



4th August 2023

Hon. Mary Muthoni Muriuki, HSC
Principal Secretary
Ministry of Health
Afya House, Cathedral Road
Nairobi.



Head Office
Likoni Road, Industrial Area
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Nairobi, Kenya

Tel: +254 (0) 711 062000
Email: info_ke@bat.com
Website: www.batkenya.com

Honourable Principal Secretary,

Re: HEALTH WARNING LABELLING REQUIREMENTS FOR ORAL NICOTINE POUCHES

As part of our ambition to transform the tobacco industry and reduce the health risks associated with smoking, the BAT Group has continually invested in science and innovation with a view to offering diverse and less risky ways of consuming nicotine. In this regard, BAT Kenya has invested in a state-of-the-art KShs. 2.5 billion manufacturing facility to produce oral nicotine pouches. The factory will serve the domestic and export markets in the EAC and COMESA trade blocs and beyond.

BAT Kenya introduced 'LYFT' nicotine pouches into the Kenyan market in 2019 under the Pharmacy and Poisons Act (Cap. 244), which regulates other nicotine-containing products. In line with the BAT Group global strategy, the company has since rebranded 'LYFT' to 'VELO'.

The Ministry of Health undertook a review and directed that the main legal framework for the control of oral nicotine pouches is within the purview of the provisions of the Tobacco Control Act 2007 (the Act), Tobacco Control Regulations 2014 (the Regulations) and other applicable laws. This clarification was communicated to BAT Kenya via a letter dated 21st January 2021, Ref: MOH/BOARDS/13/1/150 Vol 1(83) (*enclosed*). In the intervening period pending the above clarification, BAT Kenya temporarily ceased local distribution and sale of the product.

Acknowledging this classification, BAT Kenya pointed out that provisions of the Act primarily address the regulation of traditional tobacco products. It is notable, for instance, that neither the Act nor the Regulations prescribe a health warning message applicable to oral nicotine pouches that do not contain tobacco. On this basis and in exercise of powers granted under Paragraph 3 of the Schedule to the Act as read together with Section 21, and to promote greater understanding of the risks associated with the use of oral nicotine products presented for sale in Kenya, the Ministry gave a directive via letter dated 4th October 2021 [Ref. MOH/BOARDS/13/1/150 Vol.1(84)] (*enclosed*) prescribing Text Health Warnings only specified as follows:

- i. **Front panel**
Text Health Warning only comprising of not less than 15% of the total surface area of the front panel in English located on the lower portion.

ii. **Back panel**

Text Health Warning only comprising of not less than 25% of the total surface area of the rear panel in Kiswahili located on the lower portion.

iii. **Text Health Warning Message**

The warning label displaying the health message to be used on oral nicotine products shall be **"WARNING: this product contains nicotine and is addictive"** in English and Kiswahili as described above.

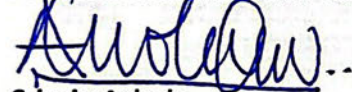
The directive above was further aligned with the provisions of the Act via letter dated 15th June 2022 [Ref: MOH/BOARDS/13/1/150 Vol 1(84)] (*enclosed*), directing that the size of the Text Health Warnings be increased to 30% (front) and 50% (rear) respectively effective 1st July 2023. We confirm that all products imported or manufactured after this date are fully compliant with this requirement. Based on this directive, we resumed importation and sale of VELO in July 2022. Additionally, we are at an advanced stage in transitioning to local manufacturing of this product.

Considering the above, we write to request that the Ministry maintains application of the above directive, pending the development of specific regulations on this product and related categories.

We look forward to your response on the above and remain available to further discuss this matter.

Yours sincerely,

For: **BRITISH AMERICAN TOBACCO KENYA PLC**



Crispin Achola

MANAGING DIRECTOR

Encls.



