BofA SECURITIES

European Tobacco

US regulation expert call feedback: Review of moving parts

Government Regulations

US menthol cigarettes ban. Vape PMTAs. Enforcement.

We hosted Azim Chowdhury, Partner at Keller & Heckman LLP, to discuss the current moving parts in US Tobacco regulation. Investor questions focused on 1) The FDA's anticipated menthol cigarettes ban, 2) The vaping PMTA processes and the FDA's enforcement potential, 3) The nicotine reduction act. While the menthol cigarettes ban has been a long-term concern for sector participants, the recent emergence of an illicit vaping/e-cigarette market in the US has increased scrutiny on the FDA's PMTA processes. The final ruling on the menthol ban is still expected by March-end, while the FDA estimates it will have cleared most of the vaping/e-cigarette market by June-end.

Continuous postponement of the menthol ban

Congress gave the FDA authority to rule on flavoured cigarettes in 2009. Since then, it banned flavoured cigarettes (excl. menthol) and decided to ban menthol cigarettes (launching multiple studies including PATH along the way), without taking action on the latter. We are now nearing completion of the final rulemaking, according to Azim. Through this process, the FDA had to respond to c.175,000 comments before submitting the final to the OMB. The OMB is now reviewing the ruling, and while a final decision was initially expected in Spring 2023, it was then postponed to August, then December, and now March 2024. Effectively, there is no hard deadline for the FDA or the OMB to make a decision, but the expert would be surprised if it were postponed to post-US elections. After the final ruling, he anticipates a lawsuit from manufacturers, which could take a couple of years, before a final implementation (if confirmed).

Vaping/e-cigarette PMTAs: Focus on enforcement

While the FDA is clearing its PMTA "backlog" (26m submissions), most investors focused the rising share of illicit vapes in the US, estimated to be c.70% of the overall market. Enforcement action remains quite limited and $19,000 fines have limited impacts at the moment. The FDA's enforcement toolbox enables to increase fines up to $1m which could have a wider impact on the illicit market, but it remains a slow process. Separately, over the years, the FDA became myopically focused on banning all flavours, without considering the benefits of the lower-risk offering of vapes. The FDA announced this week it would complete all covered marketing applications by 30 June (all vaping products with 2%+ volume market share), 94% of which by 31 March.

Heat-not-burn, modern oral PMTAs. Nicotine reduction.

FDA will prioritize applications for products that already on the market, hence the iQOS heat-not-burn and nicotine pouches category. Both categories' flavoured variants could be at risk considering the FDA's current focus on flavours (following market denial orders in the vapour category and the proposed menthol cigarettes ban). Any ruling on nicotine reduction would have to go through the same rulemaking process as the menthol cigarette ban, which would make another long process.

24 January 2024

Equity
Europe
Tobacco

Joffrey Bellicha Meller >>
Research Analyst
MLI (UK)
+44 20 7995 7497
joffrey.bellichameller@bofa.com

Victoria Petrova >>
Research Analyst
BofA Europe (Frankfurt)
victoria.petrova@bofa.com

Antoine Prevot >>
Research Analyst
MLI (UK)
antoine.prevot@bofa.com

PMTA = Pre-market Tobacco Applications

FDA = US Food and Drug Administration

PATH = Population Assessment of Tobacco and Health

OMB = Office of Management and Budget at the White House

PM = Philip Morris

Refer to important disclosures on page 2 to 3.

Disclosures

Important Disclosures

BofA Global Research personnel (including the analyst(s) responsible for this report) receive compensation based upon, among other factors, the overall profitability of Bank of America Corporation, including profits derived from investment banking. The analyst(s) responsible for this report may also receive compensation based upon, among other factors, the overall profitability of the Bank's sales and trading businesses relating to the class of securities or financial instruments for which such analyst is responsible.

