BAT
A BETTER TOMORROW

Product Vigilance

A Blueprint For The Future

Omni™

This report contains certain statements referring to Smokeless Products being less risky than conventional cigarettes. These statements are often, but not always, made through the use of phrases such as "reduced-risk", "lower risk", "less risky", "lower profile of risk", "lower risk profile", "reduced-risk potential", "reduced harm potential" and similar expressions. These statements are made based on the weight of evidence and assuming a complete switch from cigarette smoking.

Reduced-Risk

*** Based on the weight of evidence and assuming a complete switch from cigarette smoking. These products are not risk free and are addictive.**

† Our products as sold in the U.S., including Vuse, Velo, Grizzly, Kodiak, and Camel Snus, are subject to FDA regulation and no reduced-risk claims will be made as to these products without agency clearance.

These apply for each instance such terms are used in the report.

US Data

For products sold in the U.S. by Reynolds American Inc.'s Operating Companies, procedures and data are managed under a dedicated product vigilance programme at subsidiary companies of Reynolds American Inc. For this reason, when this report discusses specific product vigilance procedures and related data, such procedures and data exclude the US.

Smokeless Products

For the purpose of this report, references to data on BAT's Smokeless Products do not include smoking cessation devices or other products licensed for Nicotine Replacement Therapy. With the exception of certain oral nicotine products, BAT's Smokeless Products are not smoking cessation devices and are not marketed for that purpose.

This report focuses on the Group's Product Vigilance as it relates to its Smokeless products. For more information on the Group's combustibles business, please refer to the Group's Combined Annual and Sustainability Report 2024.

Audience

The material in this report is provided to scientists, public health authorities, regulators, policy makers, and investors only and is not intended for general consumers. BAT, its directors, officers, employees, agents or advisers do not accept or assume responsibility to any other person to whom this material is shown or into whose hands it may come and any such responsibility or liability is expressly disclaimed.

Unless stated to the contrary, all figures relating to BAT's performance have been taken from the 2024 Combined Annual and Sustainability Report.

The material in this report is not provided for product advertising, promotional or marketing purposes. This material does not constitute and should not be construed as constituting an offer to sell, or a solicitation of an offer to buy, any of our products. Our products are sold only in compliance with the laws of the particular jurisdictions in which they are sold.

The information contained in this report in relation to British American Tobacco p.l.c ("BAT") and its subsidiaries has been prepared solely for use in this report. This report is not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident or located in any jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction.

References in this report to 'British American Tobacco', 'BAT', 'Group', 'we', 'us', and 'our, when denoting opinion refer to British American Tobacco p.l.c. and when denoting business activity refer to British American Tobacco p.l.c. and its subsidiaries, collectively or individually as the case may be, as well as in some circumstances those who work for them. When denoting business activity these collective expressions are used for ease of reference only and do not imply any other relationship between British American Tobacco p.l.c. and its subsidiaries. The companies in which British American Tobacco p.l.c. directly and indirectly has an interest are separate and distinct legal entities.

Cautionary Statement

This report contains certain forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "may," "will," "expect," "aim to," "being committed," "being confident" and similar expressions.

These include statements regarding our intentions, beliefs or current expectations concerning, amongst other things, our strategies and the business circumstances occurring from time to time in the countries and markets in which the Group operates.

In particular, these forward-looking statements include, among other statements, statements regarding advancing the product vigilance process in the future.

All such forward-looking statements involve estimates and assumptions (based on knowledge and information available at the date of preparation of this report only, for which we undertake no obligation to update or revise) that are subject to risks, uncertainties and other factors. It is believed that the expectations reflected in this report are reasonable but they may be affected by a wide range of variables that could cause actual results to differ materially from those currently anticipated.

Among the key factors that could cause actual results to differ materially from those projected in the forward-looking statements are uncertainties related to the principal risks the Group is facing, as discussed in BAT's Combined Annual and Sustainability Report 2024. Please also see the Cautionary Statement on page 447 of BAT's Combined Annual and Sustainability Report 2024 and any future annual and interim reports, which may be obtained free of charge at BAT's website http://www.bat.com.

asmokelessworld.com

> As BAT's portfolio continues to shift from traditional combustible cigarettes toward a growing smokeless product portfolio, it has become essential to evolve our postmarket surveillance capabilities. In response to this transformation, we have established a dedicated Product Vigilance team.

Dr Hugo Tan
Global Medical Safety Officer

A Message from our Chief Corporate Officer

A decade ago, the BAT Management Board asked me to lead the 'Next Generation Products' function. At the time, it was a small team of about 50 people, operating in a single country and focused on one product category - vapour. Today, we offer a range of Smokeless Products in over 80 countries, serving close to 30 million consumers[#], and this business now accounts for nearly 20% of BAT's total revenues.

Aligned with our goal of building a global Smokeless Products business, we have remained committed to offering adult smokers who would otherwise choose to continue to smoke a range of reduced-risk[*†] profile alternatives as compared with combustible cigarettes in markets worldwide. That's why we created Omni™: our manifesto for a smokeless future and a platform for dialogue with stakeholders scientists, public health authorities, regulators, policy makers, and investors - and across the wider scientific and regulatory ecosystem related to tobacco and nicotine products. Omni™ is designed to accelerate the adoption of Tobacco Harm Reduction (THR) to play a central role in global public health strategies on tobacco. I am delighted to introduce Product Vigilance to Omni™, and I am confident it will highlight to our stakeholders our commitment to product quality and THR.

Kingsley Wheaton
Chief Corporate Officer

> "I am delighted to introduce Product Vigilance to Omni™, and I am confident it will highlight to our stakeholders our commitment to product quality and THR."
>
> **Kingsley Wheaton**
> **Chief Corporate Officer**

Our focus on advancing Tobacco Harm Reduction goes hand in hand with strengthening postmarket surveillance to gain a more clear picture of the potential impact of Smokeless Products when used by consumers in real-world conditions.

This enhanced insight cannot be achieved in a laboratory setting alone; it demands a rigorous and transparent vigilance framework, and in our case we have backed this with a substantial investment. Through Product Vigilance, BAT can better anticipate, assess, and address potential product issues, an essential foundation for sustaining the confidence of regulators and public health authorities. This approach is a driving force behind the publication of this Product Vigilance Report.

Our ambition is to provide adult consumers who would otherwise choose to continue to smoke, with reduced-risk*† alternatives, underpinned by a comprehensive and elevated Product Vigilance programme. Through this, we aim to deliver product choice responsibly and uphold high quality standards.

The number of consumers of Smokeless Products is defined as the estimated number of Legal Age (minimum 18 years) consumers of the Group's Smokeless Products – which does not necessarily mean these consumers are solus consumers of these products. In markets where regular consumer tracking is in place, this estimate is obtained from adult consumer tracking studies conducted by third parties (including Kantar). In markets where regular consumer tracking is not in place, the number of consumers of Smokeless Products is derived from volume sales of consumables and devices in such markets, using consumption patterns obtained from other similar markets with adult consumer tracking (utilising studies conducted by third parties, including Kantar).

Foreword
Product Vigilance

Our Product Vigilance Strategy, Vigilance360, follows three dimensions: Awareness, Action and Assurance

AWARENESS

Collect and monitor adverse events, perform signal detection

ACTION

Effective action to investigate and resolve / mitigate risk, in particular with adverse events (AEs)

ASSURANCE

Assurance that BAT is committed to product stewardship and upholding the company's core values

Since the launch of our first vapour product in 2013, we have grown a smokeless product business that spans our global business.

Today, we have three categories of Smokeless Products, Heated Products, Vapour Products and Oral Products. As most of these products are relatively new to consumers and stakeholders alike, postmarket surveillance in 'real-world conditions' is fundamental for smoker adoption, switching, and the long-term sustainability of the categories.

In certain markets, we are required to submit postmarket data to regulators and other stakeholders. But for all markets, we uphold the same high standard in our vigilance activities, to maintain a comprehensive end-to-end stewardship process which encompasses premarket stewardship and postmarket surveillance.

I hope this report gives an insight to all our stakeholders on the breadth and depth of our Product Vigilance programme and underscores that product stewardship is a top priority.

Dr James Murphy
Director, Research and Science

We set ourselves the following key objectives:

1. **Improved Product Quality:** Continuous monitoring of Smokeless Products, enhancing product quality and integrity.
2. **Signal Detection:** Vigilance enables timely identification and response to product related risks.
3. **Data-Driven Decisions:** Real-time analysis supports informed decisions by BAT.
4. **Risk Management:** Systems in place to identify, assess, and minimise product-related risks.
5. **Regulatory Compliance:** Adherence to pharmacovigilance guidelines and Good Vigilance Practices (GVP).
6. **Postmarket Monitoring:** Ongoing postmarket surveillance to detect any new adverse events in real-world use.

> “Combining Product Vigilance with our established premarket product stewardship, creates a truly end-to-end global product stewardship approach.”

Dr James Murphy
Director, Research and Science

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Smokeless Product Categories

Innovation that drives results

BAT's Product Vigilance programme is important in shaping a portfolio of innovative products that support A Better Tomorrow™. By embedding product integrity, insight and compliance into every stage of development, we enable the development of a range of enjoyable, scientifically-substantiated, reduced-risk*† alternatives to smoking.

Inhalable

	Heated Products	Vapour Products
Absorption	Inhalation (Lung)	Inhalation (Lung)
BAT Lead Brand	glo	Vuse
Consumer Operation	 The consumer inserts the consumable into the battery-powered device and starts the heating session. Once the consumable has reached the necessary temperature, the consumer puffs on the product and inhales the aerosol. (Note: the consumable remains in the device)	 The consumer inserts the consumable into the battery-powered device and turns on the device. Once on, if the device is puff-activated, the consumer will puff on the consumable and inhale the formed aerosol. If the device is button-activated, the consumer will press the button, puff on the consumable, and inhale the formed aerosol. Note: for Vapour Products that do not have separate consumables (i.e. a disposable e-cigarette) the consumer only needs to turn on the device before then puffing on the product as required.

Our portfolio reflects:

- Commitment to Tobacco Harm Reduction – Delivering products that align with global THR objectives
- Innovation with Integrity – Seeking to ensure every new product meets rigorous quality standards
- Future-Focused Solutions – Driving continuous improvement and diversification across categories

Oral

Oral Tobacco Products

Buccal Mucosa (inner lining of the cheek between the lip and gum)

Camel, Lundgrens

The consumer takes a single portion or pouch and places it within the mouth, between the lip and gum.

Oral Nicotine Pouches

Buccal Mucosa (inner lining of the cheek between the lip and gum)

Velo

The consumer takes a single pouch and places it within the mouth, between the lip and gum.

Reduced-Risk*† Alternatives

A continuum of risk

Scientific research has demonstrated that Smokeless Products produce fewer and lower levels of harmful chemicals, compared to cigarettes, and expose smokeless product consumers to lower levels of harmful chemicals, compared to smoking. We have built a 'weight of evidence' for each category – Heated Products, Vapour Products and Oral Products (Oral Nicotine Pouches and Oral Tobacco Products) - based on the scientific assessment of emissions (what comes out of the product), exposure (what consumers take in) and potential comparative health risks at both an individual and population level.

