Issues of concern regarding TRIS notification 2024/0257/BE
Draft Royal Decree amending the Belgian Royal Decree of 7 April 2019 on the traceability and safety features of tobacco products

Executive Summary

On 14 May 2024, Belgium notified a draft *Royal Decree amending the Belgian Royal Decree of 7 April 2019 on the traceability and safety features of tobacco products* to the European Commission and to EU Member States through the EU's Technical Regulations Information System (TRIS). In simple terms, Belgium foresees the following changes:

- The extension of the obligation to provide track and trace (T&T) equipment to "*current and future*" (Article 3(8) of the Royal Decree, if amended).

- The introduction of a new obligation for manufacturers to reimburse economic operators the costs associated with the operation of the traceability system, *inter alia*, staff costs, equipment renewal and maintenance costs, and software costs (Article 3(9) of the Royal Decree, if amended).

- The introduction of a new requirement providing that, in order to obtain a Unique Identifier, tobacco products must figure on Belgium's list of validated products (Article 3(1) of the Royal Decree, if amended).

Tobacco Europe[1], its members and Philip Morris International believe that the draft Royal Decree clearly conflicts with the EU Tobacco Products Directive (TPD), raises issues of compliance with general EU law, and appears inconsistent with certain international trade principles and obligations. The draft Royal Decree and the envisaged changes to the T&T system would have a significant impact on the current well-functioning Single-Point-Of-Contact (SPOC) framework, which has been created to fulfil the obligation of tobacco manufacturers and importers under Article 15(7) of the TPD to provide equipment and has been successfully adopted by over 90% of economic operators across the EU since 2019. The draft Royal Decree would lead to important challenges for economic operators, including for tobacco manufacturers, and would likely impact supply chains across the EU by creating barriers to trade forcing, among others, tobacco manufacturers to significantly re-organise and modify their trading processes only for the Belgian market, creating unequal conditions for manufacturers operating in different EU Member States and introducing a trade access barrier.

First of all, and most evidently, **Belgium's envisaged amendments to the Royal Decree are in conflict with the TPD and its transposition across all other EU Member States**. More specifically, the extension of the scope of the obligation to provide "*current and future*" T&T equipment to operators, and the introduction of a new obligation for manufacturers to reimburse economic operators of the costs associated with the operation of the traceability system, *inter alia*, staff costs, equipment renewal and maintenance costs, and software costs in Article 3(8) and (9) of the Royal Decree, if amended, would be inconsistent with the clear wording of Article 15(7) of the TPD.

Article 15(7) of the TPD is clear in that it only requires tobacco manufacturers to *provide* the necessary equipment. It does not require manufacturers to cover any further operating costs of economic operators involved in the trade of tobacco products, including the costs related to the equipment already provided, its maintenance, or the related software or staff costs. Furthermore, Belgium's measure would create legal uncertainty, instead of the allegedly pursued legal certainty, in that it does not comprehensively define the scope of the reimbursement obligation by only providing examples. From a practical perspective, it would also be extraordinarily difficult to separate the share

[1] https://www.tobacco-europe.eu/. Tobacco Europe AISBL is the umbrella organisation representing major European-based tobacco and nicotine products manufacturers.

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of the operating costs from the operating costs of supply chain operators' broader logistical, accounting, and human resource operations.

Article 15(7) of the TPD does not contain an obligation for tobacco manufacturers to continuously cover the operational costs incurred by economic operators, namely the economic operators that are responsible under the TPD and EU Member States' law to collect and transmit data. Article 15(7) of the TPD clearly limits the obligation of tobacco manufacturers to the provision of equipment only. The provision of equipment should always be limited to **the initial provision** and must not extend to instances where operators require new equipment due to any other reasons under their responsibility, such as negligent conduct, improper storage, misuse, or theft. Economic operators must assume responsibility for the business choices they make and the relevant costs of doing business in this sector.

We consider the envisaged measures to be **disproportionate**, aiming to address problems that do not exist. Given the involvement of the economic operators from manufacturing to the last economic operator before the first retail outlet, there is and must be a **shared obligation borne by tobacco manufacturers and by economic operators, which would be disproportionately altered and imbalanced by Belgium's envisaged regulatory changes**. For instance, operators that were to choose solutions that involve periodic operational costs beyond the initial provision of equipment should bear full responsibility for such autonomous business decisions, as it would be unfair, unreasonable, and disproportionate for manufacturers to bear the risk of any business decision taken by third parties.

The measures would also be disproportionate by having an excessive impact on tobacco manufacturers. Notably, Article 3(8) and (9) of the Royal Decree, if amended, would significantly expand the burden and costs imposed on tobacco manufacturers. Consequently, **tobacco manufacturers would need to significantly re-organise and modify their trading processes only for the Belgian market**, which would lead to market fragmentation and go beyond what is necessary to establish a well-functioning T&T system as specified under Article 15 of the TPD.

The TPD sought to harmonise the EU rules for tobacco products. Belgium now seeks to regulate differently, on its own initiative, which **would fragment the internal market, pose significant challenges to operators on the EU internal market, and create unnecessary barriers to trade**. Any significant deviation from the rules harmonised by the TPD would lead to a disparity of requirements, creating unequal conditions for manufacturers operating in different EU Member States, and would risk jeopardising the very objective of harmonisation in the EU internal market.

