Establishing a Smoke-free 2030 Fund

Abstract

Background. The Chief Medical Officer says that smoking will kill more people in the UK than Covid, both this year and last. Recent analysis shows it kills up to two thirds of long-term users and the UK Government's ambition is for England to be smoke-free by 2030. However, approximately 14% of the UK adult population still smoke and on current trends the most deprived communities will not be smoke-free until 2045. Comprehensive tobacco plans are being developed to meet the challenge but in a post-pandemic world public finances will be tight.

Despite relatively high tobacco excise taxes the UK remains an attractive market for tobacco companies. About 90% of the UK tobacco market by value is controlled by just four global manufacturers, with estimated UK profits of £900M per annum. Unlike the tobacco companies operating in the UK, the level of profits that pharmaceutical companies may earn on the sale of branded medicines to the NHS is heavily regulated. A pharmaceutical profit control scheme has been operated by the UK Government since 1957.

Paper objectives. As requested by the Government's Green Paper, this note sets out a mechanism for making tobacco companies pay as 'producer polluters', which is also aligned with public opinion. It proposes taking elements from previous pharmaceutical schemes, successfully operated by the Department of Health and Social Care (DHSC) over many years, to create a profit control and pricing scheme for the tobacco industry operating in the UK. The central aim of the scheme is to control tobacco company profits, but it can also be used to encourage tobacco companies to transform their business models to producing e-cigarettes and vaping products. Such a scheme is only possible following the UK's departure from the European Union as the UK Government now has freedom to set tobacco prices, which are currently ~90% comprised of excise duty and VAT.

Conclusion. The scheme could raise £700M per annum, £315M of which should be retained by DHSC to fund a comprehensive tobacco control programme. The more complex pharmaceutical scheme required just 10 paragraphs of primary legislation, which could easily be amended and added to the forthcoming NHS Bill to give the Secretary of State similar powers over the tobacco industry and its products. The Covid-19 pandemic has shown us that effective public health measures require adequate funding, which in turn requires political mettle.

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Establishing a Smoke-free 2030 Fund

Smoke-free 2030 ambition

In July 2019, the UK Government announced an extremely challenging ambition for England to be smoke-free by 2030; rates <5% of the adult population. There is a 2034 target for Scotland,[1] with no dates set for Wales or Northern Ireland. Approximately 14% of the UK population aged 18 years and above still smoke cigarettes, which equates to around 6.9 million people; broken down by countries, 13.9% of adults in England, 15.5% of adults in Wales, 15.4% of adults in Scotland and 15.6% of adults in Northern Ireland.[2]

Smoking remains more prevalent in those with lower socio-economic status. Around 1 in 4 (23.4%) people in routine and manual occupations smoke, which is around 2.5 times higher than people in managerial and professional occupations (9.3%)[2]. Smoking kills up to two thirds of long-term users [3] -irrespective of socio-economic status - so failing to meet the Smoke-free 2030 ambition means smoking will disproportionately kill more poor or disadvantaged people. Moreover, it will exacerbate their situation, as analysis of government data shows the cost of smoking drives more than a million people into poverty in the UK: [4]

- 447,000 households in the UK (around 1,011,000 people) are currently living in poverty due to the cost of tobacco.
- 263,000 children live in poverty as a result of income lost to tobacco, with a detrimental impact on their life chances.
- 143,000 pensioners are pushed into poverty by the cost of tobacco.

The UK is a world-leader in tobacco control, but there is a risk of complacency towards the 2030 ambition as other public health issues, such as obesity, command greater attention.[5] In order to reach the 2030 ambition, Cancer Research UK says that the reduction in smoking prevalence needs to be 40% faster than current trends. The risk is that while the least deprived (population quintile) in England will be smoke-free by 2030, the most deprived will not benefit from the government's ambition until fifteen years later. [6]

The Covid-19 pandemic has shown us that effective public health measures require adequate funding, which in turn requires political mettle. The public health charity, Action on Smoking and Health (ASH) has estimated that the total cost of implementing a comprehensive tobacco control programme in England to realise Smoke-free 2030 is around £266 million per annum (local authority programmes £177.8m, regional programmes £47.6m, and £40m for national programmes) and £315 million for the UK as a whole.[7] This reinstates spending at the levels prior to cuts in public health budgets, and is commensurate with the US Centers for Disease Control (CDC) minimum recommended level of per capita spending on tobacco control. [a]

[a] In the US the Centers for Disease Control (CDC) recommend a sterling equivalent of a minimum level of £5.26 per capita, with recommended best practice of £7.47. For England, using population levels in 2018, this would equate to a minimum of £310.9 million, for best practice £441.6 million.