Other Important Disclosures

From time to time research analysts conduct site visits of covered issuers. BofA Global Research policies prohibit research analysts from accepting payment or reimbursement for travel expenses from the issuer for such visits.
Prices are indicative and for information purposes only. Except as otherwise stated in the report, for any recommendation in relation to an equity security, the price referenced is the publicly traded price of the security as of close of business on the day prior to the date of the report or, if the report is published during intraday trading, the price referenced is indicative of the traded price as of the date and time of the report and in relation to a debt security (including equity preferred and CDS), prices are indicative as of the date and time of the report and are from various sources including BofA Securities trading desks.
The date and time of completion of the production of any recommendation in this report shall be the date and time of dissemination of this report as recorded in the report timestamp.

Recipients who are not institutional investors or market professionals should seek the advice of their independent financial advisor before considering information in this report in connection with any investment decision, or for a necessary explanation of its contents.
Officers of BofAS or one or more of its affiliates (other than research analysts) may have a financial interest in securities of the issuer(s) or in related investments.
Refer to BofA Global Research policies relating to conflicts of interest.
"BofA Securities" includes BofA Securities, Inc. ("BofAS") and its affiliates. Investors should contact their BofA Securities representative or Merrill Global Wealth Management financial advisor if they have questions concerning this report or concerning the appropriateness of any investment idea described herein for such investor. "BofA Securities" is a global brand for BofA Global Research.
Information relating to Non-US affiliates of BofA Securities and Distribution of Affiliate Research Reports:
BofAS and/or Merrill Lynch, Pierce, Fenner & Smith Incorporated ("MLPF&S") may in the future distribute, information of the following non-US affiliates in the US (short name: legal name, regulator): Merrill Lynch (South Africa): Merrill Lynch South Africa (Pty) Ltd., regulated by The Financial Service Board; MLI (UK): Merrill Lynch International, regulated by the Financial Conduct Authority (FCA) and the Prudential Regulation Authority (PRA); BofASE (France): BofA Securities Europe SA is authorized by the Autorité de Contrôle Prudentiel et de Résolution (ACPR) and regulated by the ACPR and the Autorité des Marchés Financiers (AMF). BofA Securities Europe SA ("BofASE") with registered address at 51, rue La Boétie, 75008 Paris is registered under no 842 602 690 RCS Paris. In accordance with the provisions of French Code Monétaire et Financier (Monetary and Financial Code), BofASE is an établissement de crédit et d'investissement (credit and investment institution) that is authorised and supervised by the European Central Bank and the Autorité de Contrôle Prudentiel et de Résolution (ACPR) and regulated by the ACPR and the Autorité des Marchés Financiers. BofASE's share capital can be found at www.bofaml.com/BofASEdisclaimer; BofA Europe (Milan): Bank of America Europe Designated Activity Company, Milan Branch, regulated by the Bank of Italy, the European Central Bank (ECB) and the Central Bank of Ireland (CBI); BofA Europe (Frankfurt): Bank of America Europe Designated Activity Company, Frankfurt Branch regulated by BaFin, the ECB and the CBI; BofA Europe (Madrid): Bank of America Europe Designated Activity Company, Sucursal en España, regulated by the Bank of Spain, the ECB and the CBI; Merrill Lynch (Australia): Merrill Lynch Equities (Australia) Limited, regulated by the Australian Securities and Investments Commission; Merrill Lynch (Hong Kong): Merrill Lynch (Asia Pacific) Limited, regulated by the Hong Kong Securities and Futures Commission (HKSFC); Merrill Lynch (Singapore): Merrill Lynch (Singapore) Pte Ltd, regulated by the Monetary Authority of Singapore (MAS); Merrill Lynch (Canada): Merrill Lynch Canada Inc, regulated by the Canadian Investment Regulatory Organization; Merrill Lynch (Mexico): Merrill Lynch Mexico, SA de CV, Casa de Bolsa, regulated by the Comisión Nacional Bancaria y de Valores; Merrill Lynch (Argentina): Merrill Lynch Argentina SA, regulated by Comisión Nacional de Valores; BofAS Japan: BofA Securities Japan Co., Ltd., regulated by the Financial Services Agency; Merrill Lynch (Seoul): Merrill Lynch International, LLC Seoul Branch, regulated by the Financial Supervisory Service; Merrill Lynch (Taiwan): Merrill Lynch Securities (Taiwan) Ltd., regulated by the Securities and Futures Bureau; BofAS India: BofA Securities India Limited, regulated by the Securities and Exchange Board of India (SEBI); Merrill Lynch (Israel): Merrill Lynch Israel Limited, regulated by Israel Securities Authority; Merrill Lynch (DIFC): Merrill Lynch International (DIFC Branch), regulated by the Dubai Financial Services Authority (DFSA); Merrill Lynch (Brazil): Merrill Lynch S.A. Corretora de Títulos e Valores Mobiliários, regulated by Comissão de Valores Mobiliários; Merrill Lynch KSA Company: Merrill Lynch Kingdom of Saudi Arabia Company, regulated by the Capital Market Authority.
