November 2021: NICE guidelines PH45 (June 2013) PH48
(November 2013) have been updated and replaced by NG209. The recommendations labelled [2013] or [2013, amended 2021] in the updated guideline were based on these evidence reviews.
See www.nice.org.uk/guidance/NG209 for all the current recommendations and evidence reviews.

Tobacco Harm Reduction: Mapping the Ripples

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Going to scale

The idea of tobacco harm reduction (HR) – that smokers who cannot wean themselves off nicotine should be encouraged to adopt less harmful ways of consuming it – has much to recommend it. It is an encouraging example of inter-silo thinking: HR has been used in both the alcohol and drug fields. It is refreshingly pragmatic, avoiding the trap of making the excellent (complete cessation) the enemy of the good (vastly reduced harm). It is profoundly humanitarian, providing a way forward where otherwise there is only a cruel impasse. Finally, it provides a clear focus: the enemy is disease and premature death - not tobacco, addiction, or the tobacco industry – and this enemy, like so many medical problems before it, will be defeated with rigorous evidence, effective medicines and skilled treatment.

In principle then, HR reduction is an enlightened and promising idea.

Until recently, the debate has remained at this hypothetical level, but now it has become a realisable strategy: Alternative Nicotine Delivery devices (ANDs) – including electronic cigarettes - are proliferating and improving in performance. This raises a completely new set of issues about what would happen if tobacco control put its shoulder behind the HR wheel and actively promoted it. It is the classic public health dilemma of rollout: what happens when you have a good idea or intervention at an experimental level and then try to take it to scale?

In this case the implications of rollout are profound; tobacco control is a relatively calm mill pond into which the rock of harm reduction is about to be dropped. It is always difficult to foretell the future, but with HR the complexities are greatly exacerbated because two major corporate sectors – the tobacco and pharmaceutical industries - have extensive vested interests. They will each be tossing their own carefully-chiselled rocks into the pond.

Mapping the resulting ripples is challenging, but essential. They lap first around tobacco control, then continue on to the business sector (tobacco and pharma), before reaching the wider polity.

Tobacco Control

There are a small number of smokers who have tried everything to quit but simply cannot manage without nicotine. For these people, the case for HR seems self-evident and morally undeniable. Immediate lives will be saved. However, caution is still needed. As with methadone schemes, tobacco harm reduction essentially replaces one chemical addiction with another. Thus whilst ANDs are much less harmful than conventional cigarettes, they do have some risk and will exacerbate inequalities by tying the least well off into unnecessary expenditure (or use up limited public resources to subsidise this).

The need for caution increases when we broaden our vision to check whether measures intended to help the relatively small numbers who cannot quit might have unintended consequences on the rest who can – or even on those who are still to start. There are greater causes for concern here. First, implementing harm reduction at a population level raises an awkward dilemma for tobacco control. ANDs are not intuitively appealing; people need to be persuaded about their benefits. From a public health perspective, there is actually only one such benefit: they provide those who cannot quit with

an alternative, less harmful, source of nicotine. In marketing parlance, then the competition for ANDs is quitting, and any sales pitch to boost their appeal must make it seem less attractive.

The problem with this is that the vast majority of smokers are perfectly capable of quitting – there is no evidence, even in a low prevalence country like the UK, that we have come anywhere near a hard core. For this large majority, the communications effort should be focused in precisely the opposite direction - on making quit attempts *more* appealing.

So any officially sanctioned and wide scale implementation of HR will put public health in the impossible position of having to stress both the difficulties and attractions of quitting – of promoting competing offerings. This is like Coke committing half its adspend to endorsing Pepsi.

There is a related, if less obvious, danger that children will pick up on this apparent confusion and interpret it as a more nuanced public health stance on tobacco. Whilst previous generations were told tobacco is bad per se; new ones would be told that nicotine is acceptable, just be careful how you access it. HR also implies – indeed states – that there are safe ways of mitigating the harm done by tobacco, which may, in turn, reduce the 'cost' of uptake. Many young smokers convince themselves that they can smoke for a few years (eg while at college) and then quit; HR may provide an additional dimension to this self-delusion – I'll smoke for a few years and then move to a safer source of nicotine.

The media, which after many years has, at least in the UK, 'got tobacco' and become a reliable supporter of comprehensive control measures, might also struggle with this more complex position. In this way there is a danger that tobacco loses it enviable status as a uniquely 'bad product', and joins food and alcohol in a more nuanced part of the public health domain.