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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Pharmacy & Poisons Board Hse
Along Lenana Road
P. O. Box 27663-00506
NAIROBI

When replying please quote our ref No:
PPB/HPT/LET/VOL.I/51/20

8th October, 2020

The Managing Director,
British American Tobacco
Likoni Road, Industrial Area
P.O Box 3000-00100
NAIROBI

Dear Sir/Madam,

**RE: NICOTINE POUCHES "LYFT" LICENSE UNDER THE PHARMACY
AND POISONS ACT**

Reference is made to the above subject matter.

The Pharmacy and Poisons Board ("the Board") is mandated under the Pharmacy and Poisons Act (Cap 244 Laws of Kenya) to regulate and control health products and health technologies.

The products regulated under Cap. 244 include nicotine and its salts classified as "Part I poisons". This includes nicotine that has been processed and purified or synthesized to pharma-grade but excludes nicotine that naturally occurs in tobacco.

The Board recognizes that nicotine has potential benefits in tobacco cessation programs as nicotine replacement therapy or as safe alternatives to cigarette smoking and can therefore be useful to protect the public from tobacco-related diseases and death. However, the Board also notes that nicotine is highly addictive and may be prone to abuse and misuse.

The implementation of "*annual retention*" accords the Board, under the Ministry of Health, an opportunity to continually monitor and review all appropriate product safety information.

The Board has continued to carry out continual post market surveillance (PMS) with the latest being in September 2020. This surveillance has revealed that the product is readily available in the market and is popular among the youth.

Following the PMS report, the Board therefore takes the following actions:-

- a) The market authorization holder is instructed to ensure compliance with marketing authorization requirements and directed to distribute and market the Nicotine pouches under the trade name "lyft" as "Pharmacy-only";
- b) BAT is directed to withdraw all the nicotine pouch products and marketing materials from the general outlets including vending machines and online platforms;
- c) Advertisements of nicotine pouches, as per Section 36 of the Act, shall be approved by the board in consideration of addictive nature of nicotine, its potential for abuse and harm;
- d) Advertisement and promotion of these products shall be approved for health care professionals only; advertisements to the general public is prohibited;
- e) It is a requirement that access and availability of the product among children and persons under the age of 18 is prohibited;
- f) The marketing authorization holder shall ensure that distributors and retailers maintain proper records of consumption which should be available for verification by the Board.

Yours faithfully,



Dr. Ahmed Mohamed

Deputy Director General

HEALTH PRODUCTS AND TECHNOLOGIES DEPARTMENT

AK/lw



**MINISTRY OF HEALTH
OFFICE OF THE CABINET SECRETARY**

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When replying please quote

**AFYA HOUSE
CATHEDRAL ROAD
P O Box 30016
NAIROBI.**

REF: MOH/BOARDS/13/1/150 VOL 1 (83)

21st January, 2021

Crispin Achola
Managing Director
British American Tobacco Kenya plc
P.O. Box 30000 – 00100
Nairobi.

RE: NICOTINE POUCHES 'LYFT' SOLD IN KENYA.

The above subject matter refers.

Kenya signed and ratified the World Health Organization Framework Convention for Tobacco Control (WHO-FCTC). In domesticating the treaty, the Government enacted the Tobacco Control Act 2007 and Tobacco Control Regulations 2014 so as to safeguard public health of the population.

The Ministry has conducted a series of consultations so as to address the concerns raised regarding nicotine pouches sold in the Country. It is important to note that British American Tobacco K. Ltd. (BAT), being the company selling the product was also heard in the said consultations.

Following the above process, it was established that LYFT contains nicotine. The nicotine therein is extracted from tobacco plant. It should be noted that Section 2 of the Tobacco Control Act, 2007, defines a tobacco product to include "any extract from tobacco". We are cognisant of the value of your investment and job creation in Kenya and we value and appreciate your contribution but, understandingly we consider health matters above all else.

In view of this therefore, the I hereby directs as follows;

1. Nicotine pouches "LYFT" shall, with immediate effect, be regulated under the provisions of the Tobacco Control Act 2007, Tobacco Control Regulations 2014 and other applicable laws.