This information: has been approved for publication and is distributed in the United Kingdom (UK) to professional clients and eligible counterparties (as each is defined in the rules of the FCA and the PRA) by MLI (UK), which is authorized by the PRA and regulated by the FCA and the PRA - details about the extent of our regulation by the FCA and PRA are available from us on request; has been approved for publication and is distributed in the European Economic Area (EEA) by BofASE (France), which is authorized by the ACPR and regulated by the ACPR and the AMF; has been considered and distributed in Japan by BofAS Japan, a registered securities dealer under the Financial Instruments and Exchange Act in Japan, or its permitted affiliates; is issued and distributed in Hong Kong by Merrill Lynch (Hong Kong) which is regulated by HKSFC; is issued and distributed in Taiwan by Merrill Lynch (Taiwan); is issued and distributed in India by BofAS India; and is issued and distributed in Singapore to institutional investors and/or accredited investors (each as defined under the Financial Advisers Regulations) by Merrill Lynch (Singapore) (Company Registration No 198602883D). Merrill Lynch (Singapore) is regulated by MAS. Merrill Lynch Equities (Australia) Limited (ABN 65 006 276 795), AFS License 235132 (MLEA) distributes this information in Australia only to 'Wholesale' clients as defined by s.761G of the Corporations Act 2001. With the exception of Bank of America N.A., Australia Branch, neither MLEA nor any of its affiliates involved in preparing this information is an Authorised Deposit-Taking Institution under the Banking Act 1959 nor regulated by the Australian Prudential Regulation Authority. No approval is required for publication or distribution of this information in Brazil and its local distribution is by Merrill Lynch (Brazil) in accordance with applicable regulations. Merrill Lynch (DIFC) is authorized and regulated by the DFSA. Information prepared and issued by Merrill Lynch (DIFC) is done so in accordance with the requirements of the DFSA conduct of business rules. BofA Europe (Frankfurt) distributes this information in Germany and is regulated by BaFin, the ECB and the CBI. BofA Securities entities, including BofA Europe and BofASE (France), may outsource/delegate the marketing and/or provision of certain research services or aspects of research services to other branches or members of the BofA Securities group. You may be contacted by a different BofA Securities entity acting for and on behalf of your service provider where permitted by applicable law. This does not change your service provider. Please refer to the Electronic Communications Disclaimers for further information.
This information has been prepared and issued by BofAS and/or one or more of its non-US affiliates. The author(s) of this information may not be licensed to carry on regulated activities in your jurisdiction and, if not licensed, do not hold themselves out as being able to do so. BofAS and/or MLPF&S is the distributor of this information in the US and accepts full responsibility for information distributed to BofAS and/or MLPF&S clients in the US by its non-US affiliates. Any US person receiving this information and wishing to effect any transaction in any security discussed herein should do so through BofAS and/or MLPF&S and not such foreign affiliates. Hong Kong recipients of this information should contact Merrill Lynch (Asia Pacific) Limited in respect of any matters relating to dealing in securities or provision of specific advice on securities or any other matters arising from, or in connection with, this information. Singapore recipients of this information should contact Merrill Lynch (Singapore) Pte Ltd in respect of any matters arising from, or in connection with, this information. For clients that are not accredited investors, expert investors or institutional investors Merrill Lynch (Singapore) Pte Ltd accepts full responsibility for the contents of this information distributed to such clients in Singapore.