The envisaged measure, by which products that do not figure on the **list of validated products** may not obtain a Unique Identifier, would become a **trade access barrier**. While, in theory, this requirement could be complied with for products destined for the Belgian market, as these products must figure on the list of validated products, it **could create a significant problem for products manufactured in Belgium and being shipped through Belgium, but destined for other EU Member States' markets or exported to third country markets**, products which would not or not necessarily figure on the list of validated products and for which it would become impossible to comply with the mandatory TPD requirements.

Finally, the amendments foreseen to Belgium's Royal Decree should also be considered in view of Belgium's and the EU's international trade commitments, as certain elements of the proposed rules, notably that tobacco products must appear on the list of validated products in order to obtain a Unique Identifier, could be perceived as **technical regulations posing unnecessary barriers to trade contrary to Article 2.2 of the TBT Agreement**. So far, **Belgium (*i.e.*, the EU) has not notified the draft Royal Decree to the WTO**, thus not informing other WTO Members of the draft Royal Decree and depriving them of their right to submit comments and try to minimise the trade restrictive and disproportionate features or effects of the proposed measure.

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Tobacco Europe, its members and Philip Morris International respectfully request Belgium to reconsider its draft Royal Decree and maintain the harmonised EU approach to the transposition of the relevant TPD legal requirements in line with other EU Member States, so as to not fragment the EU market, not impact the current well-functioning SPOC framework, not trigger disproportionate challenges for tobacco manufacturers, and not impact supply chains across the EU in a way that is arguably contrary to EU law and to the EU's international trade obligations.

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1. Introduction

On 14 May 2024, Belgium notified a draft *Royal Decree amending the Belgian Royal Decree of 7 April 2019 on the traceability and safety features of tobacco products* to the European Commission and to EU Member States through the EU's Technical Regulations Information System (TRIS).[2]

The draft Royal Decree and the envisaged changes to the track and trace system would have a significant impact on the current well-functioning framework, would lead to important challenges for economic operators, including for tobacco manufacturers, and might impact supply chains across the EU. We believe that the draft Royal Decree clearly conflicts with the EU's Tobacco Products Directive (hereinafter, TPD), raises issues of compliance with EU law, and appears inconsistent with certain international trade principles and obligations.

On the basis of the above considerations, as further detailed below, we respectfully request Belgium to reconsider its draft Royal Decree and maintain the harmonised approach to the transposition of the relevant EU legal requirements in line with other EU Member States.

2. Background and context

Belgium intends to amend its transposition of certain elements of the EU's Tobacco Products Directive (TPD).[3]

The TPD regulates the sale and marketing of tobacco products in the EU. Article 15 on '*Traceability*' requires the establishment of a tracking and tracing system for tobacco products in the EU, which aims at combating counterfeiting and illicit trade by requiring all tobacco products to be marked with a Unique Identifier (UI).

The Unique Identifier allows to track the movement of tobacco products from the manufacturer to the last economic operator before the first retail outlet, providing information on the date and place of manufacture, the intended market, and the shipment route.

Paragraphs 5 and 6 of Article 15 of the TPD provide that:

> "*5. Member States shall ensure that all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.*
>
> *6. Member States shall ensure that all natural and legal persons engaged in the supply chain of tobacco products maintain complete and accurate records of all relevant transactions*".

In most relevant part, Article 15(7) of the TPD provides that:

> "*Member States shall ensure that the manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic*

[2] Draft Royal Decree amending the Royal Decree of 7 April 2019 on the traceability and safety features of tobacco products, as notified through the EU's Technical Regulations Information System (TRIS), Notification 2024/0257/BE (Belgium), available at https://technical-regulation-information-system.ec.europa.eu/en/notification/25882 (accessed 30 July 2024).

[3] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0040-20231023 (accessed 30 July 2024).

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> *operator before the first retail outlet, including importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to paragraph 8*" (emphasis added).

The information related to the tracking and tracing system is stored electronically by a third party and can be accessed by authorised bodies.

Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products provides further details for the implementation of the traceability system.[4] *Commission Implementing Regulation (EU) 2018/574* supplements the TPD by outlining the technical specifications for the mandatory tracking and tracing system for tobacco products. *Inter alia*, *Commission Implementing Regulation (EU) 2018/574* mandates a secure data storage system overseen by an independent body to store the collected information.

Notably, Article 30 of *Commission Implementing Regulation (EU) 2018/574* on '*Costs of the repositories system*' outlines how the costs of the repository system are to be divided between manufacturers, importers, and repository providers:

> "*1. All ordinary costs related to the repositories system referred to in Article 24(1), including those that arise from its establishment, operation and maintenance, shall be borne by manufacturers and importers of tobacco products. Those costs shall be fair, reasonable, and proportionate: (a) to the services rendered; and (b) to the amount of unit level UIs requested over a given period of time.*
>
> *2. The ordinary costs, as applicable, of establishing, operating and maintaining the secondary repository and the router shall be passed onto the manufacturers and importers of tobacco products through the costs charged to them by the providers of the primary repositories.*
>
> *3. All extraordinary costs related to the reprocessing operations referred to in Article 28(4) charged by the provider of the secondary repository to the provider of the primary repository that made the request shall be fair, reasonable and proportionate to the services rendered. The provider of the secondary repository shall however itself bear any extraordinary costs of the reprocessing operations referred to in Article 28(4) to the extent that it is responsible for the causes leading to the reprocessing operations*" (emphasis added).

