The role of electronic cigarettes and heated tobacco products in tobacco control in Italy and Europe

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Impact Statement
In this chapter I detail how the main results of this thesis have been disseminated during the PhD trajectory and discuss their impact from a public health perspective. Moreover, I will discuss how our findings might have an impact on the planning, implementation and evaluation of future research and public health practice.

The dissemination of results during the PhD trajectory

During my PhD trajectory, the dissemination of study results have been disseminated to a broad audience, including researchers, policy makers, journalists, students and the general public, through the following means:

**Peer-reviewed publications**

Study findings from five out of eight manuscripts written within the present thesis have already been published in various peer-reviewed journals [1-5]. These findings, combined with those from researches conducted by other independent tobacco control experts, build up robust scientific evidence pointing out the negative benefit-risk balance for novel (tobacco) products. Electronic cigarettes (e-cigarette) and, particularly, heated tobacco products (HTP) represent more a strategy of the tobacco industry to spread nicotine and to find new customers among future generations, rather than a mean to reduce tobacco harm.

**Other publications**

Our findings have been spread also in local Italian journals or websites to reach a broader audience of Italian experts in the field of tobacco control. Since January 2020, I am the editor-in-chief of Tabaccologia - the Journal of Tobacco Sciences, which is the quarterly journal of the Italian Society of Tobaccolo (SITAB). Since my first editorial, I shared my viewpoint on the role of e-cigarettes and HTP on tobacco control, supported by findings of my research within the present dissertation [6]. The last editorial dealt with the unjustified fiscal and regulatory benefits of e-cigarettes and HTPs in Italy. Within this editorial, we reacted to the open letter signed by a group of 100 specialists claiming to be independent of commercial conflicts of interest with the tobacco industry [7]. In this letter, addressed to the delegates of the Framework Convention on Tobacco Control (FCTC), who met in November 2021 for the Conference of Parties (COP-9), the 100 specialists recommended the use not only of e-cigarettes but also of HTPs for harm reduction purpose, even in the absence of a clinical anti-smoking context. After preliminary investigations, it turned out that most of those specialists was not expert in tobacco control and, more importantly, some of them had links with the e-cigarette or tobacco industry, including for example four members of the scientific board of the Lega Italiana Anti Fumo (LIAF), an organization that, according to TobaccoTactics, received grants from the
Foundation for a Smoke-Free Word (FSFW; the foundation of Philip Morris International, PMI) and is a partner of COEHAR and ECLAT, having received millions of US$ from FSFW [8]. In an attempt to raise the voice of the Italian truly independent experts on tobacco control, in support of WHO, we promptly posted the editorial also on tobaccoendgame.it, a website held by a group of independent experts on tobacco control in Italy, often followed by Italian policy makers. Finally, it is worth to mention the publication on the website of the Union for International Cancer Control (UICC), to tell the story of HTPs in Italy, the country chosen by PMI as the pilot country for the launch of Iqos, the first HTP [9].

**Oral speech**

Oral presentations were used to disseminate study results to a broad audience, including researchers, policy makers, journalists, students and the general public. 

**Researchers:** our scientific findings were presented at various national and international conferences and symposia for audiences with a heterogeneous background. At a national level, every year we were invited at the Italian Health Institute (Istituto Superiore di Sanità, ISS) in occasion of the World No Tobacco Day and at the congress of the Italian Society on Tobacco (Società Italiana di Tabaccologia, SITAB) for an oral speech, often on my research on the effects of e-cigarettes and HTPs on tobacco control in Italy. The same topic has been considered also at an international level, in some webinars organized by the European Network for Smoking and Tobacco Prevention (ENSP) and at the 2020 European Conference on Tobacco or Health (ECToH) in Berlin. Moreover, we were invited as speakers at the final conference of the TackSHS project at the European Parliament, to present data of the TackSHS survey - conducted in 12 European countries - analyzed within the present PhD trajectory [3-5]. Furthermore, I have been included in the Expert Group of the WHO on Articles 9 and 10 of the FCTC and I participated in the corresponding 2-day meeting in Bilthoven (NL) in 2019. Finally, in 2020 I was invited as an international expert to critically comment on a monograph on e-cigarettes prepared by the Spanish National Committee of Tobacco Prevention (CNPT).