A seminal study was conducted by Professor David Nutt using an international expert panel convened by the Independent Scientific Committee on Drugs that developed a multicriteria decision analysis model of the relative importance of different types of harm related to the use of nicotine-containing products.[1]

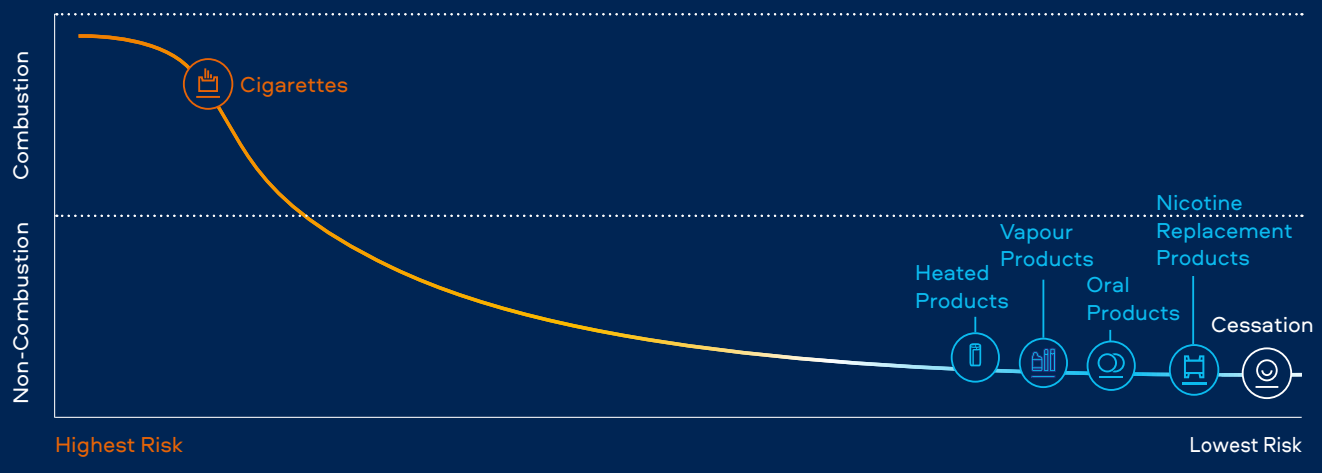
Different types of tobacco and nicotine products were then placed on a continuum of risk relative to cigarettes (the most risky form of tobacco use) and cessation (the measure that most effectively avoids harm from tobacco or nicotine use).

The future

As the relevant science evolves, new clinical and population assessment methodologies will further advance our knowledge, to give us even deeper insights into the impact of Smokeless Products on disease-relevant harm reduction.

[1] Nutt, D.J., et al., Estimating the harms of nicotine-containing products using the MCDA approach. Eur Addict Res, 2014. 20(5), p. 218-225. DOI: 10.1159/000360220

A model to show the continuum of risk of tobacco and nicotine products



A summary of conclusions for our Smokeless Products from key scientific studies within our risk assessment framework.

	Heated Products glo‡	Vapour Products Vuse	Oral Nicotine Pouches Velo
Combustion studies	**No Combustion** Our glo products heat their consumables up to 300°C, at which temperature combustion does not occur.	**No Combustion** Our Vuse products heat its e-liquid below 200°C delivering an aerosol without combustion	**No Combustion** Our Velo products are oral products that are consumed without heat.
Emissions studies	**90-95%** less toxicants*† ^	**99%** less toxicants*† ^	**>99%** less toxicants*† ^
Toxicology studies	**98%** lower genotoxic response^ **90%** lower cytotoxic response^ **95%** less cell stress^	**>99%** lower genotoxic response^ **95%** lower cytotoxic response^ **>98%** less cell stress^	**>99%** lower genotoxic response^ **99%** lower cytotoxic response^ **>98%** less cell stress^
Clinical: Exposure	**Statistically Significant Reductions in Exposure** Complete switching to glo can reduce a smoker's exposure to several harmful chemicals as compared to continued smoking.	**Statistically Significant Reductions in Exposure** Adult solus consumers of our Vuse products have lower levels of exposure to several harmful chemicals compared to adult smokers.	**Statistically Significant Reductions in Exposure** Adult solus consumers of our Velo products have lower levels of exposure to several harmful chemicals compared to adult smokers.
Clinical: Individual Risk	**Favourable Changes in Biomarkers of Potential Harm** Complete switching to glo from combustible cigarettes can result in favourable changes in biomarkers of potential harm.	**Favourable Differences in Biomarkers of Potential Harm** Adult solus consumers of our Vuse products have shown favourable differences in biomarkers of potential harm as compared to smokers.	**Favourable Differences in Biomarkers of Potential Harm** Adult solus consumers of our Velo products have shown favourable differences in biomarkers of potential harm as compared to smokers.

‡ Stated glo studies exclude the glo™ Hilo range
^ On average, in comparison with smoke from a scientific standard reference cigarette (approximately 9 mg tar)

Quality of our products

BAT is committed to ensure that quality is at the forefront of every product we deliver, through:

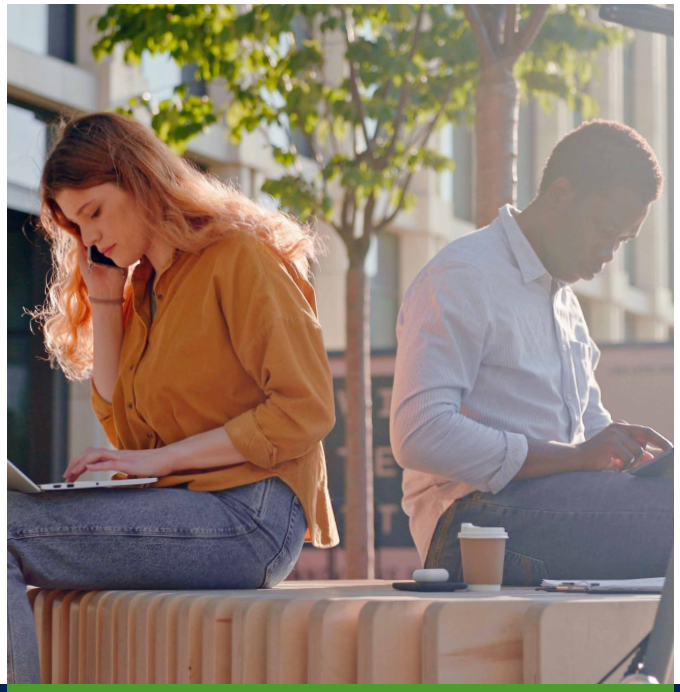
- rigorous research
- high calibre ingredients & materials
- advanced testing protocols
- manufacturing quality standards
- postmarket surveillance

We uphold high standards of quality and performance across our smokeless product portfolio.

By embedding robust research and testing into our processes, BAT delivers products that not only meet expectations but set benchmarks for responsible innovation aligned with our THR ambition.

Responsible Product Landscape at BAT

The critical insights from postmarket surveillance activities feed back into the comprehensive product assessment. This process ensures that real-world, postmarket observational data on possible consumer harm is systematically integrated into the overall product stewardship process.



By bridging this gap, a continuous cycle of product evaluation is established, where reactive signal detection proactively informs risk management decisions. This essential link ensures our monitoring is dynamically updated based on empirical evidence, reinforcing the high standards of quality and performance.

Our commitment to product stewardship runs throughout the product lifecycle, with postmarket surveillance being one integrated aspect. In the upcoming sections of this report, we will outline our standards and practices in the following connected areas:

- Scientific and Regulatory Affairs
- Product Regulatory Compliance
- Toxicology

> “This 9-step scientific framework is inclusive of Product Vigilance, underscoring the importance we place on both premarket product stewardship and postmarket surveillance.”
>
> **Chris Junker**
> Group Head of Life Sciences

Our 9-step scientific Risk Assessment Framework allows us to understand:

How the product works;

How the product may impact an individual;

How the product may impact a population;

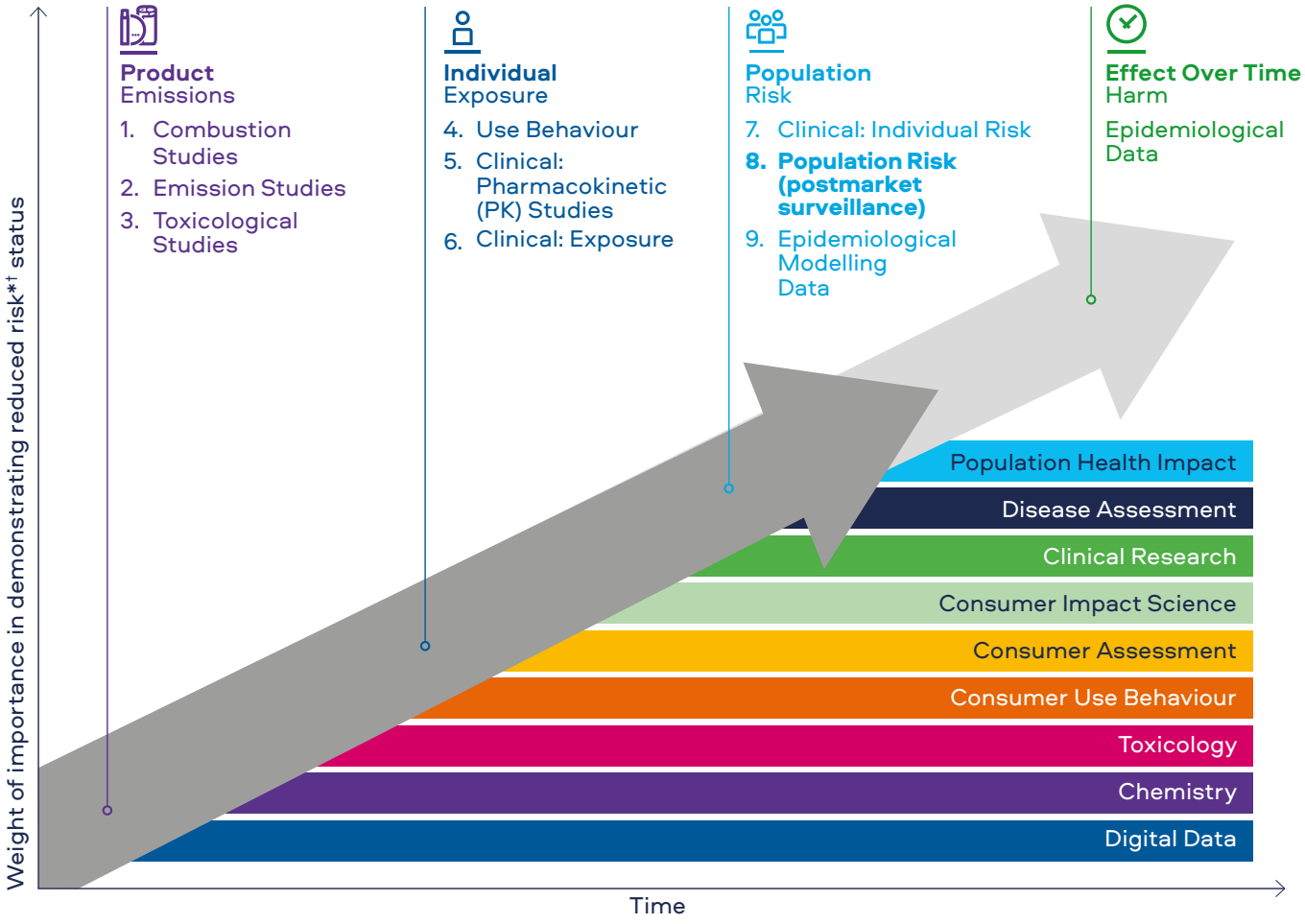
What the effect of time may be.

