









May 14, 2019

Mr. Mitchell Zeller Director, Center for Tobacco Products U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Re: <u>Marketing order for IQOS</u>

Dear Director Zeller:

Our organizations are writing in connection with the April 30 action by the U.S. Food and Drug Administration (FDA) issuing a marketing order to Philip Morris International (PMI) and Philip Morris Products S.A. allowing the U.S. marketing of IQOS heated tobacco products, to be distributed in the U.S. exclusively by Altria Client Services LLC (Altria).

FDA states that its action in issuing this marketing order is premised on representations that Altria and PMI made that the IQOS products will be marketed only to adult smokers in the U.S. for the purpose of encouraging them to switch completely from the use of conventional cigarettes, while avoiding marketing to audiences like non-smokers and youth. Indeed, the marketing order itself refers to two amendments to the IQOS Premarket Tobacco Applications (PMTAs) submitted by PMI (dated September 5, 2018 and March 25, 2019) in which "you include representations about your marketing plan for your products in the United States and indicate that you intend to focus marketing on adult cigarette smokers while limiting reach to unintended audiences." Moreover, PMI made express representations to the Tobacco Product Scientific Advisory Committee (TPSAC) during its January 24-25, 2018 meeting to consider the separate IQOS modified risk tobacco product application that it would market these products to adult smokers, not youth and nonsmokers. On that occasion, Sarah Knakmuhs, Vice President of Heated Tobacco Products for PM USA, assured TPSAC that "[o]n the one hand, we're committed to maximizing our reach to adult smokers and supporting them so they can switch completely to IQOS. On the other hand, we want to limit our reach to unintended audiences such as nonsmokers and youth."2

In connection with PMI's PMTA and its pending modified risk product application, we repeatedly have submitted evidence to FDA that PMI's marketing of IQOS across the globe is

¹ FDA Marketing Order Letter from Matthew R. Holman, Ph.D, Director Office of Science, to Philip Morris Products S.A., April 30, 2019, at 2.

² PMI Presentation to TPSAC, January 24, 2018, Transcript, https://www.fda.gov/downloads/AdvisoryCommittees/Committees/MeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM599234.pdf

entirely inconsistent with a marketing focus on adult smokers. Instead, in numerous countries, PMI has pursued a strategy of marketing these products to the broadest range of consumers, with messaging and imaging presenting IQOS as a fashionable and trendy lifestyle product – precisely the kinds of images that appeal to young people. This is demonstrated by a representative sample of IQOS global marketing, including social media marketing, submitted with this letter, showing:

- IQOS retail stores attempting to replicate the appeal of other high-tech retail outlets, in locations highly visible to broad audiences, including youth;
- IQOS advertising to the general public;
- IQOS kiosks in shopping malls;
- IQOS sponsored social events and parties;
- IQOS marketing at public events, including music events;
- IQOS partnerships with trendy fashion magazines and designers, clearly associating IQOS with publications and products popular among young women;
- IQOS marketing at cultural events; and
- IQOS marketing through social media "brand ambassadors" or "influencers" with images showing IQOS as part of an exciting and youthful lifestyle.

It is instructive that, late last week, PMI announced that is has suspended its global promotion of IQOS through "influencers" on social media, but only after it was exposed in a Reuters story³ and, even then, PMI distorted the extent to which it was using "influencers" on social media. The company, however, has made no commitment to permanently end this type of marketing or to avoid the tactics or images cited in the Reuters story in the U.S. marketing of IQOS; nor has it disavowed its sponsorship of beer fests, beach parties, fashion shows and other tactics to reach young people with its marketing.

In the Technical Project Lead Review that accompanied its IQOS PMTA decision, FDA ignored and failed to consider the evidence provided it of how PMI had marketed IQOS in country after country. These marketing tactics cannot be reconciled with an expressed intent to limit IQOS marketing to adult smokers who may use the IQOS products as an alternative to cigarettes.

Given the tobacco industry's long history of marketing its products to youth, a history that the tobacco companies have never acknowledged, and the recent impact on so many American families of the irresponsible marketing of e-cigarettes, resulting in an epidemic of youth usage of those products, we are deeply concerned that similar marketing of IQOS in the US would have a devastating impact on public health, particularly on the health of young people.

