

BEYOND SMOKE

CONSUMER-CENTRIC
SCIENCE & INNOVATION



WHAT
ARE NEXT
GENERATION
PRODUCTS?



INTRODUCING
OUR SCIENTIFIC
ASSESSMENT
FRAMEWORK

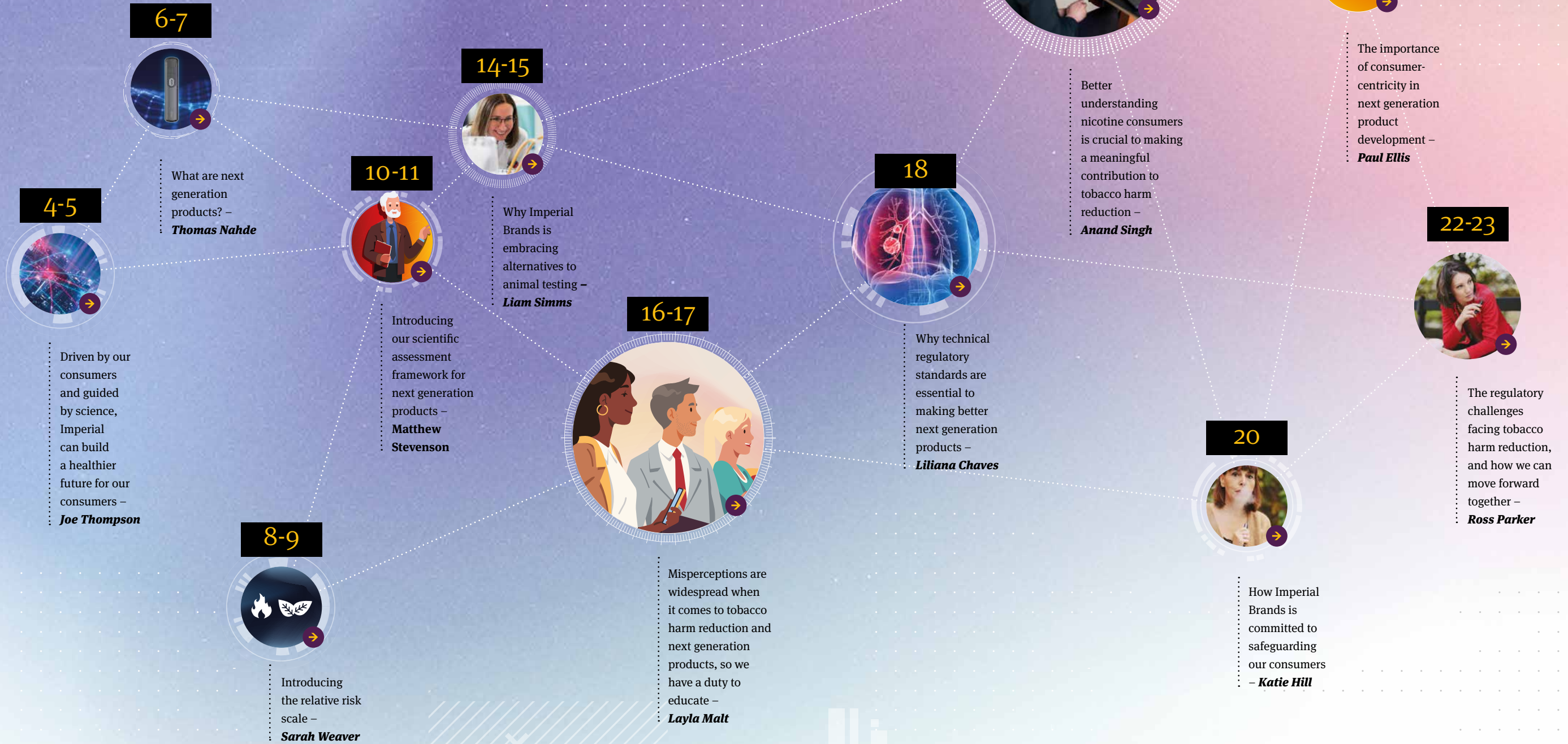


THE REGULATORY
CHALLENGES
FACING TOBACCO
HARM REDUCTION



AND MORE...

CONTENTS



GUIDED BY SCIENCE

IMPERIAL CAN BUILD A HEALTHIER FUTURE FOR OUR CONSUMERS



Joe Thompson, Group Science & Regulatory Affairs Director

Imperial Brands is undergoing an exciting transformation.

We understand society's concerns about the health risks of smoking, and as a responsible business we also recognise our role in helping to potentially reduce smoking-related harm through making a meaningful contribution to the public health concept of tobacco harm reduction (THR).

Harm reduction involves taking mitigating action to reduce the potential harm associated with a risky behaviour – like using a seatbelt when driving a car or putting on sun cream before going to the beach.

THR works on the same principle.

In the past, nicotine has mostly been consumed through burning tobacco. The greatest health risk of smoking comes from inhaling the resulting smoke, which contains thousands of chemicals. Cigarettes deliver nicotine, but it's crucial to understand nicotine *isn't* the primary cause of smoking-related disease.

THR refers to strategies designed to reduce the health risks associated with tobacco smoking, but which may involve the continued use of nicotine/tobacco.

The best course of action adult smokers can take to improve their health is not to use any tobacco or nicotine product. However, despite being aware of the risks, millions are currently either uninterested – or unwilling – to take this step.

That's where next generation products (NGP) come in. They're designed to meet the complex needs of consumers, including the delivery of nicotine, without involving harmful tobacco combustion.

While we're excited about the harm reduction potential of NGP, we also recognise it's crucial they're not also attractive to non-smokers – including youth. This would potentially undermine any contribution to THR made by switching adult smokers. Our philosophy is based on the THR equation (see right) and reflects a responsible approach to marketing and advertising our products, combined with a no-tolerance approach to youth access through every stage of our products' lifecycles.