01/2015
Certified

2. In this regard, the nicotine pouches will be required to comply with the provisions of the Tobacco Control Act 2007, Tobacco Control Regulations 2014 and any other provisions of similar laws that regulate tobacco products. These includes compliance with packaging, labeling and pictorial health warnings.

The Ministry of Health remains committed to deliver its mandate of safeguarding health for all Kenyans.



**SEN. MUTAHI KAGWE, EGH,
CABINET SECRETARY**

Cc:

1. **Susan Mochache, CBS**
Principal Secretary
Ministry of Health
2. **Dr. (Eng.) Karanja Kibicho, CBS**
Principal Secretary
Ministry of Interior and Coordination of National Government
3. **Dr. Fred Siyoi,**
Chief Executive Officer
Pharmacy and Poisons Board
4. **Prof. Wifred Lesan**
Chairman
Tobacco Control Board
5. **James Githii Mburu**
Commissioner General
Kenya Revenue Authority

7th September 2021

Hon. (SEN). Mutahi Kagwe, EGH
Cabinet Secretary
Ministry of Health
Afya House, Cathedral Road
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Nairobi, Kenya

Tel: +254 (0) 711 062000
Email: info_ke@bat.com
Website: www.batkenya.com

Dear Sir,

Re: Health Warning Labelling Requirements for Oral Nicotine Pouches

As part of our ambition to transform the tobacco industry and reduce the health risks associated with smoking, BAT Kenya has invested in a new Kshs. 2.5 billion state of the art manufacturing facility to produce oral nicotine pouches branded LYFT (also known as Velo). The factory will serve both domestic and export markets in the EAC and COMESA trade blocs.

However, the manufacture, distribution and sale of our LYFT product has **been temporarily ceased in the market since October 2020**. Our resumption of factory operations and the sale of LYFT in Kenya hinges on the provision of appropriate **Text Health Warnings** for the product.

At present, the intended export markets and indeed, all countries where oral nicotine pouches are sold apply **Text Health Warnings**, reflecting the growing international consensus and scientific evidence in respect of both the absolute and relative risks associated with the use of the product category.

These markets use Text Health Warnings typically containing some or all of following information: (See appendix for pictures attached)

a) On Top of the pack:

"This product contains nicotine and is addictive"

b) On the Back of the pack:

- i. Age restriction logo – 18+ only
- ii. NOT RECOMMENDED FOR NON-SMOKERS OR NON-NICOTINE USERS. THIS PRODUCT MAY BE HARZADOUS TO HEALTH. THIS PRODUCT IS NOT SUITABLE FOR USE BY PERSONS: Allergic/sensitive to nicotine and other ingredients/who should avoid tobacco/nicotine for medical reasons/with an unstable heart condition, severe hypertension/diabetes/by pregnant or breast-feeding women.
- iii. IMPORTANT SAFETY INFORMATION: Immediately stop use of this product and seek medical advice if you experience: development of an irregular heartbeat; allergic reaction such as rash, itching or swelling of the tongue, mouth/throat; feeling dizzy; nausea; headache; or any adverse effect.

- iv. Warning: Harmful if swallowed. Contains Nicotine. If Swallowed: Call a POISON CENTER/doctor if you feel unwell.
- v. Dispose of contents/ container to hazardous or special waste collection point in accordance with local, regional or national regulations
- vi. Keep out of reach of children and animals. Keep the Lid tightly closed.

The list of countries where BAT's tobacco-free nicotine containing oral pouches use the above Text Health Warning format are:

No	Country	Health Warning Labelling
1	United Kingdom	10% Text Health Warning
2	Denmark	10% Text Health Warning
3	Sweden	10% Text Health Warning
4	Austria	10% Text Health Warning
5	Croatia	10% Text Health Warning
6	Czech Republic	10% Text Health Warning
7	Germany	10% Text Health Warning
8	Indonesia	10% Text Health Warning
9	Pakistan	10% Text Health Warning
10	Slovakia	10% Text Health Warning
11	Slovenia	10% Text Health Warning
12	Ukraine	10% Text Health Warning
13	United States of America	10% Text Health Warning
14	South Africa	10% Text Health Warning

Under Paragraph 3 of the Schedule to the Tobacco Control Act, the Cabinet Secretary has the discretion to adjust the size, text and type of any of the health messages, pictures or pictograms prescribed in Section 21(2), if such change would promote greater understanding of the risks associated with the use of any tobacco product.


