ASH policy paper for the APPG on Smoking and Health: Establishing a Smokefree Fund

Abstract

Background. Smoking kills up to two thirds of long-term users, and is estimated to cost public finances in England £9.4 bn in 2023 net of tobacco taxes. The UK Government's ambition is for England to be Smokefree by 2030, defined as smoking rates of 5% or less. However, 12.7% of the adult population in England still smoke, around 5.3 million people,[1] and on current trends the most deprived communities will not be smokefree before 2050.[2] Although welcome, the investments set out in the recent plan to create a smokefree generation[3] will not be sufficient to deliver the Smokefree ambition by 2030, and public finances remain tight for the foreseeable future with UK Government debt interest payments doubling during 2023 to £108 bn per annum[4]

Despite relatively high tobacco excise taxes the UK remains an attractive market for tobacco companies. About 95% of the UK tobacco market by volume is controlled by just four global manufacturers,[5] 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. It is difficult to justify that the tobacco industry, whose products are addictive and life-destroying, should not have its prices and hence profits controlled for the benefit of society and public finances, in the same way as utilities like energy, water and even medicines, all of which are essential and life-saving.

Paper objectives. This policy paper sets out a mechanism for making tobacco companies pay a 'polluter pays' levy as 'producer polluters'. This idea was envisaged in the 2019 Government Green Paper, has cross-party support, and is aligned with public opinion. It proposes taking elements from previous pharmaceutical pricing schemes, successfully operated by the Department of Health and Social Care (DHSC) over many years, to create a pricing and hence profit control scheme for the tobacco industry operating in the UK. The central aim of the scheme is to control the monopoly-like pricing power of tobacco manufacturers, but it can also be used to encourage tobacco companies to transform their business models away from harmful tobacco 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 proposed scheme could raise ~£700 mn per annum, which could be used to fund a comprehensive tobacco control programme. The primary legislation required to give the Secretary of State powers to make such a scheme has already been drafted and received widespread cross-party support and should be a priority for a reforming government. The Government needs to seize this once in a generation opportunity and continue its world-wide leadership position in public health and tackling smoking.

Smokefree 2030 ambition

In July 2019, the UK Government announced an extremely challenging ambition for England to be smokefree by 2030, which is defined as less than 5% of adults classified as smoking. There is a 2034 target for Scotland,[6] with no dates set for Wales or Northern Ireland. In 2022 12.9% of the UK population aged 18 years and above still smoked cigarettes, which equates to around 6.4 million people; broken down by countries, 12.7% of adults in England, 14.1% of adults in Wales, 15.4% of adults in Scotland, and 13.9% of adults in Northern Ireland.[7]

Smoking remains more prevalent in those with lower socio-economic status. More than 1 in 5 (22.8%) people in routine and manual occupations smoke, which is 2.7 times higher than people in managerial and professional occupations (8.3%)[7]. Smoking kills up to two thirds of long-term users [8] - irrespective of socio-economic status - so smoking disproportionately kills more poor or disadvantaged people. Moreover, the impact on cost of living is significant, since in 2023 smokers spent on average £3,096 a year on cigarettes, over 50% more than the current Ofgem energy price cap for a typical household of £1,834. [9]

The UK is a world-leader in tobacco control, but in order to reach the 2030 ambition, Cancer Research UK estimates that the reduction in smoking prevalence needs to be 70% faster than current trends. The risk is that while the least deprived (population quintile) in England will be smokefree by 2024, the most deprived will not benefit from the government's ambition until more than twenty-five years later.[10] The increased investment in tobacco control announced by the Government this year is welcome, but is still not sufficient to deliver a Smokefree 2030. Although investment in tobacco control is cost saving, pressures on public finances are such that it will be difficult to secure further additional investment without new sources

of funding. A 'polluter pays' levy payable on the profits of the tobacco industry can provide a new revenue stream.