As NGP categories continue to evolve, we're seeing growing diversity in consumer behaviour within different markets. For instance, France is a significant vaping market, Italy is the largest heated tobacco market in Europe while oral nicotine's the dominant NGP in Austria.

In response, we're rolling out a range of exciting new products at pace to markets like these while contributing important scientific research to the broader compelling evidence base demonstrating their THR potential.

It's also crucial to continue to have fruitful conversations with regulators and public health bodies, while listening to our consumers and their evolving preferences. Understanding their needs and gaining their invaluable insights helps inform our innovation.

We're committed to working at pace with both in-house teams and external partners to create satisfying NGP that further boost switching rates away from cigarettes. If we succeed, we'll contribute to improving broader consumer health – specifically, the health outcomes of millions of adult smokers across the globe.

That's the amazing public health opportunity THR represents; it's a singular opportunity that's energising us all.

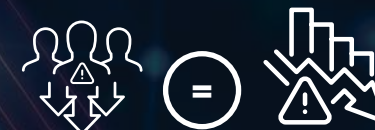


THE THR EQUATION: UNPACKED

THE THR EQUATION EXPLAINS THAT, FOR NEXT GENERATION PRODUCTS TO MAKE A MEANINGFUL CONTRIBUTION TO PUBLIC HEALTH THROUGH TOBACCO HARM REDUCTION, THEY MUST BE:

- Scientifically proven to be less harmful than cigarettes
- Satisfying, accepted and used by a significant number of adult smokers instead of cigarettes.
- Not appealing to, or used, by never smokers – including youth.

Only if all elements of the equation are in harmony can next generation products help enable tobacco harm reduction.



population level tobacco harm reduction

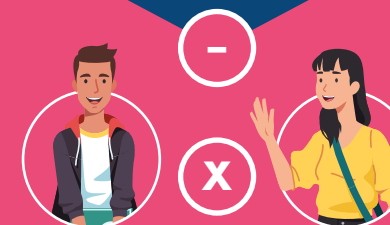
scientifically substantiated reduced risk product



adult smoker acceptance

adult smoker usage

'ON RAMP' TO NICOTINE USE



unintended user appeal

unintended user usage

'OFF RAMP' FROM SMOKING

CONSUMER ACCEPTANCE



FIND OUT MORE

WHAT ARE NEXT GENERATION PRODUCTS?



Thomas Nahde,
Head of Harm Reduction
& Engagement

There are still more than a billion smokers globally. Encouragingly, ever-increasing numbers are seeking harm reduced alternatives to cigarettes.

Traditionally, nicotine could only be consumed through burning tobacco and inhaling the smoke. But alongside nicotine, cigarette smoke also contains thousands of chemicals – hundreds of which are harmful.

Thanks to advances in science and technology, there are now fortunately other, potentially less harmful, ways to consume nicotine.

We recognise every single adult smoker consumer's journey away from cigarettes is likely to be unique, so to help make a meaningful contribution to the public health concept of tobacco harm reduction (THR) we're offering them a broad range of satisfying, non-combustible next generation products, or NGP.

SAFETY FIRST

As part of our consumer safeguarding responsibilities, all our NGP undergo rigorous risk assessments by our in-house professional consumer safety toxicologists – and many other scientific and technical experts – to determine the suitability of ingredients and materials.



Disclaimer: Not all our potential harm reduction products are sold in every market in which we operate, including the US. Those products sold in the US are subject to FDA regulation and no specific reduced-risk or cessation claims will be made as to those products without FDA clearance.



This product contains nicotine which is a highly addictive substance



This product contains nicotine which is a highly addictive substance



HEATED PRODUCTS

The burning tobacco in a cigarette reaches about 900°C at the tip, generating smoke which contains approximately 7000 chemicals.

Conversely, heated products are a type of NGP that heat – but, crucially, don't burn – bespoke sticks. These sticks contain either a portion of refined tobacco (which naturally contains nicotine), or a herbal tea-based substrate (to which pharmaceutical-grade nicotine is added during manufacture).

Heating the sticks creates an inhalable aerosol containing nicotine and flavour aromas – alongside fewer and substantially lower levels of harmful chemicals compared to cigarette smoke. Our research has also shown our heated aerosol doesn't pose air quality issues to bystanders, when compared to indoor air quality regulations and guidelines.

VAPES

Vapes are a type of NGP which can contain nicotine but – crucially – no tobacco leaf. Devices are available in several formats, including open tank, pod-based and disposable.

Instead of burning tobacco to generate smoke, vapes gently heat an e-liquid to create a harm reduced aerosol that users inhale. Our research has also shown vaping indoors doesn't release chemicals or toxins into the air at levels that would pose air quality issues to bystanders.

Our vape e-liquids contain pharmaceutical grade high-purity nicotine derived from tobacco leaf, propylene glycol and vegetable glycerol alongside flavourings.

We're aware of societal concerns around vaping and are committed to discouraging unintended use. We don't offer baked goods, confectionery or candy flavours and target mature consumers making a broader lifestyle shift.



TOBACCO-FREE ORAL NICOTINE POUCHES

Tobacco-free nicotine pouches are an oral NGP.

They contain pharmaceutical grade high-purity nicotine from tobacco leaf that's either combined with a plant fibre-based substrate (e.g., wheat or bamboo) or in a dry powder format.

Nicotine is absorbed via the gums, meaning any lung-related toxicity and disease risks associated with smoking are not to be expected.

As well as far lower levels of, and substantially fewer, harmful chemicals compared to cigarette smoke, these NGP don't even produce smoke – so there's no impact on air quality or risk to bystanders, either.

MAKES SENSE

All our NGP deliver nicotine without the creation of harmful smoke through tobacco combustion. They also replicate many, or all, of the sensorial and behavioural elements of the smoking experience to help adult smokers transition away from cigarettes.