Monopoly position of tobacco firms operating in the UK

In setting out its proposals for the reorganisation of Public Health, the Government recognised its responsibility to take action to tackle the harm and ill-health caused by the power imbalance between individuals and industries based on addictions such as smoking. The 2019 Green Paper on prevention identified the need for additional funding to deliver the Smokefree 2030 ambition and committed to consider a range of options, as set out in the box below. [8] Moreover, there is majority public support for a Smoke-free 2030 Fund to cover the annual costs of tobacco regulation and interventions to achieve the Government's ambition.[9]

HM Government Advancing our health: prevention in the 2020s

"We are setting an ambition to go 'smoke-free' in England by 2030.

"This includes an ultimatum for industry to make smoked tobacco obsolete by 2030, with smokers quitting or moving to reduced risk products like e-cigarettes. Further proposals for moving towards a smoke-free 2030 will be set out at a later date...

"Other countries, such as France and the USA, have taken a 'polluter pays' approach requiring tobacco companies to pay towards the cost of tobacco control. We're also open to other ideas for funding, including proposals to raise funds under the Health Act 2006. We would aim to use any funds to focus stop smoking support on those groups most in need, such as pregnant women, social renters, people living in mental health institutions, and those in deprived communities; and to crack down on the illicit tobacco market by improving trading standards enforcement."

In the past the Government consulted on raising funds through increasing taxation, and rightly concluded that the costs would be passed on to consumers, who already pay high taxes. As requested in the Green Paper, this note sets out a mechanism for making tobacco companies pay as the 'producer polluters' rather than further targeting consumers addicted to tobacco products.

The excess profitability of the UK tobacco market is well-described in the academic literature.[10] [11] [12] Studies have questioned whether gradual and sustained increases in duty have allowed the tobacco industry to hide significant price increases in high income countries like the UK – so called 'overshifting' - thus generating exceptional profits.[13] This is because ~90% of the retail price of tobacco in the UK is tax (excise duty plus value added tax) and relatively small increases in pre-duty tobacco prices have negligible impact on sales but significantly increase tobacco company revenue and profitability. Such market power in the utility industries is addressed through price controls,[14] [15] [16] and one of the dividends from Brexit is that this is now possible for tobacco, where previously it was prohibited by EU legislation.[17] [18]

In the UK, about 90% of the tobacco market by value is controlled by just four global manufacturers, with estimated UK profits, in 2013, of £1.04BN to £1.76BN.[19] Increasing lack of transparency in industry data has made it impossible to carry out further detailed analysis, but the same author estimated that in 2018 the industry made profits of at least £900 million in the UK, despite declining sales volumes.[20] To date, no

action has been taken to address this oligopolistic market power and divert some of the excess profits to address the costs imposed by tobacco upon UK society. Moreover, these firms pay little profit-based taxation in the UK despite high levels of reported profits as they employ a range of common tax avoidance methods.[21] [22]

Table 7: Estimated Profitability of the UK Tobacco Market

	2009	2010	2011	2012	2013
Conservative scenario (£ million)	1,037.9	1,096.4	1,003.8	1,084.0	1,103.7
Less Conservative scenario (£ million)	1,091.4	1,161.7	1,094.1	1,214.0	1,235.7
Gallaher scenario (£ million)	1,347.2	1,368.9	1,275.0	1,426.4	1,453.7
Imperial scenario (£ million)	1,472.5	1,512.7	1,428.4	1,707.0	1,757.5

Source: Branston, JR & Gilmore, A 2015, The extreme profitability of the UK tobacco market and the rationale for a new tobacco levy. University of Bath.

Research from 2010 indicates that tobacco companies operating in the UK are twice as profitable as other food, beverage (including alcohol) or consumer product companies,[10] Imperial Tobacco, which sells around 40% of cigarettes in the UK market, is the most profitable, making operating profit margins of 71% in 2019, meaning that for every £100 of revenue in the UK, £71 was profit.[23] This is far higher than the margins for any other consumer staple products, which typically range from 12-20%.[12] Some may that argue there should be no limits on tobacco company profitability for selling a legal product, but the excess profits and oligopolistic power, given the addiction, morbidity and mortality associated with tobacco consumption, requires intervention.