2

³ Chris Kirkham, "Exclusive, Philip Morris suspends social media campaign after Reuters exposes young 'influencers,' Reuters, May 10, 2019, https://www.reuters.com/article/us-philipmorris-ecigs-instagram-exclusiv/exclusive-philip-morris-suspends-social-media-campaign-after-reuters-exposes-young-influencers-idUSKCN1SH02K

This concern is increased by how FDA addressed the mandatory legal consideration of the evidence provided by the applicant with regard to the risk to youth. The experts at FDA in social science issues concluded as follows:

The social science review concludes that based on the information submitted by the applicant, we have concerns with respect to: the lack of information about youth under age 18, as well as the lack of a discussion of submitted data's applicability to youth and the lack of presentation of the data in stratified categories that would allow us to make inferences about youth, the potential for initiation among young adult never smokers, and the potential for dual use among current smokers with only a one cigarette per day decrease in use frequency.

Philip Morris Products S.A.'s premarket tobacco product applications do not contain sufficient information to address these concerns from a Social Science perspective. ⁴

Yet this expert observation and conclusion was overruled by the Technical Project Lead of the Office of Science,⁵ and the IQOS PMTA was granted by FDA, based on two studies and limited experience in two different countries (Japan and Italy) with different cultures, different marketing rules and different circumstances. There was no meaningful data or analysis to demonstrate the applicability of the limited experience in those countries to the American setting.

In light of the experience with e-cigarettes and youth in the United States, and the examples that demonstrate that PMI has marketed IQOS in many countries using the same marketing techniques, strategies and images that have fueled the e-cigarette epidemic in this country, the decision by the Office of Science reviewer, and the FDA, to discount the conclusions of the social science review team is not only arbitrary, it is dangerous long term.

Given FDA's reliance on PMI's assurances about the intended marketing of IQOS in the U.S., and the decision of the senior leadership at FDA to ignore the findings of the Social Science review team, our organizations urge FDA to issue a public commitment that, if the agency becomes aware of IQOS marketing in the U.S. that reflects any of these marketing strategies and tactics used by PMI in other countries, FDA will revoke forthwith the marketing order issued on April 30, 2019.

We look forward to your prompt response.

Respectfully submitted,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

⁴ FDA, Technical Project Lead Review for PMI heated tobacco products (April 29, 2019), at 83 (emphasis added).

⁵ Id.

Examples of PMI's Global Marketing of iQOS

IQOS Retail Stores

IQOS store in Lisbon, Portugal

https://www.behance.net/gallery/33712684/IQOS-Flagship-Store-Chiado-Lisboa-Philip-Morris



IQOS store in UK

https://www.boxpark.co.uk/shoreditch/shopping/iqos/



IQOS store in Tokyo, Japan, with cafe

https://jp.iqos.com/iqos-store



IQOS store in Moscow, Russia

http://poliansky.com/portfolio/427/



IQOS Advertisements to General Public: Outdoor Ad, Berlin, Germany



Source: TFK, Picture taken July 1, 2017

IQOS Advertisements to General Public: Displays in Non-Tobacco Related Places

These displays in Italy clearly do not adhere with PMI's claim that it intends to introduce adult smokers to these products in adult-only device stores. By placing these displays in everyday venues, such as workout gyms, cafes, and barber shops, these products are being linked to an everyday lifestyle.



Instagram post from June 21, 2017, https://www.instagram.com/p/BVm612BDnwb/ ?taken-by=iqos_friends





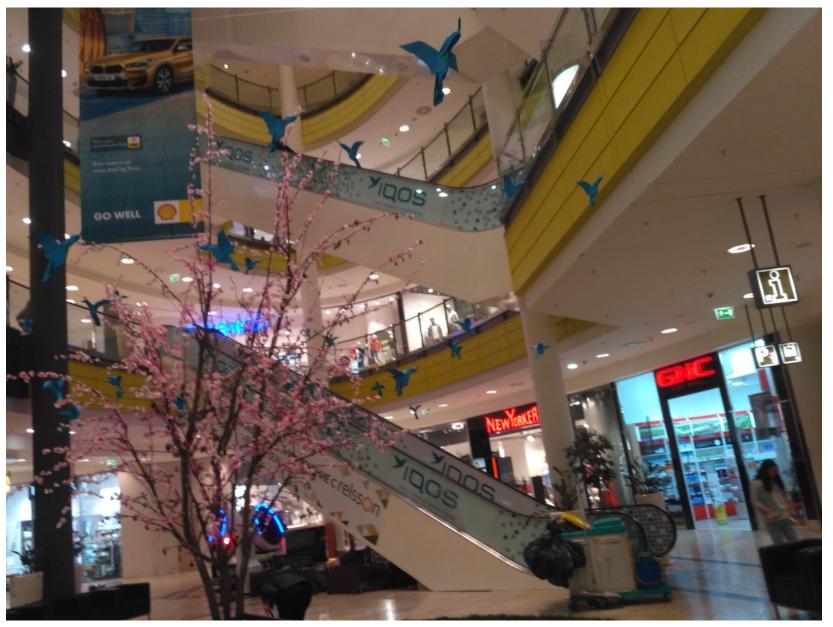
Instagram post from June 10, 2017, https://www.instagram.com/p/BVKXj7ejTa0/?taken-by=iqos_friends