INTRODUCING THE RELATIVE RISK SCALE

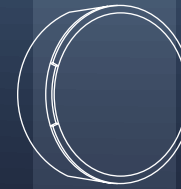
AN ILLUSTRATIVE REPRESENTATION OF THE CURRENT SCIENTIFIC EVIDENCE



Sarah Weaver,
Senior Harm
Reduction
Engagement
Manager



FIND OUT
MORE



TOTAL
CESSATION

COMBUSTIBLE
CIGARETTE



COMBUSTIBLE TOBACCO
PRODUCTS



COMBUSTION



NON-COMBUSTIBLE
TOBACCO PRODUCTS



NON-COMBUSTIBLE
NICOTINE PRODUCTS

HIGHER RISKS
MORE TOXICANTS

LOWER RISKS
FEWER TOXICANTS

As a challenger, Imperial is committed to consumer choice – so we’re offering increasing numbers of our adult smokers a wide portfolio of next generation products (NGP).

Both our own – and independent – scientific evidence suggests they’re all potentially less harmful to consumers than continuing to smoke cigarettes.

To better set the scene though, it’s helpful to unpick the differences between tobacco, nicotine and smoking – plus address the confusion and misinformation that often exists around these topics.

Nicotine is a naturally occurring constituent of the tobacco plant. It’s also found in some vegetables, like potatoes, tomatoes, and aubergines – albeit at far lower levels.

Much like caffeine, nicotine is a stimulant with a long history of being consumed for enjoyment and pleasure by humans.

Public health bodies have concluded nicotine is addictive. However, they also agree it’s the smoke created by the burning of tobacco leaf that contains most of the

hundred-plus harmful chemicals that are responsible for smoking-related disease. This is a crucial distinction.

While our NGP usually contain nicotine, advances in science and technology enable consumers to consume it without having to burn tobacco.

Relatively Speaking

To aid understanding of the harm reduction potential of each NGP relative to cigarettes, we’ve created an illustrative representation of the current scientific evidence, the relative risk scale.

Rather than focusing on any specific brand or product type, it presents an illustrative summary of the totality of the current scientific evidence base underpinning the broader nicotine-containing product categories.

The scale also highlights that NGP possess

varying characteristics. Some contain tobacco; others don’t. Some deliver nicotine via inhalation; others deliver it via the gum linings. These characteristics determine their respective positions on the scale, as you can see overleaf.

Crucially, though, no NGP involves tobacco combustion and the generation of harmful smoke. This means they’re *all* potentially substantially harm reduced, relative to continuing to smoke cigarettes.

We’re clear that the best course of action any smoker can take to improve their health is not to use any tobacco or nicotine product. However, millions are either uninterested – or unwilling – to do this.

We therefore believe offering adult consumers the choice to switch to potentially harm reduced NGP is the next best option and hope our relative risk scale helps to communicate the available options.

	CIGARETTE	HEATED TOBACCO	SNUS	VAPE	ORAL NICOTINE POUCHES	NICOTINE REPLACEMENT THERAPY
COMBUSTION						
TOBACCO						
METHOD OF USE						
TOXICANTS						
NICOTINE DELIVERY (FAST TO SLOW)						

OUR SCIENTIFIC ASSESSMENT FRAMEWORK FOR NEXT GENERATION PRODUCTS



Matthew Stevenson,
Investigative & Mechanistic
Toxicology Senior Manager

As part of our commitment to offering adult smokers potentially harm reduced next generation products (NGP) as an alternative to smoking cigarettes, we've developed a multi-stage and multi-discipline scientific assessment framework (SAF) – to evaluate them.

The framework ensures we're rigorously validating our NGP safety profiles throughout their lifecycles while scientifically assessing their benefits and relative risks compared to cigarettes – focusing on both individuals and wider adult smoking populations.

Results from individual studies within the SAF are important, but in combination they

begin to provide a compelling weight of evidence demonstrating the tobacco harm reduction (THR) potential of our NGP.

We believe the totality of this research, alongside promising new in-market consumer data on adult smoker switching/retention rates, plus the broader scientific literature, will ultimately confirm our NGP contribute to improved public health

outcomes compared to continued smoking. Meanwhile, our diligent product safety assessment processes ensure we're delivering quality products to safeguard our consumers.

Below, we'll explore each stage of the SAF, and how this multidisciplinary approach allows us to feel confident our NGP have the potential to make a compelling contribution to tobacco harm reduction.



FIND OUT MORE



TALKING THR

Engaging externally around the science we conduct is crucial, so we invite critique through the process of peer-review in international scientific journals, regularly present our research at international conferences and make our work publicly available on our dedicated science website.

We believe this openness, transparency and collaboration enhance the scientific understanding of NGP and provide adult smoker consumers with the greatest opportunity to make informed choices about their health.

STAGE 1: PRODUCT CHARACTERISATION SCIENCE



This stage is essential before any further research is conducted. Analysis may include risk assessment, product quality, aerosol chemistry and indoor air quality studies.

What have we discovered so far?

We've shown all our NGP contain far fewer, and substantially lower levels of, harmful chemicals than those found in cigarette smoke.



STAGE 2: BIOLOGICAL SCIENCE



This stage provides the first indication of our products' impact on consumers. Laboratory studies are used to assess product safety and the impact on cells compared to cigarette smoke.

What have we discovered so far?

We've demonstrated reductions in harmful chemicals in our NGP translate to markedly reduced biological measures of *in-vitro* toxicity in human cells, compared to cigarette smoke.



STAGE 3: CLINICAL SCIENCE



After we've established there are no concerns in laboratory tests, we recruit adult smoker volunteers for clinical studies. These assess short-term safety, tolerability, performance and acceptance of NGP.

What have we discovered so far?

Our research suggests our NGP offer a satisfying alternative to cigarettes, reduce adult smokers' desire to smoke and have encouraging short-term safety and tolerability profiles.



STAGE 4: PERCEPTION & BEHAVIOURAL SCIENCE



Complementing the work of our insights teams, we scientifically assess how our NGP are being perceived and used in the 'real world'.

What have we discovered so far?