According to Article 32 of *Commission Implementing Regulation (EU) 2018/574*, the obligation to register and transmit traceability data to the repository system lies with the economic operator in possession of the goods.

Belgium's transposition

Belgium has transposed the TPD's provisions on the traceability of tobacco products in the *Royal Decree on traceability and security features for tobacco products of 7 April 2019* (hereinafter, Royal Decree).[5]

Notably, Article 3 on '*Unique Identifier*' outlines the requirements for a UI that must be affixed to each unit of tobacco packaging placed on the market. The UI is used to track the movement of tobacco products from the manufacturer to the last operator before the first retailer. Article 3(1) and (7) provide that:

[4] Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02018R0574-20231221 (accessed 30 July 2024).

[5] Arrêté royal relatif à la traçabilité et aux dispositifs de sécurité des produits à base de tabac du 7 avril 2019, available at https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/2019_04_07_ar_tracabilite.pdf (accessed 30 July 2024).

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> "*§ 1. Each unit packet of tobacco products placed on the market shall bear a unique identifier.*
> *In order to ensure the integrity of the identifier, the identifier shall be printed or affixed in an irremovable, indelible manner, and shall not be concealed or interrupted in any way, including by fiscal signs or price labels, or by the opening of the unit packet.*
>
> § 7. *Manufacturers of tobacco products shall provide all economic operators involved in the trade of such products from the manufacturer to the last economic operator before the first retailer, including importers, warehouses and transport companies, with the necessary equipment to record tobacco products purchased, sold, stored, transported or otherwise handled. This equipment shall enable the recorded data to be read and transmitted in electronic form to a data storage facility referred to in Article 4 of this Decree.*
> *In order to ensure the compatibility of the equipment supplied by manufacturers of tobacco products, economic operators shall define the technical characteristics of the equipment they need in the context of the implementation of this Order, as regards both the necessary hardware and software*" (emphasis added).

Thus, with respect to the provision of equipment, Belgium followed the text of the TPD and pursued a very literal transposition of the requirements. It should be noted that the second subparagraph to Article 3(7) of the Royal Decree additionally requires economic operators "*to define the technical characteristics of the equipment they need in the context of the implementation of this Order, as regards both the necessary hardware and software*", which is not foreseen under Article 15 of the TPD.

On 14 May 2024, the Government of Belgium notified a draft Royal Decree amending the Royal Decree through the EU's Technical Regulations Information System (hereinafter, TRIS).[6] The notified amendments foresee the following changes to Article 3 of the Royal Decree (additions underlined):

> "*§ 1. Each unit packet of tobacco products placed on the market shall bear a unique identifier.*
> *Tobacco products which do not appear on the list of validated products published by the Service on its website in accordance with Article 4, § 11, of the Royal Decree of 3 March 2024 on the manufacture and marketing of tobacco products and herbal products for smoking cannot obtain a unique identifier.*
> *(…)*
> *§ 8. Manufacturers of tobacco products shall provide all economic operators involved in the trade of such products from the manufacturer to the last economic operator before the first retailer, including importers, warehouses and transport companies, with the necessary equipment (current and future) to record tobacco products purchased, sold, stored, transported or otherwise handled. This equipment shall enable the recorded data to be read and transmitted in electronic form to a data storage facility referred to in Article 4 of this Decree.*
> *In order to ensure the compatibility of the equipment supplied by manufacturers of tobacco products, economic operators shall define the technical characteristics of the equipment they need in the context of the implementation of this Order, as regards both the necessary hardware and software.*
> *§ 9. The costs associated with the operation of the traceability system shall be reimbursed to economic operators by tobacco manufacturers. These costs shall include, inter alia, staff costs, equipment renewal and maintenance costs, and software costs*".

According to Belgium's TRIS notification, these amendments aim at avoiding "*any risk of legal uncertainty regarding the costs of the traceability system*" and to "*provide explicitly that manufacturers of tobacco products must bear, in addition to the costs already reimbursed under the current SPOC, all costs (direct and indirect) related to the traceability system for tobacco products*".

In simple terms, Belgium foresees the following changes:

[6] Draft Royal Decree amending the aforementioned as notified by TRIS Notification 2024/0257/BE (Belgium), available at https://technical-regulation-information-system.ec.europa.eu/en/notification/25882 (accessed 30 July 2024).

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- The introduction of a new requirement providing that, in order to obtain a Unique Identifier, tobacco products must figure on Belgium's list of validated products (Article 3(1) of the Royal Decree, if amended)

- The extension of the obligation to provide track and trace equipment to "*current and future*" (Article 3(8) of the Royal Decree, if amended)

- The introduction of a new obligation for manufacturers to reimburse economic operators the costs associated with the operation of the traceability system, *inter alia*, staff costs, equipment renewal and maintenance costs, and software costs (Article 3(9) of the Royal Decree, if amended)

A more detailed overview of the allocation of obligations in the framework of the track and trace system and of the functioning of the Single-Point-Of-Contact (hereinafter, SPOC) is provided in the Appendix to this submission.

