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76th Tobacco Science Research Conference

E-Cigarette Regulatory Non-Compliance in the UK Marketplace



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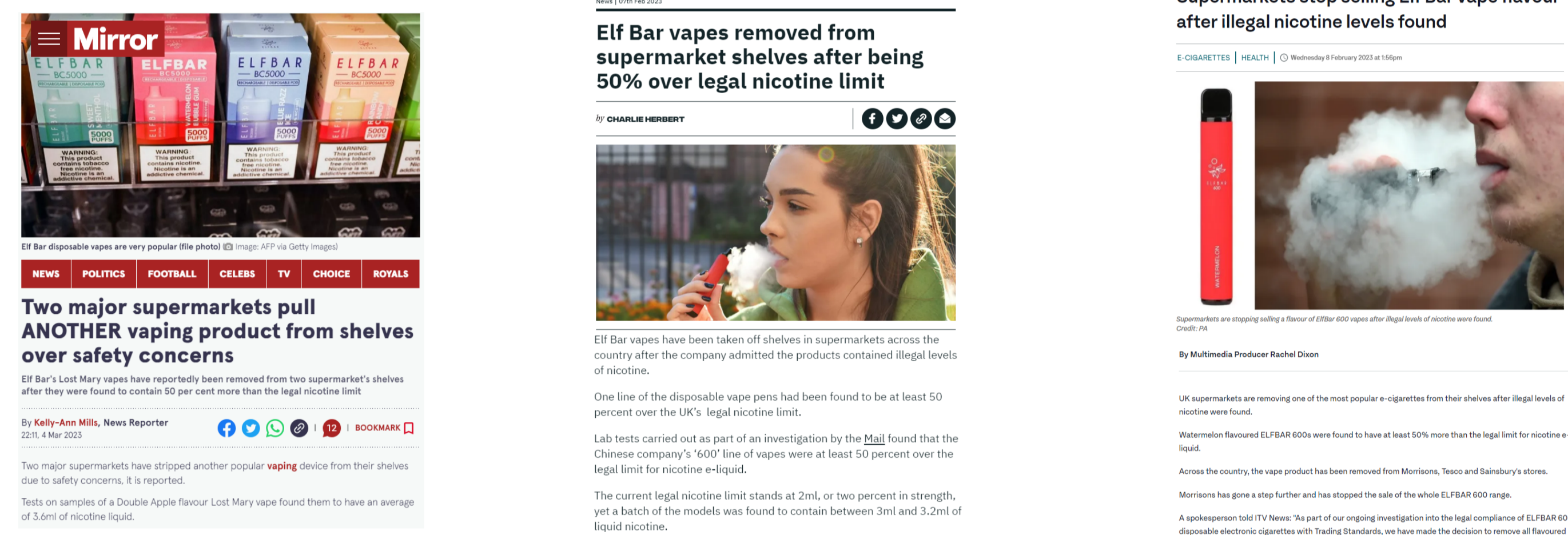
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INTRODUCTION

A strong and growing body of science now exists, showing that switching from conventional, combustible cigarettes to e-cigarettes significantly reduces a user's exposure to harmful and potentially harmful constituents (PHHCs). While this evidence has been accepted by some health bodies, notably in the UK, where the use of e-cigarettes in smoking cessation is official health advice, many regions of the world still view e-cigarettes as a potential health and addiction issue.

A recent concern in convincing consumers, health professionals, and regulators of the benefits of switching to e-cigarettes is the perception that a not insignificant number of products available to consumers fail to comply with the regulatory requirements of markets for which they are on sale.

This concern has been driven by media stories and a perception that the Tobacco & Related Products Regulations (TRPR) notification is an isolated event with a lack of in-market surveillance from the MHRA.



What is the TRPR?

In May 2017, the TRPR brought the European Tobacco Products Directive (TPD) regulations into UK law. Since the UK left the European Union (Brexit), the UK government implemented legislation (Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020), which amends how the TRPR applies in Great Britain (GB) and Northern Ireland (NI). The 2020 Regulations set out the requirements for notification of new products from 1 January 2021.

The purpose of the TPD and, by extension, TRPR regulations is to ensure that e-cigarettes in the EU and UK markets meet basic safety and quality standards.

Required information to notify a new product:

- ▶ **Submitter details**
- ▶ **Product details**
- ▶ **Product ingredients**
- ▶ **Emissions**
- ▶ **E-cigarette device**
- ▶ **Production process**
- ▶ **Product annual sales data**

One of the fundamental requirements of TRPR is to ensure liquid volume and nicotine content are compliant with the levels laid down in the regulation; for disposables and pod systems, this means no more than 2mL of liquid at a nicotine concentration of no more than 20mg/mL.

