Public Health England

ITPAC Meeting at Skipton House
21 September 2016 09:30 – 11:00

Number	In attendance: PHE [redacted] – [redacted] (Chair) [redacted] – [redacted] and [redacted] In Attendance: ITPAC [redacted] – Hunters Frankau/ITPAC CHAIR [redacted] – Gawith Hoggarth/ITPAC VICE-CHAIR [redacted]: ITPAC Secretary-General	
1	**Meeting Purpose:**	
	The meeting was covered by Article 5.3 an agenda had been pre-agreed and the following note taken. [redacted] opened the meeting. He introduced the PHE as an organisation; he explained the relationship PHE has with the Department of Health. [redacted] queried whether PHE had jurisdiction over all of the UK. [redacted] clarified that countries within the UK had devolved administrations however affirmed that the TPD2 is the responsibility of the Department of Health for the UK as a whole and the Devolved Administrations had formally agreed to PHE undertaking this role on their behalf. He further explained that the meeting held today would be addressing the implementation of TPD2 in the UK. [redacted] reiterated the meeting was focused on the notification of ingredient's and emissions. The meeting also focused on PHE's management of the EU-CEG process and guidance for industry stakeholders.	[redacted]
2	**Introductions to ITPAC**	
	[redacted] introduced ITPAC. He provided a handout detailing the 12 ITPAC Core Members. He also affirmed that these enterprises mainly traded in specialist tobacco products eg. cigars, pipe tobacco and snuff. He stated that specialist tobacco products only have c. 1% of the share of tobacco consumption in the UK. He further explained that ITPAC is an Associate Member of the European Cigar Manufacturers Association and manages regulatory issues as they arise. [redacted] highlighted the impact suffered by SMEs from the significant quantity of recent regulation.	[redacted]
3	**TPD ingredients and sales reporting:**	
	Overview of Requirements and PHE Guidance: [redacted] provided an overview of the requirements for notification. He confirmed that the requirements for e-cigarette reporting had been published by MHRA and that PHE would soon publish their own guidance specific to tobacco. [redacted] presented the draft publication to the group. [redacted] had sent various publications regarding notification which were received by [redacted]. He agreed to resend these publications to [redacted] and [redacted]. [redacted] had also send a copy of the MHRA e-cigarette guidance to [redacted], [redacted] and [redacted] ITPAC Summary: WC confirmed there were about 20 importers of specialist tobacco products in the UK and that 12 of them are ITPAC Core Members. EU-CEG: [redacted] confirmed that the EU-CEG system was now functioning, and stated that notifications had been made by some ITPAC members. He further stated	[redacted]

	we were now able to assess notifications received. Technical Issues: [redacted] raised that has been an incident where a manufacturer is providing products both in the UK and in Spain. He asserts the system does not allow a second notification to be made in the UK where a notification has already been provided by another importer in Spain. [redacted] said he would escalate the concern to the Commission however asked [redacted] to email details of the incident he was referring to in order to include this specific occurrence [redacted] also wished to clarify reporting responsibilities on importers in the UK in the occurrence that notification has been provided in another Member State. Standalone Option vs System to System: The former is slower to implement, but cheaper; the latter requires material IT resources and investment, but is faster. Because of their size, ITPAC Core Members have opted for the former.	
4	**Points for Clarification:**	
	Reporting Responsibility: [redacted] explained that smaller companies have smaller notifications to be made. For example novel tobacco products may have more data to report on than say herbal products for smoking. [redacted] raised that importers from the UK may not have all the ingredients readily available for the product they are importing. It was decided that either the manufacturer could complete the notification as they are aware of all the ingredients in the product they are producing, or alternatively the burden would lie on the importer to liaise with the manufacturer to get information regarding ingredients or ensure that they themselves report. Variant Brands: [redacted] confirmed that where a product is the same and contains all the same ingredients however has been rebranded and referred to by a different name, it may not be necessary to make a second notification. [redacted] to clarify. However the group discussed the difficulty that may arise; namely that different importers may seek to make notification of the same product owing to a product being referred to in a variant brand name. [redacted] mentioned that this will be looked into further, [redacted] to highlight this as a question for the EU Commission expert working group. [redacted] raised the question of rebranding by UK businesses of products already imported and registered. This was considered acceptable providing the initial individual products have been notified. He also raised the issue of retailers blending their own products from loose tobaccos available in the market at the point of sale, in which case [redacted] believed that the product should be classified as a new product as it has been manufactured and will require a separate notification. [redacted] to clarify. Definition of a Sale The group discussed how sales data can be monitored. ITPAC questioned whether the 'sales' figures should comprise (i) shipments from a	[redacted] & [redacted]