3. Legal review

We believe that the amendments foreseen by Belgium's draft Royal Decree are inconsistent with the relevant legal provisions at the EU and international level. Notably, we see:

- Evident conflicts and inconsistencies with the EU's Tobacco Products Directive (TPD);

- Evident conflicts and inconsistencies with EU law more in general; and

- Evident conflicts and inconsistencies with international trade commitments and obligations.

3.1 Conflicts with the EU's Tobacco Products Directive (TPD)

First of all, and most evidently, we consider that Belgium's envisaged amendments to the Royal Decree are in conflict with the TPD and its transposition across all other EU Member States, taking into account the wording of the provision at issue, as well as its specific context and related objectives in accordance with the established method of EU legal interpretation [7].

3.1.1 The obligation is limited to the provision of equipment

We consider the introduction of a new obligation for manufacturers to reimburse economic operators the costs associated with the operation of the traceability system, *inter alia*, staff costs, equipment renewal and maintenance costs, and software costs in Article 3(8) and (9) of the Royal Decree to contradict Article 15(7) of the TPD.

In very simple and clear terms, **Article 15(7) of the TPD requires tobacco manufacturers to provide equipment** to economic operators that is necessary for the recording of the tobacco products purchased, sold, transported, or otherwise handled. Thus, it appears that this provision is clear in that it only requires tobacco manufacturers to *provide* the necessary equipment. It does not require manufacturers to cover any further operating costs of other economic operators including costs related to the equipment already provided, its maintenance, or the related staff costs, or any future costs of any kind.

[7] Please refer to Case C-425/17 *Günter Hartmann Tabakvertrieb*, para 18

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With respect to the operating costs, it should also be noted that, from a practical perspective, it would be extraordinarily difficult to separate the share of the operating costs associated with the track and trace system from the operating costs of supply chain operators' broader logistical operations.

Article 3(9) of Belgium's Royal Decree, if amended, would provide that "*the costs associated with the operation of the traceability system shall be reimbursed to economic operators by tobacco manufacturers*" and that these "*costs shall include, inter alia, staff costs, equipment renewal and maintenance costs, and software costs*".

In relation to the costs for software licenses, the European Commission's Regulatory Scrutiny Board issued an opinion on *Commission Implementing Regulation on technical standards for the establishment and operation of a traceability system for tobacco products* and provides some relevant elements of explanations.[8] In an Annex to the Opinion, the Board makes a distinction between the different types of costs related to the track and trace system, namely between capital expenditure (CAPEX), which refers to funds used by a company to acquire or upgrade physical assets, and operational expenditure (OPEX), which refers to funds spent on a day-to-day basis in order to run a business or system.[9] In the same Annex, it is clearly stated that **license costs represent operational costs** (OPEX).[10] Therefore, operational costs, since software license costs are classified as OPEX by the European Commission, should be covered by the economic operators taking part in the supply chain of tobacco products.

Finally, it should be underlined that Belgium's measure would create legal uncertainty instead of the allegedly pursued legal certainty, in that it does not comprehensively define the scope of the reimbursement obligation by only providing examples, referring to "*costs associated with the operation of the traceability system, inter alia, staff costs, equipment renewal and maintenance costs, and software costs*" (emphasis added).

3.1.2 There should be no indefinite obligation for tobacco manufacturers

Article3(8) of Belgium's Royal Decree, if amended, would provide that "*Manufacturers of tobacco products shall provide all economic operators involved in the trade of such products from the manufacturer to the last economic operator before the first retailer, including importers, warehouses and transport companies, with the necessary equipment (current and future)*" (addition emphasised), evidently expanding the obligation to provide equipment in the future.

Article 15(7) of the TPD does not contain an obligation for tobacco manufacturers to cover continuously the operational costs incurred by economic operators, namely economic operators that are responsible under the TPD and EU Member States' law to collect and transmit data. Article 15(7) of the TPD clearly limits the obligation of tobacco manufacturers to the provision of equipment only. While not further defining what the provision of equipment entails, the TPD and *Commission Implementing Regulation (EU) 2018/574* contain various obligations referring to the coverage of all costs related to a specific obligation. This is not the case with respect to the equipment, where tobacco manufacturers are only obliged to provide the equipment.

[8] REGULATORY SCRUTINY BOARD OPINION, Commission Implementing Regulation on technical standards for the establishment and operation of a traceability system for tobacco products and Commission Implementing Decision on technical standards for security features applied to tobacco products, 15 December 2017, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=PI_COM:SEC(2017)531&from=EL (accessed 30 July 2024).

[9] REGULATORY SCRUTINY BOARD OPINION, Commission Implementing Regulation on technical standards for the establishment and operation of a traceability system for tobacco products and Commission Implementing Decision on technical standards for security features applied to tobacco products, 15 December 2017, Annex B, p. 35, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=PI_COM:SEC(2017)531&from=EL (accessed 30 July 2024).

