Module 6 : Research

6.3 Effect on Tobacco Use Initiation Among Non-Users

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1. INFORMATION ON TOBACCO USE INITIATION AMONG NON-USERS

To measure the potential benefit of marketing an MRTP to the public, the FDA Modified Risk Tobacco Product Applications Guidance recommended investigating several areas, including the effect on tobacco use initiation among non-users[1]. In this section, we provide data from both pre-market studies included in the original MRTPA[2], and postmarket studies conducted both within the U.S. and internationally, on the effect of *IQOS* on tobacco use initiation among non-users. In addition, we cross-reference Module 7 of the initial MRTPA for the Authorized *IQOS* products with related appendices and data, and with subsequent amendments, and Module 7 of the supplemental PMTA for the Authorized *IQOS* 3 System (PM0000634), as well as Module 7 of the supplemental MRPTA for the *IQOS* 3 System (MR0000192).

1.1. Premarket U.S. data

1.1.1. Background

To provide data on the effect on tobacco use initiation among non-users, PMI conducted a U.S. premarket quantitative study (THS-PBA-05-REC-US) to assess the effect of the authorized reduced exposure claim, included as part of the THS Label, Labeling and Marketing Materials (LLM), on behavioral intentions among adult tobacco non-users. A summary of the methodology of this study is presented in section 6-2 (Table 1).

Below, we provide a brief summary of previously submitted evidence from this U.S. pre-market quantitative study on behavioral intentions among adult tobacco non-users.

1.1.2. (b) (4)

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[1] FDA. Modified Risk Tobacco Product Applications. Guidance for Industry. Rockville, MD: U.S. Department of Health and Human Services. March 2012. https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf.

[2] MRTPA Modified Risk Granted Order - Exposure Modification of December 12, 2019, authorizing the marketing of the modified risk product *IQOS* 2.4 System Holder and Charger (STN: MR0000133).

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1.1.3. Conclusion of U.S. Pre-market Studies

Based on the above data that was previously submitted to the FDA as part of the original MRTPA (MR0000059-MR0000061, MR0000133), the FDA TPL review[5] determined that

- *Among former smokers: the results suggest some interest in trying the product among former smokers, but the addition of the claim did not appear to increase interest among this group. Accordingly, the results do not suggest that the products, if marketed with a reduced exposure claim, would generate a high level of interest among former smokers. This finding is consistent with a potential benefit to population health.*
- *Among adult never smokers: the results suggest almost no interest in trying the product among adult never smokers, and the addition of the reduced exposure claim did not appear to increase interest among this group. Accordingly, the results do not raise concerns that the proposed MRTP would generate a high level of interest among never smokers. This finding is consistent with a potential benefit to population health.*
- *Among young adult never smokers: the evidence related to young adult never smokers suggests low interest in trying the product. In the applicant's studies, the addition of the claim did not appear to increase interest in trying IQOS. Accordingly, the results do not raise concerns that the proposed MRTP would generate a high level of interest among young adult never smokers. This finding is consistent with a potential benefit to population health.*

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[5] Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act – Technical Project Lead, p. 62, July 6, 2020.

(b) (4)

