide details:  
All activities mentioned in relation to articles 12, 14 and 22 build on the exchange of information or have an information component to it.

27) Article 22 (Cooperation in the scientific, technical and legal fields and provision of related expertise)?  
Yes

28) If yes, please provide details:  
A number of European WSMI Member Associations (e.g. the Association of the European Self-Medication Industry, the Proprietary Association of Great Britain and the Association Francaise de l'Industries Pharmaceutique pour une Automedication Responsable) as well as member companies engaged and continue to engage directly at EU and Member State level at several meetings in discussions regarding the review and update of the EU Tobacco Products Directive, with a particular focus on the regulation of non-tobacco nicotine

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products including electronic cigarettes. Members also provide

expert advice at European Commission meetings to Members of the European Parliament and Council Member States on the need to regulate electronic cigarettes to improve public health. Johnson & Johnson continues to be active around the EU Tobacco

Products Directive and amongst other things has submitted a number of responses to national tobacco control consultations addressing national implementation of the Directive. WSMI member companies serve regularly as a scientific resource

for respected tobacco cessation advocacy organizations to support their efforts in clarifying smokers' misperceptions about quitting with the aid of NRT compared to continued smoking.

GSK and Johnson & Johnson both have provided and continue to provide expert testimony at US FDA public hearings supporting the expanded access and usability of OTC smoking cessation medicines and the need to regulate electronic cigarettes. GSK has also submitted comments to FDA dockets supporting the need

to consider ways to improve public health by reexamining the regulation of smokeless tobacco products and menthol in cigarettes.

Johnson & Johnson continues to engage directly with regulatory

agencies and policy makers around the world on the topic of non-tobacco nicotine product regulation seeking to ensure access and choice for consumers whilst also addressing the need for appropriate levels of safety, efficacy and quality as

well as ensuring acceptable marketing practices in order to protect public health and users.

Other relevant activities to support the work of the WHO FCTC

1) Please provide any other relevant information:

2) Please attach any other relevant file(s)

Declarations

1) Please confirm that your organization does not receive, has not received and will not receive in the future, either directly or indirectly, any financial or other contributions or assistance from the tobacco industry or its affiliates. Please also confirm that neither your members nor your partners are affiliated directly or indirectly with the tobacco industry or its affiliates or those furthering the interests of the tobacco industry.

Yes

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2) By electronic signature I confirm that the above information is accurate and completed to the best of our abilities.  
Signature by head of organization and date  
Gerald Dziekan

3) Please confirm that the activities of your organization are in conformity with the 17th and 18th preambular paragraphs and Article 5.3 of the WHO FCTC.  
Yes