Instagram post from June 13, 2017, https://www.instagram.com/p/BVRpZvvjhdo/?taken-by=iqos_friends

IQOS Advertisements to General Public:

Advertisements throughout a shopping mall in Sofia, Bulgaria.



Mall in Sofia, Bulgaria. Image taken April 19, 2018.

IQOS Advertisements to General Public: Advertisements on Vehicles

IQOS branded cars seen around Russia and Ukraine in 2016



Source: https://www.drive2.ru/l/8529919/



Picture taken in 2016



Source: https://geometria.ru/events/other/2016/5/12/924708/pictures/53985492

IQOS Kiosks in Shopping Malls



Located in Greece. Source: http://www.voria.gr/article/thessalonikisti-tsimiski-to-flagstore-gia-to-enallaktiko-tsigaro-iqos





Located in Greece. Source: http://my-spectrum.com/iqos-at-golden-hall/

Located in Russia. Source: http://inter-tabak.ru/project/iqos/

IQOS Kiosks in Shopping Malls: Exposure to Children



Greece, February 2018, https://www.instagram.com/p/BfOGwJTl9LT/?takenby=senor_babbar



IQOS-Sponsored Parties: Launch Events

These are images from two South African IQOS Launch events, in Cape Town and Johannesburg. The images show there were DJs, drinks available, differing lounge areas, and IQOS products themselves. Not shown were the acrobatic entertainment acts and food served.









IQOS-Sponsored Parties: Italy, July 2017

An exclusive IQOS event hosted at "Qubba" a dance/night club in Catania, Italy. There was a special guest Saturnino Celani.





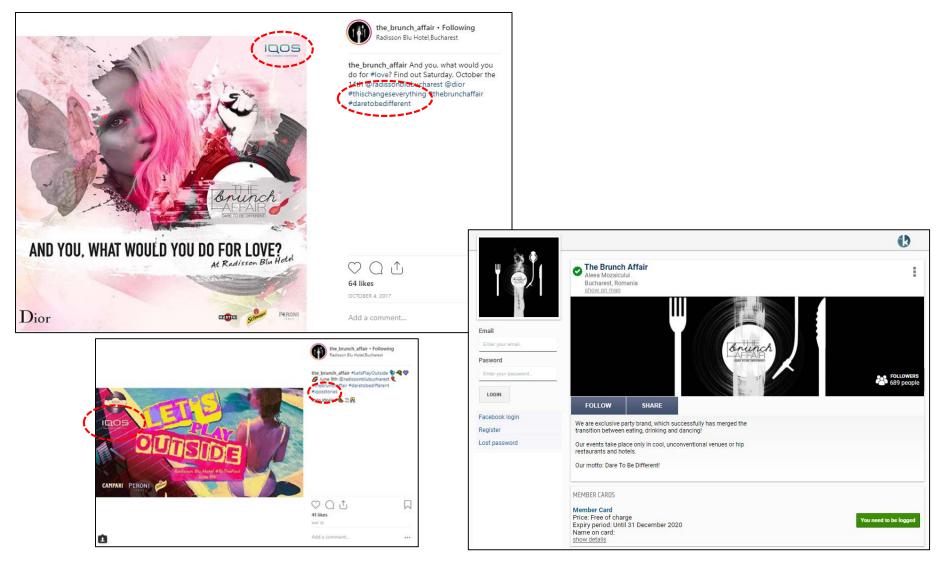




Source: http://www.welookaround.com/portfolio_page/philip-morris-iqos-night/
Additional video at: https://vimeo.com/233679380, http://www.welookaround.com/portfolio_page/philip-morris-iqos-night/