1.2. Postmarket U.S. Data

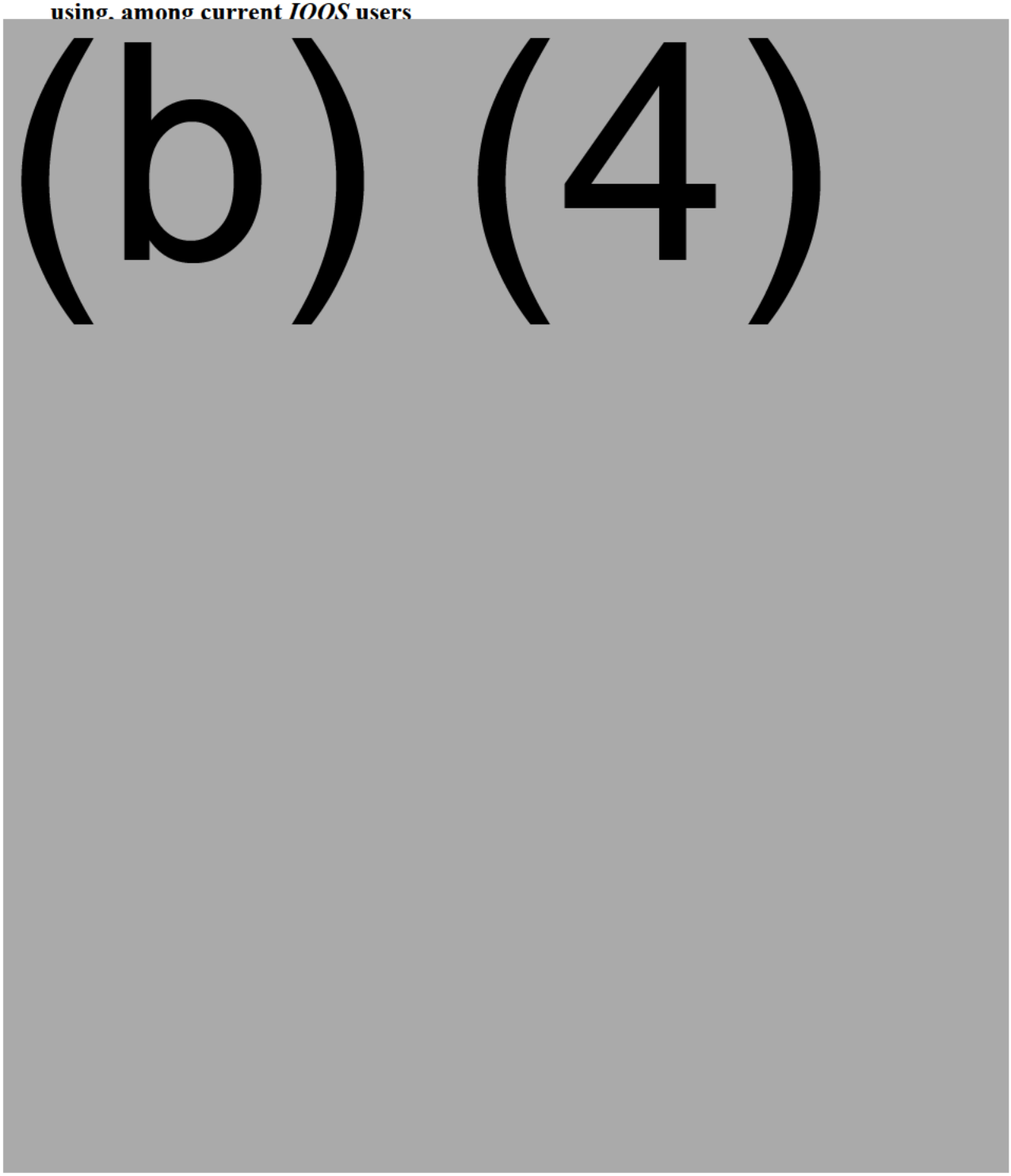
1.2.1. Background

As part of the PMSS program for *IQOS* pursuant to the MRGOs orders from the FDA, PMP S.A. has developed a comprehensive post-market surveillance program within the United State that permits evaluation of the impact of the marketing of the *IQOS* System (b) (4) is provided in Section 8.1. (b) (4) .

