Module 4: Labeling and Marketing

4.2 Marketing Plans

TABLE OF CONTENTS

4.2 INTRODUCTION 2
4.2.1 Marketing Plan Overview 2
4.2.2 Cross-Referenced Documents 3
4.2.3 Information Collected in the U.S. Market to Date 3
4.2.4 Conclusion and the APPH Standard 4

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4.2 INTRODUCTION

This section addresses the marketing plan for the *IQOS* 3 System. Because the plan is the same as the marketing plan for the Authorized *IQOS* System, we provide plan information in this section by cross-referencing amendments to theoriginal PMTA for the Authorized *IQOS* System as well as reference to post-authorization submissions made pursuant to the Marketing Order for the Authorized *IQOS* System.

In addition, as the Authorized *IQOS* System has been on the market for short period of time following FDA authorization, we include (Section 4.2.2 below) information collected since the launch of that product, including purchaser information and outcomes of the marketing restrictions for the Authorized *IQOS* System.

The marketing plans for the *IQOS* 3 System, are the same as the marketing plans for the Authorized *IQOS* System. This fact, along with the information recently gathered about the Authorized *IQOS* System in the U.S. market confirms that marketing the *IQOS* 3 System is appropriate for the protection of the public health.

4.2.1 Marketing Plan Overview

Upon issuance by FDA of a Marketing Order for the *IQOS* 3 System, Altria Client Services LLC (ALCS)[1] and an ALCS affiliate will be licensed to distribute and sell the *IQOS* 3 System (*IQOS*) in the United States, just as they have been licensed to distribute and sell the Authorized *IQOS* System in the United States. The ALCS affiliate that will distribute and sell the product in the U.S. is Philip Morris USA Inc. (PM USA)[2].

The marketing plan for the *IQOS* 3 System will be the same as the marketing plan for the Authorized *IQOS* System. The target audience for the *IQOS* 3 System will continue to be adult smokers age 21+. PM USA will continue to provide adult consumers with a high level of education and guidance. Marketing will continue to be grounded in the existing *IQOS* Brand Book and Good Conversion Principles, and current marketing restrictions will remain in place.

PM USA prefers that adult tobacco consumers have available to them the most updated version of the *IQOS* device. However, PM USA does not plan an immediate switch to *IQOS* 3 System upon authorization and may sell both the Authorized *IQOS* System and *IQOS* 3 System in some markets, as affected by inventories, product availability, and the need for adult consumer support.

[1] Altria Client Services LLC (ALCS) is a wholly-owned subsidiary of Altria Group, Inc. ALCS provides certain services to the Altria family of companies.

[2] PMP S.A.'s parent, Philip Morris International Management S.A. (PMI), has entered into an agreement with ALCS by which ALCS and its affiliates, including PM USA, are licensed to sell *IQOS* in the United States.

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4.2.2 Cross-Referenced Documents

Because the marketing plan for the *IQOS* 3 System will be the same as the plan for the Authorized *IQOS* System, we cross-reference amendments to the PMTA for the Authorized *IQOS* System that provide more detail about the marketing plans. PMP S.A. and PM USA communicated details about the marketing plan for *IQOS*, including age verification processes, in response to FDA's requests for additional information during the review of the original PMTA. These amendments are contained in the following documents:

- Response to August 20, 2018 Advice/Information Request for PM0000424-PM0000426 and PM0000479, dated September 5, 2018, and
- Response to March 19, 2019 Advice/Information Request for PM0000424-PM0000426 and PM0000479, dated March 25, 2019

Also, in response to the requirement in the Marketing Order for the Authorized *IQOS* System that all "labeling, advertising, marketing, and/or promotional materials" be provided to FDA "at least 30 days prior to the initial publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials," PM USA provided additional information about its marketing plans for the Authorized *IQOS* System in certain 30-Day notifications submitted to FDA. For ease of reference those notifications are provided as part of this submission:

- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, June 7, 2019 (Appendix A4-2-1-iqos-30day-notification-2019-06-07),
- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, August 23, 2019 (Appendix A4-2-2-iqos-30day-notification-2019-08-23),
- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, January 15, 2020 (Appendix A4-2-3-iqos-30day-notification-2020-01-15).

The amendments to the original PMTA and the 30-Day Notifications referenced above all set forth PM USA's marketing plan for the Authorized *IQOS* System. That marketing plan will be used for the *IQOS* 3 System as well.

4.2.3 Information Collected in the U.S. Market to Date

FDA provided a Written Response to PMP S.A.'s request for a pre-submission meeting with regard to this supplemental PMTA.[3] In response to PMP S.A.'s Question 1, FDA recommended the submission of information collected since the launch of the Authorized *IQOS* System in the U.S. market to support our conclusion that marketing of the

[3] Written Response, FDA Submission Tracking Number (STN): TC0005319, December 18, 2019.

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IQOS 3 System would be appropriate for the protection of the public health.[4] We provide that information here.

PM USA introduced the Authorized Product into the Atlanta, Georgia market on September 21, 2019 in PM USA-owned retail outlets. On November 16, 2019 PM USA introduced the Authorized *IQOS* System into the Richmond, Virginia market. Therefore, at the time of the submission of this supplemental PMTA, there has been a short period of in-market sales in two markets. Nevertheless, PM USA has collected data on sales and distribution and product purchasers, analyzed the delivery of advertising impressions, and summarized media tracking and optimization. This information has been submitted to FDA through two periodic reports:

- Periodic Report for PM0000424-PM0000426 and PM0000479, October 30, 2019 (Appendix A4-2-4-2nd-quarterly-reporting), and
- Periodic Report for PM0000424-PM0000426 and PM0000479, January 30, 2020 (Appendix A4-2-5-3rd-quarterly-reporting).

Although provided in more detail in the referenced Periodic Reports, these data show that early sales of the Authorized *IQOS* System are consistent with PM USA's careful introduction to limited markets and the high level of adult consumer education and guidance provided. In addition, almost 95% of *IQOS* purchasers who provided their age with registration are over age 25 and none were reported to be under age 21. This age data is consistent with PM USA's practice of restricting owned-retail store entry and purchase, face-to-face engagement, and e-commerce purchase to adults verified as age 21+. In addition, where tracking is available, advertising impressions have been delivered predominately (over 95% in all tracked channels) to persons over age 25. These results are consistent with implementation of PM USA's age restriction and verification practices, and immediate corrective actions in the event that such practices are not applied properly.

4.2.4 Conclusion and the APPH Standard

The marketing plans for *IQOS* 3 System will be consistent with the plans implemented for the Authorized *IQOS* System, as described in amendments to the PMTA for the Authorized *IQOS* System and post-authorization submissions to FDA. In the early in-market experience for the Authorized *IQOS* System, that plan has resulted in reaching PM USA's target audience, avoidance of unintended audiences, and steady sales in limited markets.

Given the congruence of the marketing plan for the *IQOS* 3 System with the Authorized *IQOS* System, the marketing of which FDA determined is appropriate for the protection of the public health, the marketing of *IQOS* 3 System should similarly be appropriate for the protection of the public health.

[4] *Id.*, pp. 9-10.

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