**Policy makers and journalists:** We were invited by the ENSP to the Lithuanian Parliament in Vilnius and the Spanish Ministry of Health in Madrid to inform selected politicians, policy makers and journalists about the concerns on HTP spread in Italy. Moreover, we were and are still in contact with officers of selected ministries or governmental agencies from Italy and a few other countries. We regularly meet to inform about our research on novel (tobacco) products.

**Students:** During the PhD trajectory, we had the opportunity to teach during the Public Health course in the Faculty of Medicine at the University Vita-Salute San Raffaele, invited by the co-promoter of the PhD, Prof Anna Odone, and at Master courses of Mario Negri Institute and the Business School Sole24Ore, presenting lessons on HTPs and more in general on tobacco control. Following the IG-Nobel prize on medicine obtained in September 2019 for some early studies on the
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association between pizza consumption and cancer risk [10], I was invited to give speeches in a few Universities, including an on-site seminar at Sant’Anna School of Advanced Studies, Pisa, Italy and an online lunch lecture for the science faculty of the Radboud University in Nijmegen, The Netherlands. In those occasions, I also presented findings on novel (tobacco) products in Italy and Europe.

**General population:** Extremely important was the dissemination of our findings to the general population. For example, in 2019 I was invited as speakers in Milan at a meeting of the event “Tempo della Salute” organized by Corriere della Sera - one of the main Italian newspapers - to provide a speech on my research about e-cigarettes.

**Lay press**
Findings from this dissertation were widely disseminated in the lay press through several interviews in national and international newspapers. At a national level, in the last interview dated 22 October 2021 we informed the Italian audience about our viewpoint on tobacco harm reduction [11]. More importantly, we have posted several articles in tobaccoendgame.it, a website of a group of independent tobacco control experts with the aim of carrying on selected advocacy actions or to support increases in taxation of e-cigarettes or HTPs in Italy. At an international level, it is worth mentioning our contribution to the Organized Crime and Corruption Reporting Project (OCCRP), which has conducted a series of investigations [12, 13] on HTPs, to unmask the hidden tactics of the tobacco industry to prevent, reduce, or stymie efforts to control tobacco.

**Television**
In January 2019, PMI made a formal request to the Italian authorities to evaluate the relative harmfulness of their novel tobacco products. The Italian Ministry of Health and the Italian Health Institute declared that it was impossible to acknowledge both the reduction of HTP’s toxic substances and the potential risk reduction of HTPs compared to combusted products, under the same conditions of use. The results of this evaluation were sealed for more than one year, but we contributed to ensuring that they were made publicly known through an investigation broadcast on the national TV program “Report” [14]. Moreover, I was recently interviewed for an investigation on HTPs in Italy that will be broadcasted soon in a Greek TV channel.

**Impact of the dissemination of findings during the PhD trajectory**
It is not easy to evaluate the exact impact that this thesis had on a social and public health perspective and which of our numerous actions or dissemination methods were more effective. However, this impact appears to be substantial, if we assume it is proportional to the reactions of the industry. More and more often,
in fact, the publication of our findings or our interviews in the lay press is promptly criticized by people linked to the tobacco industry or e-cigarette producers [15, 16].

In Italy, our research on HTPs has been likely relevant in the decision of the National Health Institute to reject the claims by PMI alleging that Iqos devices are less harmful than conventional cigarettes [1, 17, 18]. Moreover, the TV Program “Report” enabled our research to reach a broad audience beyond the scientific community. Besides revealing to Italians the hidden tobacco tactics of PMI in promoting their HTPs [14], “Report” allowed us to inform millions of Italians about our research on HTPs, claiming that, based on our findings, there is no argument to justify the huge fiscal and regulatory benefits these products continue to have in Italy.

The research conducted within this dissertation has been used for advocacy actions by the Italian independent scientific community. For example, we have supported some politicians committed to increasing excise taxation from 20% up to 80% of that of conventional tobacco cigarettes through amendments to government decrees [19]. However, that proposed amendment was not approved and current legislation foresees a negligible increase in taxation for HTPs and e-cigarettes by 5% each year. Thus, today the excise tax of HTPs and e-cigarettes in Italy is 25% compared with that of conventional tobacco cigarette. This disappointing result is likely due to the lobbying actions of the tobacco industry, clearly more effective than our advocacy actions. This appears to be the direct consequence of the relatively low efforts by the Italian government to counter the tobacco industry interference. We contributed to the 2021 Global Tobacco Industry Interference Index providing scores for Italy. This index showed that Italy, together with Romania, is the EU Member State with the worst tobacco industry interference index [20]. It is not by coincidence that PMI launched Iqos in Italy and that the main tobacco industries, including PMI and British American Tobacco (BAT), are investing their money in Italy to create research institutes and tobacco production plants.