Thus the benefits of HR are not nearly as obvious as it first seems. With any population level move in this direction, the lives saved among the small minority of can't-quitters have to be weighed against lives lost by weakening the pro-quitting and anti-tobacco message to the remaining (much larger) majority.

The two corporate players will further muddy the water.

The business sector

Perhaps surprisingly, the tobacco and pharmaceutical industries have much in common. Both sectors are dominated by multinational corporations bound by the fiduciary imperative. This mandates a focus on shareholder returns 'above all others' and provides 'no legal authority to serve other interests'[1]. Both employ the full panoply of consumer marketing, using product design, distribution, promotion and pricing to build evocative brands that maximise the profitable consumption of their products. Both also have an equally acute interest in what the NCI calls 'stakeholder marketing'[2]: public relations, corporate social responsibility, corporate affairs and strategic partnerships are used to build links with those who influence the business environment. Thus pharma will target doctors and the tobacco industry shopkeepers – and both have an abiding interest in policy makers, academics, health professionals and all those involved in the regulatory system. In this arena the two industries also share a mutual interest in being presented as part of the solution.

It may seem perverse to equate the tobacco industry, which is on course to cause the premature deaths of 10 million people a year by 2030, with one focused on the production of cures and

medicines. However it is so. This is not a matter of good and bad people or industries, but the nature of the system. It is not about the dangers that result from business doing things it should not, but those that emerge when it does exactly what it is supposed to do. Corporate capitalism is amoral, and will always seek out the most profitable option within the bounds of any (suitably robust) regulatory framework.

Historically one of the most extreme illustrations of this profit imperative occurred during the Second World War. In his forensic analysis of declassified government documents Charles Higham demonstrates with unnerving clarity that major US corporations – including the Chase Bank, Standard Oil, ITT and Ford - were doing business with the Nazi regime and German corporations like IG Farben (who built Auschwitz) throughout the war. They supplied combat essentials: trucks, finance, fuel, communications equipment – and even armaments: 'Colonel Sosthenes Behn, head of the American international telephone conglomerate ITT, flew from New York to Madrid to Berne during the war to help improve Hitler's communications systems and improve the robot bombs that destroyed London'[3]

We should be under no illusions then – the tobacco and pharmaceutical industries will look on harm reduction as a profit making opportunity. They will not be concerned with public health except to the extent that it benefits their respective bottom-lines. Whether or not we approve of this is irrelevant; it is simply a fact of commercial life. It is therefore vital for the public health community to answer two sets of questions before it travels much further down the HR road: what is in it for them? and what implications do these benefits have for public health?

What is in it for the tobacco industry?

It is nearly half a century since the tobacco industry recognised that it is really '*in the business of selling nicotine, an addictive drug'*[4]. However it has been notoriously shy about this reality, so much so that thirty years after the original admission it was prepared to perjure itself very publically in front of congress rather than even admit that nicotine is addictive – let alone that it would ever exploit the resulting human frailty for commercial gain. The harm reduction agenda, however, introduces the possibility of public health formally recognising that selling recreational nicotine is an acceptable – even good – idea, provided you clean up the delivery mechanism. What has previously been a shameful secret is becoming a badge of respectability.

This is not in and of itself a bad thing; it all depends on what corporate tobacco does with its new found legitimacy. In at least one area – the advancement of harm reduction - it could well be an important force for good. Moving smokers from cigarettes to much less harmful nicotine delivery devices will be extremely challenging, and if any sector has the marketing know-how to pull it off it is the tobacco industry.

However this advantage has to be balanced against a number of significant dangers.

For the foreseeable future the tobacco industry will continue to get the vast majority of it profits from cigarettes, the most dangerous nicotine delivery device. Thus 2008 Euromonitor figures[5] for the UK show that in a total tobacco market of just under £13 billion, almost 12.2 billion was accounted for by cigarettes and RYO, with most of the rest coming from cigars. Smokeless tobacco sales were too small even to be recorded. Over 99% of the UK industry's profits, then, come from smoked tobacco. Separate Euromonitor data shows that total sales for NRT and cessation products amounted to only £125 million[6] - just under 1% of tobacco sales.

Hence the tobacco industry's involvement in HR is mired in double standards. When BAT, for instance, calls for 'a broader approach – one that accepts that many adults are going to continue to use tobacco and nicotine products'[7] the words are overshadowed by the fact that the vast majority of the company's marketing budget is focused on encouraging this same continued usage. And later in the document when it states 'as a manufacturer of tobacco products, we have a responsibility to pursue ways in which we might reduce the health risks of our products' the reflex response from public health has to be: 'well stop marketing them so assiduously across the globe then'.

