Author's response to reviews

Title: Tobacco Control in the Russian Federation - A Policy Analysis

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Author's response to reviews: see over
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Re: Manuscript BMC Public Health, MS: 1885844708786528

Title: Tobacco Control in the Russian Federation: A Policy Analysis

Dear Ms Reyes,
dear Dr. Thomson:

Thank you for your review of our manuscript submitted to BMC Public Health, MS# 1885844708786528. We also appreciate the reviewers’ time and efforts, and we thank them for their helpful suggestions about our manuscript.

We appreciate the opportunity to address the issues raised by you and the reviewers. We have made all formatting changes you requested.

The following pages address your comments and the concerns of the reviewers, which precede our responses and are in italics. We identify the specific changes in the manuscript based on reviewers’ comments and discuss any suggestions that we did not incorporate into the text. In addition to a clean copy of the revised manuscript, we have included an additional draft using "track changes" so that you can more easily identify our edits to the original submission.

We look forward to your thoughts.

Sincerely,

Karsten Lunze
Editor’s comments:

1. Copyediting:
   After reading through your manuscript, we feel that the quality of written English needs to be improved before the manuscript can be considered further. We advise you to seek the assistance of a fluent English speaking colleague, or to have a professional editing service correct your language. Please ensure that particular attention is paid to the abstract.

We had the manuscript and its revisions reviewed and edited by a native-English speaker with scientific expertise in public health. In the draft showing "track changes", these are displayed in blue, while the authors’ changes as detailed below are marked in red.

2. Title page: It should contain, at minimum, the names, institutions, countries and email addresses of all authors, and the full postal address of the submitting author.

The title page now contains the names, institutions, countries and email addresses, and full postal addresses of both authors.

3. Please include email addresses for all the authors on the title page, using the following format:
   AB: abcd@institution.ac.uk
   EF: efg@generic.co.uk
   IJ: IJKL@corporation.com

The email addresses on the title page now reflect the required format.

4. Please remove the authors’ qualifications (e.g. PhD / MD) or job titles from the manuscript file.

We have removed all authors’ qualifications and titles from the manuscript.

5. Acknowledgment: “We strongly encourage you to include an Acknowledgments section between the Authors’ contributions section and Reference list. Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include their source(s) of funding. Please also acknowledge anyone who contributed materials essential for the study. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgments. Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgments section. Authors must describe the role of the funding body, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

We included the Acknowledgments section between the Authors’ contributions section and Reference list, and obtained permission from all those mentioned in the section.

6. Please remove the visible vertical lines of the Tables.

   --Tables: Please ensure that the order in which your tables are cited is the same as the order in which they are provided. Every table must be cited in the text, using Arabic numerals. Please do not use ranges when listing tables. Tables must not be subdivided, or contain tables within tables. Please note that we are unable to display vertical lines or text within tables, no display merged cells: please re-layout your table without these elements. Tables should be formatted using the Table tool in your word processor. Please ensure the table title is above the table and the legend is below the table. For more information, see the instructions for authors on the journal website.

We removed the vertical lines using the Table tool in Word.
We thank reviewer 1 for his very constructive criticism, which was very helpful, and have addressed all issues as follows:

The data are sound in terms that available sources of information are used. However quality of sources is variable and this should be clearly stated. For example recent GATS and GYTS provide reliable information for international comparisons. Majority of references used by the authors are English language ones originating from sources outside Russia. Plan of actions on tobacco control which was adopted with the Concept is not mentioned. Only a few of many available important MoH documents are used. The key Russian local sources are lacking, for example, Civil Chamber policy report on tobacco, issued in 2009 www.oprf.ru/files/tabakokurenie.doc; a book on tobacco policy by N.F. Gerasimenko and A.K. Demin, numerous policy publications at the website of the Russian Public Health Association raoz.ru, and others. Maybe it would be helpful also to use the recently published volume “Russia: Deal is Tobacco. Investigation of Mass Killing” by A.K. Demin and co-authors, 550 pp. Industrial sources are used without comment, such as Russian Tobacco Media Group, which is promoting industry interests.

