

Reports of NGO observers to COP 2018

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Section: Contact Details

- * Name of organization
- * World Self-Medication Industry Association - WSMI

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Section: General Information

- * Please indicate if your organization would like to retain it's status as observer to the Conference of the Parties
- * Yes

- * Does your organizations mission statement specifically refer to tobacco control?
- * No

- * If yes, please specify:
- *

- * Does your organization have regional branches to enhance activities in different regions or groups of countries?
- * Yes

* 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.

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

* Yes

* If yes, is tobacco control covered in these meetings?

* Yes

* If yes, please provide details:

* WSMI organizes annual international conferences (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. At the 2017 Annual Meeting of our European Member Association AESGP, (Vienna, 30 May - 2 June), presentations delivered by GSK's and Johnson & Johnson's Consumer HealthCare CEOs looked at smoking cessation and the role of NRT and self-care; 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.

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

* 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.):

* .Seventh Session of the Conference of the Parties to the WHO FCTC, (November 2016, Delhi, India). WSMI has attended all seven sessions of the CoP in the past.

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

* .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.

In September 2016 the 11th Asia Pacific Conference on Tobacco or Health was held in Beijing. Johnson & Johnson supported this conference and also delivered a presentation titled "Tobacco Cessation: Creating an environment that supports smokers to live a life free from tobacco"

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

* Article 5 (General obligations)?

* Yes

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

WSMI has noted and brought to the attention of the FCTC that one of its board member companies has the Chief Executive of a trans-national tobacco companies sitting as a Non-Executive Director on their corporate board.

WSMI does not believe that this situation of having a Non-Executive Director on this Member Company Board, who does not directly or indirectly influence the operations of WSMI is a conflict.

However, given the current situation outlined in the attachment below, WSMI is making this submission as we wish to remain our observer status with FCTC.

In support of the WSMI view, we would provide the following for your consideration:

1. A definition of a non executive director is provided below:

A non-executive director or external director is a member of the board of directors of a company or organisation who does not form

part of the executive management team. They are not employees of the company or affiliated with it in any other way and are differentiated from inside directors, who are members of the board who also serve or previously served as executive managers of the company.

Non-executive directors are directors who act in advisory capacity only. Typically, they attend monthly board meetings to offer the benefit of their advice and serve on committees concerned with sensitive issues such as the pay of the executive directors and other senior managers; they are usually paid a fee for their services but are not regarded as employees.

All directors should be capable of seeing company and business issues in a broad perspective. Nonetheless, non-executive directors are usually chosen because of their independence and initiatives, and are of an appropriate calibre and have particular personal qualities.

Fundamentally, the non-executive director role is to provide a creative contribution and improvement to the board by providing dispassionate and objective criticism. Their role may change depending on the organisation, though they are usually not involved in the day-to-day management of the company but monitor the executive activity and contribute to the development strategy.

Non-executive directors can also be referred to as external directors; they are usually people of stature and experience who can act as both a source of wise independent advice and a check on any wilder elements on a board.

Non-executive directors are expected to focus on board matters and not stray into 'executive direction,' thus providing an independent view of the company that is removed from day-to-day running.

2. We believe that the following excerpts from the WSMI Articles of Association, which support and reinforce the interests of our association and of our membership to advance self care, may also be relevant for consideration in this situation:

"The World Self-Medication Industry (WSMI or the federation) is a non-governmental, voluntary, non-profit association in terms of

Article 60 and following of the Swiss Civil Code. It is a federation of national, regional, multinational associations and persons, firms, or corporations who or which manufacture, own, or control any consumer healthcare product and whose business does not consist in substantial part of the retail sale of goods other than consumer healthcare products manufactured or controlled by them (manufacturers).

The term "consumer healthcare product" refers to a product intended for internal or external use by humans and sold or offered for

sale to the general public under local law without a prescription as defined by the Board.

The objects of the federation are:

to promote the highest standards in the safety of, manufacturing practices for, distribution of, and public information

concerning medicines legally sold without a prescription, food supplements, or other consumer healthcare products as

defined by the Board of Directors;

to maintain contact and cooperation among its various members;

to cooperate with, and to contribute expertise to, national and multinational organizations, both governmental and nongovernmental;

to preserve and improve the integrity and stability of the international consumer healthcare products industry;

all in order to advance the health standards of the peoples of the world."

and,

"MEMBERSHIP

Any national, regional or multinational association of manufacturers, and persons, firms, or corporations who or which manufacture,

own, or control any consumer healthcare product and whose business does not consist in substantial part of the retail sale of

goods other than consumer healthcare products manufactured or controlled by them

(manufacturers) may apply for admission to

the federation as a full member."