We've demonstrated adult smokers and non-smokers understand our NGP contain nicotine and aren't risk-free, but are potentially less harmful than cigarettes. Also, our NGP appeal overwhelmingly to adult smokers, with very low interest amongst non-smokers (in products tested to-date).



STAGE 5: COMPUTATIONAL SCIENCE



Data modelling is used to support various stages of the SAF to identify trends, patterns and predict future outcomes. Modelling approaches can be used to predict the long-term impact of NGP in terms of prevalence and THR potential.

What have we discovered so far?

Our modelling has demonstrated there is a noticeable correlation between the adoption of pro-NGP regulation and potential decreases in smoking prevalence over time.



STAGE 6: POST-MARKET SURVEILLANCE



We collect data to understand how our products perform once on the market in consumers' hands, and throughout their lifecycles. This enables us to assess consumer safety, product quality and THR potential.

We'll also perform additional scientific studies once NGP are in-market to mitigate any remaining gaps in the data, if required.



WELCOME TO IMPERIAL BRANDS SCIENCE...

HERE YOU CAN...

EXPLORE DETAILED 3D MODELS OF OUR NGP



FIND US ON LINKEDIN



DIVE INTO OUR NEXT GENERATION PRODUCT (NGP) SCIENCE AND INNOVATION



WATCH VIDEOS



READ OUR LATEST PRESS RELEASES



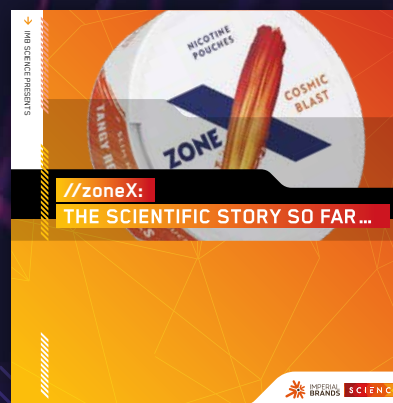
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ACCESS OUR ENTIRE SCIENTIFIC RESEARCH ARCHIVE



LEARN MORE ABOUT OUR ALTERNATIVES TO ANIMAL TESTING PROGRAMME



DIGITAL BROCHURES



AND MUCH MORE...



WHY IMPERIAL BRANDS IS EMBRACING

alternatives TO ANIMAL TESTING



Liam Simms,
Principal Toxicologist

Animal testing has been prevalent in biological research since the 1950s, and many scientists still rely on these relevant, but arguably unethical, techniques.

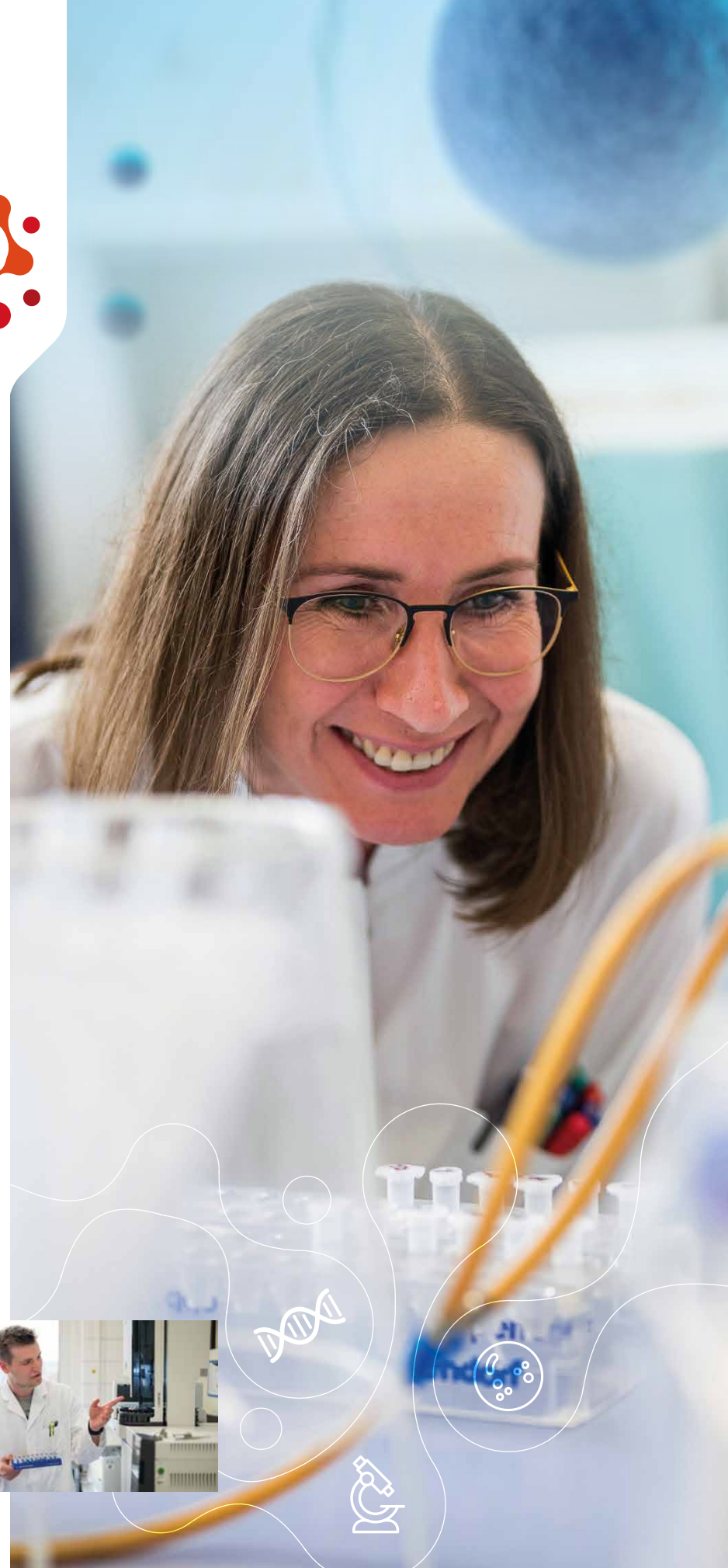
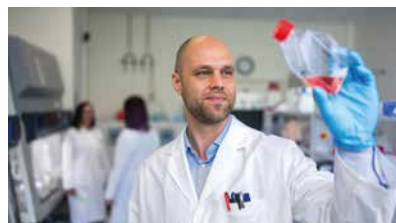
The approach started to change around two decades ago, when the US National Research Council (NRC) began to recognise rapid advances in biotechnology.

