

HEATED TOBACCO PRODUCTS: WHAT WE KNOW

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Supplemental Table S1. TPSAC Vote on PMI IQOS MRTP Application, January 25, 2018*					
		Yes	No		Abstain
1.	Discuss evidence related to the health risks of the IQOS system and the appropriateness of the proposed modified risk information.				
a.	Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: “Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases.”? (Vote)	0	8		1
b.	Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: “Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes.”? (Vote)	4	5		0
2.	Discuss evidence related to human exposure to harmful or potentially harmful chemicals when combusted cigarette smokers completely switch to the IQOS system, including the implications of changes in exposure for long-term disease risk and the appropriateness of the proposed modified risk information.				
a.	Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: “Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals.”? (Vote)	8	1		0
b.	If the answer to question 2a is “yes”, has the applicant demonstrated that the reductions in exposure are reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality? (Vote) [To be answered by Committee members who voted “yes” to 2a.]	2	5		1
		High	Medium	Low	Abstain
3.	Discuss evidence regarding the likelihood that existing combusted cigarette smokers will initiate use of the IQOS system, completely switch to IQOS, and/or become long-term dual users of IQOS and combusted cigarettes.				
a.	What is the likelihood that U.S. smokers would completely switch to use of the IQOS system? (High/Medium/Low)	0	2	7	0
b.	What is the likelihood that U.S. smokers would become long-term dual users of IQOS and combusted cigarettes? (High/Medium/Low)	3	5	1	0
4.	Discuss evidence regarding the likelihood that persons who do not use tobacco products will start using the IQOS system.				
a.	What is the likelihood that U.S. never smokers, particularly youth, will become established users of the IQOS system? (High/Medium/Low)	2	1	4	2
b.	What is the likelihood that former smokers will re-initiate tobacco use with the IQOS system? (High/Medium/Low)	0	0	9	0
		Yes	No		Abstain
5.	Discuss evidence regarding consumer comprehension and perceptions of the proposed modified risk labeling and advertising.				
a.	Has the applicant demonstrated that, after viewing the proposed modified risk labeling and advertising, consumers accurately understand the risks of IQOS use as conveyed in the modified risk information? (Vote)	0	9	0	0
b.	What additional information, if any, needs to be communicated, other than what has been proposed by the applicant, for consumers to understand the health risks of the IQOS system? [No vote was taken.]				
*FDA TPSAC Meeting Materials and Information, January 24-25, 2018: Transcript Day 2. [accessed 3 Apr 2018]; Available from: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM599235.pdf .					