We thank the reviewer for these comments, and particularly for pointing out additional sources for our policy analysis.

We included the main documents of the Russian MoHSD and, in order to address the international readership of BMC Public Health, provided a reference that lists key documents in both the Russian originals and English translations [1]. The revised manuscript now details the action plan included in the concept:

On 23 September 2010, Russia’s Prime Minister Putin approved the “Concept of the Government Policy on Combating Tobacco Use for 2010-2015”, which mandates the government and the Duma to pass legislation bringing Russia into full alignment with the FCTC and the FCTC Guidelines and specified an action plan, by which Russia had to be 100 percent smoke-free in indoor public and work places, and public transport; a complete ban on all forms of advertising, promotion and sponsorship for tobacco products; and graphic health warnings on all tobacco packaging by 2015 [1]. The concept also formulated a 10—15% reduction in smoking by 2015; although not legally binding, this goal was considered “a strategic platform for future legislative steps” by the WHO [2].
As suggested by the reviewer, we discuss the role of NGOs and civil society in closer detail, including the suggested references:

Russian non-governmental organizations have long called attention to the tobacco industry’s influences on law and policy making, and have tried to counteract the tobacco industry’s influence against stronger tobacco control [3] and demanding greater transparency and disclosure of interactions between industry and public stakeholders [4].

Under the section “Policy content”, we discuss that reliable, international comparable data is available in Russia, and added:

The GATS and GTSS results provide internationally comparable data on tobacco control in the country.

*Conclusion on the need to monitor and denormalize tobacco industry, exposing and preventing conflict of interest based on FCTC Article 5.3. is lacking in the manuscript.*

We appreciate the sources the reviewer identified, and summarized them in the revised manuscript:

Russian non-governmental organizations have long called attention to the tobacco industry’s influences on law and policy making, and have tried to counteract the tobacco industry’s influence against stronger tobacco control [3] and demanding greater transparency and disclosure of interactions between industry and public stakeholders [4].

We purposively aimed to base our policy analysis on sources from a variety of stakeholders, including NGOS, but also transnational tobacco companies and Russian lobby organizations. We detailed this in the revised “Methods” section:

As has been suggested previously [5], data include not only published academic sources, but also important policy documents and other reports from government and public institutions in Russia, from international organizations, as well as from transnational tobacco companies and Russian industry lobby organizations.

*Limitations of the work should be stated in terms of the following important factors, not mentioned in the manuscript, as shown in current publications, including “Russia: Deal is Tobacco. Investigation of Mass Killing”:
- Russia turned into global stronghold of tobacco industry, attenuating WHO efforts to control tobacco epidemic.
- Tobacco market in Russia is not transparent.
- Russian tobacco scene is criminal, and this is an important policy factor, not considered by the authors.
- Dominating industry role in the policy process and its collaboration with the state are outlined not adequately. The largest 5 foreign tobacco companies provide over 95% of tobacco production in Russia worth over $10 bn annually and have been leading in policy development since USSR dissolution.
- Analysis of the role of such policy actors as WHO, including office in Moscow, BGI, international NGOs deserves inclusion in the manuscript.*
We agree with the reviewer that the tobacco use in Russia is counterproductive to health promotion and disease prevention. Corruption and criminal activities are clearly important policy factors, and in the sources the reviewer refers to, he and colleagues describe Russian tobacco market activities as intransparent and criminal. Our analysis focuses on the sources available to us. We have revised the manuscript, as suggested by the reviewer, to better portray the landscape of stakeholders in Russian tobacco control policy making.

The manuscript discusses the dominance of transnational tobacco companies:

Currently, transnational companies (mainly Japan Tobacco International, Phillip Morris, British American Tobacco and Imperial Tobacco) control over 90% of the Russian tobacco market, while national companies such as Donskoii Tabak have lately increased their market share [6].

The manuscript also mentions the role of WHO in the tobacco control policy process:

In the period to follow, WHO in Russia facilitated the high-level policy dialogue and provided technical support to the Russian Federal Ministry of Health and Social Development (MoHSD) and other national key counterparts in order to coordinate efforts of the Russian Federation towards joining FCTC.