However, given the fiduciary imperative, the tobacco industry will continue to do everything it can - including harnessing the opportunities that come from HR - to maximise its cigarette sales. For example, using existing brands for harm reduction products might offer a way of increasing their acceptability. Arguably this has already happened with Marlboro and Lucky Strike Snus, and non-tobacco HR offerings would potentially have greater sanitising power. Concerns about this 'respectability by association' underpinned the efforts to ban other forms of brand stretching – like Camel boots and Marlboro Classic clothing – a generation ago.

Similarly, non-tobacco HR products are being promoted with evocative advertising (see Figure 1a). These ads bear a close resemblance to the tobacco promotion that many countries have fought so hard to remove – and the addition of tobacco branding (suppose, for example, Silk Cut were to add a Superslims electronic cigarette to its range) would make the distinction even harder to draw.

Figure 1a: A recent advert for ecigarettes from New York	**Figure 1b: Marlboro when you want it**

At a more basic level, HR also offers the tobacco industry an opportunity to keep people in the nicotine market, and thereby in close proximity to smoking. The industry has long recognised that inter-company competition notwithstanding, the real *'threat' to the existing smoker base for the brand seems more likely to come from a desire to give up smoking rather than from competitor brands'*[8] and a decade ago '*low tar was'* therefore used as *'a way of making quitting less urgent or necessary"*[9]. Similar forces may come into play – or be engineered - even with non-tobacco products. Might an electronic cigarette that is designed to mimic a real one as closely as possible reinforce – or even model - the idea of smoking? If imitation is the sincerest form of flattery, doesn't any copy pay tribute to the original?

The commercial imperative of cigarettes sales will encourage the exploitation of these opportunities for ANDs to be used as a conduit to continued or new smoking. Again this thinking is already in evidence, with smokeless products (whether tobacco based or not) being promoted as 'work-friendly' or 'when smoking isn't an option' (see Figure 1b) and so presenting an alternative to quitting in the face of smokefree ordinances.

Even where the tobacco industry genuinely pursues the AND market, rather than using it is a blind for continuing to boost conventional products, there are concerns. The gulf in market size between cigarettes and NRT noted above is principally a function of how long the respective products are used for; this is measured in decades for cigarettes, but weeks for NRT. The tobacco companies will undoubtedly try to repeat this success with e-cigarettes. When they can't pull people back to smoking, they will use their marketing muscle to ensure that they continue using ANDs for as long as possible.

Turning to stakeholder marketing, harm reduction offers tobacco companies great opportunities to build positive links with traditional rivals, especially in tobacco control. BAT's recent Sustainability Report, for example, emphasises how the company is 'preparing for the future' by 'engaging with regulators, scientists and the public health community to develop the scientific and regulatory frameworks needed to deliver reduced-risk products'[10]. The credibility that a company like BAT gets from being invited to present at a NICE evidence session, as happened a couple of years ago, is difficult to understate – and the use that will be made of this enhanced corporate reputation is worrying to contemplate. How easy will it be for a developing country to close the door on BAT when it can wave such respectable UK credentials?

At the same time as trying to build links with public health, the tobacco industry will also continue to see it is a big competitive threat. (Such apparent contradictions are the norm in business, where strategic alliances with arch-rivals will quickly emerge when faced with a joint threat – and melt away as fast.) HR offers the tobacco industry several ways of furthering this agenda: it is extremely divisive and so can deplete our energy and focus; it can be used to undermine tobacco control measures (including smokefree ordinances, as we have already noted, and FCTC article 5.3); and, most fundamentally, it takes our attention away from alternative ways forward.

This last is particularly concerning from a global perspective: most countries have not yet achieved the basic FCTC provisions, which are known to drive down prevalence. Having a leading tobacco control player like the UK focusing on what is only ever going to be a minor part of tobacco control is at best unhelpful. At the same time, there are numerous jurisdictions which have achieved lower prevalence without widespread recourse to HR, so even at a UK level it is debatable whether HR offers the best prevention value for money.

What is in it for the pharmaceutical industry?

Harm reduction also offers significant opportunities for the pharmaceutical industry.