[10] REGULATORY SCRUTINY BOARD OPINION, Commission Implementing Regulation on technical standards for the establishment and operation of a traceability system for tobacco products and Commission Implementing Decision on technical standards for security features applied to tobacco products, 15 December 2017, Annex B, p. 37, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=PI_COM:SEC(2017)531&from=EL (accessed 30 July 2024). Each set of activities includes: 1) Capital costs (equipment and infrastructures, including installation); and 2) Operational costs (repair and maintenance, supplies, office and facility expenses, salaries and wages, and licences and registration).

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While it is clear that tobacco manufacturers must provide the necessary equipment, their obligation is fulfilled once the equipment has indeed been provided. Given that the TPD did not provide further rules or guidance regarding the implementation of this obligation, tobacco manufacturers established their own system, which does not foresee the physical provision of the necessary equipment, but a system of compensation that allows economic operators to purchase the equipment of their choice. Given this approach, which has been successfully in place for several years (see Appendix), tobacco manufacturers have fulfilled their obligation under Article 15(7) of the TPD once they have reimbursed the economic operator. The provision of the equipment should always be limited to such initial provision and should not extend to instances where operators require new equipment due to any other reasons, such as negligent conduct, misuse or theft.

Such interpretation, namely limiting the provision of equipment to the initial provision, is supported by various documents detailing the functioning of the traceability system and is confirmed by the transposition in all other EU Member States. Notably, the European Commission's Inception Impact Assessment regarding the implementation of Articles 15 and 16 of the TPD demonstrates that the European Commission assumed a division of the obligations resting on manufacturers and on other economic operators, which is based on a differentiation between the obligations during the deployment phase and the operational phase. During the deployment phase, the European Commission clearly refers to, *inter alia*, the manufacturers' obligation to provide equipment, while other economic operators are responsible for the integration of the equipment into their procedures. More specifically, the Inception Impact Assessment provides that:

> "*Stakeholders affected during the deployment phase:*
> - *Manufacturers – will have to adapt the production lines in order to print or affix a unique identifier and a security feature and adapt the procedures/infrastructure to provide the information related to the unique identifier. They will also have to provide all other economic operators involved in the trade of tobacco products (before the first retail outlet) with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled.*
> - *Importers – will have to secure that the supplies from non-EU manufacturers comply with Articles 15 and 16 of the TPD.*
> - *Wholesalers and distributors will have to adapt their procedures in line with the tracking and tracing requirements (e.g. the entry and exit scanning of the products).*
> - *Public authorities – will have to take the measures necessary for implementation and overview of the system deployment and to create any necessary links between the system and other parts of the control environment.*
> - *Suppliers of equipment and services – will be asked for the supply of equipment and services necessary in the deployment phase, including the establishment of the data storage facility(ies) for all the relevant data.*
> - *Transport – may be, depending on the ultimate design of the system, affected in a similar way to wholesalers and distributors; however the scope of required actions may be very limited given the likely overlaps with wholesalers and distributors (e.g. the same tracking and tracing event may not need to be recorded twice)*".[11]

During the operational phase, namely the phase when the system is in operation, the European Commission no longer refers to any obligation of manufacturers in relation to the provided equipment. Rather, it underlines the obligation of other economic operators regarding the recording of data on the movement of goods. This differentiation clearly shows that the European Commission intended from the outset to limit the provision of equipment obligation only to the deployment phase and not perpetually.

> "*Stakeholders affected in the operational phase:*
> - *Manufacturers – will have to adapt to a system of printing, affixing and verifying a unique identifier and a security feature and of recording the moves of tobacco products and the related information. Their legal sales will be better protected from counterfeit and other illicit sales.*
> - *Wholesalers and distributors – will have to record the moves of tobacco products and the related information.*

[11] European Commission, Inception Impact Assessment, Implementing and delegated acts under Articles 15(11), 15(12) and 16(2) of the Tobacco Products Directive 2014/40/EU, 5 July 2016, p. 4-5, available at https://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_694_695_696_ia_da_tpd_en.pdf (accessed 30 July 2024).

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- *Public authorities – will have to oversee and control the operations of the system, and be able to replicate the data for systematic use in control and risk management tasks. The existence of the system is likely to create savings in terms of higher efficiency of the control measures and the cross-border compatibility of the systems. Public health will gain from the reduction of illicit trade and the consequent lower accessibility of the products not in compliance with the TPD requirements and being sold at artificially low prices. As a positive side effect, the fiscal authorities may expect an increase in the tax revenues from the legal sales.*
- *Retailers – will have better reassurance about the legal status of their products.*
- *Consumers – will have access to more controlled products.*
- *Suppliers of equipment and services – will service the equipment and provide other services required for the functioning of the system, including the data storage.*
- *Transport – may be, depending on the ultimate design of the system, affected in a similar way to wholesalers and distributors; however the scope of required actions may be very limited given the likely overlaps with wholesalers and distributors (e.g. the same tracking and tracing event may not need to be recorded twice)*".[12]

In order to function, the EU TPD's track and trace system requires the engagement and compliance from all actors in the supply chain, not only from tobacco manufacturers. Economic operators beyond the tobacco manufacturers are entrepreneurs and, as such, they must assume responsibility for the business choices they make and the relevant costs of doing business in this sector. In this sense, it must be highlighted that all operators were free to choose how to organise compliance with the traceability obligations. Operators that were to choose solutions that involve periodic operational costs beyond the initial provision of the equipment should bear full responsibility for this autonomous business decision, as it would be unfair, unreasonable, and disproportionate for manufacturers to bear the risk of any business decision taken by third parties.

