

Tobacco and Related Products Regulations (TRPR)

Lead department	Department for Health and Social Care
Summary of measure	The TRPR transposed provisions from the European Union's Tobacco Products Directive (TPD) into UK law. This covered a range of measures such as notification, labelling and advertising regulations for novel tobacco products, herbal products for smoking, and electronic cigarettes.
Submission type	Post-implementation review
Implementation date	20 May 2016
Department recommendation	Keep
RPC reference	RPC-DHSC-5126(1)
Opinion type	Formal
Date of issue	15 February 2022

RPC opinion

Rating¹	RPC opinion
Fit for purpose	The RPC considers the post-implementation review (PIR) to be fit for purpose and the evaluation to be proportionate to the scale of impact of the measures. The Department has used a range of evidence to support the decision to keep the regulations, including externally commissioned research and stakeholder engagement. The PIR acknowledges key unintended impacts and discusses how the Department are continuing to explore how to move forward with smoking related policy. On first submission the IA received an initial review notice (IRN) – see below for details.

¹ The RPC opinion rating is based on whether the evidence in the PIR is sufficiently robust to support the departmental recommendation, as set out in the [better regulation framework](#). The RPC rating will be fit for purpose or not fit for purpose.

RPC summary

Category	Quality	RPC comments
Recommendation	Green	The evidence that the Department has considered is relevant to the regulations. It appears to support the proposition that regulations have had a positive effect towards meeting their objectives. The Department has worked to address the Committee's concerns. We recommend that the Department should undertake further analysis to justify measures that could be taken within a future strategy.
Monitoring and implementation	Satisfactory	The PIR makes use of research and evidence that has been gathered on this policy. It outlines the external research that has been commissioned and the stakeholder engagement, to inform the review. The PIR considers how updates to baseline impact upon the costs and benefits attributed to the regulations, and how this affects the net present value (NPV) and equivalent annual net direct cost to business (EANDCB). The PIR should evaluate the representativeness and robustness of the evidence base, while providing clarification of the actions taken to fill evidence gaps that remain.
Evaluation	Satisfactory	The Department highlights that there has been a continued positive impact in delivering against the Government's wider smoking policy objectives. While the PIR identifies some unintended impacts, and now includes these in the summary of the review, it concludes that the regulations remain, as part of the overall policy objectives, necessary to continue protecting people from the harms of tobacco. The PIR should consider setting out a plan to monitor the long-term impacts of the regulations, including for any future regulations within this policy area, as well as discussing whether assumptions used in the IA remain appropriate.

Response to initial review

As originally submitted, the PIR was not fit for purpose as the Department did not, as part of their recommendation, fully consider the unintended impacts that the introduction of these regulations had, such as manufacturers introducing new products and concerns relating to e-cigarettes, despite presenting evidence of their existence within the PIR report. In addition, the Department had not considered what improvement, or alternatives, to the regulations could be introduced to correct for these unintended impacts, as well as more general areas of weakness that the review discussed.

The Department has now added some more discussion of the unintended impacts of the regulations, while also drawing out these key areas within their summative discussion of the review. In the Department's discussion of the recommendation, these are clearly acknowledged and weighed up alongside the success of the policy, when considering whether to retain the regulations. The Department therefore acknowledges the existence of some unintended consequences which it believes would be considered more fully as part of the future Smokefree 2030 ambition.

Linkages to Standardised Packaging of Tobacco (SPoT)

The RPC notes the common evidence base that has been used to support not only this PIR covering TRPR, but also the Department's other PIR, for which an opinion was issued in November 2021, the SPoT 2015 regulations. Notwithstanding the shared evidence base and the closely related policy objectives, the RPC believed that due to the broader scope of TRPR and sufficient distinction between the subject of the PIRs, they were able to be assessed on their individual merits. As such issues, such as the discussion around unintended consequences, were raised specific to TRPR and justified the decision for the RPC to issue an IRN for the original submission of this PIR only.

These two policies were part of a broader package of smoking related policies introduced by the Department and have had PIRs submitted for in recent years. All of these measures sought to further the Governments aims with respect to smoking. It is acknowledged that in the PIR that it is difficult to attribute the impact of each measure on the rate of smoking prevalence in isolation.

Summary of proposal

The policy, building on earlier regulations, set to deliver on three objectives. The first was to transpose provisions from the European Union's Tobacco Products Directive (TPD) into UK law. The second and third were seen as the direct health benefits from this and sought to discourage young people from taking up smoking, and support smokers who wanted to quit to do so.