From a theoretical perspective, monopoly pricing power is most often controlled through government action on the supply-side through Rate of Return (RoR) regulation, which is a feature of both utility and pharmaceutical markets where price caps or controls are employed. Alternative methods to control monopoly power exist; for example, through price by setting and negotiation, which can be complex and costly for both Government and suppliers; cost-effectiveness analysis, which is conducted on all new NHS medicines by the National Institute for Health and Care Excellence (NICE); and in extreme cases nationalisation of the relevant firm or industry.

At a macro-policy level, the Competition and Markets Authority has powers to open up markets by removing or lowering barriers to entry. It is difficult to see the CMA's role with respect to tobacco, however, when the Government's policy objective is to make the product obsolete. Indeed, regulations which have reduced consumption and prevalence have, as a by-product, also limited competition. For example, the prohibition of all advertising promotion and sponsorship, controls of packaging and labelling and prohibition of product display at point of sale all seek to reduce tobacco product differentiation and branding. It is suggested the appropriate regulatory response therefore is to control the profitability of the industry rather than open it up to competition. If the market power of utilities and the pharmaceutical

industry can be regulated, surely it is justified to do the same for an industry whose products are addictive and lethal when used as intended. An additional benefit of the proposed approach is that it would limit tobacco companies ability to use price as a marketing tool to differentiate and promote products, as is currently the case.

A model for addressing tobacco company pricing power in the UK

Unlike tobacco companies operating in the UK, the level of profits that pharmaceutical companies may earn on the sale of branded prescription medicines to the NHS is heavily regulated through legislation overseen by an expert team within the DHSC. Primary legislation in the 2006 NHS Act provides the legislative powers (details are implemented through regulation) although a pharmaceutical profit control scheme has been operation in the UK since 1957.[24] The pharmaceutical model has been implemented on the basis of a patent holding company being the monopoly provider and the NHS being the monopoly purchaser, which is different from the tobacco market. However, the functions and expertise needed to operate the proposed tobacco scheme are very similar as they both operate on the supply-side.

Further details on the current Voluntary Scheme for branded medicines Pricing and Access (VPAS) and its long-standing predecessor, the Pharmaceutical Price Regulation Scheme (PPRS) are available in the appendix. On average, the VPAS and PPRS raise £560M per annum on measured NHS sales of about £8BN. The proposed UK tobacco scheme would also build on the US user fee scheme which funds US tobacco control programmes and regulation (see page 9), with the addition of controls on prices.

Additional tax increases above the tax escalator on tobacco at this time could be unduly regressive, especially for poorer and disadvantaged smokers, as the manufacturers would pass any tax increases through to the consumer. Adopting a "producer polluter pays" mechanism would specifically distribute funding from tobacco companies with excess profits to a Fund designed to deliver the Smoke-free 2030 objective by preventing uptake and helping addicted smokers to quit. This is not a novel idea, it is already in place in the US for tobacco and primary legislation already exists in Section 123 of the Gambling Act 2005 for a similar industry levy in the UK. [b]

This paper proposes adapting elements from previous PPRS and VPAS schemes, successfully operated by the DHSC over many years, to create a profit control and pricing scheme for the tobacco industry operating in the UK. Prices would be fixed so the charge could not be passed on to consumers, as is currently the case with tobacco taxes. The scheme would not apply to retailers, who would be allowed to set their own prices with a profit margin on top (retail profit margins are estimated to be around 6%).[25]

The objectives of this new scheme are threefold:

1. To control the market power and limit the profits of tobacco companies operating in the UK

[b] Section 123 provides the primary legislation to enable government to make regulations for a levy based on industry receipts and profits to fund projects related to the addiction and harm caused by gambling. Although the gambling levy has not to date been implemented, it is now under consideration by the Government following widespread agreement that the voluntary scheme currently in operation has been a failure.

As with the PPRS and VPAS, the central part of this scheme would be a requirement on tobacco companies to submit a detailed Annual Financial Return (AFR), independently audited and certified as true and fair by their respective finance and managing directors. Detailed examination of the AFR would enable DHSC to determine the level of profitability of individual tobacco companies, based on an assessment of the genuine costs each firm faces in its operations, and an assumption about the efficiency savings it would be expected to make, with the excess above a pre-determined level of profit paid to the Department of Health & Social Care (DHSC) to finance the Smoke-free 2030 Fund.