Through our published peer reviewed science, we can summarise the following key conclusions for our Smokeless Products: glo, Vuse and Velo.

We first shared our framework approach 'for the assessment of Reduced-risk*† Tobacco and Nicotine products' in 2015. Over time, the presentation of our approach has evolved; however, the principles behind how our weight-of-evidence approach is used to assess our Smokeless Products have remained consistent.

Today's multi-disciplinary R&D builds on the strong legacy of those origins, where we conduct research using multiple core scientific disciplines and have implemented the revised and elevated Product Vigilance programme, all aligned to our scientific assessment framework. Step 8 represents this area and shows where it falls within the broader landscape of our scientific framework.

This approach to our transformation has married recruiting new talent from other industries with specific new skillsets, alongside a focused technical capability development programme of our longer-tenure scientists.



Examples of mechanisms to support responsible product stewardship

Product Design	**Product Validation**	**Substantiated Claims**
Labelling & Guidance	**Regulatory Compliance**	**Postmarket Surveillance**

Scientific & Regulatory Affairs

At BAT, the S&RA organisation is responsible for the scientific stewardship of all products in each of BAT's product categories in all global markets where they are commercialised[2].

We are committed to ensuring that our products are designed and manufactured responsibly. We have a rigorous framework to ensure our products meet consistently high quality standards.

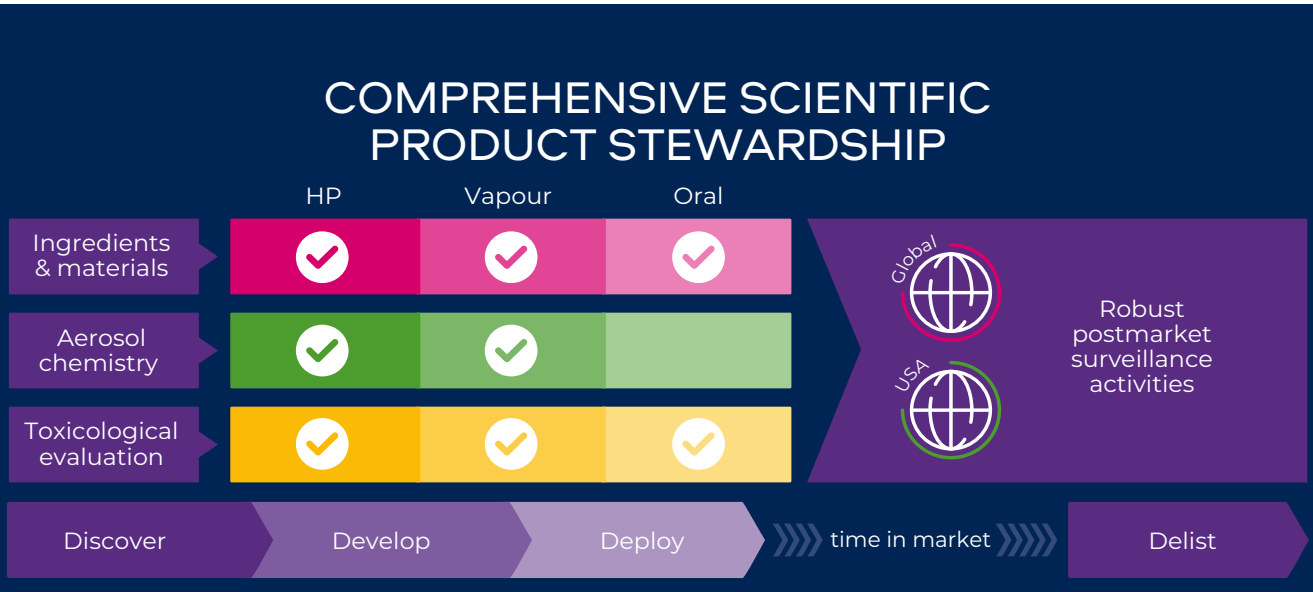
Product stewardship guides both the development and testing of all our products, ensuring we have a vigorous and systematic approach.

Our product stewardship activities start in the early discovery phase of new technology identification and verification and total product proposition development as our S&RA teams work hand-in-hand with the product developer community in each of our product categories to provide guidance on product standards and legal compliance requirements for any new product as it evolves through the iterative product development process. This helps to shape supportable and regulatory resilient innovation.

Stewardship proceeds through full scientific qualification of new product specifications before market launch, meaning every product innovation has had a significant number of hours of laboratory testing and evaluation before it may be used by the consumer.

This oversight continues throughout the product's life in-market, through our postmarket surveillance capabilities, ensuring appropriate response and management of in-market events, and that any insights harvested from in-market consumer experience of our products is fed back into the S&RA organisation to inform future pre-launch stewardship assessments.

[2] For products sold in the U.S. by Reynolds American Inc.'s Operating Companies, procedures and data are managed under a dedicated product vigilance programme at subsidiary companies of Reynolds American Inc. For this reason, when this report discusses specific product vigilance procedures and related data, such procedures and data exclude the US.



Ensuring our products are developed and manufactured in a responsible manner and are legally compliant for launch & throughout their life cycle

> We are committed to ensuring that our products are designed and manufactured responsibly. We have a rigorous framework to ensure our products meet consistently high quality standards and comply with regulations. To advance Tobacco Harm Reduction, it's important that regulators have confidence in our products.

Danni Tower
Group Head of Scientific & Regulatory Affairs

These capabilities support BAT's progressive regulatory framework and inform and enable proactive regulatory engagement for appropriate industry technical product standards - including advocacy for science-based product standards, ingredients negative lists, appropriate nicotine content ceilings and appropriate flavour restrictions.

Product Stewardship Approach[3]

Our Toxicology team works hand in hand with the wider scientific community to ensure high standards of product stewardship.

Dr Karina McQuillan PhD
Global Head of Toxicology

Product stewardship statement:

1. In line with the business principle of responsible product stewardship, we will endeavour to ensure that our products are developed and manufactured in a responsible manner. This means products will meet legal and regulatory requirements in the country of sale and will meet the Group's commitment to use adequate attention, caution, and prudence in bringing a product to market. In addition, we maintain scientific expertise relevant to our products by undertaking our own programme of research, participating in scientific engagement and keeping abreast of external scientific and regulatory developments.

2. **Our teams work collectively to:**

   1. Understand our products from idea to retail and consumer consumption, spanning all stages of product development and all elements of our products, including ingredients, materials, electrical safety, and consumer exposure to emissions.
   2. Respond and act on new information that may impact our products.
   3. Confirm that our products meet the appropriate standards required to deliver consumer products that align with our Tobacco Harm Reduction (THR) strategy.

   The toxicology team apply their specific expertise to the evaluation of all compounds contained in and delivered by our products.

3. Toxicological Assessment: For our Smokeless Products, we apply toxicological assessment principles to identify hazards and contextualise the risk to adult consumers. A toxicological risk assessment takes into account ingoing ingredients and materials as well as the conditions they are subject to during use of that product, the final mixture delivered to the consumer e.g. in emissions and the stability of the product over its shelf life. This includes a scientific assessment of flavours. We assess our flavours in both consumables (Heated Product consumables, Vapour e-liquids and Oral Products) and product aerosols (Heated and Vapour Products) to understand the impact on these ingredients the aerosolisation process has.

4. Our Toxicological assessment largely relies on the use of published peer reviewed data available in the literature, when insufficient data is available, targeted studies may be required. Toxicological studies can be: In silico: using computer models built on previous studies to assess the likely impact of any toxicants, In vitro: using laboratory biological systems typically developed and validated for many different chemicals and mixtures to observe the impact of the emissions on cells cultured in the laboratory on biological changes to the cells or, very rarely, in vivo: which uses live animals and is not undertaken by BAT unless there is no recognised alternative, in order to meet safety, legal and/or regulatory requirements. This looks at changes in organs or other biological material after exposure. Regulatory toxicology studies are conducted to the relevant, internationally agreed testing guidelines by the Organisation for Economic Co-operation and Development (OECD).

[3] For products sold in the U.S. by Reynolds American Inc.'s Operating Companies, procedures and data are managed under a dedicated product vigilance programme at subsidiary companies of Reynolds American Inc. For this reason, when this report discusses specific product vigilance procedures and related data, such procedures and data exclude the US.

“Product stewardship remains a top priority. Our highly qualified team of toxicologists take care to assess the elements of our Smokeless Products to help meet high quality standards.”

Dr Karina McQuillan PhD
Global Head of Toxicology

5. Our Toxicology team encompasses a broad range of scientific expertise including many registered toxicologists, their dedication to continued technical learning and development ensures continued confidence in the quality of our products.

*COI = Constituents of Interest.

Smokeless Product Stewardship: Our Toxicological Assessment Approach

	Heated Products (Inhalation)	Oral Tobacco Products (Buccal Absorption)	Vapour Products (Inhalation)	Oral Nicotine Pouches (Buccal Absorption)
System (Emissions Toxicology)	✓	N/A	✓	N/A
Device (Electrical, Mechanical Materials)	✓	N/A	✓	N/A
Consumable (Content, Toxicology)	✓	✓	✓	✓

Scientific challenge increases ▲

Product Regulatory Compliance

We seek to ensure that all of our Smokeless Products comply with global and national regulatory requirements and applicable product standards in each country of sale.

BAT-developed Smokeless Products include electronic products and accessories supplied to us, and to our subsidiary companies, by third-party manufacturers. Our supply chain uses material declarations to track and declare specific information about the material composition of its products.

To harmonise requirements across the supply chain and to improve economic efficiency, we follow international standards and practices covering the determination of regulated substances. This allows for a global, harmonised approach to the exchange of material composition data, and provides the requirements for material declarations and test methodologies.

Aideen Daly
Head of Product Compliance

REACH

We seek to ensure that our products and materials supplied to us comply with the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which addresses the production and use of chemical substances and their potential impacts on human health and the environment or to equivalent regulations in other markets. Materials used in all product and product packaging-related applications are assessed against the REACH Candidate List published and updated regularly by the European Chemicals Agency.

Electromagnetic compatibility

Electromagnetic interference (EMI), or radiofrequency interference (RFI), may degrade the performance of a circuit or even stop it from functioning.

We comply with the International Electrotechnical Commission's (IEC) standards to provide a presumption of conformity with the protection requirements of Electromagnetic Compatibility (EMC) regulations, covering emission and immunity.