In 2007, the NRC outlined an official long-term vision and strategic plan to advance toxicity testing through new methodologies that evaluated changes in biological processes using cells, cell lines or cellular components of human origin – rather than traditional *in-vivo* methods using live animals.

They called it **Toxicity Testing in the 21st Century**, or **TT21C**.

In the time since, those manufacturers and scientists who support the movement to use fewer animals in research in laboratories across the world have made seismic strides in proposing and developing cutting-edge alternative methods that are more human-relevant.

That includes our own industry – and we're proud to be among those pioneering a TT21C-driven approach.



Human Interest

Our own TT21C research programme – 'Alternatives to Animal Testing' (ATAT) – began in 2016. During the last half a decade, we've been exploring the potential of this approach to assess next generation product (NGP) aerosols compared to cigarette smoke.

The results have been very promising, highlighted by the acceptance of several of our studies into the peer-reviewed academic literature.

For instance, in conjunction with recognised regulatory *in-vitro* test methods, we've examined the effect of our NGP on cardio endpoints. (See the scratch wound assay, below).

We're also using a range of other assays to assess cancer and chronic

respiratory disease endpoints, heart disease, organ interactions, and *in-vitro* models to populate parts of adverse outcome pathways (AOP).

Using multiple assays related to different areas of smoking-related disease allows a weight-of-evidence approach to help draw compelling conclusions around the harm reduction potential of our NGP.

Future Tox

ATAT has incredible potential, but it's still an emerging framework in some ways – not least because it's still less than two decades young. This means there's still lots to do in terms of educating regulators, media, and the public around its advantages.

However, we're confident many ATAT methods and assays will

become established as future regulatory standards.

Several agencies are demonstrating keenness to encourage this shift: the most high-profile being the U.S. Food and Drug Administration, who have previously acknowledged the need for New Assessment Methodologies through their own Tox21 programme and roadmap.

We continue to scientifically engage with regulators to build the knowledge around, and acceptance of, approaches like ATAT to help enable more ethical and human-relevant assessments in the future.

TT21C is a real toxicological game-changer and our Alternatives to Animal Testing team is proud to work on this cutting-edge harm reduction science.

TAKING A DEEPER DIVE INTO SOME OF OUR ATAT ASSAYS...



HIGH CONTENT SCREENING

This assay combines imaging and quantitative data analysis to provide rich systems biology information, detecting any notable events in the human cell lines tested.

Using this methodology we've shown, for instance, that vape aerosols cause lower biological activity compared to cigarette smoke.



3D LUNG MODEL

For this assay, a 3D model representative of human bronchiole tissue is exposed to cigarette smoke/NGP aerosols, and various endpoints are measured to observe any effects. Assays include examining mucus production and measuring the beat frequency of cilia – mobile, hair-like structures that line the larger airways.

Our lung model studies to-date have all provided promising evidence of the harm reduction potential of NGP for lung health compared to cigarettes.



SCRATCH WOUND

This assay evaluates the impact of product samples on human endothelial cells (the single layer-thick cells that line all human blood vessels) that are essential for healthy cardio-vascular function. In this assay, a scratch is made in the cell layer and the time taken for the normal cell response of filling – or 'healing' – the ensuing gap is measured.

Cigarette smoke has been shown to delay wound healing, inhibiting endothelial cell normal migratory behaviour. In marked contrast, our research shows exposure to NGP aerosols has little (vape) or no notable (heated tobacco) inhibiting impact under test conditions.



FIND OUT MORE

MISPERCEPTIONS ARE WIDESPREAD

...WHEN IT COMES TO TOBACCO HARM REDUCTION AND NEXT GENERATION PRODUCTS, SO WE HAVE A DUTY TO EDUCATE



Layla Malt,
Senior Surveillance
Manager

Newspapers and websites are brimming with scientific analysis and advice. Yet reporting of some studies can miss the mark; for instance, have you ever read a story telling you that red wine or chocolate was good for you, only to see the exact opposite headline a short time later?

The same goes for studies about the potential harms of next generation products (NGP). One headline reports vapes are “95% safer than smoking”; another claims a new study proves vapers are damaging their lungs or blood vessels.

How does anybody – including regulators, public health bodies and, perhaps most importantly, adult smokers and NGP users themselves – make sense of such a seemingly shifting landscape?

It’s a fair question, so let’s take the opportunity to debunk some of the biggest myths surrounding tobacco harm reduction and NGP to help inform all our stakeholders – from journalists, public health, regulators, and retailers to consumers themselves.

As a responsible manufacturer we share concerns unintended use of NGP is increasing in some countries, and could undermine confidence in tobacco harm reduction (THR).

We’re committed to playing our part in ensuring all NGP are created for, and marketed towards, existing adult smokers and NGP users only.

“
NGP like vapes appeal to youth.”

Unlike cigarettes, NGP don’t produce ‘side-stream’ emissions – while exhaled aerosol quickly evaporates. We’ve conducted several pieces of scientific research suggesting neither vaping nor using heated tobacco negatively impact indoor air quality.

For instance, air quality in a room where blu was vaped for almost three hours still comfortably fell within acceptable boundaries. Recorded emissions were also notably lower than those from, for instance, a burning scented candle.

However, NGP users should always be courteous to those around them.

“
NGP pollute indoor environments, just like smoking.”

We understand society’s concerns about the health risks of smoking, and recognise our important role helping reduce the harm caused by tobacco.