The revised manuscript further describes the role of other stakeholders in the policy making process:

International NGOs such as the “Bloomberg Initiative To Reduce Tobacco Use” or the “Campaign for Tobacco-Free Kids” are supporting tobacco control in Russia, while organizations such as “Council on Issues of Development of the Tobacco Industry” or “Media Group Russian Tobacco” advocate on behalf of the tobacco industry.

Other points that might require consideration and revision:

* Tobacco supply. First paragraph. So called “Russian Tobacco Rebellion” is a minor phenomenon exaggerated by the industry for its benefit, scaring the leaders and the public with invented “political and criminal risks” of tobacco control. In the volume “Russia: Deal is Tobacco” the fact is described that Boris Yeltsin, the leader of the main tobacco producer in the USSR – Russian Socialist Federative Socialist Republic, ordered to close overnight on pretext of “renovation” 24 of 26 tobacco factories operating then in Russia, making inevitable physical shortage of tobacco products and resulting public discontent and penetration of foreign companies. Thus this shortage was hand made and has nothing in common with current measures corresponding to WHO FCTC, despite disinformation of the industry.

We thank the reviewer for adding this interesting perspective on the events during the Russian economic default to our review (both accounts of the events are described in the literature), which the revised manuscript incorporates as follows:

Due to the breakdown in distribution networks and lack of spare parts for deteriorating production machinery, the domestic tobacco industry nearly collapsed [7], while the Russian economy defaulted on its debts in August 1998 and imports plummeted. Some propose that in the summer of 1990, the resulting cigarette shortage prompted smokers in major cities to take to the streets in what is now known as the Russian Tobacco Rebellion. Then-
Last paragraph. The share of Donskoy Tabak is decreasing due to increasing role of foreign companies: South Ossetia and Abkhazia are negligible in terms of consumption compared to other regions and might not deserve mention.

For the market share of Donskoy, we cite the number and trend we were able to obtain from the tobacco industry. We agree with the reviewer that South Ossetia and Abkhazia represent a rather insignificant share of the market. However, these regions illustrate the effect of lack of tobacco control in the absence of political stability, and how domestic companies seize that opportunity. In fact, the reviewer might find it remarkable to read that Donskoy Tabak has openly approached the Abkhaz parliament to engage in health-related projects, proposing to invest in a sanatorium there. The revised manuscript clarifies that link:

In the context of political instability, tobacco companies seize the opportunity of lack of tobacco control: Donskoy Tabak approached the Abkhaz parliament to engage in health-related projects, proposing to invest in a sanatorium there [9].

Health Effects. First paragraph. MoH data on improving vital statistics in Russia has been published recently and should be cited and commented.

The revised manuscript references the improving health trends in Russia:

Although recent trends signal some improvements in death rates and life expectancy [10], Russia’s unprecedented, tobacco-mediated health crisis, affecting primarily the middle-aged population, thus not only negatively affects the economic well-being of individuals and households, but might also be a barrier to economic growth [11].

Policy Process and Policy Actors. First paragraph. Not only limitations on advertisements, but also many other important effective measures were removed from the draft law due to industry pressure, as shown in available policy publications, for example, Andrey Demin. Osnovnie strategii i deyatelnost transnacionalnyh tabachnyh kompaniy i ih soyuznikov v Rossii. (Major strategies and activities of transnational tobacco companies and their allies in Russia (in Russian, 2008) (http://lobbying.ru/content/persons/id_3542.html) and Andrey Demin. Understanding and counteracting tobacco industry GR in Russia (in English, 2010) http://www.raoz.ru/english/77/

We commend the reviewer on his and his organization’s respectable work on the topic. The revised manuscript specifies that measures removed from the bill draft were not limited to advertisement bans, and includes an additional reference:

As a consequence of what was later called “a textbook demonstration of the lobbyist’s art” [12], the limitations on advertisements included in the initial bill and other proposed tobacco control measures were eventually removed, when the Federal Law No. 87-FZ of July 10, 2001 on the “Imposition of Restrictions on Tobacco Smoking” was passed in the Duma [13]
Warnings on the pack remained small – I believe that the exact size should be specified - 4% of the pack.