Given the involvement of the economic operators from manufacturing to the last economic operator before the first retail outlet, there is and must be a **shared obligation borne by tobacco manufacturers and by other economic operators, which would be disproportionately amended by Belgium's envisaged regulatory changes**.

The TPD places obligations on all economic operators involved in the trade of tobacco products, all of which participate in the track and trace system. According to Article 15(5) of the TPD and Articles 32 and 33 of *Commission Implementing Regulation (EU) 2018/574*, the obligation to register and transmit traceability data to the repository system rests with the economic operator in possession of the goods (*e.g.*, distributors, wholesalers etc.). Consequently, these operators must also assume the costs related to their business activities that have not been assigned to the manufacturers and importers by TPD or by *Commission Implementing Regulation (EU) 2018/574*.

Such interpretation is supported by various documents detailing the functioning of the traceability system and is confirmed by the transposition in all other EU Member States. Prior to the application of the traceability rules and in the context of the preparation of the relevant implementing rules, the European Commission's *Report on the Analysis and Feasibility Assessment Regarding EU T&T systems* of March 2015 clarified that, while certain costs would be borne by tobacco manufacturers, certain costs would have to be assumed by the other economic operators in the supply chain as a cost of doing business.[13] More specifically, the report provides that, except for the investment in equipment, which is required from tobacco manufacturers, the operational impact of compliance with the scanning and transmitting requirements would be expected to have an impact on the business processes of the economic operators involved in the trade of tobacco other than the tobacco manufacturers.[14]

[12] European Commission, Inception Impact Assessment, Implementing and delegated acts under Articles 15(11), 15(12) and 16(2) of the Tobacco Products Directive 2014/40/EU, 5 July 2016, p. 5, available at https://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_694_695_696_ia_da_tpd_en.pdf (accessed 30 July 2024).

[13] European Commission, Analysis and Feasibility Assessment Regarding EU systems for Tracking and Tracing of Tobacco Products and for Security Features, Final Report, p. 218, available at https://health.ec.europa.eu/system/files/2016-11/2015_tpd_tracking_tracing_frep_en_0.pdf (accessed 30 July 2024).

[14] The report provides that: "*While TPD Article 15(7) takes into account that the compliance burden for distributors is at least partially shifted to manufactures, it is anticipated that beyond the investment in equipment for the operation of the traceability solution itself, that the operational impact on business processes to comply with requirements to record the receipt, movement and dispatch of tobacco products may result in some operators determining that the cost of the impact does not justify the revenue contributions of tobacco products in their distribution portfolio*".

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3.1.3 The EUTPD does not contemplate the reimbursement of costs

Article 3(9) of Belgium's Royal Decree, if amended, would provide that "*the costs associated with the operation of the traceability system shall be reimbursed to economic operators by tobacco manufacturers*" and that these "*costs shall include, inter alia, staff costs, equipment renewal and maintenance costs, and software costs*".

On the mere basis of the TPD and current transpositions across EU Member States, tobacco manufacturers would be legally allowed to physically provide the necessary equipment to the other relevant economic operators. For purposes of facilitation and given the considerable number of operators involved, tobacco manufacturers set up the SPOC, which provides economic operators with the possibility to purchase themselves the relevant equipment, but to be compensated for such purchase by the tobacco manufacturers. This system was entirely set up on a private basis to allow for the proper and efficient implementation of the legal requirements.

Notably, the TPD and current transpositions across EU Member States do not rely on any concept of reimbursement but require tobacco manufacturers to "*provide*" equipment. The SPOC approach was developed by tobacco manufacturers in their pursuit of finding a practical way of implementing the obligation of providing equipment. Belgium now intends to introduce the concept of "*reimbursement*" into its legal framework, leading to a misalignment of the TPD and the Belgian transposition. This could constitute an important precedent of EU Member States developing different approaches to implement the obligations under the TPD, jeopardising the current framework, which has proved workable and simple to use.

3.1.4 The role of the Sub-Group on '*Traceability and Security Features*'

While we recognise the relevance and importance of the Expert Sub-Group on "*Traceability and Security Features*", composed of officials from the European Commission and from EU Member States, we object to referring to this Sub-Group as an alternative legislator or, at least, delivering the blueprint for legislative or regulatory initiatives by individual EU Member States.