At an international level, thanks to our reputation as highly trusted independent tobacco control experts, we believe to have contributed to creating the scientific evidence, embraced by WHO [21], rejecting harm reduction as an effective strategy for tobacco. At least, we are confident that the research conducted within this dissertation helped in the drafting of the position paper by ENSP on e-cigarettes, supporting the WHO in recommending for e-cigarettes strict regulations, bans, and increased taxation [22]. Paradoxically, our research was used less in Italy rather than in other countries. In fact, officers from governmental agencies or ministries of selected countries acknowledged the contribution provided by us, which helped politicians to deny or delay the marketing of HTPs in their countries.
Future impact of the generated knowledge

The findings presented in this dissertation are expected to have great scientific and social implications in the (nearby) future. In particular, the most important investigations of the present dissertation are still unpublished, and they are currently under review in high impact journals [17, 18, 23]. These papers will likely have a major impact in Italy and worldwide. A large representative survey showed for the first time the trend of e-cigarette and HTP use during the COVID-19 lockdown in Italy [17].

More importantly, we conducted one of the few available prospective cohort studies tracking transitions in conventional cigarette smoking in relation to the use of e-cigarettes and HTPs. Our study confirmed previous findings from cross-sectional investigations, showing that in Italy e-cigarettes and HTPs increase the risk of initiation of conventional cigarette smoking among those who have never smoked, increase the risk of relapse among ex-smokers and reduce the risk to quit for current smokers [18]. These findings, from one of the few cohort studies on the issue, have been presented at a national conference, obtaining wide attention from the media. These results represent the main rationale provided by ISS to reject harm reduction as an effective tobacco control strategy. The publication of these data in a peer-reviewed journal, followed by a press release, will likely have major implications on a public health perspective, not only in Italy, but also globally.

Probably the paper potentially with the highest impact on a public health perspective is the systematic review of the scientific literature about HTPs [23]. It shows for the first time that the scientific knowledge on these novel tobacco products is largely based on studies conducted or supported by the tobacco industry that appear to reach biased conclusions. This review shows that the tobacco companies, through their massive investment, have succeeded in creating a situation in which the scientific community is divided, when there is overwhelming evidence from independent research consistently opposing HTPs. Moreover, we confirm that it is not uncommon that the tobacco industry scientific affiliates (i.e., researchers who are paid directly or indirectly from the tobacco industry, fail to disclose their conflicts of interest [24]. This seems to be a growing tactic that is not limited to scientific research. Thus, a recent investigation by Le Monde (FR) and The Investigative Desk (NL) revealed the lobbying actions towards tobacco harm reduction by selected consumer organizations, including World Vapers’ Alliance or the Consumer Choice Center, pretending to be independent, which were in fact disguised entities financially supported by the tobacco industry [25]. Today, endorsing HTPs as a tobacco harm reduction tool appears to be the best predictor of having a conflict of interest with the tobacco industry. Consequently, the hoped and expected implications of this work are that authorities and policy makers of various governments, for decisions on how to
regulate novel tobacco products, rely exclusively on the scientific evidence from truly independent research, and that policy makers understand that there is an urgent need to fund and sustain independent research on novel tobacco products. In addition, after having disseminated our findings, we expect the few tobacco harm reduction advocates, who are truly independent of conflicts of interest with the industry, to make a clear distinction between e-cigarettes and HTPs (the latter, being tobacco, to be rejected always and without any conditions).

In case the several recommendations provided within this thesis, which will be spread through different means, are followed by various stakeholders, including policy makers, healthcare providers and public health researchers, the work conducted could guide the planning, implementation, monitoring and evaluation of i) public health interventions (e.g., information campaigns and health promotion in different settings as schools or workplaces), primary prevention interventions targeting selected subgroups (e.g., students, young generations) and advocacy communication; ii) regulations/normative action at the regional, national and international level; and iii) future research and collaborations (e.g., cohort studies or pooled analyses and intervention studies).

References