IQOS-Sponsored Parties: Party Series in Romania

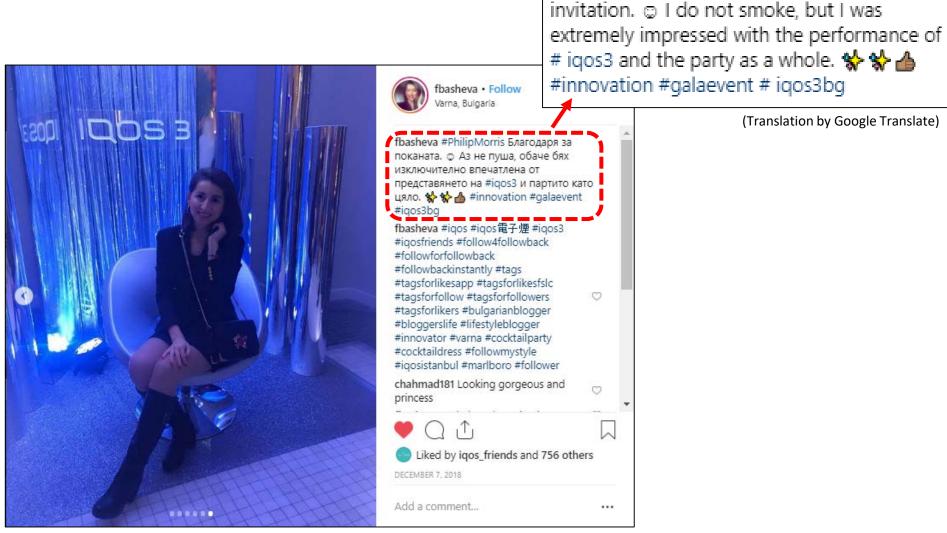
These examples of IQOS sponsoring a series of parties is from across Romania. The Brunch Affair hosts members-only themed parties and then posts about them on social media using IQOS-related hashtags including #thischangeseverything and #daretobedifferent. Social media advertisements for these parties clearly identify IQOS as the sponsor.



IQOS Party Invitations to Non-Smokers

This Instagram post, from a blogger in Bulgaria with over 23,000 followers, shows that non-smokers were invited to and attended a sponsored event featuring the new IQOS 3 product. This contradicts PMI's claims that its sponsored events are for smokers only.

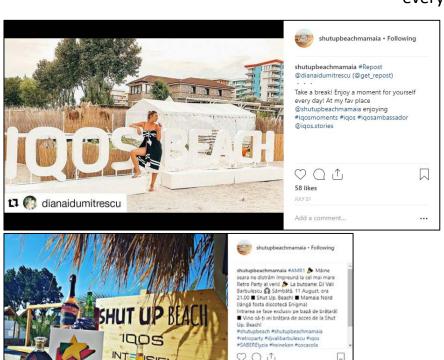
fbasheva #PhilipMorris Thanks for the

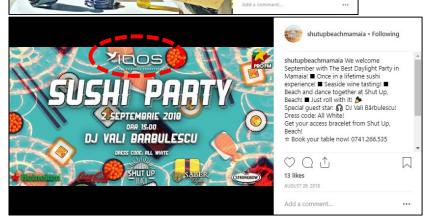


Instagram post, December 7, 2018, https://www.instagram.com/p/BrGXPBjg6ye/

IQOS-Sponsored Beach Bar: Shut Up, Beach!, Romania

An IQOS-sponsored beach bar, where IQOS branding is ubiquitous. These types of sponsorships and "IQOS-Friendly Place" messages are beyond PMI's claimed focus on adult smokers, but rather normalizes use of the product and links it to everyday activities.





44 likes





https://www.instagram.com/shutupbeachmamaia/

IQOS-Sponsorships at Events: Street Food Festival, Kyiv, Ukraine, July 2017

An IQOS booth set up at the Ulichnaya Eda street food festival. Children were present at the festival. IQOS representatives also wandered around the festival grounds to show the product to attendees and offer free samples.