We consider Oral Nicotine pouches to be the lowest risk product in our product portfolio – a portfolio which includes vaping products. This assessment is based on BAT's analysis of, among others, *TobReg 9* emissions¹, heavy metals as well as cellular analysis² across its product portfolio. It is an analysis that is now supported by peer-reviewed evidence³. Accordingly, there is ample basis, including scientific evidence and international best practice, on which to support the use of the powers referred to in Paragraph 3 to implement text health warnings for oral nicotine pouches in order to enhance awareness amongst smokers of the relative risks of cigarettes and oral nicotine pouches.

We therefore kindly request that the Cabinet Secretary exercise this discretion and direct that oral nicotine pouches such as Lyft (also known as Velo) apply Text Health Warnings in the form and format as shared in this letter and as shown in the pictures in the appendix.

Your positive consideration of this request will allow us to operationalize our factory for both the domestic and export markets EAC and COMESA trade blocs.

Yours sincerely,

For: British American Tobacco Kenya plc.



Crispin Achola
MANAGING DIRECTOR

¹ David Azzopardi, Chuan Liu & James Murphy (2021) Chemical characterization of tobacco-free "modern" oral nicotine pouches and their position on the toxicant and risk continuums, *Drug and Chemical Toxicology*, DOI: [10.1080/01480545.2021.1925691](https://doi.org/10.1080/01480545.2021.1925691)
<https://www.tandfonline.com/doi/full/10.1080/01480545.2021.1925691>

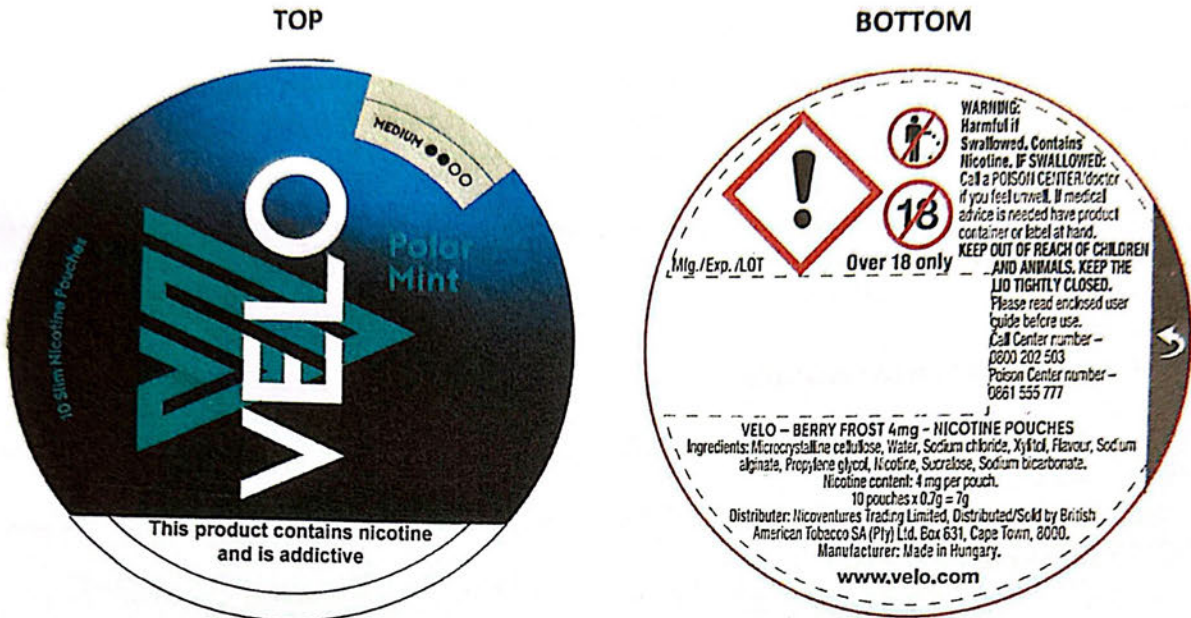
² Bishop E, East N, Bozhilova S, et al. An approach for the extract generation and toxicological assessment of tobacco-free 'modern' oral nicotine pouches. *Food and Chemical Toxicology*, Volume 145, November 2020, 111713
<https://www.sciencedirect.com/science/article/pii/S0278691520306037>