International harmonised standards are designed to satisfy the protection requirements of various global EMC approaches, for example, the European Union's EMC Directive.

Low voltage safety

The standards that apply to electrical appliances that fall within low voltage regulations - including the EU's Low Voltage Directive (LVD) voltage limits - also encompass battery-operated appliances at much lower ratings. These include our Heated Product and Vapour Product devices.

Our simplest route to compliance is to use standards that cover the whole of the LV protection requirements of the appropriate product standards. IEC 60335-1 is the core international standard for our appliances, since it deals with the safety of electrical appliances for household and similar purposes.

As part of our commitment to product vigilance and regulatory compliance, we ensure that mandatory global poison centre notifications are completed. These notifications provide poison centres and emergency responders with critical information about product composition, toxicological profiles and appropriate first aid measures. This enables swift and effective medical intervention in the event of accidental exposure or misuse.

> “Maintaining accurate and timely submissions are a vital part of our product stewardship & vigilance strategy and demonstrate our compliance with international regulations.”

Aideen Daly
Head of Product Compliance

Wireless (connected appliances)

Wireless regulations are often governed by end market product specific regulations that establish the requirements for all wireless transmitters and receivers, apart from devices used exclusively for military, state security, radio amateurs, and civil aviation. We follow the appropriate regulations, articles and approaches for wireless standards when producing connected products in the Heated Products and Vapour Products categories.

Product packaging

BAT Group’s guidelines for packaging help to ensure that product packaging materials do not pose a toxicological risk to the consumer, either directly, or via contamination of the product by the packaging.

Substances not to be used as ingredients in packaging materials include but are not restricted to: substances classified as carcinogenic, mutagenic or toxic for reproduction, according to the Provisions of Regulation (EC) No 1272/2008 on classification, labelling and packaging substances and mixtures.

Introduction to Product Vigilance

As BAT's portfolio continues to shift from traditional combustible cigarettes toward a growing smokeless product portfolio, it has become essential to evolve our postmarket surveillance capabilities. In response to this transformation, we have established a dedicated Product Vigilance team.

Product Vigilance & Our Business Purpose

Product Vigilance (PV) encompasses the science and activities involved in detecting, assessing, understanding, and preventing adverse events. This is not merely a regulatory function but a core tenet of our corporate integrity and our purpose to build A Better Tomorrow™ by reducing the health impact of our business. As a manufacturer of tobacco and nicotine products, we recognise the importance of monitoring and managing risks across the entire product lifecycle.

Dr Hugo Tan
Global Medical Safety Officer

The Strategic Imperative of Vigilance

We have evolved our postmarket surveillance activities into a dynamic Product Vigilance operation that keeps pace with advancing technology and evolving regulations - strengthening our standards. It serves as a critical feedback loop informing research and development.

Integration with Corporate Purpose

Our Product Vigilance operation is integral to our corporate strategy. Insights from vigilance activities can reinforce our product standards for Smokeless Products and help support Tobacco Harm Reduction strategies. This evidence-based approach underpins our scientific narrative and strengthens our contribution to public health discourse.

The Architecture of Our Vigilance System

Our Product Vigilance framework is a carefully engineered process, built upon four pillars:

1 Proactive Surveillance and Data Collection

Across the business, global systems are maintained for systematic data capture on product quality and performance, including adverse event monitoring, consumer feedback, market intelligence and batch-level quality control

2 Scientific Assessment and Causality Analysis

Collected data undergoes rigorous review by multiple subject matter experts as required - toxicologists, physicians, engineers, quality managers and regulatory affairs specialists, to determine causality, severity, and frequency, distinguishing use-related issues from potential product quality issues.

> “An ethically grounded practice that ensures we remain vigilant stewards of our products.”

Dr Hugo Tan
Global Medical Safety Officer

Summary

Product Vigilance at BAT is a disciplined, science-led, and ethically grounded practice that ensures we remain vigilant stewards of our products. As we transform our portfolio and innovate for the future, this framework provides the foundation for responsible growth and the sustained delivery of our corporate purpose.

3 Risk Management and Mitigation

When potential risks are identified, predefined protocols can guide proportionate actions, such as design refinements, manufacturing adjustments, updated user instructions, or, in rare cases, targeted market interventions.

4 Regulatory Compliance and Reporting

Our strengthened operations framework enhances oversight, documentation and reporting, enabling us to maintain regulatory compliance.

Product Vigilance Centre of Excellence

Product Vigilance at BAT is a centre of excellence dedicated to continuous surveillance and management of adverse events associated with our smokeless product portfolio.

A consumer- and data-centric department, with a commitment to Product Vigilance, through data optimisation and responsible stewardship, while promoting good vigilance practices across the entire product lifecycle of our smokeless product portfolio.

Throughout our day to day work and activities, we leverage and draw together, both external subject matter expertise and internal business knowledge. This combination is essential for seamless vigilance operations in a fast-paced and dynamic environment, but also to make certain that we are obtaining the correct understanding and performing the most accurate assessment, of each individual adverse event case.

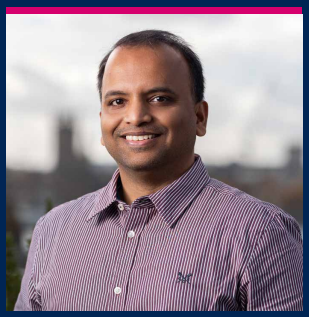
This department operates as a highly capable, adaptive hub within a complex and evolving regulatory landscape. It is powered by a broad internal network of internal subject matter experts working simultaneously through the defined adverse event management process.

Global PV Management Team

Dr Hugo Tan
Global Medical Safety Officer

Alice Ossa Trivino
Global Product Vigilance Manager

Charlotte Strange
Product Vigilance Project Manager



Mahendra Sompalle
Product Vigilance Case Manager

> At BAT, one of our core values is *Stronger Together* - a principle that truly reflects the spirit of Product Vigilance. Our team brings together diverse skillsets and experiences, united in purpose, working collaboratively to achieve our mission.

Dr James Murphy
Director, Research and Science

We define an adverse event (AE) as: any untoward medical occurrence associated with the use of a product by a consumer or clinical investigation subject, whether or not it is considered causally related.

Definition adapted from the ICH (E2D Guideline 2003) & FDA (2021), draft guidance for Modified Risk Tobacco Product Applications.

Our Commitment

Over the past five years we have been on a transformative journey – building upon existing postmarket surveillance processes and establishing a dedicated Product Vigilance Centre of Excellence. We have proactively expanded our expertise and resources, to strengthen our overall operation and amplify the value we deliver.

'Doing the Right Thing'

Our ambition in Product Vigilance is integral to BAT's vision of Building a Smokeless World, by supporting the development and stewardship of innovative alternatives that meet product standards and are responsibly monitored. As these new product categories represent a critical shift away from traditional combustibles, our resources dedicated to post-launch monitoring have grown increasingly important.

We receive reports of adverse events associated with our Smokeless Products from our consumers, clinical research and consumer research participants worldwide. Our products are rigorously developed and tested to high standards, however, as with other consumer products, some adverse events may still be possible.

Once a product is in market, ongoing postmarket surveillance should be standard for all responsible manufacturers.

Fulfilment of Expectations

Stakeholders and regulators expect accurate data collection and management, and we take this responsibility seriously. Each consumer report is reviewed by multiple subject matter experts to allow the correct triage and an accurate assessment. High importance is placed on actively listening to feedback and turning insight into action where needed.

By heightening our standards and focus on adverse event management, we can better support product improvements and ensure stable risk profiles to reduce the likelihood of misuse. This all equates to delivering reputable products for adult smokers seeking smokeless alternatives.

Alice Ossa Trivino
Global Product Vigilance Manager

The North Star in Product Vigilance

While the overwhelming majority of our Smokeless Products are not pharmaceutical products, we look to the pharmaceutical industry as inspiration for postmarket surveillance, guiding the evolution of our programme. Core pharmacovigilance principles - structured quality monitoring, adverse event management, and reporting, are critical to the approach. Our primary reference is the European Medicines Agency's Good Vigilance Practices (GVP), which serves as our regulatory framework and North Star.

At the heart of our operation is a pharmaceutical-grade specialised vigilance database (PV database) housing BAT's adverse event data. Each AE is processed through a bespoke case workflow, inspired by pharmaceutical standards. We have adopted MedDRA* coding to standardise the dictionary of terms used for coding adverse events.

Certain products, dependent upon the market and regulatory regime, require vigilance reporting. This may require reporting of individual events that meet specific criteria to regulatory authorities or the preparation of annual summary reports - requirements enabled by these principles.

While inspired by pharma, our standards are tailored and appropriate for the tobacco and nicotine category. Rather than replicating the model, we have built upon these well-established foundations to create a framework that is fit-for-purpose and aligned with regulatory expectations for our product categories.

The following sections of this report outline key components of this framework supporting BAT's vigilance programme.

*MedDRA - Medical Dictionary for Regulatory Activities, developed by the International Council for Harmonisation (ICH).

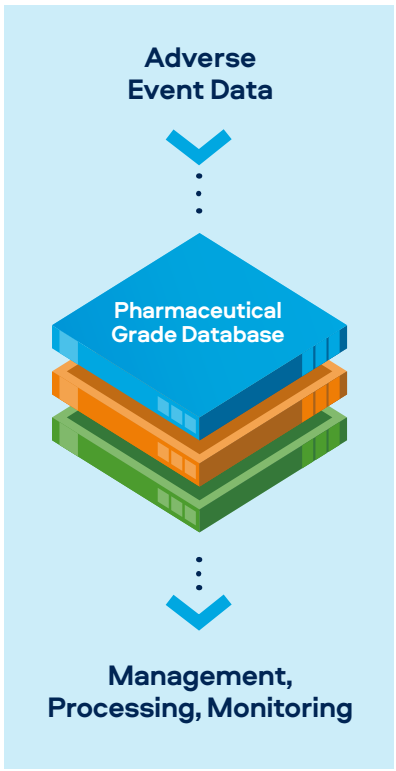
> "I've worked across three industries, each committed to putting the consumer first. What strikes differently at BAT, is the opportunity to make a positive contribution to public health. Our team is deeply passionate about driving change and maintaining product quality standards every single day."

Alice Ossa Trivino
Global Product Vigilance Manager

Data Collection

Data is collected from multiple sources, including consumer complaints, clinical research, and consumer studies. To maintain consistency in management and analysis, all data is routed into a single, centralised PV database.

Consumers are directed to their local careline team for product-related concerns. Contact details are available through multiple channels, such as brand websites, trade representatives, and product packaging. Careline agents log all reported cases, support each consumer, and classify each case as an enquiry, complaint, or other.



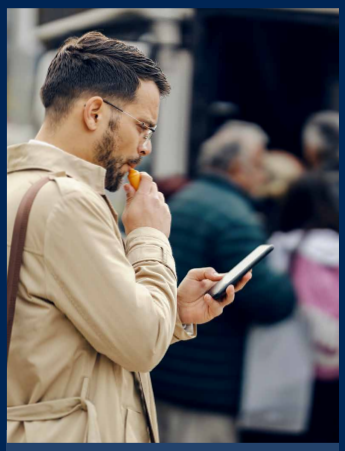
Careline Teams

BAT's careline teams worldwide operate in line with local policies and participate in a Global Consumer Complaint Training Programme twice a year.