A key issue is what price should be set for tobacco products. Previously, HM Treasury announced it was introducing a Minimum Excise Tax (MET) in 2016[26] to curb the ability of tobacco manufacturers to 'overshift' taxes which saw in greater price increases on premium brands. [27] By overshifting, companies were able to ensure cheap cigarettes continued to be available which appeal to price-sensitive poorer and younger smokers, while continuing to increase prices on premium brands to maximise their profits. In the scheme being proposed prices could be fixed at current levels with the Minimum Excise Tax effectively setting the floor, or a single fixed price could be set, based for example, on the Weighted Average Price. What is essential, however, is that prices on average should not be permitted to be lowered as a result of the scheme as this would lead to increases in consumption, particularly among young people who are more price sensitive.[28]

For administrative ease, once the total level of payment has been calculated for each company from examination of the AFR, it would be applied and collected as a % of the value of actual sales. This is the same as with the current VPAS, with companies submitting quarterly sales information and a payment to the DHSC. Different tobacco companies would repay different % of sales, although an annual reconciliation on total repayments received measured against pre-determined profit levels would be required as part of the annual AFR process.

This scheme would not require the creation of an additional stand-alone utility-type profit and pricing regulator. The DHSC has already developed the necessary expertise through the operation and refinement of the PPRS and VPAS over the last 50 years. Four companies account for around 95% of the market so a tobacco scheme would require the analysis of an additional 4 AFR returns each year. The other 5% is accounted for by relatively small companies and own-label products, which given their small market share will have little impact on overall results, and could potentially be excluded from the scheme, as is the case with small pharmaceutical companies.

The level of profitability for tobacco companies should be pre-determined at around 10% operating profit which is aligned to the lower end of consumer food and drink industry benchmarks.[11] [12] This is rightly less than the 17-21% for the research based pharmaceutical industry, with these values being selected as the average profitability in all FTSE500 sectors in the UK in the 1980's. [29] The operating profit margin would be assessed individually on a company basis rather than product by product, with manufacturers returning the surplus to the DHSC, which would be used for the Smoke-free 2030 Fund. Given current levels of profitability the scheme would be expected to raise in the region of £700M per annum.

2. Shift tobacco company behaviour to focus on electronic cigarettes and vaping products

The pharmaceutical scheme is best thought of as a mechanism which allows companies to offset reasonable costs (e.g. cost of goods; distribution; sales & marketing; research & development) against stated NHS revenue before assessing final profit against the 17-21% profit limit. The proposed tobacco scheme would require companies to submit similarly detailed information on spending on operating costs such as production and distribution, (including cost of production of goods by brand, sales & marketing data by brand, distribution costs by brand.), for the analysis of profitability. This data should also be published in aggregate form for monitoring purposes.

By excluding non-tobacco products like e-cigarettes and vaping products from the scheme tobacco companies would be encouraged to transform their business models, over the short to medium term, to focus production on much less harmful products. Exceptions could also be made for niche products such as snuff and large cigars which are currently a very small part of the market, but not for known substitutes for factory made cigarettes such as cigarillos, which are equally harmful as cigarettes.

E-cigarettes are now the most popular quitting aid bought over the counter in the UK and we are a world leader in the use of e-cigarettes to help smokers quit,[30] while protecting children from uptake.[31] Vaping prevalence among adults in England in 2019 was stable at between 5% and 7%, with former smokers being the most frequent users where its use has continued to rise and was 12% to 13% in 2019.[32]

However, the scheme should not disadvantage independent providers of these products. Tobacco manufacturers already have a significant market advantage over independent e-cigarette and vaping companies because of their extensive distribution networks. So that a level playing field is maintained and tobacco companies do not dominate the market for e-cigarettes and vaping products, or to control any growth in excluded niche products, a periodic review process would be required. This would permit adjustment of the exemptions and allowances to tobacco companies and has proved successful in the pharmaceutical scheme.

3. Raise funds to support the Smoke-free 2030 ambition, and additional public health objectives

As outlined above, based on current operating profit for the large manufacturers of £900M, (average profit margin just under 50%), the tobacco profit control scheme could raise in the region of £700M per annum. It is estimated that, the DHSC would receive around £700M from smokers with manufacturers retaining around £200M from the wholesale price to cover costs and their 10% margin.

This additional revenue from smokers should be used to support the UK Government's Smoke-free 2030 ambition through a Smoke-free 2030 Fund, under the control of the DHSC. The US scheme is overseen by a Center for Tobacco Products within the Food and Drug Administration. In the UK, the obvious home for oversight of the Fund would be the new Office for Health Promotion, which is currently being set up within DHSC.[33] ASH estimates that around £266M per annum is required to fund a comprehensive tobacco control programme in England to realise Smoke-free 2030, with an additional £49 million on a per capita basis for the other nations in the UK. The extra £385M generated from this scheme could be put towards other public health programmes, with the ambition of restoring some of the real-terms losses that have accumulated over the last five years.