Source: https://geometria.ru/events/other/2017/7/22/993787/pictures/62686985

IQOS-Sponsorships at Events: "IQOS Zone" at 2017 Belgrade Beer Fest

IQOS sponsored a stage and lounge area at the Belgrade Beer Fest, extending its brand recognition beyond adult smokers.



Image by Goran Srdanov, at http://www.telegraf.rs/vesti/beograd/2889153-nastup-grupe-sars-kao-kruna-jubilarnog-beer-festa-foto

IQOS-Sponsorships at Events: IQOS Area at Oktoberfest Romania



Instagram post by IQOS team member, September 8, 2018, https://www.instagram.com/p/BneIUqKFwDU/?takenby=iasmiiina



Instagram post, September 9, 2018, https://www.instagram.com/p/BnhDCxlAh6R/?taken-at=391214416

IQOS-Sponsorships at Events: IQOS Lounges at Music Festivals in Portugal, Summer 2018

These IQOS-sponsored lounges included Instagram-ready photo opportunities, which attendees could then share on their personal Instagram accounts. This extends the IQOS-related marketing beyond the companies' reach to the followers of the individuals who post these images.



NOS Summer Opening Music Festival, Instagram post, July 21, 2018, https://www.instagram.com/p/BlgPLb2laA9/?tagged=mundosemfumo



| MEO Sudoest | MEO Sudoest, Instagram Post, August 13, 2018, https://www.instagram.com/p/BmbD8HTHLWA/? tagged=mundosemfumo





MEO Sons de Mar, Instagram post, September 1, 2018, https://www.instagram.com/p/BnMb1XnnQfS/?tagged=mundosemfumo

IQOS-Sponsorships at Events: Estereo Picnic Music Festival, Bogota, Columbia, March 2017

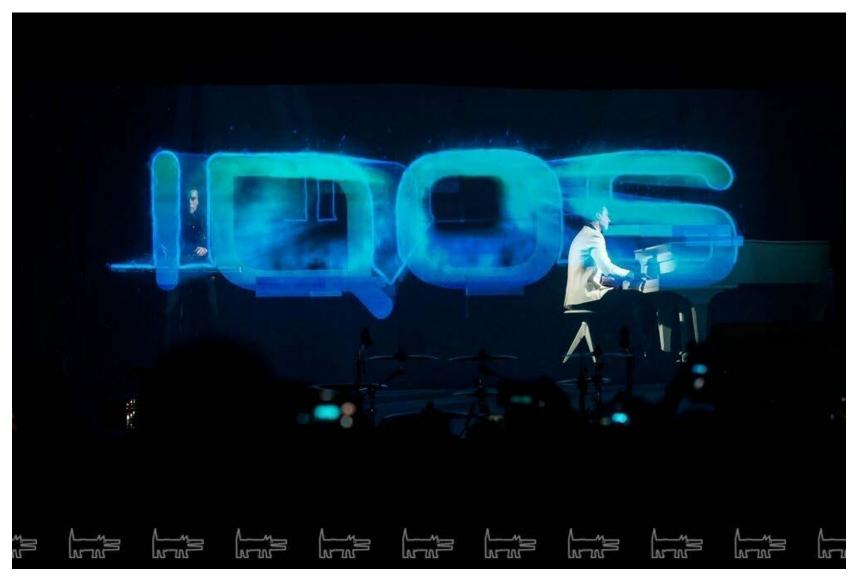


http://www.aeromedios.com/esp/globos aire frio.html



IQOS-Sponsorships at Events: Concert in St. Petersburg, Russia, May 2017

The popular group "Leningrad" played the concert. The concert was put on for IQOS users and their friends.



IQOS Fashion Partnerships: Marie Claire Magazine Event

Public Marie Claire event in conjunction with IQOS held in an IQOS space within a mall in Russia, October 2016.













Source: https://www.youtube.com/watch?v=fPRaz3Qeu5Q

IQOS Fashion Partnerships: Collaboration with Designer Karim Rashid

PMI has recruited fashion and lifestyle designers to create limited edition "sleeves" for IQOS devices. These images were posted on the designer's Instagram account, which means people who follow him for his designs and who are not necessarily tobacco users are exposed to these brand-positive images.