³ *ibid* (note 3)

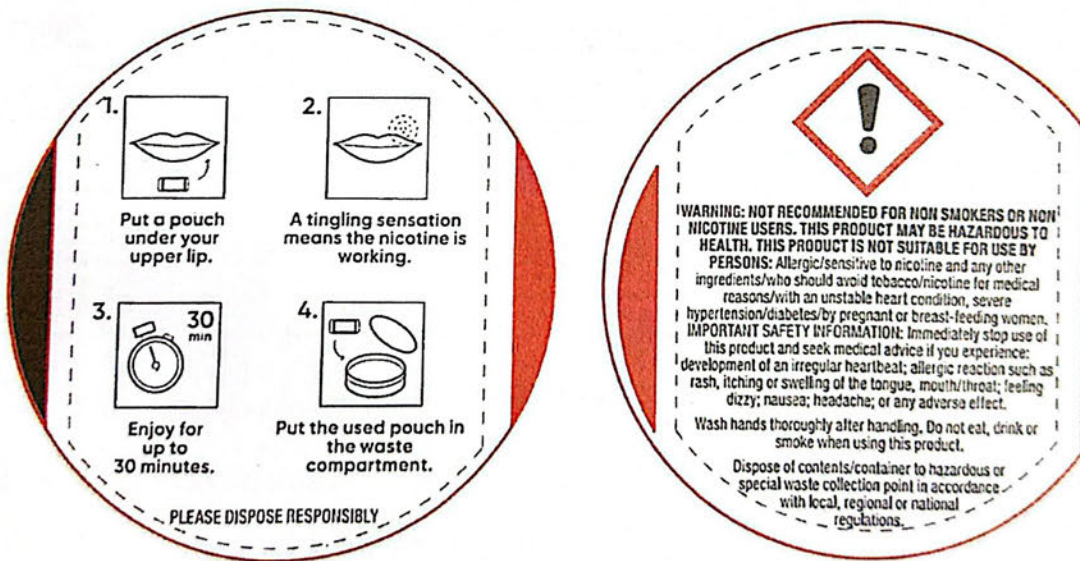
APPENDIX

1. Health Warning Labelling Requirements in South Africa

a) Packaging and labelling for Cans



Page 1



Page 2

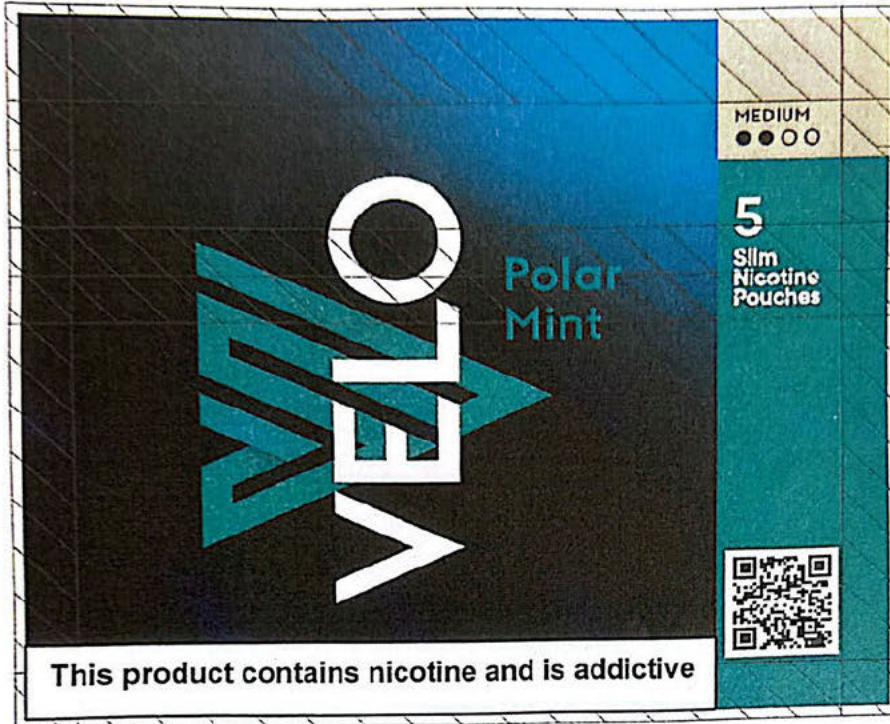
Page 3



Side Label

b) Packaging and labelling for Sachets

FRONT



BACK



2. Health Warning Labelling Requirements in United Kingdom (same approach used in Denmark)

Packaging and labelling for Cans

TOP



BOTTOM



SIDE





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OFFICE OF THE CABINET SECRETARY

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NAIROBI

REF: MOH/BOARDS/13/1/150 Vol 1 (84)

4th October, 2021.

Mr. Crispin Achola,
Managing Director,
BAT Kenya,
P.O. Box 30000-00100,
NAIROBI.

**RE: HEALTH WARNING LABELLING REQUIREMENT FOR ORAL
NICOTINE POUCHES**

Reference is made to the above and to your letter dated 7th September, 2021 seeking approval to apply text health warnings of oral nicotine pouches in the format proposed in your letter.

We have noted your concerns and request and wish to advise as follows;

1. While we appreciate your reference to other Countries where BAT's tobacco –free nicotine containing oral pouches use the text health warning labelling that translates to 10%, we advise that Kenya is a sovereign country with one of the most comprehensive tobacco legislations globally.
2. The Tobacco Control Act, 2007 and subsequent Tobacco regulations, 2014 is Kenya's main legal framework to control the production, manufacture, sale, labelling, advertising, promotion and sponsorship of tobacco products.
3. LYFT like any other tobacco and nicotine product is within the purview of the provisions of the Tobacco Control Act 2007, Tobacco Control regulations 2014 and all other applicable laws.