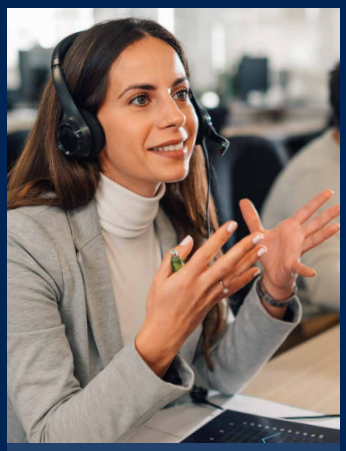
This global programme, as governed in our internal standard operating procedure, reflects our commitment to continuous improvement and equips consumer-facing teams with knowledge on key topics, including:

- **Adverse event definitions**
- **Categorisation and triage**
- **Questionnaires**
- **Support and guidance**

The flow chart illustrates the complaint intake and initial triage performed by careline agents, who then route cases to the appropriate department for further assessment.



Consumer complaints received by careline agents locally

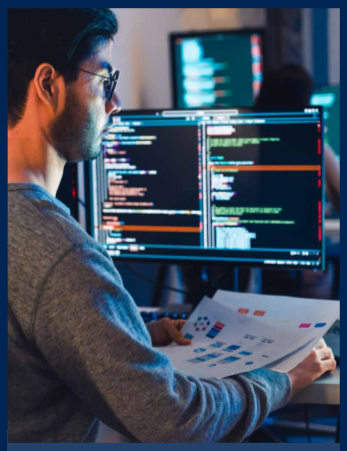


The agents log the case with a 'type' either:

AE',

'Quality',

'AE+Quality'

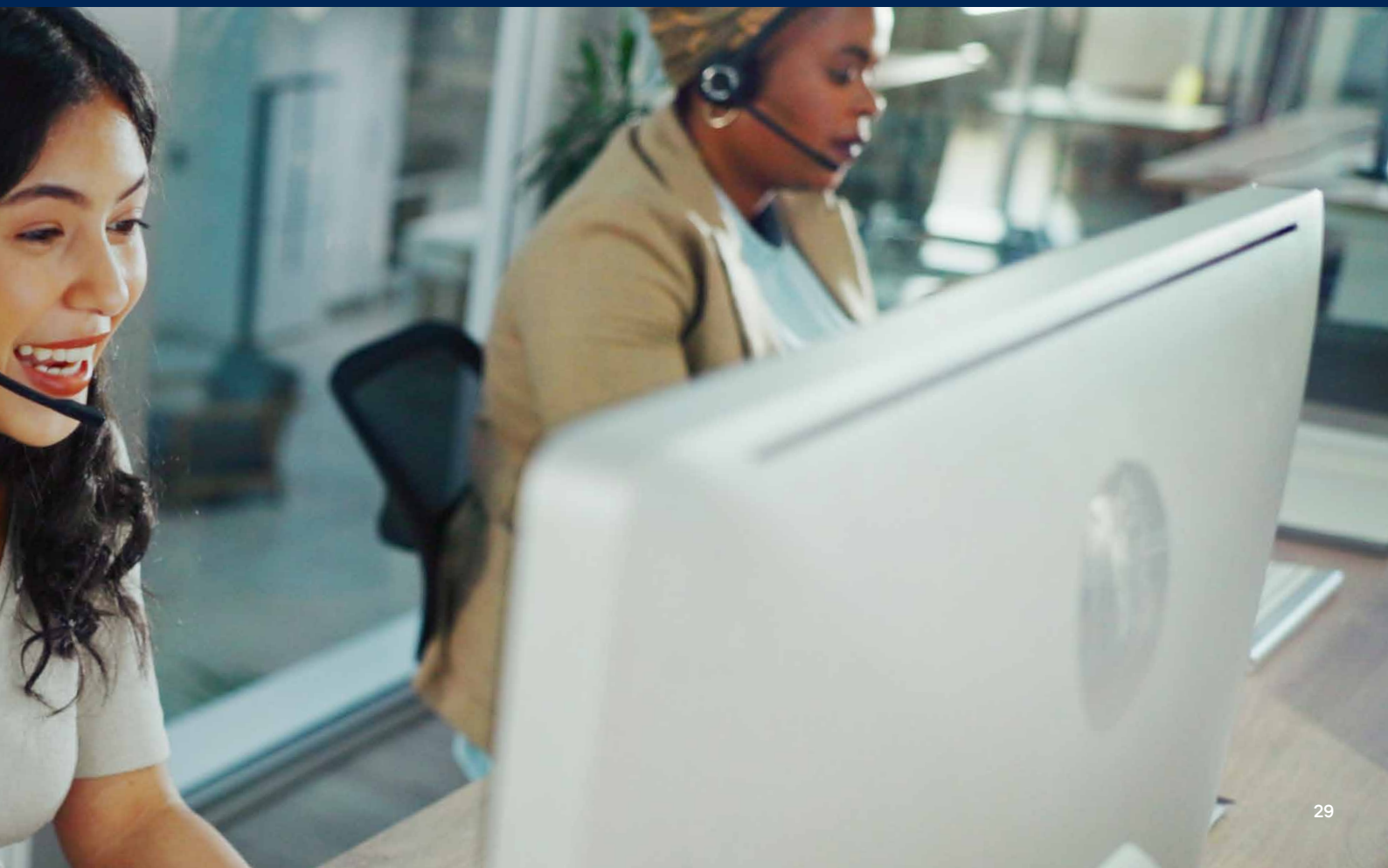


AEs flow to the PV database

Quality cases flow to the Quality department

Combined cases flow through both routes

We have designed and implemented routine reconciliation activities in collaboration with our Global Quality division. These serve as a key control to support data accuracy and enhance process efficiency.



BAT's Product Surveillance Network

A globally coordinated operation, with over 60 careline centre locations, covering over 80 smokeless product markets, all interacting and supporting our consumers on a daily basis.

End to End Process Flow

- All adverse events reported by consumers are received by the local careline team
- The careline agent engages with and supports the consumer
- After initial processing, AE reports are triaged and flow into the PV database
- The PV department acknowledges each case with the relevant market and follows up when required
- The case is closed and archived when assessed as complete as possible

Please note, this is an illustrative diagram. Careline centre locations may be subject to changes. Some careline centre locations cover multiple markets.
Data as of November 2025.

Adverse Event Case Management

The PV Database

As referenced in earlier sections, a core component of the vigilance programme is the PV database - a live repository of adverse event data and associated case information. Beyond serving as a central repository for BAT, the database is an active platform, enabling systematic data management aligned with Good Vigilance Practices (GVP) and regulatory reporting standards.

Unlike traditional combustible products with well-established and known risks, the emergence of reduced-risk*† products introduce new dynamics. Consumers report new types of adverse events, reflecting both the novel nature of these products and greater engagement with compliant reporting. This evolution demands enhanced surveillance and robust technologies to meet emerging product requirements and BAT's expanding role in proactive postmarket surveillance.

Leveraging a pharmaceutical-grade specialised vigilance database provides significant advantages, including: data management, data security, regulatory reporting, supporting PV operations and advancement in signal detection.

Features:

- Seamless digital connection with local careline centre platforms
- Consistent end to end handling of ICSRs (individual case safety reports)
- Includes appropriate fields and functions for data
- Allows a bespoke, relevant, case processing workflow
- Compliant with general global vigilance standards

Adverse Event Case Processing Workflow

Cases from all data sources flow into the PV database, with the majority integrating automatically. For instance, when a consumer contacts the BAT Japan careline centre, the agent logs the case and full engagement details into their system. Upon saving, the record synchronises into the database within minutes, triggering the adverse event case processing workflow.

The workflow follows a structured five-phase process:

Case Intake

The process begins with case intake - an early quality control whereby reports that do not meet four basic criteria are filtered out:

- Reporter
- Consumer
- Product
- Adverse Event

This criteria is aligned with regulatory submission requirements. All non-valid cases are reviewed individually before archiving, with access available if required in future. Valid cases proceed onwards.

Assessment

Here, all required fields are quality checked for completeness, any translation and additional internal coding performed. Individual adverse events are coded using the MedDRA dictionary standard.

Medical Review

If a case hits pre-defined criteria or is coded with a specific MedDRA term, it will follow this step. The medical review evaluates the clinical relevance, expectedness, severity, seriousness and potential causality of the reported event. MedDRA coding is validated.

Supplemental Review

The supplemental review is conducted from a regulatory legal perspective, to identify any cases that may give rise to a regulatory reporting obligation or require escalation.

Final Review

The last phase of the workflow is the holistic final review, involving a cross-functional assessment to ensure each case is appropriately evaluated before closure. Subject matter experts (SMEs) provide their input, either providing information or triggering an investigation. For example:

- Quality assessors may request a due diligence manufacturing check for any associated product-related incident
- Toxicology may cross check product specifications and ingredients; providing insight into biological plausibility

Key to Note:

- In line with our internal definition, we adopt a conservative approach in the assessment of adverse events and database cases, even when the causal association cannot be established, or when, following medical review and investigation, we are confident that the reported event was not caused by product use.
- At each step there is an escalation route, should a case require urgent attention or potential submission to a regulatory authority.

Overall, this multi-layered workflow enables robust product oversight.

The Funnel Effect:
Distilling the Data

Our global Product Vigilance network reports a large volume of data daily.

- Through structured triage and consistent management, we can identify the number of adverse events reported by our consumers with a high level of accuracy.
- Medical reviews assess key case aspects, particularly seriousness.

The funnel effect provides perspective:

- Adverse events represent 0.49% of the total consumer complaints reported to BAT in 2024.
- Serious adverse events accounted for 0.89% of all consumer reported adverse events in 2024.

Overall consumer complaints

Complaints categorised as 'adverse event' or 'adverse event + quality'

Coding individual adverse events per case

Conducting the medical review

Determination of case seriousness

The reports which make up this dataset are spontaneous and voluntary; consumers are not prompted to submit them.
Data is presented on an adverse event level rather than individual case level.
For products sold in the U.S. by Reynolds American Inc.'s Operating Companies, procedures and data are managed under a dedicated product vigilance programme at subsidiary companies of Reynolds American Inc. For this reason, when this report discusses specific product vigilance procedures and related data, such procedures and data exclude the US.

Adverse Event Data

Consumer Complaints

This section provides an overview of adverse event data to reinforce our commitment to continuous monitoring and responsible product stewardship.

Definitions

Adverse Event (AE)

An adverse event is any untoward medical occurrence associated with the use of a product by a consumer or clinical investigation subject, whether or not it is considered causally related.

Definition adapted from the ICH (E2D Guideline 2003) & FDA (2021), draft guidance for Modified Risk Tobacco Product Applications.