Monopoly-like pricing power 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.[11] 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. [12]

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. …

"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 2014 the Government consulted on imposing a levy on tobacco manufacturers and importers to ensure that they made a greater contribution to the costs of smoking to society.[13] The decision was taken not to proceed, because the costs would be passed on to smokers, who already pay high excise taxes, and behavioural effects would limit the revenue that could be raised.[14]

Market power in the utility industries in the UK is addressed through price controls.[15] [16] [17] However, this was not possible for tobacco while the UK was a member of the EU, as direct price controls on tobacco were prohibited. [18] [19] A dividend from Brexit is that price controls are now also possible for tobacco.

As requested in the 2019 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. There is majority public support for a

Smokefree Fund to cover the annual costs of tobacco regulation and interventions to achieve the Government's ambition.[20]

The excess profitability of the UK tobacco market is well-described in the academic literature.[21] [22] [23] 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.[24] This is because ~90% of the retail price of tobacco in the UK is tax, largely specific rather than ad valorem, and relatively small increases in pre-duty tobacco prices have negligible impact on sales but significantly increase tobacco company revenue and profitability.

In the UK, about 95% of the tobacco market by volume is controlled by just four global manufacturers, with estimated UK profits, in 2013, of £1.04 bn to £1.76 bn.[25] 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.[26] 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.[27] [28]

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 more than twice as profitable as other food, beverage (including alcohol) or consumer product companies.[21] Imperial Brands is the most profitable, and also has the largest market share in the UK. In 2021, when Imperial's market share in the UK by volume was 44.7%, its operating profit margins were 70.5%,[29] meaning that for every £100

of revenue, £70.50 was profit. This is far higher than the margins for UK manufacturing which are under 10%,[30] or any other consumer staple products, which typically range from 12-20%.[23] Some may that argue there should be no limits on tobacco company profitability for selling a legal product: but the excess profits and monopoly-like pricing power of tobacco companies; the addictive nature of the products; and the associated morbidity and mortality from tobacco consumption, requires intervention.

From a theoretical perspective, monopoly-like pricing power is most often controlled through government action on the supply-side through price or rate of return regulation, which is a feature of both utility and pharmaceutical markets. Alternative methods to control monopoly power exist; for example, through 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, including the option of requiring firms to cease anti-competitive behaviours. This is not, however, relevant for tobacco, 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 on packaging, labelling and prohibition of product display at point of sale all seek to reduce tobacco product differentiation and branding, and hence competition.

If market failure and oligopolistic behaviour of tobacco companies generating exceptional profits were not reason enough for introducing a scheme to limit industry profits, it should be noted that smoking continues to impose a cost burden on UK society, despite the high rates of total tobacco taxation. Analysis by Landman Economics for ASH shows that the full cost of smoking to society in England was £75.1 bn in 2023, while the cost to public finances was £21 bn, nearly double that generated by tobacco taxes.[31]

The 'polluter pays' proposal

The scheme being proposed is called the 'polluter pays' levy. 'Polluter pays' is a long accepted principle, already applied to environmental regulation,[32] property

development[33] and the soft drinks industry,[34] and is soon to be applied in the gambling industry.[35] A pharmaceutical profit control scheme of one form or another has been operated by the UK Government since 1957, has seen over £7 bn repaid over the last five years,[36] and this from an industry whose products are essential and life-saving. 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. Therefore, the appropriate regulatory response to the monopoly-style pricing power of the tobacco manufacturers is to control the pricing of the industry rather than open it up to competition, which should ensure that the industry cannot pass the cost of the levy on to the consumer.[37] [38] [39]

There is cross-party support for the 'polluter pays' proposal and the primary legislation necessary has already been set out in amendments to the Health and Care Bill 2021.[40]

Compliance with the WHO Framework Convention on Tobacco Control (FCTC).

A fully statutory scheme would be essential for the Smokefree Fund to comply with the UK's legal obligations as a Party to the WHO Framework Convention on Tobacco Control (FCTC).[41] 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."*[42]

Capping tobacco manufacturers' prices and hence profits

The 'polluter pays' levy would cap producer prices and hence profits. The scheme would not apply to retailers, who would be allowed to set their own prices including a profit margin (retail profit margins are estimated to be around 6%).[43] By capping prices, as is the case already for utilities such as energy and water, manufacturers could be prevented from passing the cost on to consumers, as they do currently with tobacco taxes. An additional benefit of the scheme is that it would further limit tobacco companies' ability to use price as a marketing tool to differentiate and promote products, so undermining the effectiveness of tobacco taxation, as is still the case, despite the introduction of a Minimum Excise Tax in 2017.[44]