We addressed this in the “Policy content” section, which specifies:

**Tobacco labeling:** Cigarette package labels in Russia have been in compliance with the FCTC requirements text health warnings on the packaging to motivate smokers to quit smoking. While current warnings do not include a picture or pictogram [14], in May 2012, the Russian Ministry of Health issued a decree (to go into effect in May 2013) mandating pictorial warnings, which will cover 50% of the back side of each pack [15].

*Second paragraph.* BAT employee Mr. Leonid Sinelnikov hiding under the cover of expert of Ministry of Agriculture, was exposed to the international community at the INB meeting in Geneva, Switzerland in March 2003 by civil society activist, President of Russian Public Health Association Andrey Demin.

The manuscript references that finding:

Remarkably, among the Russian delegation was also a British American Tobacco (BAT) employee [16].

*Same paragraph:* FCTC signing is not a prerequisite to joining FCTC. Russia did not sign in the specified period of time, but joined FCTC a few years later.

The revised manuscript corrects that:

After years of campaigns by organizations such as the Russian Public Health Association, the Russian Anti-Tobacco Coalition, and the Russian Academy of Medical Sciences [17, 18], Russia was one of the last of the currently 172 countries to sign the FCTC in 2008 [19]

*Fourth paragraph.* Formally Mr. Ivan Savvidi, former director of Donskoy Tabak, being Deputy, was not owner of Donskoy Tabak, having had transferred his shares to other persons; this gentleman was not reelected at the recent Duma elections. However at the recent Duma elections the leading industry lobbyist, former head of Council of issues of development of tobacco industry established in Russia by foreign tobacco companies, Ms. Nadezhda Shkolnikova was elected as a member of the ruling party “United Russia”. In 2009 she was openly selected and praised by the industry sources as the best GR manager of the industry in Russia. This is also a real policy factor.

The revised manuscript corrects the role of Donskoy Tabak’s director and includes Ms Shkolnikova’s case:

In fact, the director of the only remaining domestic tobacco manufacturing company in Russia (Donskoi Tobacco) was a member of the State Duma and co-authored all legal drafts concerned with tobacco control [20]. The director of one of the most prominent tobacco industry lobby organizations was recently introduced into the Duma by taking over the mandate for a deputy from the leading party, who was leaving the parliament [21].
Fifth paragraph. *The claim was rejected by the court.*

The revised manuscript reflects this update:

This claim was rejected but has received some attention [20].

*Policy Content. Monitoring. GYTS 1999 was conducted by Russian Public Health Association; GYTS 2004 – by MoH.*

The manuscript summarizes that the GYTS was conducted twice in Russia:

Russia has strong technical capacity appropriate implementing agencies to conduct surveillance and was one of the 11 countries to pilot test the Global Youth Tobacco Survey (GYTS) in 1999, which was repeated in 2004.

*Tobacco Cessation Programs. Third paragraph. In Russia, besides NRT and Varenicline, Tabex (Cytizine) is registered drug for treating tobacco dependence, it is purchased over the counter, cost of pack for a course is less than 8 USD and it has been used in USSR and other countries of the former Socialist system since mid-1960s. Recently Cytizine is in the focus of international attention as an effective, available, safe and efficient product, the most promising for use on a global scale in large scale state supported interventions, including in low and medium level economies.*

We thank the reviewer for this very valuable information! This information is added to the revised manuscript:

Another over-the-counter drug, available at a lower cost (less than US$8) is Cytizine, a nicotinic receptor agonist (marketed under the brand name Tabex) and licensed in Russia for the treatment of tobacco dependence. Although it has been suggested to be effective for smoking cessation and have some potential for smoking cessation therapies in low- and mid-income countries due to its lower costs than other pharmacotherapies [22], the drug has remained largely unnoticed in the English-language literature and in countries outside of Eastern Europe and former Socialist states, where it has been used since the mid-1960ies [23].