However, given the purpose of the fund is to make smoking obsolete and deliver a Smoke-free 2030, tobacco sales would decline significantly over the period to 2030 and hence the revenue generated. One way to balance out the Smoke-free 2030 Fund contributions would be to make over-payments in the earlier years to cover lower payments expected in later years. This would ensure resources were available to support the 'hardcore' of most addicted smokers who will still need help.

If market failure and oligopolistic behaviour of tobacco companies generating exceptional profits were not reason enough for introducing this scheme; it is noted that smoking continues to impose a cost burden on UK society. Previous attempts to address the externalities of smoking suggested aligning the costs of smoking to society in England of £12.9BN at a time when excise duties were less than £10 billion for the UK as a whole.[34] (Updated figures by ASH based on a methodology which was originally developed by Policy Exchange[35] and is similar to that used by the DHSC [36]). The picture has changed little since then, as the most recent estimate for the costs to society in 2019 was £12.5BN for England alone,[37] while excise taxes brought in only £8.8BN for the UK as a whole.

Lessons from the pharmaceutical scheme

Price regulation. Now that the UK has left the European Union (EU), the UK Government can exercise its freedom to set tobacco prices, as it does through NICE for new branded medicines. Price setting would be simpler than for branded medicines, and a maximum tobacco company profit of around 10% would be set based on costs of production and distribution, with very limited sales and marketing costs as tobacco marketing is heavily restricted. The DHSC would set wholesale prices paying regard to HM Treasury duty levels, including the annual escalator uplift required, for tobacco products.

As with the pharmaceutical scheme, review of wholesale prices could be conducted every 3-5 years, or sooner if there is significant change in the market dynamics. This would require a memorandum of understanding between HMT and DHSC that a specific amount would be set aside from the new scheme to fully cover the Smoke-free 2030 Fund. An immediate priority for this scheme to operate effectively – and for the Smoke-free 2030 ambition to be realised - is for the elimination of the current price differential between cigarettes and hand-rolled tobacco.[c] & [38] This could be achieved with a one-off duty increase on hand-rolled tobacco, which would then allow for easier administration of the sales-based rebate scheme on a per stick basis.

Inefficient overinvestment in capital. Theoretically, rate of return regulation generates few incentives for efficiency and with the PPRS, it generated incentives to cost-shift into the UK and encouraged overinvestment where the allowed rate of return exceeds the cost of capital - the Averch-Johnson effect. [39] This was one of the findings from the Office of Fair Trading market study into the PPRS and therefore

[c] Rollups are currently less than half the price of factory-made cigarettes, but each creates the same harm as smokers compensate by inhaling deeper and more frequently. Minimum price for a pack of 20 cigarettes (minimum pack size) bought from Tesco's (3 April 2021) is £9.25 = 46 pence per cigarette. A pack of 30g hand rolling tobacco (minimum pack size) is £11.40 = 19 pence per rollup, based on evidence that the average weight per rollup is 0.5g in the UK.

care should be taken that tobacco companies do not move global functions in the UK to benefit from any capital allowances that may be developed into the scheme. [40]

Hypothecation. After many years of trial and error on hypothecation, the VPAS repayments from the pharmaceutical industry now go directly to the DHSC to be spent on healthcare and not into general funds to be allocated by HM Treasury. Although the repayments go directly to the DHSC they are not directly spent on medicines in England. The devolved nations employ a greater degree of hypothecation (i.e. repayments spent on medicines) with repayments being allocated to the New Medicines Fund in Scotland and the New Treatment Fund in Wales. In the same way, £315M of the funds raised by a tobacco profit control scheme should be distributed directly to the DHSC to fund the Smoke-free 2030 ambition, with the remaining £385M being available for other public health interventions. A UK wide tobacco profit control scheme would also need to ensure an appropriate allocation to devolved nations, should they wish to opt in, which could be used to fund their own Smoke-free activities.

Transparency & Review. Under the scheme comprehensive data would be provided by tobacco manufacturers and importers to DHSC for publication in a standard agreed electronic format so as to be easily aggregated, accessible and analysable. This should include profits, and taxes at national and international level on an annual basis; brand specific price and sales data and marketing and research spend at national level; and monthly sales data by product type for all products (including factory made, HRT, heated tobacco products, and e-cigarettes). An annual Report to Parliament containing aggregate data should also be introduced as was previously undertaken for the pharmaceutical scheme. This would facilitate further scrutiny by Parliament or one of its relevant Select Committees.