September 3, 2018, https://www.instagram.com/p/BnO67Eth-3N/?taken-by=karim_rashid_official

IQOS Sponsorships at Fashion Events: Mercedes-Benz Fashion Days, Kiev, Ukraine, September 3, 2016

IQOS sponsored an area at the Mercedes-Benz Fashion Days event in Ukraine, where it linked the brand with fashion, created an interactive display for people to take pictures and share, and, as seen in the top image, also exposed children to its brand and product. The "95% less don't's" message could be a tongue-in-cheek reduced risk claim.

Benz

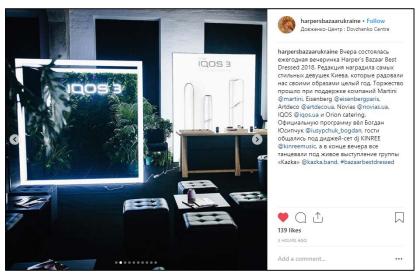
KIEV





IQOS Sponsorships at Fashion Events: Harper's Bazaar Ukraine Magazine's Best Dressed Event

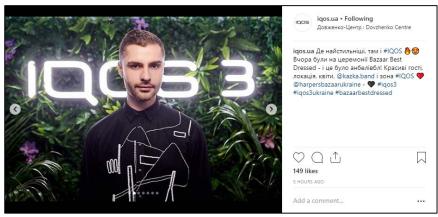
Another example of IQOS sponsoring a fashion event in Ukraine where, again, attendees can take pictures of themselves and share on their personal account. Note the young girl in the post on the top right.



December 5, 2018, https://www.instagram.com/p/BrAp-hyBAy5/



December 4, 2018, https://www.instagram.com/p/Bq-xaxjhXdN/



December 5, 2018, https://www.instagram.com/p/BrAesPKHv6l/

IQOS-Sponsored London Fashion Week Blog Post



MARCH E 2019

LONDON FASHION WEEK X IQOS AT THE ROSEWOOD HOTEL

London Fashion Week: My stay at the Rosewood hotel in collaboration with IQOS

So usually I would be absolutely dreading the stress of fashion week, the trawling around London and the early and late commute home – but this LFW I absolutely did it the way you should thanks to IOOS (heated tobacco technology)

1008 provided me the most beautiful room at the Rosewood Hotel (I had literally wanted to stay here for years since I first visited it!) during London Fashion Week which was walking distance to all the shows so perfect location and just the best place ever!





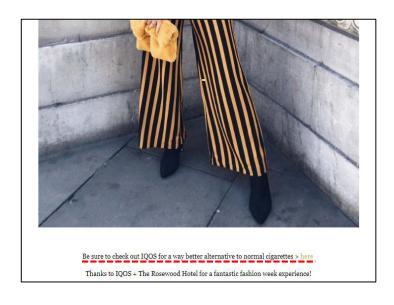
Toula Rose. London based fashion & lifestyle blogger. Affordable Style.

The rooms were IQOS friendly. If you guys smoke but don't know about IQOS then you'll be glad you've read this post.

It uses heat technology rather than burning tobacco, which gives you the true taste of tobacco with no smoke, no ash and a lot less smell. One of the things that I hated about normal smoking was the smell that can get left on you, whereas with IQOS your hair or clothes don't smell of smoke at all afterwards! So I was fashion week ready! The device is super sleek and comes in a variety of colours.

Shop IQOS here

See what I wore on the first day of fashion week below:



IQOS-Sponsored Fashion Magazine Articles

While some articles are explicitly identified as sponsored by IQOS, others highlight the product but do not include sponsoring information. This article featured high-quality images of the product and had the two subjects mention how IQOS is part of their winter plans.

VOGUE

Мой идеальный зимний вечер: рассказывают Ульяна Нешева и Тимур Мирошниченко

28 **ЯНВАРЯ** 2019

Зима – идеальное время года, когда можно хоть ненадолго замедлить темп, посвящать больше времени себе и собственным хобби: наслаждаться искусством, кататься на лыжах, читать книги в компании IQOS, играть с друзьями в настольные игры. В нашем новом материале тату-мастер Ульяна Нешева и телеведущий Тимур Мирошниченко рассказывают о том, что такое для них идеальный зимний вечер и без чего они не представляют свою зиму.