Therefore, it was undertaken to carry out a market survey of disposable and pod products in the UK-to test for TRPR compliance with respect to nicotine concentration and fill volume.

METHOD

The Determination of Fill Weight and Fill Volume



Sample Selection

Disposable and pod e-cigarettes were intermittently collected throughout the year from a variety of outlets, including both major national supermarkets and independent retailers.

Determination of Nicotine in Liquid by HPLC

Nicotine in e-liquid was measured using an in-house method derived from a standard pharmaceutical nicotine assay method. Briefly, nicotine is extracted from the e-liquid in an aqueous buffer system before being quantified against external standards using a reversed-phase C18 HPLC-UV analytical method.

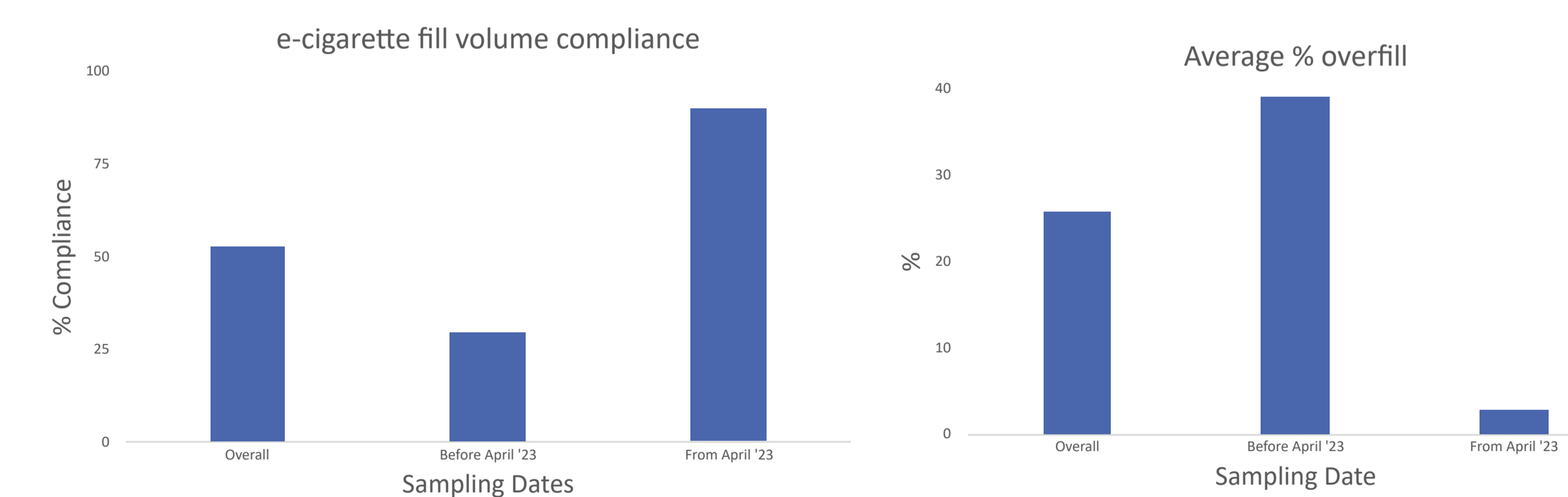
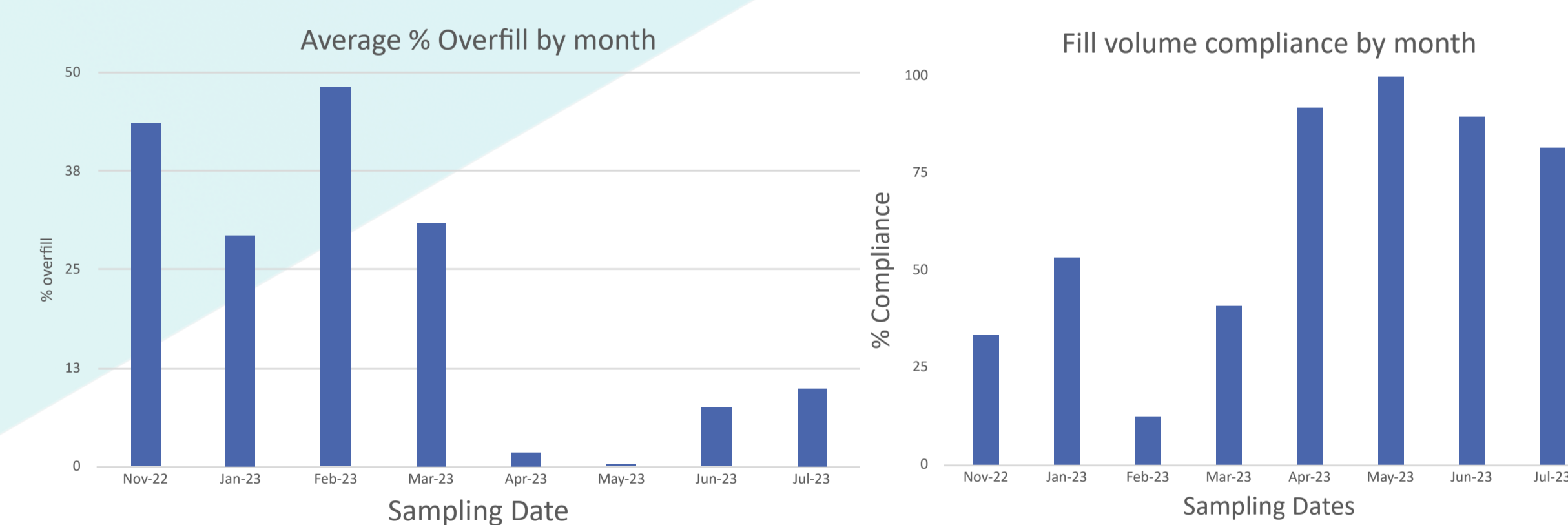
RESULTS