In addition, further detailed reviews of the operation of the tobacco scheme, implementing any adjustments required, should be conducted and published by an independent body such as the Competition and Markets Authority (CMA) or National Audit Office (NAO). These reviews would also need to consider the evolving market dynamics for e-cigarettes and vaping to promote competition and not allow tobacco company dominance.

Analysis of the evolution of the scheme over the last 30 years reveals a game of cat and mouse, with the DHSC closing any loopholes that have thought to have been exploited during the previous scheme.[41] It is expected that tobacco manufacturers would similarly find and exploit any loopholes and regular reviews would be an important element of the initiative. In line with our obligations under the WHO Framework Convention on Tobacco Control and the guidelines on Article 5.3 the scheme would be fully statutory and it is not suggested there should be any form of negotiation between government and the tobacco industry of the content of the tobacco control scheme, its reviews or allowances or how the Smoke-free 2030 Fund is spent. Publication would improve the transparency of tobacco company accounts which are becoming increasingly difficult for academics to analyse and determine monopolistic behaviour.

Lessons from the USA

In the United States, the principle of charging the tobacco industry for the specific costs it imposes on the public purse has been established in law for over a decade. The Family Smoking Prevention and Tobacco Control Act 2009 [42] (TCA) requires tobacco companies to pay an annual 'user fee' to the Food and Drug Administration (FDA) to support statutorily defined activities.[42] This legislation provides broad authority to regulate the manufacture, marketing, sale, and distribution of tobacco products including running public education campaigns, and supporting enforcement to ensure compliance with the marketing, sale, and distribution laws and regulations of tobacco at the point of retail. [42]

In contrast to other FDA 'centers' (departments) that are generally funded by a combination of discretionary specific payments from the General Fund and user fees, the Center for Tobacco Products is funded solely by user fees. The levy is independent of the wider US fiscal regime and its proceeds are controlled directly by the FDA.

The value of the levy was based on a detailed calculation of the costs of tobacco regulation in the USA. This calculation was made prior to the legislation being laid down and subsequently incorporated within it. Furthermore, the legislation made clear that the funds raised could only be used for what they were intended for: the regulation of the tobacco industry. In 2020 the total annual fee was $711,997,864.[43] [44]

The costs of the levy are apportioned to tobacco companies with a presence in the USA according to their market share in the country. These companies play no part in deciding how much money is raised or how it is spent, nor is there any scope for lobbying on these issues, thanks in part to the careful specification of the levy before its implementation.

The concept of the tobacco industry user fee received cross-party support within Congress because it was understood to be a charge related to a specific cost rather than an addition to general taxation.[45] [46] Every two years the US Secretary of Health and Human Services is required to submit a public report to Congress on the progress and effectiveness of the Implementation of the TCA. Within five years of implementation the Government Accountability Office was required to report to Congress on the adequacy of the authority and resources provided to the Secretary of Health and Human Services for this division to carry out its goals and purposes; and any recommendations for strengthening that authority to more effectively protect the public health with respect to the manufacture, marketing, and distribution of tobacco products.[47]

Why now and what next?

The Government now has all the conditions necessary to forge ahead with developing a world-leading price and profit control mechanism, which can be utilised to fund its Smoke-free 2030 ambition. This is an innovative scheme which would enshrine the UK's role as a global leader in tobacco control. Where we lead others will follow.

UK has left the EU and the restrictive excise directive. Following the UK's has withdrawal from the EU, the EU Directives on excise duties, and that on tobacco tax (Council Directive 2011/64/EU), will no longer apply in the UK. Interestingly, legal opinion has previously noted that the tobacco tax directive was adopted on a legal basis that focusses on the functioning of the EU internal market, and not directly with public health. [48]

The effect of the tobacco directive, as determined by case law from the European Court of Justice, is to prevent Member States from setting tobacco prices because the directive primarily facilitates the internal market and removes distortions of competition.[17] Therefore, the UK's withdrawal from the EU now allows the UK Government to introduce the proposed tobacco profit control scheme, which includes direct price setting powers. As stated previously, over 90% of the UK retail price of tobacco is tax, so the increase in Government control over price setting is only marginal, but important.

Forthcoming NHS Bill – Integration & Innovation White Paper. The Government's White Paper proposals are designed to improve care and address health inequalities, through tackling other public health concerns such as obesity. This proposed scheme would contribute significantly to the aims of the White Paper and could easily be introduced into the forthcoming Health and Care Bill. The entire PPRS and VPAS scheme consists of just 10 paragraphs of primary legislation in the NHS Act 2006, which could easily be amended and added to the forthcoming Bill to give the Secretary of State the same powers over the tobacco industry and its products. The additional legislation would involve little Parliamentary time as it is believed there is widespread cross-party support in Parliament to tackle smoking and level up disadvantaged communities.