The family of ANDs – patches, sprays, gums, lozenges – that have been developed around nicotine replacement therapy has become a major commercial success for drugs companies. However as we have noted their principal role as cessation aids limits profitability because use is relatively short term, especially compared with tobacco. Escaping this bind is difficult because, unlike the tobacco companies, pharma is not in the recreational drugs market, but the therapeutic one; the drugs they sell are medicines not lifestyle accessories. Nor would they want their corporate image to be sullied

by the distasteful thought that they are exploiting addiction. As already noted even the tobacco industry spent decades doing all it could to avoid this charge.

HR provides a perfect way through this maze. It delivers the immensely profitable possibilities of extended use, whilst maintaining a respectable therapeutic purpose of mitigating rather than exploiting addiction. This explains why pharma has been so active in the development of HR.

In the UK the process started by promoting the idea to the regulator (the Medicines and Healthcare products Regulatory Agency or MHRA) that NRT could be a 'stepping stone'[11] to quitting, as well as a direct cessation aid. Next the concept of HR was fostered when the manufacturer of Nicorette inhalator formally requested an 'extended application' for its product. The MHRA agreed the extension, saying: 'Nicorette Inhalator relieves and/or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them.'[12] The report went on to conclude: 'In addition, the Working Group recommended a "harm reduction" element was appropriate for the indications of all other currently authorised forms of NRT'. Then in February 2010 the MHRA recognised that 'the extension of the indication for NRT to include harm reduction raises the question of the regulation of other unlicensed nicotine containing products on the market such as electronic cigarettes, which have not been assessed for safety, quality, and efficacy'[13].

So an entirely new treatment had emerged for the problem of smoking. And the commercial benefits of this change are potentially immense. Every day of additional HR has a pro rata impact on returns. If, for example, smokers can be moved from a 12 week NRT quitting regime to 24 weeks of HR, profits double. So, like the tobacco companies pharma has a massive vested interest in extending the HR timeframe – and like them will use all its marketing skills to achieve this.

HR also offers the drugs companies useful stakeholder marketing opportunities. It enables them to maintain and enhance relationships with the same scientists and policy makers the tobacco industry is courting. This may seem less important a benefit for a seemingly much more respectable industry, but the pharmaceutical sector is the subject of much criticism. No lesser authority than the UK Government's Health Select Committee felt compelled to express its 'over-riding concerns about the volume, extent and intensity of the industry's influence, not only on clinical medicine and research but also on patients, regulators, the media, civil servants, and politicians' and the need 'to examine critically the industry's impact on health to guard against excessive and damaging dependencies'[14]. Ben Goldacre[15]'s new book suggests these concerns have only increased since the HSC's report. In this climate, any opportunity to be embedded into solutions is extremely valuable.

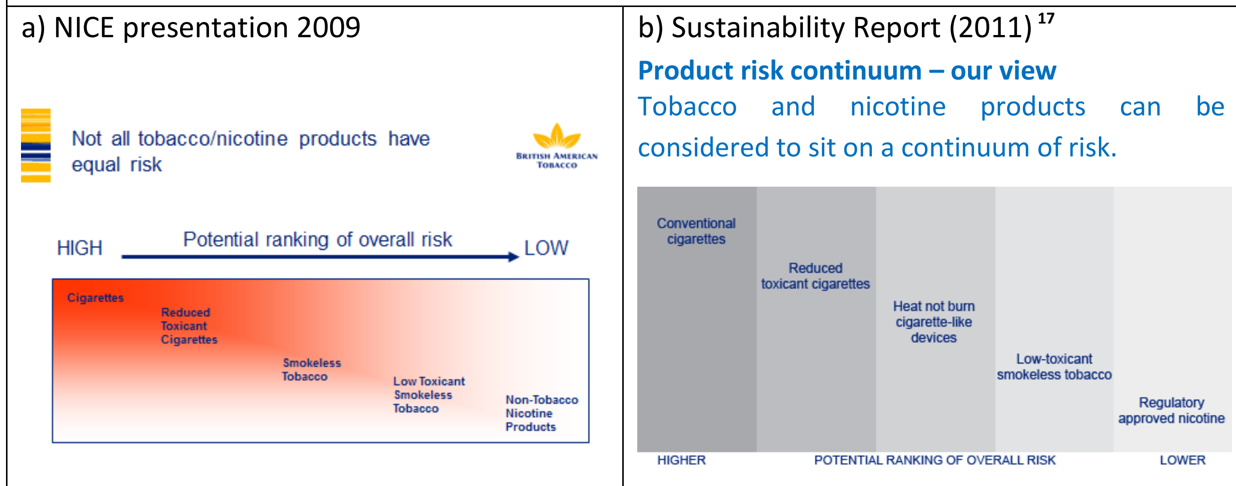
Shared interests

Thus both the tobacco and pharmaceutical industries have a large vested interest in a legitimised market for nicotine. The BAT presentation to NICE mentioned above included a graphic (Figure 2a) showing that 'not all tobacco/nicotine products have equal risk', ranging from high risk cigarettes to low risk non-tobacco nicotine products. The thinking had been honed by 2011 to include 'Regulatory approved nicotine'.