*The same paragraph. Quit line already operates, and is based in Saint Petersburg.*

The revised manuscript mentions the local quit line in St Petersburg:

Russia is currently in the process of scaling-up a national toll-free quit line, which already exists in St. Petersburg.

*Advertising, promotion and sponsorship bans. First paragraph. Tobacco industry budget is much higher in Russia, according to our research it exceeds 1 bln USD annually on all forms of promotion including PR and GR.*

The revised manuscript includes the range of estimates, including the reviewer’s:

Russia’s tobacco industry invests massively in direct and indirect advertisements in various media, promotion, and sponsorship of events, estimated between US$ 60 million [24] and more than US$ 1 billion including all forms of product placement and sponsorships [8].
Second paragraph. New draft bill.

The revised manuscript specifies that the bill is still in the draft phase:

The new draft bill aims at closing current loopholes for tobacco companies to use billboards to advertise in the metro stations, in newspapers and magazines, and through other forms of marketing such as sponsorships of sports events, promotions, etc., but is being contested by the tobacco lobby as harming the advertisement industry and reducing trade rather than tobacco consumption [25].

Conclusions. First paragraph. Not only past, but current experience suggests this.

The revised manuscript clarifies that these experiences relate to the study findings and added the need for research to document the effects of policy change on tobacco use:

Our results suggest that strong tobacco industry influences risk to attenuate future tobacco control measures.

Robust research is needed to create a solid evidence-base on the effectiveness of tobacco control measures in Russia.

Table 1. A column “expected resistance from the industry” could be introduced.

Last row “Only secondhand smoke” related to “Vulnerable populations” - is unclear.

The revised manuscript clarifies that the last row refers to “Effects from secondhand smoke” that vulnerable populations are subjected to. We agree that “expected resistance from the industry” is a major factor in the policy process, which we conceptualize in the “feasibility” category.

Comments reviewer #2:

We also thank reviewer #2 for his constructive criticism, which complements some of the points reviewer #1 raised:

Due to the time-lag between authoring and reviewing this article, however, certain facts are no longer current and should be revised. Most importantly, the Ministry of Health’s tobacco control legislation is expected to be approved by the government in October and sent to the Duma by November 1, as per a decree by President Putin from May.

Following the reviewer’s suggestion, we updated the section on policy context to reflect developments since the writing of the ms:

Against resistance from the tobacco industry [26], the MoHSD revised its tobacco control legislation draft, proposing an implementation of control measures during a transition period in several steps, from 2014 through 2017 [27].

Similarly, some policy actors have changed, with the Ministries of Agriculture and Economic Development now coming out in favor of tobacco control legislation. MOH has also recently
published guidelines for pictorial pack warnings. I would suggest a revision of parts of the Policy Process and Policy Actors section and to Table 2 to reflect all recent policy changes. These revisions would also help to strengthen and contemporize the authors' conclusion, as this draft law as currently written would conform to both FCTC and the "National Tobacco Control Concept." Revisions are suggested at the author's discretion.

We thank the reviewer for his summary of recent developments, and have revised the “Policy Process and Policy Actors” section as follows:

The bill is largely influenced by the “Concept” and closely aligns with various evidence-based policies for tobacco control proposed in the FCTC, but was returned after only two days to the MoHSD and suspended based on “technical arguments”, brought forth by the Ministries of Agriculture and Economic Development. Those ministries in Russia much more than the MoHSD are targeted by a hidden tobacco industry lobby [2]. Against resistance from the tobacco industry [26], the MoHSD revised its tobacco control legislation draft, proposing an implementation of control measures during a transition period in several steps, from 2014 through 2017 [27].

We also and added a reference to the “Policy content” section, which specifies:

**Tobacco labeling:** Cigarette package labels in Russia have been in compliance with the FCTC requirements text health warnings on the packaging to motivate smokers to quit smoking. While current warnings do not include a picture or pictogram [14], in May 2012, the Russian Ministry of Health issued a decree (to go into effect in May 2013) mandating pictorial warnings, which will cover 50% of the back side of each pack [15].

Literature and additional references