The policy when introduced, was expected to have an equivalent annual net direct cost to business (EANDCB) of £16.4 million.

Recommendation

The PIR recommends retention of the regulations, however, it also acknowledges that the policy needs to be further developed and to continue working towards the objectives of the policy. In the Department's recommendation, the unintended consequences (discussed in more detail below) are now clearly acknowledged, although it is stated that while these have occurred the policy overall has been successful in furthering the Governments objectives on smoking policy.

The PIR presents a range of evidence, including on the rate of smoking prevalence and consumption of cigarettes. It acknowledges that while the policy has met its objectives, it notes the inability to directly attribute any changes in trends in smoking prevalence solely to TRPR. It points out that TRPR is one of many interventions that the Government has made and a variety of other factors, such as changes in taxation, may also have had an influence on smoking prevalence over time.

Monitoring and implementation

Range of evidence considered

Although the PIR appears to be informed by a wide range of evidence sources, it would benefit from evaluating the representativeness of the data and whether views from all affected stakeholders have been captured. For example, the public consultation does not appear to include the views of tobacco wholesalers, which were expected to bear significant costs from the regulations. Therefore, the PIR should discuss whether there are any evidence gaps and what potential improvements could be made to address these gaps (if any) in the future.

Gaps in the evidence justified

When addressing the costs which have not been updated, the PIR often uses a blanket statement that "No further evidence has been identified or received through the consultation for this Post-Implementation Review in relation to this cost, therefore it is assumed to have remained the same". The Department should have explained what specific actions were undertaken to seek these various pieces of information. In particular, for those costs which the Department, or other Government bodies, are likely to hold relevant and appropriate information (such as peer review charges to inform the Tobacco notification costs).

Evaluation

Consideration of unintended effects

The PIR now clearly acknowledges that there were some key unintended consequences as a result of the regulations, after having not addressed these in the summary section of the PIR as first submitted. The three main areas identified by the Department related to the menthol ban (where industry introduced new product lines), e-cigarettes (where the nicotine content is viewed as insufficient) and nicotine pouches (where there has been a push for their inclusion in the regulations). The Department should have sought to discuss the level of impact that these unintended consequences are having in limiting the success of the policy and undermining the

objectives. In addition, the PIR should have discussed further, the concerns raised in relation to the introduction of health warnings on e-cigarettes which have served to legitimise potentially inferior products.

Original analysis and assumptions

The PIR includes a lengthy consideration of the cost-benefit analysis that was originally undertaken for the regulations. The Department has updated the baseline position, upon which some costs are dependent.

The Department should have considered the impact of the key assumptions that underpinned the original analysis. In the assessment of key costs, and where there is an absence of robust evidence, the Department should have discussed the key assumptions and provided a qualitative assessment of whether they remain appropriate. For the assumptions that informed the analysis relating to the illicit trade, the IA provides recent evidence to support the original assumption.

The Department could also have explored whether there is international data available to make cross country comparisons over time. Comparing smoking prevalence across different countries over time, and relating these to changes in UK regulations, may help to ascertain the relative impact of different UK policy measures.

Small and Micro business assessment

The PIR highlights that the regulations were expected to have a large impact on small and micro businesses (SMBs), as they accounted for 46% of the sales of tobacco products. It also includes some evidence from SMB stakeholders to support the position that, due to the low margin on tobacco related products, the impact of these regulations has not been that significant. The PIR should have considered including analysis looking at quantifying the scale of the impact on SMBs and whether it has been disproportionate compared to the impact on larger businesses. The PIR should have addressed whether any mitigating actions were used to aid SMBs during implementation and if these were successful or not.

Improvements or alternatives considered

Given the range of the areas of concern and unintended impacts of the regulations – as noted above – the PIR notes that, while the recommendation is to retain the regulations, there will be further work in developing wider tobacco and related products policy. The Department goes further to note, that this will need to balance work towards the objectives, along with ensuring that current smokers are well supported in being able to quit (e.g., through access to e-cigarettes).

Future monitoring and evaluation

The PIR would benefit from setting out a monitoring and evaluation plan to capture the long-term impacts of the policy, including how effective the regulations have been in decreasing smoking incidence and the prevalence of smoking-related adverse health impacts.

Regulatory Policy Committee

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Stephen Gibson did not participate in the scrutiny of this case to avoid a potential conflict of interest.