	manufacturer/producer to a country, or (ii) depletions by an importer/distributor within a country. [redacted]'s view was that (ii) constituted the figures that PHE would like to receive, but that (i) was likely also to be acceptable. [redacted] to highlight this as a question for the EU Commission expert working group. Products in the Market before 20/5/16 ITPAC requested confirmation that products which have been in the market before 20/5/16, but which will no longer be sold into the market after that date, are exempt from the reporting requirements. Such products include vintage cigars and a number of other old specialist tobacco products, which were notified under the previous system. Whilst registration via the EU-CEG is seemingly not required for these products, they might be at risk from enforcement officers because they will not appear on any record. [redacted] to clarify. Previous Ingredients Reports [redacted] confirmed that the previous ingredients reports required under TPD 1 have, as far as the UK is concerned, been repealed by the new requirements under TPD 2. Validation [redacted] commented that improvements in the functioning of the validation process had been discussed by the Member States and that information on this would be passed on as the work programmes of the Joint Actions for the Members States developed. Joint Action The authorities are sensitive to the burden and cost imposed on those businesses responsible for making submissions to the system. It is understood that they will be reviewing the data across the EU with a plan to put it to useful purposes, in addition to ensuring that it is valid. ITPAC welcomed any development that improved the quality of data available to policy makers, which at times in the past had proved a problem.	
5	**PHE Responsibilities:**	
	Confidentiality and Information Management - [redacted] raised information that the tobacco industry may be reluctant to disclose about their products, such as trade secrets. [redacted] explained that in the event of trade secrets, such information remains confidential and is not made available to the general public or any stakeholders in the tobacco industry. Storage, access and sharing of any such information would be subject to relevant legislation. [redacted] raised there was a risk that some companies may wrongfully note down ingredients as trade secrets in attempt to non-comply to notification obligations; [redacted] stated he was aware of that risk and confirmed that this was an area that the Joint Action of Members States would be considering. [redacted] said that he was aware that the validation function on the CEG tool did not check the detail of the notifications and that, as a result, successful notifications could be made even if they contained inaccurate information.	[redacted], [redacted] & [redacted]

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6	**Fees and Consultation:**	
	[redacted] explained that the issue was best addressed in consultation and that it would be initiated by DH. He reiterated that the European Commission had stated the cost of notification would be funded by the tobacco industry; [redacted], [redacted] and [redacted] agreed. He emphasised that the fees charged must cover the cost of delivery on a non-profit basis, and suggested that they must be proportionate. [redacted] agreed that Government guidance is that fees should only be set on a cost recovery basis.	[redacted]
7	**Additional TPD Issues**	
	[redacted] wanted to know about cessation and e-cigarettes, [redacted] directed the group to the independent review carried out for PHE on e-cigs and available on the gov.uk website. [redacted] further queried on the effect of Brexit under the TPD; [redacted] responded that the UK has voted to leave the European Union. The TPD is one of the many areas that the Government will want to consider carefully as part of the process of leaving the EU. TPD1 is no longer in force, the directive has been repealed by TPD2.	[redacted] & [redacted]
8	**Meeting Dates**	
	[redacted] proposed to visit the Kendal Gawith Hoggarth site on 27th September 2016 or 13th October 2016, to support the upload of data into the system. This will be confirmed in due course by [redacted].	Group

[redacted] to send to group:

- Summary Guide for Consumer Regulatory Products
- MHRA webpage instructions detailing need to know information and , and upcoming events
- Send to [redacted] and [redacted] – document detailing how to access ID and ECAS account
- MHRA e-cigarette guidance to [redacted], [redacted], and [redacted]