1.2.2. U.S. Postmarket Data among Tobacco Non-Users from IQOS Cross-sectional PACS

(b) (4)

Table 1 Types of tobacco products ever tried, used to lifetime criterion, and currently using, among current *IQOS* users



(b) (4)

Table 2 Initiation with *IQOS* among Long-Term Former Established Smokers and Long-Term Former Established Users of All Tobacco Products

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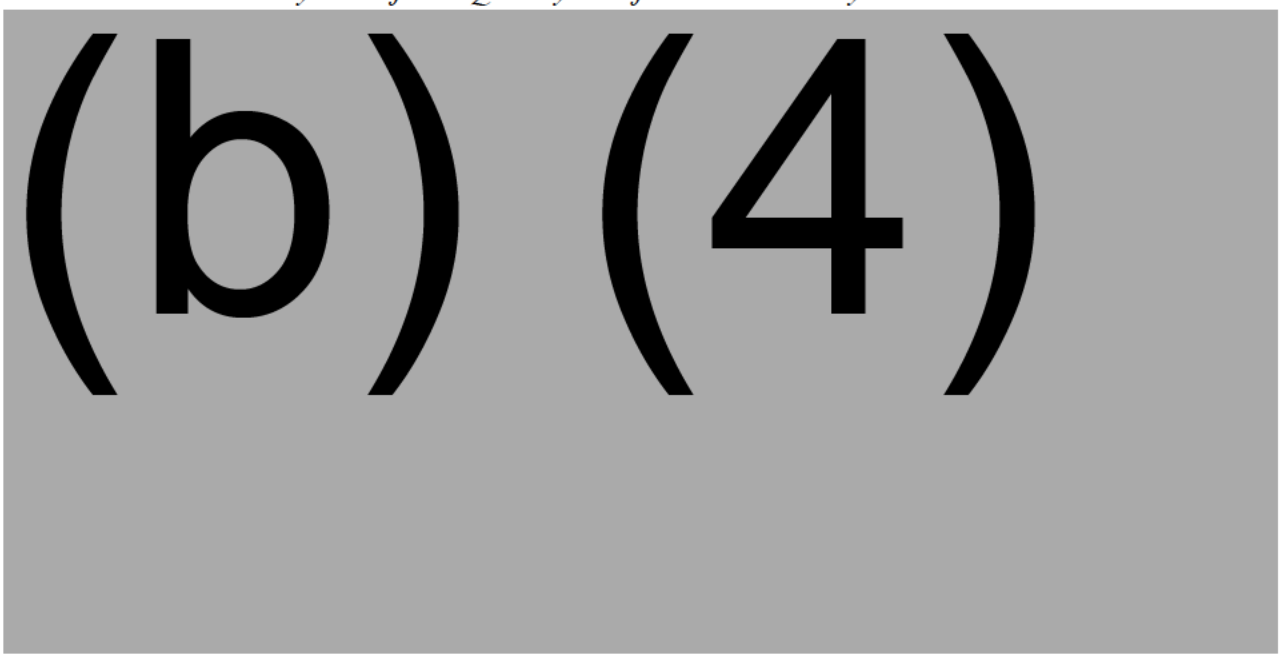
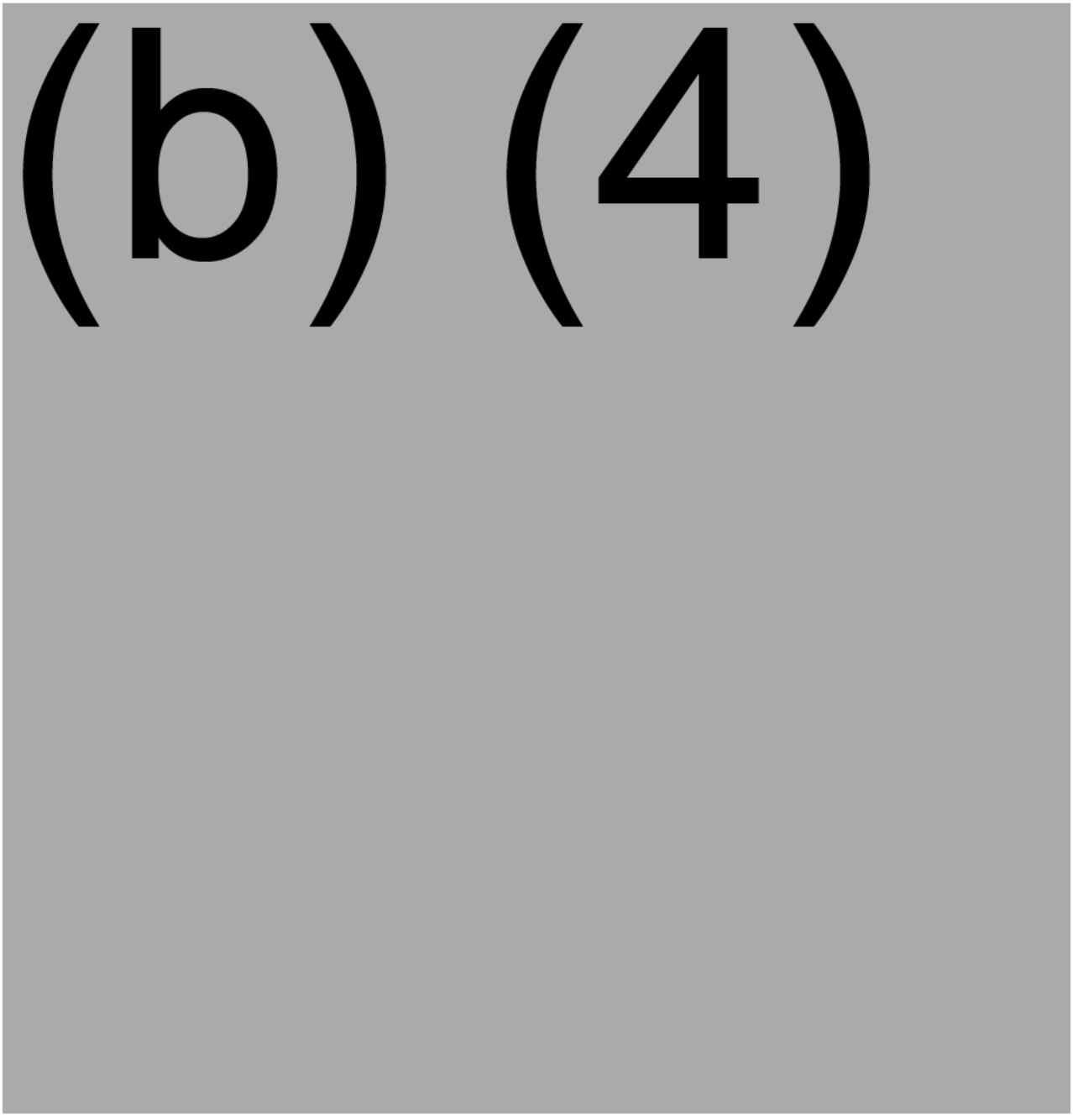
[8] (b) (4)