Setting the price to underpin the levy

The levy would operate through a cap on the wholesale price charged by manufacturers for tobacco products, which would be set at a level that would cover the costs of production and distribution plus a profit margin. The level of profitability for tobacco companies would be pre-determined at around 10% operating profit which is aligned to the lower end of consumer food and drink industry benchmarks and similar to UK manufacturing.[22] [23]

It is essential, however, that prices to consumers should not be lowered as a result of the scheme as this would increase consumption and reverse the decline in smoking prevalence. [45] The difference between the capped price and the current wholesale price would be made up with the levy. Consequently, the price to the consumer would not decline, but the profits of the tobacco industry would diminish and a large fund would be made available to make smoking history.

Capping the wholesale price charged by tobacco manufacturers' profits at 10% would enable an estimated £700 mn a year to be raised as a health promotion levy, without changing the price to the consumer. A memorandum of understanding between HMT and DHSC would be required to ensure that a specific sum from the proposed scheme is set aside to fully cover the Smokefree Fund.

Protecting tobacco taxes

The proposed 'polluter pays' levy would not impact on revenue collected from tobacco product taxation, as the money would come from industry profits not the consumer. Tobacco tax rates could continue to be raised above inflation over time, in line with commitments made by this government and its predecessors, with the proceeds going into the going to the Consolidated Fund.

DHSC has the expertise to implement such a scheme

The pharmaceutical pricing schemes, successfully operated by the UK government's health department since 1957, demonstrate that the DHSC has the expertise to create a pricing and hence profit control scheme for the tobacco industry operating 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.

The pharmaceutical pricing scheme 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.

The DHSC already has a team of experts monitoring the large and complex pharmaceutical market for the pharmaceutical pricing scheme. Tobacco is a much simpler commodity product with the vast majority of sales accounted for by two products, factory made cigarettes and hand rolling tobacco. Four manufacturers account for around 95% of tobacco sales by volume and could be covered by the existing DHSC team with only marginal additional resource needed.

This scheme would not require the creation of an additional stand-alone utility-type regulator. The DHSC has already developed the necessary expertise through the operation and refinement of pharmaceutical pricing schemes 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 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. Only marginal extra resource would be needed for the DHSC pharmaceutical analysts to carry out the work required.

DHSC also has the expertise to allocate funding to a comprehensive tobacco control programme

The proposed "producer polluter pays" mechanism would specifically distribute excess profits from tobacco manufacturers to a Fund designed to make smoking obsolete by preventing uptake and helping addicted smokers to quit.

As outlined above, based on operating profit for the large manufacturers of ~£900 mn, (average profit margin just under 50%), the tobacco profit control scheme could raise in the region of £700 mn per annum. Manufacturers would retain around £200 mn from the wholesale price to cover costs and their 10% profit margin.

Since the money raised would be coming from the former profits of tobacco companies, and hence ultimately the money paid by smokers, the additional revenue generated should be used to be support the Government's Smokefree ambition through a Smokefree Fund, under the control of the DHSC. The US polluters pays scheme is overseen by the Center for Tobacco Products within the Food and Drug Administration. In the UK, the obvious home for oversight of the

Fund would be the DHSC Office of Health Improvement and Disparities, which already oversees the Government's tobacco control programme.[46]

Given the purpose of the fund is to make smoking obsolete and deliver a Smokefree future, tobacco sales would decline significantly over time and hence the revenue generated would also decline. However, higher Smokefree Fund contributions in the earlier years could make up for lower payments expected in later years, when there will still be a significant number of the most addicted smokers who will need help to quit.

The proposed UK tobacco scheme would also build on the US user fee scheme which funds US tobacco control programmes and regulation (see below), but structured in the UK to include controls on prices which are not part of the US model.

Scheme administration

As with the previous pharmaceutical pricing scheme, the PPRS, 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.

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, distribution costs by brand). This data should also be published in aggregate form for monitoring purposes.