There’s global recognition and endorsement for the role NGP can play in helping facilitate THR. However, different NGP also possess different characteristics – which impacts their respective levels of harm reduction potential (find out more on pp.8-9).

Crucially though, no NGP burns tobacco – which produces smoke containing harmful chemicals. Although not risk-free, this means all NGP are potentially significantly harm reduced compared to continuing to smoke cigarettes.

“
NGP are just as bad for your health as cigarettes.”

Public health experts have concluded it’s the toxicants in cigarette smoke generated by burning tobacco, and *not* the nicotine, which is the cause of smoking-related diseases. To date, the scientific consensus is that nicotine has not been established to cause, by itself, cardiovascular disease or cancer.

Our NGP all contain nicotine, but importantly they don’t have to burn tobacco to deliver it to users – meaning it can be consumed in potentially less harmful ways.

“
Nicotine causes cancer.”

This isn’t a misperception sadly; it’s the truth.

Why? Well, the debate around cigarette smoking, nicotine and NGP is a multifaceted, nuanced, and emotional one – and many critics of THR cite the lack of long-term evidence. Other reasons THR isn’t accepted often include mistakenly believing nicotine is the primary cause of smoking-related disease, conflicting scientific data, confusing media headlines, concerns about unintended use of NGP and manufacturer mistrust.

However, the growing body of scientific data – combined with the significant drops in smoking rates in those countries who have embraced tobacco harm reduction like the UK, Japan, and Sweden – offers great optimism around THR’s broader public health potential.

“
There’s no regulatory consensus around tobacco harm reduction.”



“
Vaping gives you popcorn lung.”

Popcorn lung (bronchiolitis obliterans) is caused by high levels of the flavouring ingredient diacetyl, and was first observed in popcorn factory workers. In the past, it was detected in some e-liquids but at levels hundreds of times lower than in cigarette smoke.

All NGP must pass stringent testing relating to their ingredients and manufacture before they can be sold, and diacetyl was banned in e-liquids under the EU Tobacco Products Directive in 2016.

No legal vapes, including our own, contain diacetyl.

“
There’s been hardly any scientific research around NGP.”

It sounds incredible, but over 10,000 scientific studies have been published since 2010 – comprising of both industry and independent academic research. And that’s just focusing on vapes, let alone the wider NGP categories.

We’re proud to have contributed our own research too, regularly presenting data at international conferences and publishing papers in the academic literature.

The overwhelming majority of this research is building a compelling body of evidence validating the broader harm reduction potential of NGP.

“
If NGP have so much public health potential, why is the media full of negative stories about them?”

The overwhelming weight of many thousands of pieces of scientific research points to the exciting public health potential of NGP.

However, it’s likely there will always be some studies that contradict these findings, and that – inevitably – these contradictory papers are the most likely to be picked up by media outlets, particularly by those who might be less concerned with validating said research and thrive on controversy to generate engagement.

We’re committed to combating misinformation and disinformation where and whenever we encounter it.

“
NGP are unregulated.”

The only unregulated NGP are those which are illegal, or can be adulterated post-purchase.

In the UK for instance, all vape manufacturers must notify the Medicines Healthcare products Regulatory Agency (MHRA) before products are launched.

Likewise, the UK Tobacco and Related Products Regulations has imposed limits on nicotine concentrations, as well as strict labelling guidelines and various advertising restrictions.

Other countries who permit the sale of NGP enforce similar regulations before any product launches are allowed.

So NGP are anything *but* unregulated!

ANALYSE THIS

We think it’s crucial to possess the skills needed to analyse emerging scientific news stories or research papers; after all, misconceptions and misinformation can undermine peoples’ faith in the harm reduction potential of next generation products.

Follow this link for our blog on top tips our scientists use when they’re critiquing scientific studies and media stories as part of their surveillance work.



FIND OUT MORE

WHY TECHNICAL STANDARDS ARE ESSENTIAL TO MAKING BETTER NEXT GENERATION PRODUCTS



Liliana Chaves,
Product Standards
Senior Manager

Technical standards are ubiquitous in just about every industry you can think of. They help ensure your car is safe to drive and that your phone charger fits into a wall socket. There's even a technical standard for brewing tea!

It's helpful to imagine standards as tools which products, processes or services can be measured against. Standards simplify comparisons, promote quality and safety, facilitate trade, and encourage sustainability and innovation. They're sometimes also required to demonstrate regulatory compliance.

Unlike regulations though, technical standards aren't a form of legislation, so adopting them is often voluntarily. Rather, they help measure compliance *with* legislation – helping create supportive trading environments while discouraging anti-competitive behaviour.

Next generation product (NGP) technical standards can be wide-ranging, from providing methods for measuring the constituents of public health interest in a vape aerosol, to assessing the battery safety of a heated tobacco device.

To write a standard, experts in the field – including consumer associations, academia, researchers, NGOs, industry, and government bodies – cooperate to share their knowledge to determine principles of best practice. This consensus ensures they're a legitimate and reliable tool for assessment.

Technical standards are usually published by a national (like the UK's British Standards Institute), regional (like CEN, the European Committee for Standardisation) or international standards body (like ISO, the International Standards Organisation).

Standards and THR
Our scientists contribute to technical standardisation around the world. So far, we've helped to publish multiple standards on NGP, including the first international standard to determine levels of nicotine, propylene glycol and glycerol in e-liquids.

Technical standards can support effective, responsible regulation by helping us better understand the harm reduction potential of NGP compared to cigarettes and ensuring every adult smoker who tries an NGP has a satisfying experience they're keen to repeat. In turn, this is likely to have a positive impact on tobacco harm reduction – and broader public health.

That's why we firmly believe technical standards lie at the heart of THR.

EVALI: A CAUTIONARY CASE FOR PRODUCT STANDARDS

IN 2019 IN THE US, THERE WERE AROUND 2,800 HOSPITALISED CASES OR DEATHS FROM EVALI...