1.2.3. U.S. Postmarket Data on Underage Awareness, Ever Use, And Past 30-Day Use of the IQOS System from UTUS analysis



(b) (4)

Table 3 Methodology of Analysis of Relevant Data from the ALCS Underage Tobacco Use Survey



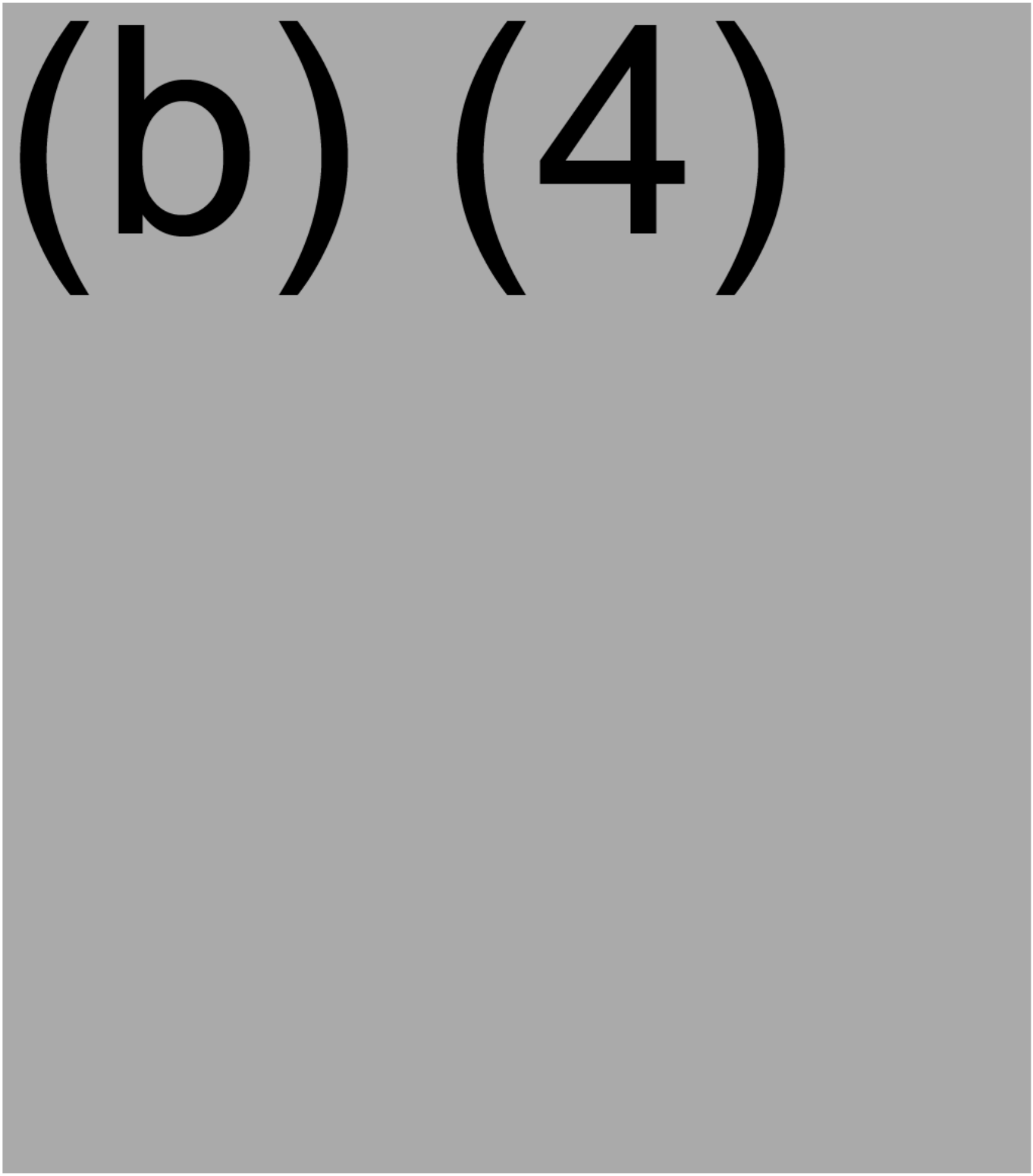


Table 4 UTUS 2022 to 2023 Estimates: Awareness, Ever Use, and Past 30-Day Use of *IQOS*

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1.3. PMP S.A. International Postmarket Data: Repeated Cross-sectional Post-Market Surveys (PMX studies)

1.3.1. Background

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1.3.2. PMP S.A. International Postmarket Data on initiation, relapse and re-initiation

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[14] (b) (4)

Table 5 Initiation, Relapse rate, and Re-initiation rate with *IQOS* among adult TNP non-users in representative samples of the cross-sectional general adult population and *IQOS* Owners' surveys in Japan and Italy

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1.3.3. Conclusion of International Postmarket studies

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1.4. Independent Studies

1.4.1. Background

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1.5. Conclusion

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2. REFERENCES

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