General Investment Related Disclosures:

Taiwan Readers: Neither the information nor any opinion expressed herein constitutes an offer or a solicitation of an offer to transact in any securities or other financial instrument. No part of this report may be used or reproduced or quoted in any manner whatsoever in Taiwan by the press or any other person without the express written consent of BofA Securities.

This document provides general information only, and has been prepared for, and is intended for general distribution to, BofA Securities clients. Neither the information nor any opinion expressed constitutes an offer or an invitation to make an offer, to buy or sell any securities or other financial instrument or any derivative related to such securities or instruments (e.g., options, futures, warrants, and contracts for differences). This document is not intended to provide personal investment advice and it does not take into account the specific investment objectives, financial situation and the particular needs of, and is not directed to, any specific person(s). This document and its content do not constitute, and should not be considered to constitute, investment advice for purposes of ERISA, the US tax code, the Investment Advisers Act or otherwise. Investors should seek financial advice regarding the appropriateness of investing in financial instruments and implementing investment strategies discussed or recommended in this document and should understand that statements regarding future prospects may not be realized. Any decision to purchase or subscribe for securities in any offering must be based solely on existing public information on such security or the information in the prospectus or other offering document issued in connection with such offering, and not on this document.

Securities and other financial instruments referred to herein, or recommended, offered or sold by BofA Securities, are not insured by the Federal Deposit Insurance Corporation and are not deposits or other obligations of any insured depository institution (including, Bank of America, N.A.). Investments in general and, derivatives, in particular, involve numerous risks, including, among others, market risk, counterparty default risk and liquidity risk. No security, financial instrument or derivative is suitable for all investors. Digital assets are extremely speculative, volatile and are largely unregulated. In some cases, securities and other financial instruments may be difficult to value or sell and reliable information about the value or risks related to the security or financial instrument may be difficult to obtain. Investors should note that income from such securities and other financial instruments, if any, may fluctuate and that price or value of such securities and instruments may rise or fall and, in some cases, investors may lose their entire principal investment. Past performance is not necessarily a guide to future performance. Levels and basis for taxation may change.

This report may contain a short-term trading idea or recommendation, which highlights a specific near-term catalyst or event impacting the issuer or the market that is anticipated to have a short-term price impact on the equity securities of the issuer. Short-term trading ideas and recommendations are different from and do not affect a stock's fundamental equity rating, which reflects both a longer term total return expectation and attractiveness for investment relative to other stocks within its Coverage Cluster. Short-term trading ideas and recommendations may be more or less positive than a stock's fundamental equity rating.

BofA Securities is aware that the implementation of the ideas expressed in this report may depend upon an investor's ability to "short" securities or other financial instruments and that such action may be limited by regulations prohibiting or restricting "shortselling" in many jurisdictions. Investors are urged to seek advice regarding the applicability of such regulations prior to executing any short idea contained in this report.

Foreign currency rates of exchange may adversely affect the value, price or income of any security or financial instrument mentioned herein. Investors in such securities and instruments, including ADRs, effectively assume currency risk.

BofAS or one of its affiliates is a regular issuer of traded financial instruments linked to securities that may have been recommended in this report. BofAS or one of its affiliates may, at any time, hold a trading position (long or short) in the securities and financial instruments discussed in this report.

BofA Securities, through business units other than BofA Global Research, may have issued and may in the future issue trading ideas or recommendations that are inconsistent with, and reach different conclusions from, the information presented herein. Such ideas or recommendations may reflect different time frames, assumptions, views and analytical methods of the persons who prepared them, and BofA Securities is under no obligation to ensure that such other trading ideas or recommendations are brought to the attention of any recipient of this information.