Further detail of the tobacco scheme would be introduced in secondary legislation, with the DHSC already holding extensive documentation and experience of operating the PPRS and VPAS schemes. Given the scheme is designed to support a specified target by a specified date, it is a moot point as to whether the primary legislation should include a sunset clause. As things stand today, the scheme would only need to be in operation until the Government's ambition to make smoking obsolete is delivered. However, the Smoke-free 2030 ambition is for smoking rates of 5% or below so the scheme is likely to continue to be required for a limited period after 2030.

Potential impact on pension funds. Any action on the excessive profitability of the tobacco industry could, in theory, impact upon corporate or personal pension funds. However, the ethics of investment are gaining greater attention and initiatives such as the Tobacco-Free Finance Pledge have over $11TN of managed assets excluding tobacco companies; signatories include Aegon, Axa, BNP Paribas, etc. Local Authority Pension Funds, such as Greater Manchester which administers the largest local authority

pension fund in the UK, are taking a similar approach and GM has disinvested from tobacco companies having considered the risks involved and concluded that there is no material financial detriment to the fund.[49]

Compliance with the WHO Framework Convention on Tobacco Control (FCTC). Furthermore, a fully statutory scheme would be essential for the Smoke-free 2030 Fund to comply with the UK's legal obligations as a Party to the WHO Framework Convention on Tobacco Control (FCTC).[50] This would ensure that public health policies with respect to tobacco control are protected from the commercial and vested interests of the tobacco industry. The guidelines to Article 5.3 of the FCTC, which the UK has adopted, state that, *"Parties should not accept, support or endorse partnerships and non-binding or non-enforceable agreements as well as any voluntary arrangement with the tobacco industry or any entity or person working to further its interests."* [51]

The Government needs to seize the once in a generation opportunity and continue its world-wide leadership position in public health and tackling smoking.

- Ends -

About the Author

Henry Featherstone submits this evidence to the APPG on Smoking and Health in a personal capacity. He is currently employed as Global Public Affairs Business Partner to Sanofi's General Medicines Business Unit. The inspiration behind this paper follows a (self-funded) MSc dissertation on the UK Pharmaceutical Price Regulation Scheme. Henry has previously worked as a junior doctor and surgical trainee in the NHS, in Parliament for a number of Conservative MPs and at the think-tank, Policy Exchange, where a number of his policy recommendations have been adopted by the UK Government. He read Medicine at Leeds University, Law & Management at the University of London and gained his Masters in Health Economics from the London School of Economics & Political Science.

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Appendix 1: Control of market power of research-based pharmaceutical companies

The patent protection applied to new medicines or vaccines gives research-based pharmaceutical companies a temporary monopoly on the supply of individual branded products, and a profit control scheme was deemed necessary by the UK Government as far back as 1957. The Voluntary Scheme for branded medicines Pricing and Access (VPAS) and its long-standing predecessor, the Pharmaceutical Price Regulation Scheme (PPRS), are often cited as examples of rate of return regulation. The VPAS still exists to limit profitability even though virtually all new medicines and vaccines undergo cost-effectiveness analysis.

In very general terms, analysis of the multiple 50-year-old schemes finds two main components of interest and relevance to tobacco:

1. Profit Cap Mechanism

The level of profits that pharmaceutical companies may earn on the sale of branded medicines to the NHS is heavily regulated. An Annual Financial Return (AFR) assesses profits against an agreed level of rate of return on capital (RoC) employed or return on sales (RoS). The return on capital or sales limits are intended to be directly comparable as the Government seeks to align prices of branded medicines with their economic costs of production, using return on capital or sales as a proxy measure in an attempt to reduce excess profits. Companies are given defined allowances against which permitted activities such as marketing and the provision information can be deducted. Additionally, there are several R&D allowances to reward innovation in developing new medicines and vaccines. Exceeding the allowed profit level will require a repayment to the Department of Health & Social Care, which under the latest VPAS is made on a quarterly basis.