 Kenya British American Tobacco Kenya Plc P. O. Box 30000 - 00100, Nairobi, Kenya	
05 OCT 2021	
RECEPTION	
TIME.....	NAME.....
SIGNATURE.....	

4. The Government has adequate systems and works through relevant agencies to exercise their mandate to ensure that any product e.g. LYFT and other tobacco products in the market meet the set standards.
5. In the pursuit of this overall objective and to secure appropriate levels of awareness on the risk associated with tobacco products, Section 21 of the Act sets out packing and labelling requirements for every packaging containing products regulated by the Act. Paragraph 3 of the Schedule of the Act also grants the Cabinet Secretary additional powers in this regard, to adjust the format type, size, text and type of any messages as may be prescribed under the Act.

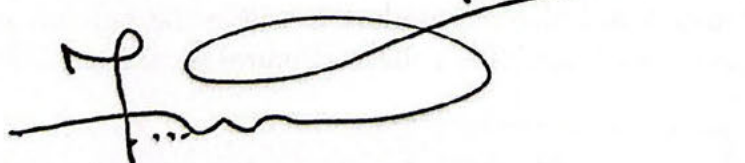
Taking note of the above and in order to promote greater understanding of the risks associated with the use of oral nicotine products presented for sale in Kenya, we advise that you apply Text Health Warnings only, pursuant to Section 21 of the Act as read together with paragraph 3 of the Schedule as specified as follows:

- i. **Front panel**
Text Health Warning only comprising of not less than 15% of the total surface area of the front panel in English located on the lower portion.
- ii. **Back panel**
Text Health Warning only comprising of not less than 25% of the total surface area of the rear panel in Kiswahili located on the lower portion.
- iii. **Text Health Warning Message**
The warning label displaying the health message to be used on oral nicotine products shall be **“WARNING: this product contains nicotine and is addictive”** in English and Kiswahili as described above.