Serious Adverse Event (SAE)

Any adverse event that results in one or more of the following:

- Death or life-threatening
- Inpatient hospitalisation or prolongation of existing hospitalisation
- Persistent or significant disability/incapacity
- Congenital anomaly or birth defect
- An important medical event to prevent one of the outcomes listed above

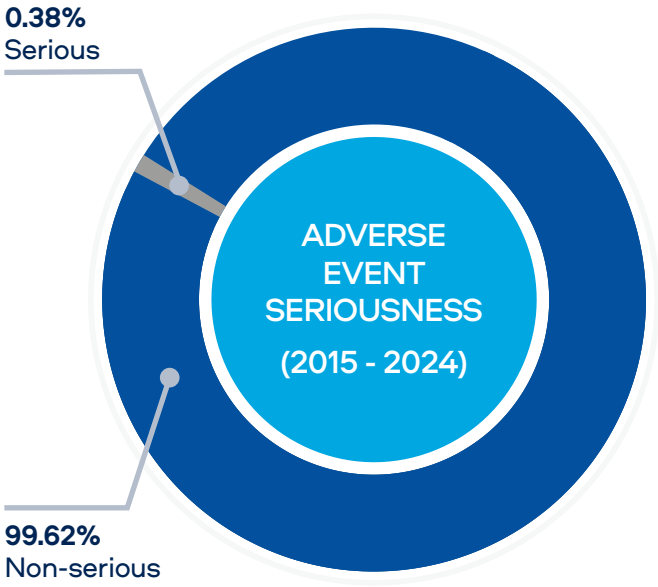
Reference: ICH (E2D Guideline 2003) & FDA (2021)

Adverse Event Seriousness

Data Snapshot: Are The Reported Adverse Events Serious?

The 2015-2024 data provide evidence which continues to give increased confidence in the integrity and quality of these products. The majority of reported adverse events were non-serious (99.62%), with 0.38% classified as serious. The overall reporting rate (encompassing both serious and non-serious adverse event cases) equates to approximately 0.45 adverse events per 1,000,000 units sold.

All cases are fully assessed, regardless of seriousness, and the continuous monitoring beyond the case management, facilitates any potential or unexpected adverse events being promptly investigated.



Contextualising Adverse Event Data

Adverse Events in Relation to Consumer Base

In 2024, BAT's Smokeless portfolio reached an estimated 29.1 million consumers. Across the same period, the proportion of consumers who reported an adverse event was approximately 0.0062%, which equates to around 62 adverse events per million consumers. This consumer-scale context indicates that reported adverse events represent a small proportion relative to overall product use.

Percentage of Adverse Events in Context of Consumer Base (2024)

- Proportion of consumers without reported adverse event **99.9938%**
- Proportion of consumers reported an adverse event **0.0062%**

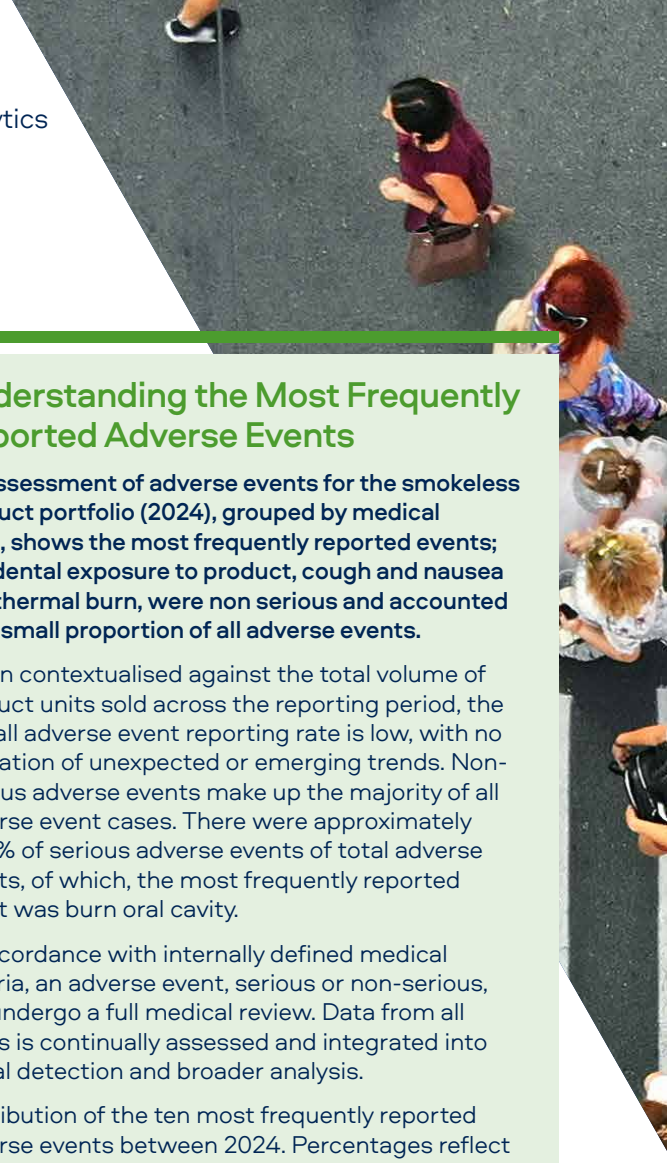
Adverse Events in Relation to Sales Volume

Considering sales volume, in 2024, the reporting rate equated to approximately 0.23 adverse events per 1,000,000 units sold. Expressed inversely, this is approximately one reported adverse event per 4.26 million units, illustrating that adverse events represent a small fraction of total product interactions.

Percentage of Adverse Events in context of Products Sold (2024)

- Proportion of units without reported adverse event **99.9999766%**
- Proportion of units associated with an adverse event **0.0000234%**

Consumer base data (~29.1 million) is derived from full year results for the year ended 31 December 2024 published by British American Tobacco p.l.c. Sales volume is based upon volume of units of smokeless products.
The reports which make up this dataset are spontaneous and voluntary; consumers are not prompted to submit them.
Data is presented on an adverse event level rather than individual case level.
For products sold in the U.S. by Reynolds American Inc.'s Operating Companies, procedures and data are managed under a dedicated product vigilance programme at subsidiary companies of Reynolds American Inc. For this reason, when this report discusses specific product vigilance procedures and related data, such procedures and data exclude the US.



Reporting Dynamics in 2024

In 2024, adverse events related to the smokeless product portfolio varied throughout the year, reflecting natural fluctuations in reporting patterns. On average, monthly cases represented around 8% of total annual cases globally. Reporting rates were observed to trend upwards between July and September, reflecting natural variations in reporting patterns, such as seasonality, where climate conditions such as hotter temperatures and increased humidity can have an effect.

The inclusion of a 12-month rolling average highlights an overall steady upward trend in reporting throughout the year, providing a clearer view of underlying dynamics beyond monthly fluctuations. When viewed with the context of sales data, which shows a steady increase in product volume throughout the year, the overall reporting rate remains proportionate to market growth.

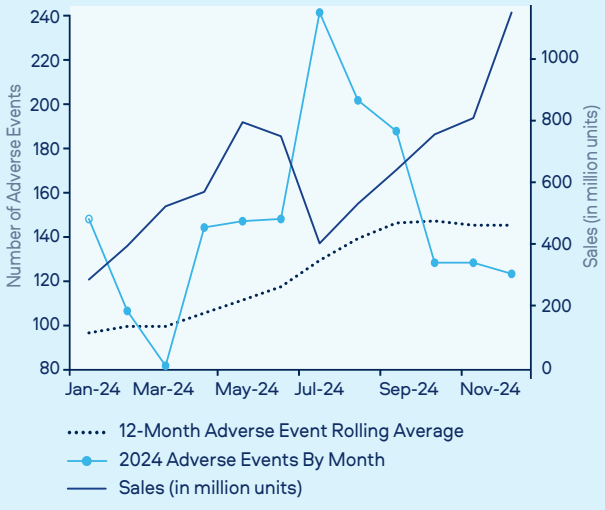
It is important to note there are multiple factors to be considered when analysing adverse event data in this industry, including:

- **product category growth**
- **product familiarity**
- **consumer use behaviour**
- **consumer reporting behaviour**
- **enhanced careline centre reporting practices**

There is typically a three-month lag between purchase and consumer feedback to a careline centre team, though individual timing varies naturally and unpredictably.

While this data does not indicate emerging safety concerns, it reinforces the need for ongoing vigilance, particularly during periods of increased reporting activity. BAT remains committed to proactively identifying and addressing any potential signals.

Reporting Dynamics in 2024



Understanding the Most Frequently Reported Adverse Events

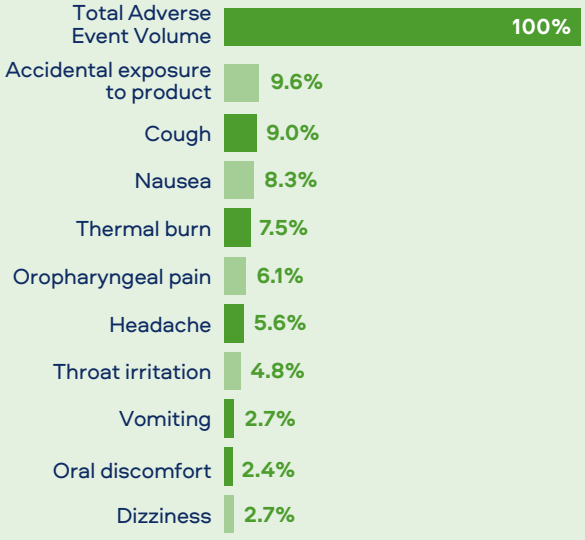
An assessment of adverse events for the smokeless product portfolio (2024), grouped by medical term, shows the most frequently reported events; accidental exposure to product, cough and nausea and thermal burn, were non serious and accounted for a small proportion of all adverse events.

When contextualised against the total volume of product units sold across the reporting period, the overall adverse event reporting rate is low, with no indication of unexpected or emerging trends. Non-serious adverse events make up the majority of all adverse event cases. There were approximately 0.89% of serious adverse events of total adverse events, of which, the most frequently reported event was burn oral cavity.

In accordance with internally defined medical criteria, an adverse event, serious or non-serious, will undergo a full medical review. Data from all cases is continually assessed and integrated into signal detection and broader analysis.

Distribution of the ten most frequently reported adverse events between 2024. Percentages reflect each preferred term's proportion within the total adverse event dataset. When considered against overall product volume, these events represent a small fraction of total units sold.

10 Most Frequently Reported (2024)



Distribution of the ten most frequently reported adverse events between 2024. Percentages reflect each preferred term's proportion within the total adverse event dataset. When considered against overall product volume, these events represent a small fraction of total units sold.

Sales volume is based upon volume of units of smokeless products.

The reports which make up this dataset are spontaneous and voluntary; consumers are not prompted to submit them.

Data is presented on an adverse event level rather than individual case level.

For products sold in the U.S. by Reynolds American Inc.'s Operating Companies, procedures and data are managed under a dedicated product vigilance programme at subsidiary companies of Reynolds American Inc. For this reason, when this report discusses specific product vigilance procedures and related data, such procedures and data exclude the US.