(Translated by Google Translate)

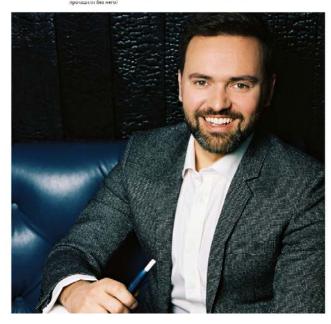
My perfect winter evening: tell Uliana Nesheva and Timur Miroshnichenko

JANUARY 28, 2019



Winter is the ideal time of the year when you can slow down the pace, spend more time for yourself and your own hobbies: enjoy art, ski, read books at IQOS, play board games with friends. In our new material, tattoo artist Uliana Nesheva and TV presenter Timur Miroshnichenko talk about what an ideal winter evening is for them and without which they cannot imagine their winter.

Зима у меня ассоциируется с лыжным костомом, а настоящих спасеннем в это время года становится IQOS. Теперь мен ен ужно выходить на холодный балкон актобі и дже открывать окна в машине. Девліс абсолотно не дамит и не производит характерных для курильшиков запахов. ІІ как чоги прошлые вимы



My winter is associated with a ski suit, and IQOS becomes a real salvation at this time of the year. Now I don't need to go out to a cold balcony in winter and even open windows in the car. The device does not smoke at all and does not produce smells characteristic of smokers. And (howadidonsyolastanslate) winters go without him?

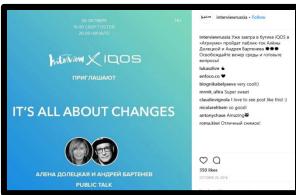
Vogue Ukraine, January 28, 2019, https://vogue.ua/article/culture/lifestyle/moy-idealnyy-zimniyvecher-rasskazyvayut-ulyana-nesheva-i-timur-miroshnichenko.html

IQOS Fashion Partnerships: Interview Magazine Russia Event

Interview Magazine Russia and IQOS partnered to host an event at the Atrium Mall in Moscow in October 2017. The event was held at an IQOS boutique and was an open interview with art innovator Andrey Bartenev and magazine editor Aliona Doletskaya.









PMI-Ferrari Sponsorship

PMI announced its renewal of its Ferrari sponsorship in early 2018. Sports sponsorships, and particularly Marlboro's sponsorship of Formula 1 racing has long been recognized as a successful way to present its brand to millions of viewers and elevate its image as a "winning" product.¹



https://www.pmi.com/media-center/press-releases/press-releasedetails/?newsId=2333298



http://formula1.ferrari.com/en/partners/philip-morris-international/



Blog post, October 7, 2017, http://sebastian-vettel-fans.blog.cz/1710/videos-photos-seb-kimi-and-maurizio-at-the-iqos-event-today

¹ National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use*, Smoking and Tobacco Control Monograph No. 19, NIH Pub. No. 07-6242, June 2008, http://cancercontrol.cancer.gov/tcrb/monographs/19/m19 complete.pdf, at 65, 68-69.

IQOS-Sponsored Cultural Events: Zurich, Switzerland, January 2017

This was an art event sponsored by IQOS where photographic art was displayed and attendees were provided the opportunity to "discover IQOS".



IQOS-Sponsored Cultural Events: "Creative Hub" Qreator by

IQOS, Bucharest, Romania









Description:

- Provides spaces and technological resources for the creative community, as well as information about IQOS and product testing.
- Hosts weekly free events and workshops for dance, music, theatre, film, photography, and art communities

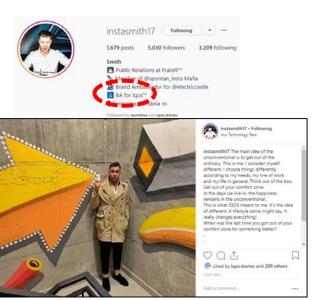
Website quotes (Google translated):

- "More than 500 square feet of creativity, inspiration and innovation... a space for creative energies looking for new opportunities and perspectives."
- "If you are from Bucharest, we are waiting for you at QREATOR by IQOS where, besides developing your talents in the 7 dedicated rooms, you can try IQOS... the revolutionary alternative to cigarettes."