It provides a vision of a future 'harm-reduced' market which would be divided between tobacco companies coming in from the left and pharma from the right. The latter would, for reputational reasons, probably not want to move into tobacco containing products and may restrict itself to fully

registered medicines - but the tobacco companies would be less reticent. Their reputations can only benefit from any move into traditional pharmaceutical territory; as one analyst put it: *'what an image boost for "tainted" tobacco – from curse to cure'*[16].

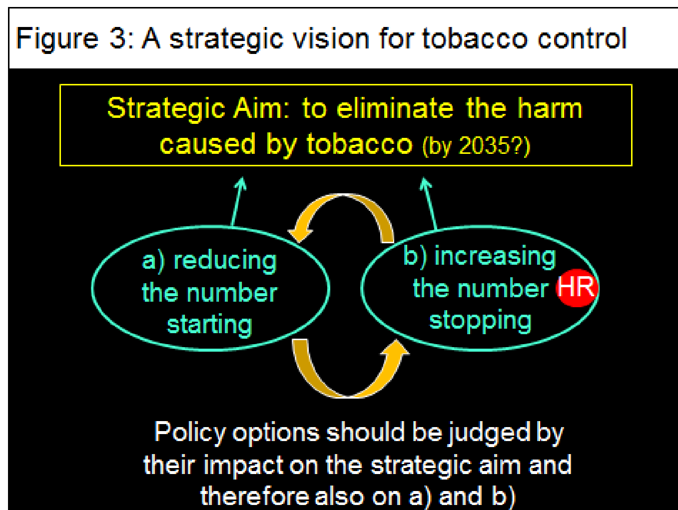
Figure 2: BAT's Evolving view of Harm Reduction



Thus it is plausible to anticipate an overlap between the pharma and tobacco markets – and given the established tendency for corporate growth and consolidation – future mergers between the two sectors. Indeed Japan tobacco has owned a pharmaceutical subsidiary for a decade – and BAT's Nicoventures is a clear bid to move into this territory. Again, the issue is not whether we approve of these developments; they are an inevitable part of corporate capitalism – a fact of life. Our concern is with the implications this has for public health.

The most obvious one is for tobacco control's strategic vision. Figure 2 presents BAT's view of the future; not ours. Our focus is not on developing a vibrant nicotine market, but on minimising harm. This can be done by reducing prevalence and encouraging cessation, with harm reduction making a potential contribution to both, but especially cessation (see Figure 3). The desirability of any tactical option – including HR – has to be judged on its contribution to the strategic aim – and hence to prevention and cessation. The danger of corporate engagement with pharma and/or tobacco is that this vital judgement will get clouded by concerns about profitability.

HR also raises more fundamental questions about the role of public health. Specifically, we need to ask whether its job is to save or to empower. If it is the former and our focus is on tobacco, then getting people to stop using whatever means possible becomes the priority – and leaving them dependent on nicotine is not a concern compared to the harm avoided. The second perspective however suggests a need to think not just about tobacco, but also diet, alcohol use, exercise and the many other behaviours which also have a big impact on morbidity and mortality. Attempting to micromanage each of these is impractical and runs the risk of being patronising. A broader, health promoting approach is needed.



A recent King's Fund report on Behaviour Change[18] emphasises the clear link between inequalities and unhealthy lifestyles (rather than individual behaviours), and shows that the gap between rich and poor has actually increased since 2003. The report criticises the Department of Health's lack of a 'holistic approach to lifestyle risk' and concludes that improvements will only happen if there is a move 'beyond siloed approaches to public health', and when 'policy and practice is adopted that addresses lifestyles that encompass multiple unhealthy behaviours'. It also emphasises the need to 'help people with multiple risk factors [especially those in lower socio-economic groups] to focus on the areas that motivate them and to give them the confidence that they can change'. From this standpoint, HR's accommodation with on-going nicotine dependence is much more problematic.