Fill Volume

To test the compliance of disposable and pod systems on sale in the UK in a variety of commercial settings, the basic requirement to meet fill volume and nicotine content requirements was chosen. Over a nine-month period from November 2022 until July 2023, 1819 individual e-cigarettes, representing 419 stock-keeping units (SKU), were tested for liquid fill volume compliance. Products tested were chosen from prominently displayed brands in both major supermarkets and local retailers.

Only 53% of the 1819 products tested over the 9-month period were found to be compliant with the 2mL liquid fill volume liquid as prescribed by TRPR. The average liquid volume across these products was 2.52mL, a 25.7% overfill; the high average fill volume is skewed by the average liquid volume for the 855 non-compliant products tested, 3.09mL per pod. The median fill volume was also calculated to correct for this bias, showing that the average product for this period had a median fill volume of 2.22mL, a 10.9% overfill when compared to TRPR regulations.

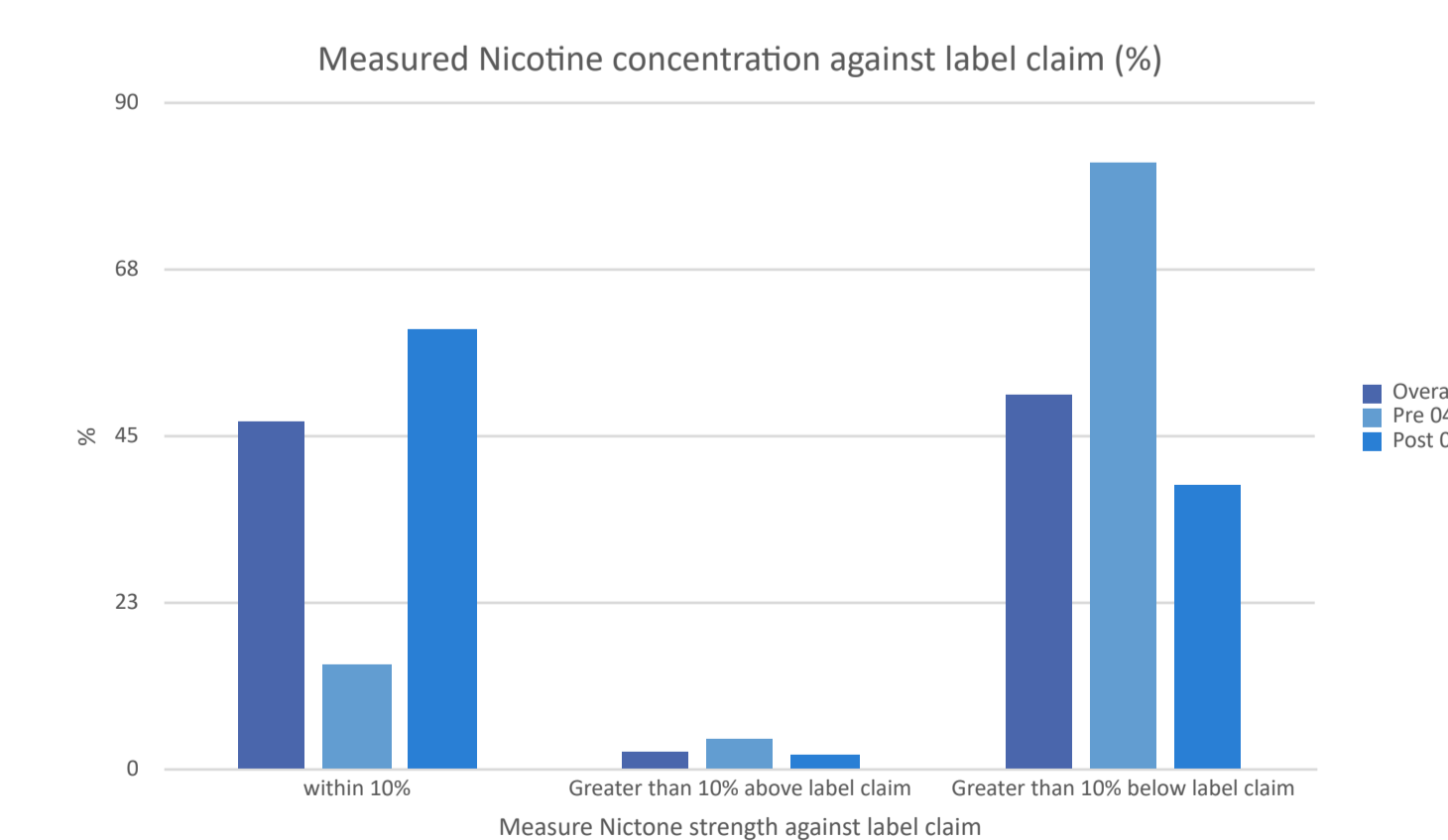
Interestingly, when liquid volume and compliance were observed across the testing period, a trend with time could be seen in Figs 1 and 2. The percentage of compliant samples by month is significantly lower before April 2023, with a high of 53.25% in January 2023 and a low of 12.39% compliance in February, with the average fill volume ranging from 2.59mL/pod in January to 2.964mL/pod in February. From April onwards, we noted significantly higher compliance rates ranging from a high of 100% compliance in May 2023 to a low of 81.46% compliant in July, with the range of average fill volumes from 2.01mL/pod in May to 2.20 in July. When the data is separated into pre- and post-April 2023, a clear difference is seen between both TRPR compliance and fill volume, Fig 3 and 4. Fill volume compliance rates before April were found to be 29.5%, with an average fill volume of 2.78mL/pod compared to 90.2% compliance and an average fill volume of 2.10mL/pod after April 2023.