In view of this, any previous directives given in our letters dated 21st January, 2021, and 9th February, 2021, shall stand modified accordingly.

Yours

Sincerely



SEN. MUTAHI KAGWE, EGH,
CABINET SECRETARY.

Copy:

Susan Mochache, CBS,
Principal Secretary,
Ministry of Health.

Prof. Wilfred Lesan,
Chairman,
Tobacco Control Board.



15 JUN 2022

LEGAL
RECEIVED



MINISTRY OF HEALTH
OFFICE OF THE CABINET SECRETARY

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REF: MOH/BOARDS/13/1/150 Vol 1 (84)

15th June, 2022

Mr. Crispin Achola
Managing Director,
BAT Kenya,
Po Box 30000-00100,
NAIROBI.

**RE: HEALTH WARNING LABELLING REQUIREMENTS FOR ORAL
NICOTINE POUCHES**

Reference is made to the above and your letter dated 13th May, 2022, seeking clearance of conformity with health warning requirements for oral Nicotine pouches as instructed in our letter reference MOH/BOARDS/13/1/150 Vol 1 (84) dated 4th October, 2021.

Receipt of the samples of the oral nicotine pouches that were forwarded by BAT is also hereby acknowledged. We note the you have applied Text health warnings with the front panel warning comprising of **not less than 15%** of the total surface area of the front panel, and back panel consisting of **not less than 25%** of the total surface area of the rear panel.

While the labelling on the samples of oral nicotine pouches ("VELO) submitted, are in line with specifications as stipulated in our reference letter above, the health warning requirements in law, pursuant to Section 21, and the Schedule of the Tobacco Control Act 2007, require that every package containing a tobacco product shall among other requirements:

- (a) Have at least two warning labels of the same health messages, in both English and Kiswahili, comprising of not less than 30% of the total surface area of the front panel, and 50% of the total surface area of the rear panel, and both located on the lower portion of the package.
- (b) Bear the word "WARNING" appearing in capital letters and all text shall be in a conspicuous and legible 17-point print unless the text label statement

would occupy more than seventy-five percent of such area, in which case the text may be of smaller a smaller but conspicuous type size, provided that at least sixty percent of such occupied area is occupied by the required text.

- (c) Bear text that is black on a white background and white on a black background in manner that contrasts by topography, lay out or colour with all other printed material on the package.

Consequently, we shall allow the labelling that has been applied on the consignment that has already been done, and for purposes of facilitating the clearance of the current consignment. The labelling **shall not** be acceptable for any future shipments, or manufacture of oral nicotine pouches or tobacco containing products.

Subsequently therefore, and with effect from 1st July, 2023, all oral nicotine pouches and other tobacco containing products will be required to comply with the provisions of the Tobacco Control Act 2007, Tobacco Control Regulations 2014 as stipulated above, and any other provisions of similar laws that regulate tobacco products in Kenya.

The Ministry of health remains committed to deliver its mandate of safeguarding health for all Kenyans.



SEN MUTAHI KAGWE, EGH
CABINET SECRETARY

Copy to:

Susan N Mochache, CBS
Principal Secretary,
Ministry of Health.

Dr. (Eng.) Karanja Kibicho, CBS
Principal Secretary,
Ministry of Interior and Coordination of National Government.

James Githii Mburu
Commissioner General,
Kenya Revenue Authority.

Dr. Patrick Amoth, EBS,
Ag. Director General for Health.

Copy: **Susan Mochache, CBS,**
Principal Secretary,
Ministry of Health.

Prof. Wilfred Lesan,
Chairman,
Tobacco Control Board.