Detailed examination of the AFR would enable DHSC to determine the level of price that would be allowed, based on an assessment of the genuine costs of production each firm faces in its operations, and an assumption about the efficiency savings it would be expected to make.

For administrative ease, once the wholesale price has been calculated from examination of the AFR, it would be applied. The pharmaceutical levy is applied as a repayment scheme such that the industry has to pay DHSC the difference between the price they charge the NHS and the profit-capped price. This model would not be appropriate for tobacco, as unlike pharmaceutical companies selling patent medicines to the NHS, tobacco manufacturers have an incentive to cut prices which would undermine a repayment scheme. The simplest way to prevent

this would be for the levy to be collected as an additional form of tobacco tax to offset any reduction in price as determined by the wholesale price cap. between current consumer prices.

Because tobacco is an excisable product subject to strict regulation companies already have to report all products by volume released for consumption and thereby subject to tax. This would also enable the specification of the levy such that prices to consumers do not fall. The application of the levy to the Smokefree Fund should be set out in legislation to ensure that the revenues so obtained were allocated to DHSC and not absorbed into the Consolidated Fund (Government's general bank account at the Bank of England,).

Incentivising tobacco companies to move away from harmful tobacco products

The previous PPRS scheme is best thought of as a mechanism which allowed 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 17-21% allowance in the PPRS was for the research based pharmaceutical industry, with the range being selected as the average profitability in all FTSE500 sectors in the UK in the 1980's and is therefore much higher than the 10% margin proposed for tobacco. [47]

By excluding non-tobacco products like e-cigarettes from the scheme, tobacco companies could be encouraged to transform their business models, over the short to medium term, to focus production on much less harmful products. If so desired, exceptions might 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 have been shown to be significantly more effective than traditional nicotine replacement therapy in helping smokers quit.[48]

The scheme should not disadvantage independent providers of alternative nicotine 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, 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 such a mechanism has proved successful in the pharmaceutical scheme.

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 if they are currently invested in tobacco shares. However, the UK is just a small part of the global market so unilateral UK action is unlikely to immediately change the value of tobacco shares. Furthermore, the ethics of investment are gaining greater attention: the Tobacco-Free Finance Pledge has over $16TN of managed assets who have pledged to exclude tobacco companies; there are over 200 signatories including Aegon, Axa, BNP Paribas, and Sovereign Wealth Funds.[49] Local Authority Pension Funds, such as Greater Manchester (GM) 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.[50]

Lessons from the pharmaceutical scheme

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. [51] This was one of the findings from the Office of Fair Trading market study into the PPRS,[52] but it is resolved by the proposed system of price cap regulation for tobacco as the companies would have no incentive to change their use of capital

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. The repayments go directly to the DHSC from where they are allocated to the NHS to spend, whereas repayments in Scotland are allocated to the New Medicines Fund and in Wales to the New Treatment Fund. In the same way, funds raised by a tobacco profit control scheme should be distributed directly to the DHSC to fund the Smokefree ambition, with any excess being available for other public health interventions. A UK wide tobacco price control scheme and associated levy would also need to ensure an appropriate allocation between England and the devolved nations, should they wish to opt in, which could be used to fund their own Smokefree activities.

Transparency & Review. 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 through one of its

relevant Select Committees. Under the scheme comprehensive data should be provided by tobacco manufacturers and importers to DHSC as part of the AFR process for publication in a standard agreed electronic format so as to be easily aggregated, accessible and analysable. This should include profits at national and international level on an annual basis; brand specific price and sales data, allowable costs of production and distribution spend at national level; and monthly sales data by product type for all products (including factory made, HRT, heated tobacco products, and e-cigarettes).

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 inhibit tobacco company dominance.

Analysis of the evolution of the pharmaceutical pricing 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 5-year scheme.[53] It is expected that tobacco manufacturers would similarly find and exploit any loopholes; for example as has been shown by their circumvention of regulations banning advertising and menthol flavours in cigarettes , and hence regular reviews would be an important element of the initiative. In line with our obligations under the WHO Framework Convention on Tobacco Control, and in particular Article 5.3 of the Convention, 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, any reviews of the scheme, or how the Smokefree Fund is spent.