> “Progress in public health depends on science that evolves – we’re committed to expanding knowledge on Smokeless Products to support Tobacco Harm Reduction.”

Helen Cowie
Head of THR Sciences

Signal Detection

Signal detection is the process of data assessment, to enable identification of any new, or previously unknown, potential issues known as signals. A signal is information that suggests a possible, causal relationship, between a product and an adverse event.

The Importance

Signal detection is a critical safeguard in postmarket surveillance, with the accuracy driven by three key factors:

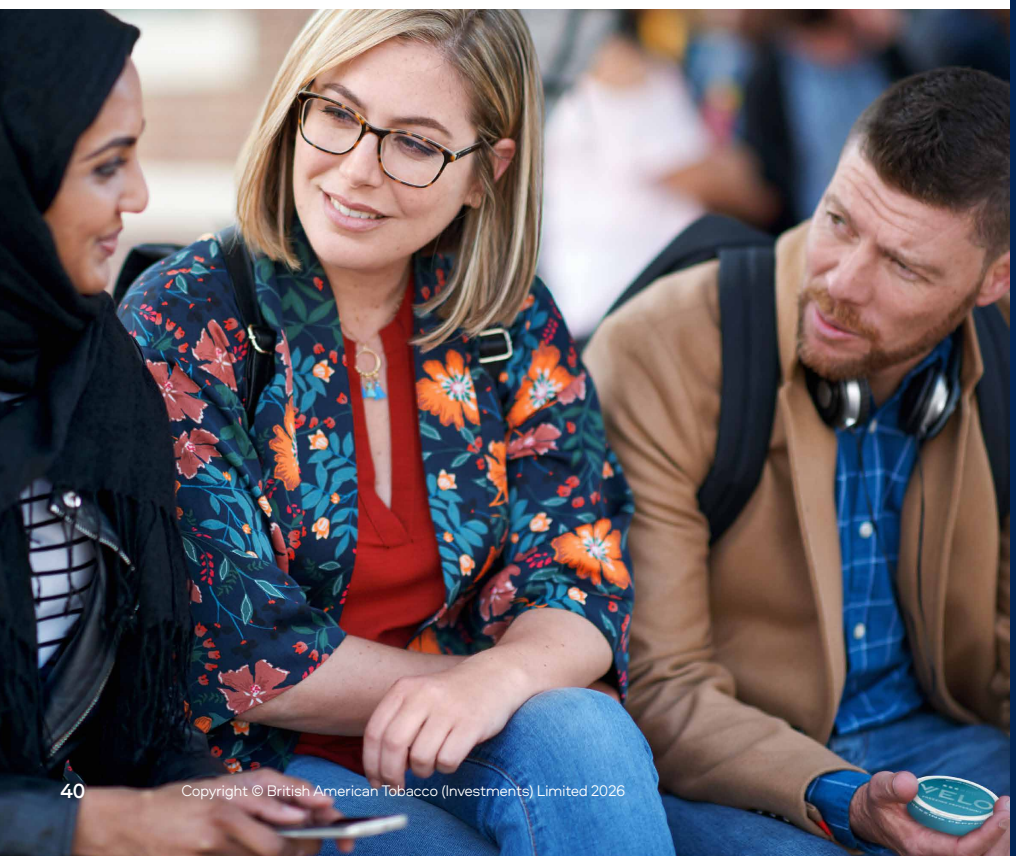
1. data quality **2.** consistent data treatment **3.** review cadence

The quality of adverse event data certainly underpins the effectiveness of signal detection. Consistent careline centre questionnaires, standardised data treatment and timely internal reporting enables data to meet the required standard for holistic assessment. Data should be monitored at predefined intervals to allow for prompt identification of potential signals.

Our Approach

Signal detection is not just about running numbers, it is about identifying and understanding trends and nuances in the data. We follow a structured process combining quantitative and qualitative assessments, enriched by insights from other teams and the local markets.

Formal reviews occur monthly, with ad hoc analyses (e.g., line listings and summary tabulations by time period, product category, and event) conducted as needed throughout the month.



Quantitative Assessment:

- statistical analysis
- trend monitoring
- frequency review
- deviation from baseline *(incorporating volume and AE expectedness criteria)*

Qualitative Assessment:

- clinical judgment
- biological and pharmacological plausibility
- consumer behaviour
- reference safety information
- related cases (MedDRA terms)
- data quality

Broader Business Context Includes:

- Review ongoing initiatives with the following departments as needed, to provide context for assessment:
  - product development
  - manufacturing
  - quality
- Evaluate cases involving both quality aspects and adverse events, to identify any connections

Market Activity:

- portfolio changes
- specification updates
- packaging updates
- sales activity
- use behaviour / consumer acclimatisation
- seasonality

Contextualised Trend Interpretation:

- A complete view of adverse events, quality and related business activities, is essential for effective signal detection and validation

From Signal to Action

Our signal management process covers multiple steps required to identify a signal, through to recommending actions:

01

Signal Detection

Monthly and ad hoc reviews of adverse event data using both quantitative and qualitative approaches, complemented by business context and insights

02

Signal Validation

Initial assessment of signal evidence to determine if full assessment warranted, considering evidence strength, clinical relevance, and existing knowledge of the association

03

Signal Assessment

Validated signal analysed, prioritised and evaluated, culminating in conclusions on whether interim risk minimisation measures are required

04

Decision & Proposed Actions

Confirm or refute the signal. If confirmed, define and propose an appropriate action plan, ensuring alignment and decision documentation, before activation and communication.
Example action: update on-pack labelling

Vigilance360

As introduced at the start of this report, our strategy and approach follows three core dimensions which are illustrated in this model:

■ Awareness ■ Action ■ Assurance

Through continuous monitoring and assessment of postmarket data, we have a much greater awareness of how Smokeless Products are being used in real-world conditions.

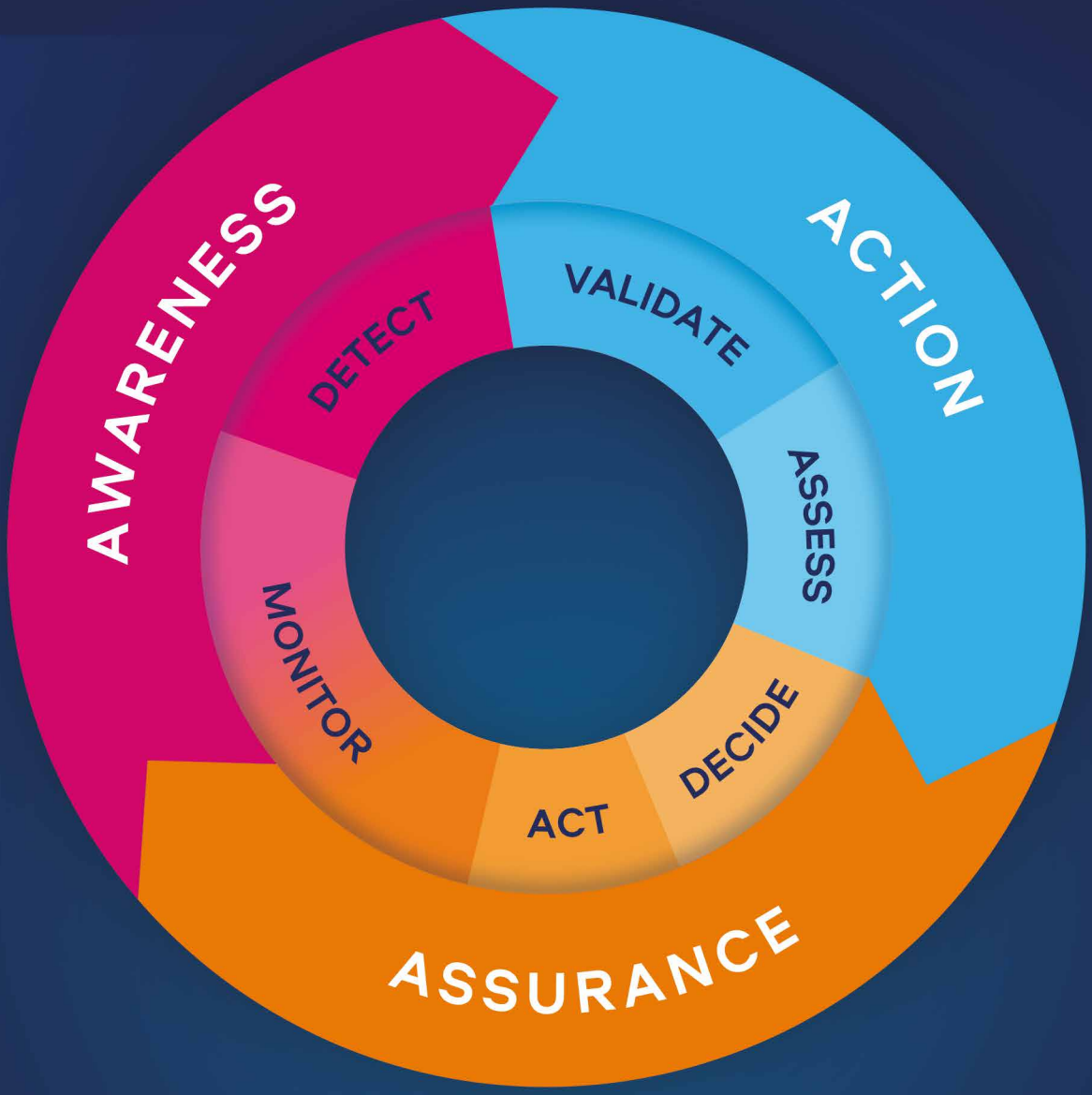
We can act decisively when necessary, knowing reported adverse events are coded precisely with the MedDRA dictionary and running through a well-managed signal detection process.

As emphasised, the quality of adverse event data underpins all vigilance activities. With this, we can act appropriately upon the data and therefore, drive assurance internally and externally, that we are listening to our consumer base, study participants and other available channels, to uphold product integrity.

> “Signal detection is an ongoing cycle embedded in BAT’s Product Vigilance framework. We monitor data continuously, validate any emerging, potential signals, and act promptly to mitigate any level of risk. This proactive approach is one of the integral ways we uphold our product standards.”

Mahendra Sompalle
Product Vigilance Case Manager

CONTINUOUS MONITORING AND PROACTIVE PRODUCT VIGILANCE



The Value & Application of Product Vigilance

In a complex industry with diverse regulatory requirements, maintaining reliable, well-structured data is essential.

Throughout this report, we have seen how Product Vigilance meets this need - ensuring compliance and efficiency. The programme was not designed with compliance as its sole purpose; it aims to generate insights and actions that reinforce product standards, strengthen decisions, and complement scientific research. This section brings these strands together, reaffirming the value Product Vigilance provides and how its outputs are applied in practice.

1. Product Stewardship

In line with the business principle of responsible product stewardship, we will continue to ensure oversight of our products through vigilant monitoring. Product integrity is not a regulatory checkbox, it is a value embedded in every decision, from product development to end use, across all markets. This commitment drives our review of every individual adverse event case and response to each originating market contact during the 'final review'.