Nicotine Concentration

452 individual e-cigarettes, representing 265 stock-keeping units (SKU), were tested for nicotine concentration. Products tested were chosen from prominently displayed brands in both major supermarkets and local retailers. Products to test were chosen separately but in the same manner as for the liquid volume testing.

In comparison to the liquid volume testing, no issues were observed with nicotine concentration compliance. Over 97% of all e-cigarettes tested were found to be in compliance, with only two individual products found to be greater than 15% above the TRPR compliance limit of 20mg/mL. Where more of a potential concern was observed was that greater than 50% of all products tested had measured nicotine concentrations greater than 10% below the labeled strength of the product, and as with the liquid volume, a variation over time was observed. Nicotine strength being measured within 10% of the label claim was most prevalent after April 2023, Fig 5.



CONCLUSIONS

Commercially available e-cigarettes were tested for compliance with TPD and TRPR liquid volume and nicotine concentration regulations. No significant compliance issues were observed with nicotine concentration, with over 97% of tested products being compliant with TRPR regulations, but what was observed was that over 50% of e-cigarettes tested were more than 10% below the nicotine concentration stated on the product information. This was likely to be due to a combination of factors: using slightly understrength formulations to ensure compliance with TRPR regulations and a reduction of the nicotine concentration after manufacturing driven by water ingress into the products.

A significant issue was observed with the compliance of disposable e-cigarettes with regard to e-liquid fill volume. Only around 50% of tested e-cigarettes complied with regulations having a fill volume of 2mL or less over the course of the study, from November 2022 to July 2023. This issue appeared to be significant prior to the end of March 2023, where less than 1 in 3 e-cigarettes were compliant compared to over 90% from April onwards. This non-compliance did not appear to be accidental due to the prevalence and significance of the overfill; on average, the non-compliant samples contained over 3mL of liquid.

This non-compliance appears to have largely disappeared post-March after significant news coverage of the issue appeared in the British media in February and March of 2023. This phenomenon of compliance only after publicity raises the important issue of a lack of regulatory surveillance of products on the market in the UK, with some manufacturers rightfully believing that the flouting of regulations to give more performance to products would go undetected. Regulatory surveillance and enforcement are required both for customer safety and also to ensure that those companies that ensure they produce compliant products have a level competitive field with companies that are either less scrupulous or competent.

KEY LEARNINGS

- ▶ Prior to March 2023, there was a significant issue with non-compliant e-cigarettes in the UK market
- ▶ The major issue observed was the overfilling of e-cigarettes
- ▶ Significant non-compliance appears to have been removed from the market following media coverage
- ▶ The importance of in-market regulatory surveillance was highlighted by the effect of media coverage

TSRC(2023)(76) - Document not peer-reviewed by CORESTA