With respect to the envisaged amendments of the Royal Decree, Belgium largely relies on discussions within the EU's Expert Sub-Group on "*Traceability and Security Features*". More specifically, in its notification, Belgium notes that:

> "*During the meetings of the expert sub-group on "Traceability and safety features" on which the European Commission and the Member States jointly sit, it was clarified that the obligation to reimburse tobacco tracing equipment is not limited to a single payment for the purchase of equipment. On the contrary, it is a permanent and continuous obligation on the part of manufacturers of tobacco products.*
>
> *The report of 14 February 2019 states as follows: "The group agreed that a one-time payment to economic operators would not be compliant with the obligations set out in that provision. (…). Reading and transmitting of data was an ongoing obligation that applied to economic operators for as long as they would be involved in the trade of tobacco products. The group regarded it was unlikely that any equipment provided would be able to fulfil this obligation over a longer period without requiring maintenance, or even replacement."*
>
> *The additional costs necessary to maintain, refurbish or replace the installed equipment therefore also fall under the obligation to reimburse the tobacco manufacturer. The maintenance, refurbishment and replacement of equipment is indeed necessary to enable economic operators to register tobacco products, and therefore fall within the scope of the obligation on manufacturers of tobacco products to provide all economic operators involved in the trade in those products with the equipment necessary to register those products. The related costs must therefore be considered necessary for the registration of tobacco products within the meaning of Article 15(7) of the Tobacco Directive*".[15]

[15] TRIS, Notification Detail, Royal Decree amending the Royal Decree of 7 April 2019 on the traceability and safety features of tobacco products, available at https://technical-regulation-information-system.ec.europa.eu/en/notification/25882 (accessed 30 July 2024).

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On this basis, Belgium then concludes in its notification that:

> "*In order to avoid confusion and any risk of legal uncertainty regarding the costs of the traceability system, it is appropriate to amend the Royal Decree of 7 April 2019 and to provide explicitly that manufacturers of tobacco products must bear, in addition to the costs already reimbursed under the current SPOC, all costs (direct and indirect) related to the traceability system for tobacco products. It will then be up to economic operators to agree how these costs are to be borne by manufacturers of tobacco products, for example through a fixed fee per unit of sale of tobacco products*".[16]

Despite being a relevant *forum* for discussion, the Expert Sub-Group on "*Traceability and Security Features*" does not have any authority to legislate and regulate and **should not serve as a '*blueprint*' for regulatory changes** by individual EU Members States, without first consulting with the other EU Member States on a harmonised approach. If the European Commission and EU Member States gathered in the Expert Sub-Group were to identify an issue in the applicable legislation, such as in the TPD and related transposition measures in EU Member States, such issue should be collectively addressed at the EU level and then implemented in a harmonised way across all EU Member States.

3.2 Conflicts with general EU law

Beyond the evident issues with respect to the TPD and the transpositions in other EU Member States, there are also a number of more general EU law considerations that should be factored in.

The amendments pursued by Belgium contradict provisions of the Treaty on the Functioning of the EU (hereinafter, TFEU) on the harmonisation and approximation of rules within the EU Single Market, as well as the provisions on the free movement of goods, and contradict general principles of EU law, notably on proportionality.

3.2.1 Proportionality

The general principles of EU law include the principle of proportionality, set out in Article 5 of the Treaty on European Union (TEU) and Article 52 of the Charter of Fundamental Rights of the European Union, and recognised by the Court of Justice of the EU (CJEU) as a general principle of EU law.[17]

According to this principle, measures adopted by EU institutions must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question. This principle must also be applied to the transposition of EU legal instruments into national EU Member States' legal systems. Depending on the measure and the legal provisions at issue, the considerations by the CJEU have varied over time, but can be summarised in a three-step test:

1) Whether the measure is appropriate to attain a legitimate objective?

2) Whether the measure is beyond necessary / Whether there are any less restrictive means to achieve it?

3) Whether the measure has an excessive impact on the applicant's interests?

[16] TRIS, Notification Detail, Royal Decree amending the Royal Decree of 7 April 2019 on the traceability and safety features of tobacco products, available at https://technical-regulation-information-system.ec.europa.eu/en/notification/25882 (accessed 30 July 2024).

[17] See for instance paragraph 13 of C-331/88 R v Minister of Agriculture, Fisheries and Food ex parte Fedesa, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61988CJ0331 (accessed 30 July 2024).

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Legitimate objective?

Belgium's draft Royal Decree pursues the stated objective of avoiding "*confusion and any risk of legal uncertainty regarding the costs of the traceability system*".[18] As noted above, Article 15(7) of the TPD, as currently transposed by Belgium in Article 3(7) of the Royal Decree, it appears clear in that it only requires the provision of the equipment.

Beyond necessary / less restrictive means

This proposed amendments and additional requirements appear **unnecessary and more restrictive than necessary**, given that the system currently functions well without such requirements. This concerns the significant expansion of the costs to be borne by tobacco manufacturers, as well as the requirement for tobacco products to figure on Belgium's list of validated products in order to obtain a Unique Identifier.

Less restrictive and less '*business invasive*' alternative means are clearly available, given that the system currently in place in Belgium and throughout the EU works well, has been delivering effective '*tracking and tracing*', has not placed a disproportionate burden on economic operators, and has allowed EU Member States and the tobacco industry to pursue the underlying objective of fighting illicit trade.