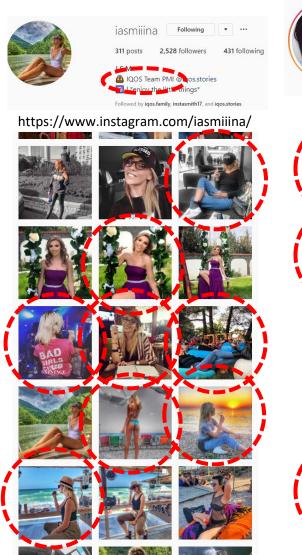
Video Tour: https://www.qreator.ro/despre#video
Source: https://www.auto-bild.ro/advertorial/iqos-deschideqreator-noul-hot-spot-pe-harta-creativa-bucurestiului-130550.html

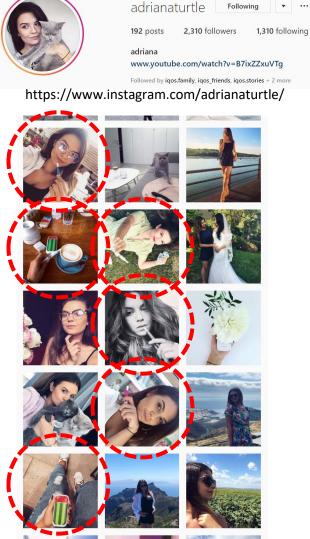
IQOS Marketing on Social Media Posts: Brand Ambassadors

These are only a few examples of Instagram posts and accounts by paid brand ambassadors for IQOS. These types of images do not at all portray adult smokers trying to quit, but rather present a glamorous lifestyle for IQOS users.



Instagram post, January 18, 2019, https://www.instagram.com/p/BsvePcoBbjS/





IQOS Marketing on Social Media Posts: Brand Ambassadors



Instagram post, December 16, 2018, https://www.instagram.com/p/BrcU66gAegu/





Instagram post, August 21, 2018, https://www.instagram.com/p/BmwFT8VhN4C/



Instagram post, June 29, 2018, https://www.instagram.com/p/BkmkY8Ml0oc/

Instagram post, December 22, 2018, https://www.instagram.com/p/BrroAjSFyrl/

IQOS Marketing on Social Media Posts: Brand Ambassadors



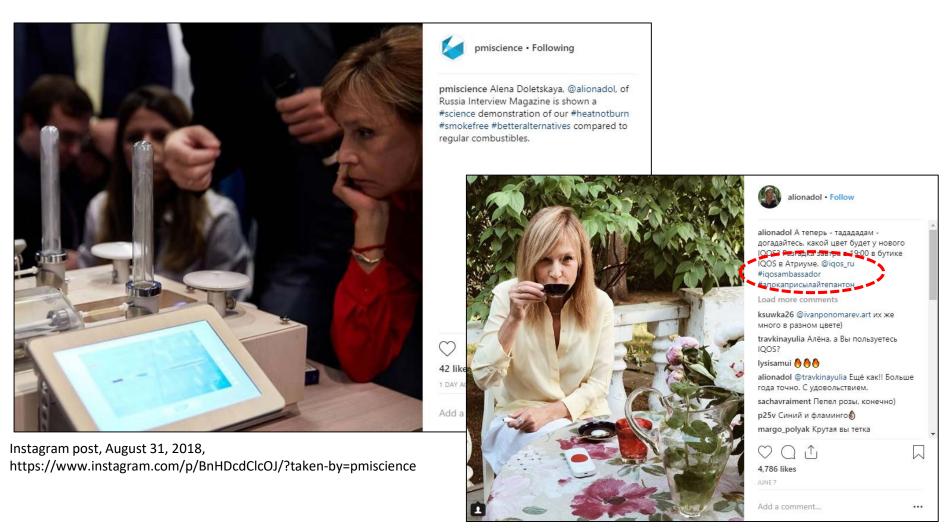
Instagram post from @mariandivalo (6.3 million followers, 12 percent in the US) that uses the hashtags #iqos and #ad. The image was taken in front of a backdrop featuring the iQOS logo. September 24, 2017, https://www.instagram.com/p/BZcHOHxDCrh/.

Instagram post from @christina_ich (429k followers, nine percent in the US) that uses the hashtags #iqos and #ad. April 28, 2018, https://www.instagram.com/p/BiH3JIrlmAq/.



IQOS Marketing on Social Media Posts: PMI Science with Russia Interview Magazine

PMI Science posted on its Instagram account about the Russia Interview Magazine editor in chief learning about IQOS, but failed to mention she identifies herself as an IQOS Ambassador (note hashtag in her personal post).



Instagram post, June 7, 2017, https://www.instagram.com/p/BjuA8sFHajb/?taken-by=alionadol