EVALI is defined as a vaping product use-associated lung injury. Vitamin E acetate was strongly linked to the outbreak after being found in product and patient samples tested by the US Food and Drug Administration and US Centres for Disease Control and Prevention.

While the evidence wasn't sufficient to fully rule out the contribution of other chemicals of concern, a proliferation of black-market cannabis vaping products was likely to

blame. In a similar manner to diacetyl (linked to cases of so-called 'popcorn lung'), vitamin E acetate is banned in regulated e-liquids in many other countries – including across Europe.

The EVALI outbreak and its tragic consequences serve as an important reminder why robust, well-defined, and industry-wide quality NGP product standards – especially in areas such as ingredient selection – are essential.



Anand Singh,
Global Insights Director

BETTER UNDERSTANDING NICOTINE CONSUMERS IS CRUCIAL TO MAKING A MEANINGFUL CONTRIBUTION TO TOBACCO HARM REDUCTION

Consumer insights are at the heart of our next generation product (NGP) development.

From collaborating on prototypes in our innovation hubs to testing our NGP using adult smoker subjects in clinical trials, it's clear that better understanding our consumers and the broader landscape in which we operate is crucial to achieving our ambition of making a meaningful contribution to tobacco harm reduction (THR).

The emergence of a range of distinct NGP categories have undoubtedly accelerated diversity in consumer usage behaviours.

On a market level, for instance, France, Italy and Austria are close European neighbours – but different NGP categories have developed in these countries. (vapes in France, heated tobacco in Italy and oral nicotine pouches in Austria).

That's extremely diverse consumer behaviour within a relatively localised geography. Similar patterns emerge when we zero in on

NGP usage by consumers' individual occasions – what we've termed 'moments.'

To understand more, we recently conducted a major piece of research, interviewing more than 8,000 consumers across eight countries and collecting in-depth information on about 16,000 different consumption occasions.

Our 'demand spaces' approach broke their lives down into individual moments when they enjoy NGP: for instance, in the morning or evening; in their houses or out and about, and either alone or with friends.

Our findings highlighted how, moment by moment, there are wide variations in how nicotine consumers behave. In several markets, NGP are already the dominant category for certain occasions – primarily when people socialise with friends outside of their homes.

Equally, however, there are other instances where NGP have currently made few in-roads and cigarettes remain the preferred choice. These are typically times when people are on their own at home, and are taking a break between tasks.

Our insights suggest there's no one-size-fits-all solution in THR, but we're confident that our continuing commitment to understanding our consumers, combined with innovative approaches, are enabling us to develop a compelling NGP portfolio able to satisfy their broad range of needs and wants.



DEMAND SPACES EXPLAINED

Demand spaces is our innovative approach to consumer insights across the nicotine landscape.

Traditional approaches tend to focus solely on consumer wants and needs. We go further by also considering their context – for instance, consumers' demographic profiles, where they are when they use nicotine products, at what times, and with whom.

We believe this added detail helps us more comprehensively understand cigarette/NGP category usage choices across specific occasions.

Once we understand what elements make consumers choose to use NGP in favour of cigarettes in certain contexts, we can better address their needs. In turn, this helps us make a more meaningful contribution to tobacco harm reduction.



Katie Hill,
Deputy Group
General Counsel

HOW IMPERIAL BRANDS IS COMMITTED TO SAFEGUARDING OUR CONSUMERS

ALL MANUFACTURERS HAVE A LEGAL RESPONSIBILITY TO THEIR CONSUMERS TO ONLY SELL PRODUCTS WHICH ARE NOT DEFECTIVE

As a responsible business, Imperial undertakes a wide range of safeguarding activities to make sure we're protecting our consumers by taking the utmost care in product design, manufacture, scientific substantiation, and marketing.

Other obligations include possessing a high standard of knowledge around our products and staying informed about their performance when on-sale, including capturing any reported unintended effects if they occur – and taking the appropriate remedial action.

That's in addition to complying with relevant market legislation and regulatory requirements.

Altogether, at Imperial there are a vast number of pre- and post-market processes, systems and teams working in harmony to ensure our approach to launching products is comprehensive and rigorous.

Stop, Continue.

Something else we're always conscious of is continuous improvement. In other words, using the vast amount of information and data we gather via our various safeguarding activities to drive advances in subsequent product generations.

That's supported by our rigorous change control process, which means any tweaks we do make to our portfolio don't result in any unintended consequences, and that

products remain compliant with safety requirements.

We've always taken our obligations to our consumers extremely seriously. With the business's increasing focus on next generation products in recent years, our activities have evolved to recognise and manage the novelty and complexities associated with product innovation in these categories; for instance, our vape and heated tobacco devices.

We're proud of our safeguarding systems and processes, and the care we all take in ensuring our consumers can feel confident they'll have a great experience when they choose a product from Imperial Brands.

PRE-MARKET ACTIVITIES INCLUDE:



Ensuring our rigorous manufacturing, quality and product assessment activities conform with Good Manufacturing Practice.



Monitoring relevant medical and scientific literature to help us stay informed around ingredient selection.



Horizon scanning so we're aware of broader industry standards and notable category innovations.

POST-LAUNCH ACTIVITIES INCLUDE:



Observing the performance of our products once they're on the market, and ensuring appropriate actions are taken if warranted.



Continuing to monitor relevant publications and academic literature, as well as media coverage of our industry and relevant product categories.



This post-launch risk review continues for all our products across their lifecycles.



Paul Ellis,
Head of R&D

THE IMPORTANCE OF CONSUMER-CENTRICITY IN NEXT GENERATION PRODUCT DEVELOPMENT

At Imperial Brands we believe true innovation is not only consumer-centric, but consumer *driven* – so starting with the consumer underpins our entire next generation product (NGP) research & development philosophy.

Our passion for consumer research and insights led us to realising that being able to seamlessly involve, and interact with, the actual people who were buying and using our products at all stages of the development process could be game-changing from an NGP innovation standpoint.

From this idea, our Sense Hubs were born.