In the event that the recipient received this information pursuant to a contract between the recipient and BofAS for the provision of research services for a separate fee, and in connection therewith BofAS may be deemed to be acting as an investment adviser, such status relates, if at all, solely to the person with whom BofAS has contracted directly and does not extend beyond the delivery of this report (unless otherwise agreed specifically in writing by BofAS). If such recipient uses the services of BofAS in connection with the sale or purchase of a security referred to herein, BofAS may act as principal for its own account or as agent for another person. BofAS is and continues to act solely as a broker-dealer in connection with the execution of any transactions, including transactions in any securities referred to herein.

Copyright and General Information:

Materials prepared by BofA Global Research personnel are based on public information. Facts and views presented in this material have not been reviewed by, and may not reflect information known to, professionals in other business areas of BofA Securities, including investment banking personnel. BofA Securities has established information barriers between BofA Global Research and certain business groups. As a result, BofA Securities does not disclose certain client relationships with, or compensation received from, such issuers. To the extent this material discusses any legal proceeding or issues, it has not been prepared as nor is it intended to express any legal conclusion, opinion or advice. Investors should consult their own legal advisers as to issues of law relating to the subject matter of this material. BofA Global Research personnel's knowledge of legal proceedings in which any BofA Securities entity and/or its directors, officers and employees may be plaintiffs, defendants, co-defendants or co-plaintiffs with or involving issuers mentioned in this material is based on public information. Facts and views presented in this material that relate to any such proceedings have not been reviewed by, discussed with, and may not reflect information known to, professionals in other business areas of BofA Securities in connection with the legal proceedings or matters relevant to such proceedings.

This information has been prepared independently of any issuer of securities mentioned herein and not in connection with any proposed offering of securities or as agent of any issuer of any securities. None of BofAS any of its affiliates or their research analysts has any authority whatsoever to make any representation or warranty on behalf of the issuer(s). BofA Global Research policy prohibits research personnel from disclosing a recommendation, investment rating, or investment thesis for review by an issuer prior to the publication of a research report containing such rating, recommendation or investment thesis.

Any information relating to the tax status of financial instruments discussed herein is not intended to provide tax advice or to be used by anyone to provide tax advice. Investors are urged to seek tax advice based on their particular circumstances from an independent tax professional.

The information herein (other than disclosure information relating to BofA Securities and its affiliates) was obtained from various sources and we do not guarantee its accuracy. This information may contain links to third-party websites. BofA Securities is not responsible for the content of any third-party website or any linked content contained in a third-party website. Content contained on such third-party websites is not part of this information and is not incorporated by reference. The inclusion of a link does not imply any endorsement by or any affiliation with BofA Securities. Access to any third-party website is at your own risk, and you should always review the terms and privacy policies at third-party websites before submitting any personal information to them. BofA Securities is not responsible for such terms and privacy policies and expressly disclaims any liability for them.

All opinions, projections and estimates constitute the judgment of the author as of the date of publication and are subject to change without notice. Prices also are subject to change without notice. BofA Securities is under no obligation to update this information and BofA Securities ability to publish information on the subject issuer(s) in the future is subject to applicable quiet periods. You should therefore assume that BofA Securities will not update any fact, circumstance or opinion contained herein.

Certain outstanding reports or investment opinions relating to securities, financial instruments and/or issuers may no longer be current. Always refer to the most recent research report relating to an issuer prior to making an investment decision.

In some cases, an issuer may be classified as Restricted or may be Under Review or Extended Review. In each case, investors should consider any investment opinion relating to such issuer (or its security and/or financial instruments) to be suspended or withdrawn and should not rely on the analyses and investment opinion(s) pertaining to such issuer (or its securities and/or financial instruments) nor should the analyses or opinion(s) be considered a solicitation of any kind. Sales persons and financial advisors affiliated with BofAS or any of its affiliates may not solicit purchases of securities or financial instruments that are Restricted or Under Review and may only solicit securities under Extended Review in accordance with firm policies.

Neither BofA Securities nor any officer or employee of BofA Securities accepts any liability whatsoever for any direct, indirect or consequential damages or losses arising from any use of this information.