2. Real World Evidence

By capturing, acknowledging and analysing 'real-world' product use data, we generate insights that can help inform product development. This evidence bridges the gap between clinical expectations and actual consumer experiences, enabling continuous review and evaluation of each product.

3. Product Quality and Product Vigilance

Our vigilance framework is grounded in close collaboration with our Global Quality division, facilitating the two-way exchange of insights, that add relevant and important context to the data we analyse. Continuous signal detection remains one of our most powerful tools for early identification of potential issues, helping us be proactive, rather than reactive.

4. Continuous improvement

Treating every adverse event case with care allows for higher accuracy at each SME touchpoint during data processing. Data quality underpins all activities performed, helping generate insights which we aim to feedback to the business, informing our teams in:

- Quality
- Product Development
- Trade, Marketing and Brand
- Research and Science

5. Consumer Engagement

We are a consumer-centric department where responsiveness to consumer reports aids regulators, and partners worldwide. Asking the right questions to our consumers and study participants, appropriately assembling the data, and acting upon emerging trends are all fundamental to this commitment. Our consumers are at the heart of everything we do and their feedback is important in shaping product development and better experiences.

6. Continuous Research

Our scientists are constantly conducting research to support the high standards in product development. The repository of real evidence can be used alongside this research and science.

Strong and consistent foundations in data coding and management from the earliest point of historical data capture, allow signal detection to be conducted meaningfully. As we build our repository further, we will have the opportunity to assess trends over greater time periods and strengthen our understanding on product use outcomes.

7. Sustainable Future

The outputs of this programme contribute to our sustainable future strategic pillar and its underpinning initiatives:

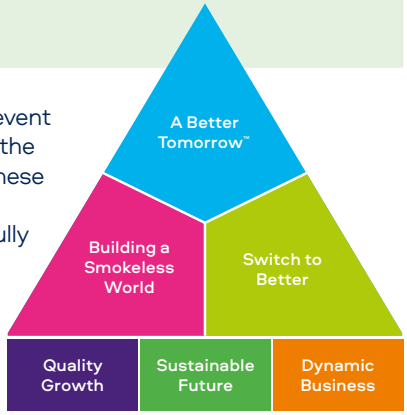
Tobacco Harm Reduction Acceptance – postmarket surveillance is an important factor reinforcing standards for Smokeless Products that underpin Tobacco Harm Reduction strategies and foster their acceptance.

Shaping the Landscape – shaping regulatory frameworks and standards in postmarket surveillance to ensure responsible product stewardship

Leading in Sustainability and Integrity – we are forward thinking, agile and evolving rapidly. We have to adapt with the dynamic of our product categories and consumer preferences.

Integrity: this is about operating with reliable data.

By applying adverse event data and connecting the programme across these dimensions, we can contribute meaningfully to public health, regulatory science and the quality and integrity of our products.



Ultimately, we are dedicated to setting our own high standard in postmarket surveillance, while contributing to and advancing industry best practices.

Future Horizon:
Commitment to Shaping the Regulatory Landscape

Future-Focused Vigilance at BAT

In an increasingly dynamic regulatory and consumer landscape, BAT is committed to advancing vigilance practices that anticipate the growth in focus of postmarket surveillance as these product categories evolve, along with updates in market regulation. Our approach is proactive and our foundation is set, in many areas, above and beyond our current obligations.

We have a future-focused strategy, designed to make sure we continue to support our smokeless portfolio offering as reduced-risk[*†] profile alternatives for adult consumers and enable sustainable growth across the BAT group.

Charlotte Strange
Product Vigilance Project Manager

> "Setting high and harmonised standards in the core areas of postmarket surveillance, benefits both consumers and regulators."
>
> **Charlotte Strange**
> Product Vigilance Project Manager

FUTURE FOCUSED VIGILANCE

01

Strengthen Capabilities

Build local expertise and knowledge, strengthen feedback loops, simplify and open up capacity

03

Advocate for Industry Innovation

Policy engagement. Measures to reduce illicit trade. Stronger measures to prevent product misuse.

02

Embrace Digital Transformation in Vigilance

Advance and improve through digital and artificial intelligence

04

Collaborate with Industry Stakeholders

Collaborate within industry to harmonise and set standards in postmarket surveillance

Evolution of Digital Vigilance

We continuously look to heighten and evolve our vigilance capabilities, building expertise in postmarket surveillance. Our future evolution embraces digital in these specific areas:

- Artificial intelligence
- Careline centre processes and training
- Adverse event forecasting
- Regulatory guideline repository

Collaborative Ecosystem for Risk Management

Collaboration across industry stakeholders; manufacturers, regulators, policy makers and even technology providers, is important and triggers strides forward, in terms of public health and risk management. The complexity of global supply chains demands such collaboration. Setting a benchmark for appropriate and harmonised standards in the core areas of postmarket surveillance, benefits both consumers and regulators. With an operating Product Vigilance centre of excellence in place, BAT can contribute in such areas through participation in groups, such as CORESTA. Examples include, standards in quality documentation, signal detection, data collection and submissions.

There are opportunities to forward this thinking across other sources which hold their own repositories of adverse event data, such as poison centres.

Envisioning the Future

Over the coming years our programme is intended to expand, as we connect further into additional data sources and design bespoke methods to draw out relevant data to enhance our breadth in surveillance. We aim to:

- Simplify and drive efficiencies
- Continue to educate our broader organisation on their role in vigilance
- Expand processes for insight sharing

Through capability building, digital transformation, advocacy and collaboration, we aim to set a benchmark for responsible vigilance business practices.

BAT remains committed to advancing this ever-evolving journey in postmarket surveillance to deliver our vigilance ambition, whilst consistently upholding our core business values including: Do the Right Thing, Love Our Consumer, Stronger Together and Passion to Win.

Conclusion

This section briefly summarises the conclusions derived from this report and the analysis of adverse event data presented for 2024.

A Holistic Approach

Vigilance360 is the underlying theme and strategy running through the postmarket surveillance activities, it reflects the importance of stewardship throughout a product's lifecycle.

Our globally coordinated approach is supported by subject matter experts and vigilance ambassadors, across careline centres worldwide. Consistency, regulatory alignment, and vigilance education enable compliance and scalability, creating an opportunity to make a real impact across the industry in the area of postmarket surveillance.

Tobacco Harm Reduction Acceptance

Postmarket surveillance is an important factor in reinforcing safety standards for Smokeless Products to underpin Tobacco Harm Reduction strategies and foster their acceptance.

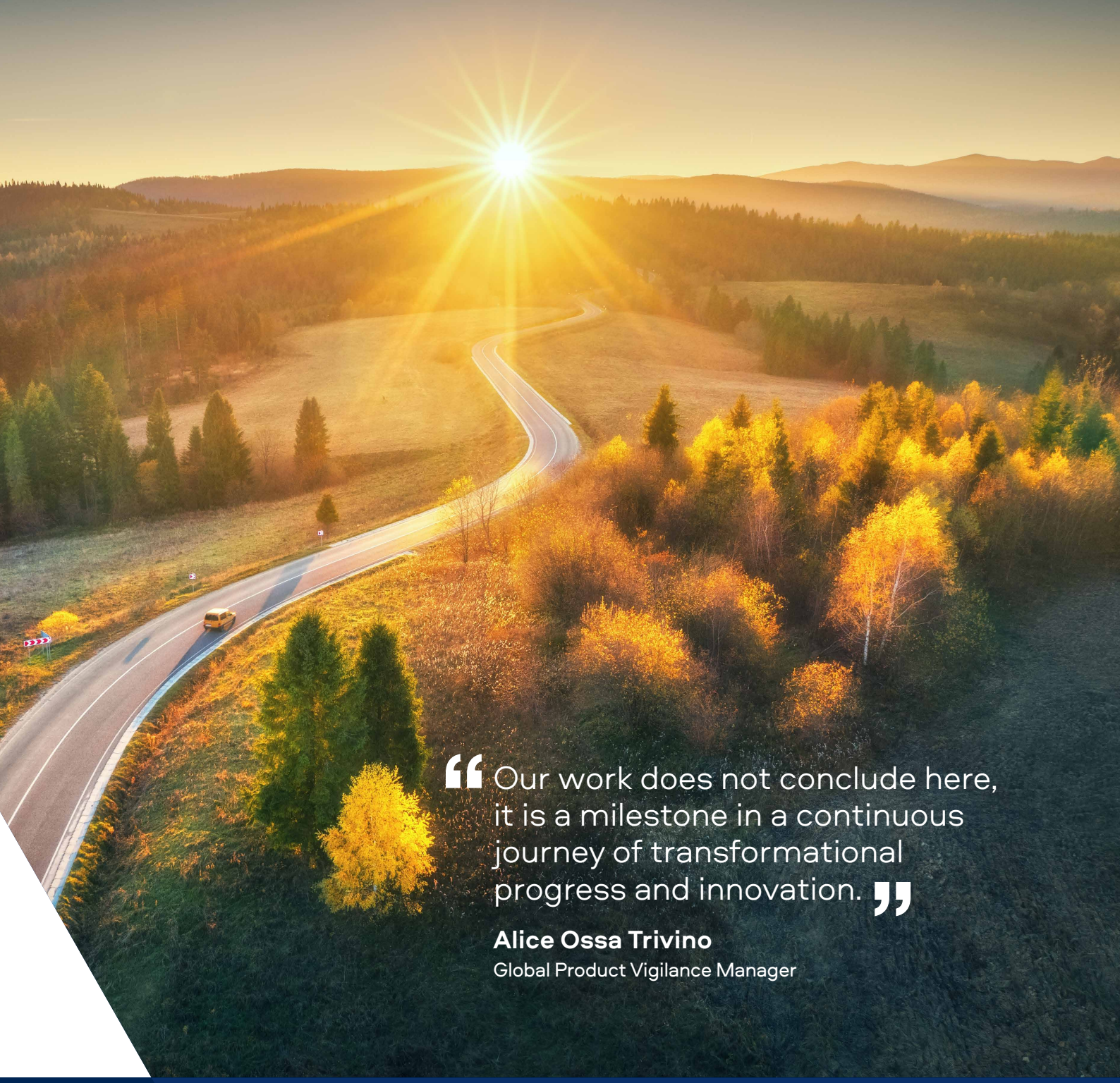
The Data

2024 consumer complaint data:

Adverse Events	
Percentage in context of products sold: 0.234%/1 million units	Percentage in context of consumer base: 0.0062%/consumer

Serious Adverse Events	
Percentage in context of products sold: 0.0021%/1 million units	**Percentage in context of consumer base: 0.000055%/consumer**

The data demonstrates that the majority of reported adverse events are non-serious. Reported adverse events represent a small proportion in relation to overall product use and total product interactions.



BAT’s Next Chapter

Our work does not conclude here, it is a milestone in a continuous journey of transformational progress and innovation. As part of the Omni™ family and our mission on Tobacco Harm Reduction, this report reflects our commitment to learning, evolving, and improving in this area. Inspired by the principles of the pharmaceutical industry, we will keep advancing with purpose, contributing to and elevating industry standards, and striving to create a positive, global impact on public health.

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