Each Sense Hub consists of three core on-site capabilities that allow us to research, prototype, develop, and test new products with consumers at speed. We've:

- Built **dedicated spaces to connect and co-create with our consumers** at all stages of the development process. This includes engaging them with early NGP

concepts and observing their reactions via our viewing studio and AV streaming capabilities, to collaborating closely to refine final products before launch.

- Developed **advanced pretotype and prototype capabilities**, where we can bring concepts to life through augmented and virtual reality, rapidly build physical devices using 3D printing before receiving real-time feedback around elements like size, shape, aesthetics, and ease of use from consumers.
- Upgraded **in-house NGP formulation, product sample development and production capabilities**, which allows us to experiment with elements including flavour and intensity, sensory experiences, and nicotine satisfaction.

Since opening, our Sense Hubs have become a core element of our NGP innovation pipeline, transforming the pace, agility, and efficiency of our product development.

Hey, Partner

As well as our in-house revolution, we continue to build deep and open partnerships with third-party businesses. Our intention is that, over time, this web of relationships will evolve into a genuine ecosystem that's best equipped to pursue a harm reduction agenda.

Our partners – all of whom are carefully selected to ensure consistently high standards of ethical practice and scientific conduct – are embedded at every stage of the NGP innovation cycle.

Together, we believe our holistic approach demonstrates our passion and commitment to continue to provide adult smokers with state-of-the-art NGP that encourage them to switch to potentially harm reduced smoking alternatives.

PRETOTYPE OR PROTOTYPE?



FIND OUT MORE



Pretotype. A rapid experiment for testing ideas quickly with our consumers to gather data before potentially progressing to prototype.



Prototype. A first, or preliminary, version of a device or product from which other iterations are often developed.

REGULATORY CHALLENGES FACING TOBACCO HARM REDUCTION, AND HOW WE CAN MOVE FORWARD TOGETHER...

A lack of collective leadership is the primary reason tobacco harm reduction (THR) currently isn't making the dent in global smoking rates it should be.



Ross Parker,
Director of Group
Corporate Affairs

Tobacco harm reduction (THR) isn't just a theoretical public health concept. It's an exciting reality.

For proof, just look at the incredible success Sweden has enjoyed in lowering smoking rates – and incidences of smoking-related disease – through embracing tobacco snus.

Bizarrely though, the Swedish experience simply hasn't resonated in the way it could – should – have with the wider media, public health bodies and regulators.

To engender genuine wider change, harm reduction academics/scientists, industry, public health bodies and regulators must all somehow break free from their various echo chambers to better engage with one another.

That's a key challenge, but far from an insurmountable one.

The exciting emergence of fresh and potentially encouraging regulatory frameworks with consumer needs and harm reduction embedded at their cores builds optimism.

Frameworks that will hopefully be guided by a genuine desire to meet adult smokers' needs instead of falling into the trap of prohibition, which often only encourages bad actors and results in a thriving illicit trade.



Switching Up

It's important that manufacturers, public health bodies and regulators alike listen carefully to what adult smoker consumers want, rather than simply telling them what they need to do.

Likewise, we shouldn't start by thinking about how to regulate products, but rather how to help those adult smokers seeking to switch to potentially harm reduced alternatives.

Aside from Sweden, there are other examples of countries using THR as a sound basis for improved public health – the UK, Japan, and the Philippines to name a few.

Our hope is that, over the next decade, more countries will step up and create best-practice frameworks for next generation product (NGP) standards that could simply and effectively be replicated elsewhere.

Robust regulatory frameworks containing undisputed quality standards have the potential to create a truly level playing field for responsible manufacturers that can help bolster consumer confidence,

giving adult smokers access to high quality products and information they can trust, so they're able to make informed choices.

Risk-proportionate regulation is also crucial, with advertising rules and tax duties reflecting the growing evidence of the relative lower harms of NGP compared to cigarettes. It simply doesn't make sense for these categories to be regulated in the same way – not only because it sends a confusing and misleading message to adult smokers trying to quit, but also because it hinders harm reduction in general.

Any regulatory frameworks helping to facilitate THR also need to strike a balance: they should allow enough advertising and marketing to make sure adult smokers know about – and understand – NGP. However, they must also ensure said marketing is only aimed at adult smokers and not youth.

Brave Choices

It's our collective responsibility to be brave in calling out those who undermine any aspect of THR – be it poor quality devices, adulterated e-liquids, or marketing or selling NGP to unintended audiences. There's simply no room for bad actors in a highly scrutinised industry like ours.

Another reason to back THR is the science, with the ever-growing body of evidence substantiating and endorsing the harm reduction

potential of NGP. Fast-forward ten years and it's increasingly likely we'll have data confirming their longer-term public health benefit.

The evidence gathered in the laboratory, the clinic, our NGP markets and through population modelling by ourselves and others is already translating through to the wider world.

For instance, the UK's smoking rate is falling thanks to increasing numbers of adult smokers switching to vapes, facilitated in part through the government and public health endorsement of the category.

It's crucial responsible manufacturers remain committed to publishing and engaging around NGP science to encourage scrutiny and debate, while also working to combat some of the biggest ongoing threats to THR – like youth vaping and nicotine misperceptions.

In conclusion, it's vital regulators, non-governmental organisations and industry demonstrate leadership and strive to work together for the common good of a billion adult smokers.

The exciting and rewarding outcome in potentially only a decade's time will likely be a huge dent in global smoking rates and vastly improved public health outcomes.

That's an ambition worth being optimistic about.



FIND OUT MORE

ENVIRONMENTAL SOCIAL GOVERNANCE (ESG)

WAYS IMPERIAL IS TRANSFORMING TO CREATE HEALTHIER FUTURES FOR OUR CONSUMERS...



Consumer Health

We're committed to harm reduction by offering adult smokers a range of potentially less harmful alternatives.



Climate Change

We're committed to reducing our impact on the climate, focusing on both mitigation and adaptation.



Packaging & Waste

We're committed to minimising waste associated with products, packaging, and production processes.

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