3. Further, the Vision and Mission of WSMI are as follows:

"Our Vision

The World Self-Medication Industry is dedicated to a world where self-care increasingly contributes to better health and more

sustainable healthcare systems

Our Mission

To foster a favorable environment for the wider adoption and practice of self-care through the responsible use of safe and effective

consumer healthcare products:

Promoting the value and benefits of self-care and responsible self-medication with relevant stakeholders, including

healthcare professionals, at the global level by consolidating and disseminating scientific evidence.

Providing guidance on global public policy and regulatory issues that impact the self-care industry.

Providing support to member associations."

Furthermore, as you know FCTC CoP 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 licensed/medicinally approved ENDS producers linked with the tobacco industry. This demonstrates WSMI's commitment to public health and to supporting initiatives to control tobacco dependencies.

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

* Yes

* If yes, please provide details:

* WSMI members have routinely supported 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.

* Article 8 (Protection from exposure to tobacco smoke)?

* Yes

* 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 them 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 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 amongst others

Johnson & Johnson has a global tobacco free worksite policy and provides support for staff seeking to quit tobacco associated to this policy. It was also a signatory, and speaker at the recent launch event, to the China CEO Round Table on Cancer Smokefree Worksite Pledge. Johnson & Johnson, as a founding member of the Global Smokefree Worksite Challenge, assisted in the development of a Smokefree Worksite Certification Toolkit developed by the King Hussein Cancer Foundation and Center (KHCC) in Jordan.

* Article 9 (Regulation of the contents of tobacco product) and/or Article 10 (Regulation of tobacco product disclosures)?

* No

* If yes, please provide details:

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* Article 11 (Packaging and labelling of tobacco products)?

* Yes

* If yes, please provide details:

* WSMI members have routinely engaged in the tobacco control debates, 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 providing quitting advice.

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

* Yes

* 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 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.

* Article 13 (Tobacco advertising, promotion and sponsorship)?

* No

* If yes, please provide details:

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

* Yes

* 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 Members provide 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 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. This work program continues today.

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.

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 "Lets 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 quit line and developing support systems (including digital platforms) for quitters. This activity is ongoing.

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. This material continues to be available and has been used with commissioners of smoking cessation services across England as well as with Clinical Commissioning Groups in Primary Care.

In February 2018 both consumer healthcare businesses of Johnson & Johnson and GSK as well as the US OTC Self-care trade association (Consumer Health Products Association (CHPA)) gave presentations at a US FDA Public Hearing around the future regulation of nicotine containing medicines. All of these organizations also submitted written responses to the US FDA.

* Article 15 (Illicit trade in tobacco products)?

* No

* If yes, please provide details:

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* Article 16 (Sales to and by minors)?

* Yes

* 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.

* Article 17 (Provision of support for economically viable alternative activities) and/or Article 18 (Protection of the environment and the health of persons)?

* No

* If yes, please provide details:

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* Article 19 (Liability)?

* No

* If yes, please provide details:

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

* Yes

* 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.

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

* Yes

* If yes, please provide details:

* WSMI member companies serve regularly as 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 appropriately regulate all non-tobacco nicotine products, including 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. It seeks to ensure access and choice for consumers whilst also addressing the need for appropriate levels of safety, efficacy and quality for all non-tobacco nicotine products as well as ensuring acceptable marketing practices in order to advance public health, protect users and to avoid uptake by non-smokers, particularly young people.

Section: Other relevant activities to support the work of the WHO FCTC

* Please provide any other relevant information:

* As stated, WSMI does not believe that the situation raised with one of our member companies, having one Non-Executive Director on their Board, who does not directly or indirectly influence the operations of WSMI is a conflict.

Attached is the WSMI correspondence with FCTC Secretariat - February 2018.

* Please attach any other relevant file(s)

* FCTC Accreditation Reports World Self Medication Industry-Correspondence Feb 2018.pdf

Section: Declarations

* 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

* By electronic signature I confirm that the above information is accurate and completed to the best of our abilities.

* William Murphy - Ad interim Director General

* 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