2. Price Control Mechanism

Companies have freedom to set initial prices for medicines and vaccines designated 'new' by the medicine regulator, which are then subject to a cost-effective analysis by NICE or the JCVI. The scheme limits subsequent price increases, with mandated cuts to list prices being the mainstay of the scheme until 2014. The 2014 PPRS made no changes to list prices but introduced annual limits on the growth of the overall level branded medicines purchased by the NHS, with companies making payments to the DHSC to cover NHS spending on branded medicines above the agreed growth level. This shift to repayments based on sales, rather than list price controls, has been maintained in subsequent VPAS schemes. Notably sales of new products are excluded so as not to disincentivise the adoption of innovation.

PPRS and VPAS in practice

The PPRS operated at the level of the individual company, and is best thought of as a mechanism which allows pharmaceutical companies to offset reasonable costs (e.g. cost of goods; distribution; sales & marketing; research & development) against stated revenue before assessing final profit against the scheme's pre-determined profit limits. The aim of the scheme was to achieve the delicate balance between value for money for the NHS and a profitable pharmaceutical industry which could research and develop new medicines and vaccines for the future.

At the heart of the profitability assessment is the submission of a comprehensive Annual Financial Return (AFR) to the Department of Health & Social Care, containing detailed financial information certified as true and accurate by finance and managing directors. The AFR is then reconciled against other data, e.g. the company's statutory annual report and accounts, previous AFRs or reported accounts by similar companies. The Department considers the extent to which companies have used their best endeavours to achieve all possible economies in, say, costs of production and supply and overheads.

Originally, nearly all assessments were made under the return on capital (RoC) target, but over the years there has been an evolution to assessment by return on sales (RoS) since companies have little research or manufacturing facilities in the UK compared to their volume of sales. The VPAS is overwhelmingly a return on sales-based assessment mechanism.

The VPAS, and PPRS before it, are voluntary non-contractual frameworks, although underpinned by the NHS Act 2006. It is negotiated every five years between the Department of Health and Social Care (DHSC) on behalf of the UK Government (and for the health departments of England, Wales, Scotland and Northern Ireland), and the Association of the British Pharmaceutical Industry (ABPI), the main trade association of the research-based pharmaceutical industry in the UK. From a practical perspective it is easier for governments to control supply-side factors as there are fewer stakeholders involved, with the VPAS PPRS exemplifying this approach with a five-year, industry-wide scheme achieved through a single negotiation. Previous analysis of the evolution of the scheme over the last 30 years reveals a game of cat and mouse, with the DHSC closing any loopholes that have thought to have been exploited during the previous scheme.[41]

Companies which choose not to join the voluntary non-contractual framework are subject to a Statutory Scheme where mandatory payments against NHS sales of branded medicines are adjusted in line with VPAS payment levels. The idea behind scheme is to change pharma company behaviour.

Revenue raising effect & soft hypothecation

The revenue raised from pharmaceutical companies is given below, but it is important to note that a linear relationship does not exist between aggregate sales and repayments because post-hoc analysis of items such as parallel imports. Crucially, however, the repayments go directly to the Department of Health & Social Care in a form of soft hypothecation, although they are not spent on medicines in England. The devolved nations employ a greater degree of hypothecation with PPRS repayments being allocated to the New Medicines Fund in Scotland and the New Treatment Fund in Wales.

Table 2: Aggregate NHS sales of scheme branded medicines and VPAS/PPRS repayments

	Aggregate sales covered by PPRS payment (£M)	PPRS/VPAS payment (£M)
2013	7,901	n/a
2014	8,337	311
2015	8,178	846

2016	8,069	629
2017	8,160	387
2018	7,868	614

Source: Department of Health & Social Care. 2014 Pharmaceutical Price Regulation Scheme (PPRS) and The Branded Health Service Medicines (Costs) Regulations 2018. March 2020.

Parallel imports & supply chain. Parallel imports were initially excluded from PPRS repayments, but not calculation of the level of the total payment, which contributed to wide variation in repayments to the DHSC from year to year. [see Table 2] The scheme would be simpler for tobacco as there is a comprehensive tracking and tracing system in place which regulates the supply chain from manufacture to retail outlet to prevent facilitation of smuggling by manufacturers, and parallel imports are prohibited.

Falsified Medicines Directive

Supply chain control in the pharmaceutical industry is exercised for reasons of patient safety by the Falsified Medicines Directive, which the UK has agreed to adopt upon leaving the European Union, by ensuring the trade in medicines is properly controlled. Through a system of unique identifiers on packs it monitors at fixed points along the supply chain to increase security and protect people from fake medicines. Unique identifiers relate to pack size and strength of the medicine, with verification along the supply chain to ensure authenticity of product and legitimate manufacturer. Decommissioning takes place at the end of the supply chain when the pack is dispensed to the patient.

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