More widely still, a political analysis of HR raises another issue. From this perspective, a key concern with tobacco is that it makes people dependent on an exploitative multinational industry. HR merely changes the identity of this industry. Comparisons with coffee have been made in response to this. Here, the argument goes, is another multinational industry exploiting our dependence on a drug (in this case caffeine) and this raises few concerns; by extension a market in nicotine becomes as innocent as our morning cuppa. However there are three crucial differences: i) caffeine consumption is not linked to any major health problems; the vast majority of nicotine consumption is, and will continue to be for the foreseeable future, extremely unhealthy ii) caffeine consumption is not related to disadvantage; nicotine consumption is deeply regressive iii) caffeine is only a small part of the coffee story as the popularity of decaf attests; de-nicotined cigarettes have never taken off.

However the trades in coffee and tobacco do have one important commonality: a powerful ethical dimension. Both markets are replete with examples of producers being exploited, badly treated and damaged by multinationals. Oxfam's report *Mugged: Poverty in your Coffee Cup*[19], for instance, removes any illusions about the tobacco multinationals being uniquely malevolent. Public health should be just as concerned about this form of harm as it is about that caused by carcinogens.

The debate about HR needs to encompass this broader level of political and moral analysis; to recognise that the framing we noted in the first paragraph of this paper that 'the enemy is disease and premature death, not tobacco, addiction, or the tobacco industry' is, in the real world, profoundly naive. It ignores the politics of health and the multiple flaws in the system. Had John Snow adopted this perspective, he would never have removed the hand pump.

Conclusion

HR matters. There have to be alternatives for those who cannot quit. Furthermore, it cannot be ignored; the commercial opportunities for both the tobacco and pharmaceutical industries are just too tempting for the issue to go away. The question then is not whether, but how we should respond. The issues are fraught, but five conclusions do seem clear to us:

- Collaboration with the tobacco industry will backfire badly. The TI's overwhelming dependence on smoked tobacco sales combined with the fiduciary duty to maximise profits mean that, for the foreseeable future, HR will be the servant to this much bigger and completely unhealthy cause. Even where ANDs are genuinely pursued, the massive commercial incentive to use the sector's prodigious marketing skills to extend their use will greatly distort the public health agenda.
- Collaboration with pharma is also extremely problematic, because this sector is also governed by the fiduciary imperative; benevolent corporate identities notwithstanding, the priority will always be on private profitability rather than public health. In the short term this will be manifested in a continued marketing focus on prolonging the use of ANDs so as to maximise revenue.
- In the long term, the aim of both the tobacco and pharmaceutical industries is to stimulate and grow the market in nicotine, and immense marketing effort will be used to further this strategy.
- HR also has the potential to deflect the strategic direction of tobacco control unless a broad perspective is adopted. Benefits need to be judged not just in the narrow sense of lives saved among the chronically addicted, but by comparison with other tobacco control options and the contribution to a comprehensive strategy.
- It is also very important to think beyond the UK. If we were to begin to collaborate with the tobacco industry on HR, for instance, this will confer a dangerous legitimacy that will be exploited in other countries with much less advanced tobacco control policies. It could also undermine the FCTC. Similarly, if an influential country like the UK is seen to put undue emphasis on HR this could set an unhelpful example to countries who have yet to implement much more basic TC measures such as those laid out in MPOWER. Finally we should also recognise that we can learn from other countries like Australia and Canada, which have driven down prevalence more successfully than the UK without significant recourse to HR.

HR then is a potentially valuable tobacco control tool, but it needs to be taken forward with great care. Anything approaching public health backed population level implementation is likely to do more harm than good, and marketing by the tobacco and pharmaceutical sectors would greatly exacerbate any problems.

Tight regulation is therefore essential. Given the current extensions for NRT, ANDs will need to be licensed for general sale (GSL). Until this happens they should be banned. After licensing, marketing restrictions should be extremely tight. As in New Zealand, the promotion of use in settings where smoking is not allowed, attractive additional attributes such as flavours, pyscho-social benefits like coolness and/or the idea that the device offers a safer way of smoking, should all be outlawed. In addition any tobacco brand sharing must be treated as a breach of the UK adban.

Even in these restricted circumstances, HR – despite the promise - presents many dangers. Robust research programmes should therefore be put in place to monitor developments and provide feedback to policy makers so that the regulatory regime can be adjusted as and when needed.

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