Further details on the current pricing scheme for pharmaceutical products, called the 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. While VPAS is described as a voluntary scheme, any pharmaceutical manufacturer not signing up to VPAS is subject to a statutory scheme, which is broadly equivalent. [54] Over the last 5 years, the VPAS has raised over £7 bn on sales of medicines to the NHS, with a current repayment rate of 26.5% of net sales being heavily criticised by Industry.[55]

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 [56] (TCA) requires tobacco companies to pay an annual 'user fee' to the Food and Drug Administration (FDA) to support statutorily defined activities.[56] 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. [56]

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 (i.e. state and federal taxation) 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. From 2019 the total annual fee was $712 mn and it has not been updated since then.[57] [58]

The costs of the levy are apportioned to tobacco companies with a presence in the USA according to their market share by volume, as determined by US tax authorities. 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.[59] [60] 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.[61]

Limitations of the US user fee

While it provides a useful model, the US user fee has limitations which the 'polluter pays' proposal is designed to eliminate. The US user fee does not include a cap on prices or profits, and so does not prevent the industry making extreme profits, and nor does it prevent the industry from passing the cost of regulation on to the consumer. Furthermore, the objectives prescribed in US legislation are tied specifically to the protection of children, which prevents funding being spent on helping adult smokers quit. By setting broader objectives tied to the smokefree ambition, the UK could use the levy to help fund a comprehensive tobacco control programme which has not been possible in the US.

Acknowledgements

The 'polluter pays' model synthesises the OFSMOKE scheme proposal, developed by Dr JR Branston and Prof A Gilmore from the University of Bath in 2010, together with Dr Featherstone's model of pricing controls as applied by the Department of Health to pharmaceutical products. Dr Featherstone provided the expert input on the workings of the pharmaceutical pricing scheme which was the starting point for this approach. Dr Rob Branston provided the tobacco data which underpins the approach taken herein and advised on the further development of the model.

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 Pharmaceutical Price Regulation Scheme (PPRS) is often cited as an example of rate of return regulation.[62] The VPAS still exists to limit profitability even though virtually all new medicines and vaccines undergo cost-effectiveness analysis. Although the scheme is described as voluntary, any company which doesn't opt in become part of a Statutory Pricing

Scheme where rebates on net sales are higher than the current 26.5% in the 'voluntary' scheme.

In very general terms, analysis of the multiple 65-year-old schemes finds a number of components of interest and relevance to tobacco, demonstrating that the DHSC has long experience of operating a price control scheme for a much more complex industry, pharmaceuticals:

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 allowable percentages for return on capital or sales 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 for costs of production 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.

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 PPRS scheme limited subsequent price increases, with mandated cuts to list prices being the mainstay of the scheme until 2014. The 2014 PPRS negotiated with a Conservative Government making cuts to public spending marked a change in scheme design; it made no changes to list prices but introduced annual limits on the growth of the overall level of 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 most newly approved 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 allowed 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 PPRS 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, 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 has now changed into a return on sales-based assessment mechanism.

The VPAS, and PPRS before it, are voluntary non-contractual frameworks, although underpinned by the National Health Service 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 PPRS and subsequently VPAS exemplifying this approach with a five-year, industry-wide scheme achieved through a single negotiation. Previous analysis of the evolution of the PPRS scheme over its last 30 years of operation reveals a game of cat and mouse, with the DHSC closing any loopholes that have thought to have been exploited during the previous 5-year scheme.[53]

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, but typically 1-2% higher than VPAS payment levels. The idea behind these schemes 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 of post-hoc analysis of items such as parallel imports. Crucially, however, the repayments go directly to the Department of Health & Social Care in and are allocated to the NHS although they are not spent on medicines. The devolved nations allocate fun 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 repayments

	Aggregate sales covered by repayment (£M)	VPAS repayment (£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
2019	8,805	845
2020	10,076	594
2021	11,054	563
2022	12,124	1,819
2023		3,300 (est) (728 in Q1, 782 in Q2)

Source: Department of Health & Social Care. 2014 Pharmaceutical Price Regulation Scheme (PPRS) and The Branded Health Service Medicines (Costs) Regulations 2018. March 2020. DHSC Transparency Data. Aggregate Net Sales & Payment Information. October 2023.

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