Excessive impact

The measures proposed by Belgium to amend the Royal Decree are disproportionate, as they have an excessive impact on tobacco manufacturers. Notably, Article 3(8) and (9) of the Royal Decree, if amended, would significantly expand the burden and costs imposed on tobacco manufacturers. Consequently, this would require tobacco manufacturers to significantly re-organise and modify their trading processes only for the Belgian market, which is beyond what is necessary to establish a well-functioning tracking and tracing system as specified under Article 15 of the TPD.

Implementing the requirements of Article 3(8) and (9) of the Royal Decree, if amended, would be **prohibitively costly and unworkable for manufacturers**, since the envisaged amendments would require manufacturers to not only reimburse the provision of the equipment necessary for compliance with the traceability requirements, but would also extend the reimbursement to any "*costs associated with the operation of the traceability system*", such as "*staff costs, equipment renewal and maintenance costs, and software costs*".

Notably, the monitoring, calculation, and review of these costs would be impossible or complex and costly on the part of the tobacco manufacturers, as there would be, *de facto*, no limits to such costs. In fact, economic operators might not have incentives to manage costs efficiently if they know that they would be reimbursed, potentially leading to inflated costs and, consequently, potentially negatively impacting consumers due to the impact on pricing across the supply chain.

Thus, the proposed measure would lead to **significant commercial unpredictability** for tobacco manufacturers. Additionally, tobacco manufacturers would not be able to influence several of these cost items, especially as they relate to equipment maintenance, staff costs, software development or licenses, or software and hardware parameters. The cost of performing a legitimate business activity in Belgium would be outside of the control of tobacco manufacturers, creating unstable conditions for them.

As noted above, in addition to the obligation to provide the necessary equipment to the economic operators, tobacco manufacturers also bear all reasonable and proportionate costs for the repository system. Since economic operators send their traceability data directly to the router and secondary repository, the costs for the transfer of such data from them to the repository system are already borne, in their entirety, by tobacco manufacturers.

[18] Draft Royal Decree amending the aforementioned as notified by TRIS Notification 2024/0257/BE (Belgium), available at https://technical-regulation-information-system.ec.europa.eu/en/notification/25882 (accessed 30 July 2024).

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In view of the above, any claimed allocation of economic operators' further operational costs would **contradict the EU principle of proportionality** that governs the obligations of manufacturers and would not take into account that other economic operators, beyond the tobacco manufacturers, also have to assume operational costs related to their own obligations to record and transmit data to the repository systems.

3.2.2 Contrary to the principle of harmonisation and approximation

The '*Approximation of Laws*' refers to a process where national laws of EU Member States are harmonised to align with a broader set of regulations. It ensures consistency and understanding between different jurisdictions across the EU.

In fact, one of the legal bases for the TPD is Article 114 of the TFEU, which allows the European Parliament and the Council of the EU to adopt measures that standardise regulations across EU Member States, "*which have as their object the establishment and functioning of the internal market.*", preventing or removing obstacles to trade within the internal market. The principle of Article 114 of the TFEU is replicated in Article 24 of the TPD on '*Free movement*', which provides that:

> "*Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.*"

An objective of the TPD is the approximation of laws to ensure the functioning of the EU internal market, as evidenced by Article 1 of the TPD:

> "*The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:*
> *(…)*
> *(b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products to ensure their compliance with this Directive;*
> *(…)*
> *in order to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the Union under the WHO Framework Convention for Tobacco Control ('FCTC').*"

The traceability system under the TPD is a measure that is, *inter alia*, destined to facilitate the functioning of the EU Internal market and to promote the free movement of tobacco products, including by strengthening the fight against illicit trade in tobacco products.

In view of these objectives related to the functioning of the EU Internal market and the harmonisation of requirements throughout the EU and across EU Member States, an EU Member State should not impose any additional requirements or amend the allocation of obligations (and related costs) foreseen by the TPD and by *Commission Implementing Regulation (EU) 2018/574*.

Any significant deviation from the rules harmonised by the TPD would lead to a disparity of requirements creating unequal conditions for manufacturers operating in different EU Member States and would risk jeopardising the very objective of harmonisation and fragmenting the EU internal market. Tobacco manufacturers relying on logistics chains in Belgium would not be indifferent to these changes, as tobacco manufacturers operating in other EU Member States where this requirement would not be imposed, would not be subject to the same ongoing costs and logistical challenges, leading to a competitive imbalance.

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The envisaged rules would put economic operators in Belgium in an advantageous position compared to economic operators in other EU Members States and this would create an important misalignment among EU Member States.

With its envisaged amendments to the Royal Decree, Belgium would not merely "*clarify*", as it asserts, the rules contained in the TPD and in Belgium's transposition, but it would instead **establish new rules and obligations**, notably for tobacco manufacturers. While it is indeed not uncommon that EU Member States legislate to a certain degree beyond the confines of a Directive (an occurrence known as '*gold-plating*'), such legislating may not contradict the Directive being transposed. Belgium is doing just that with its envisaged measures, which would go **significantly beyond the provisions of the TPD** as currently transposed in Belgium.

3.2.3 Implications for the EU freedoms in the EU internal market

As detailed above, Article 15(7) of the TPD clearly provides that "*the manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products (…) with the equipment that is necessary for the recording of the tobacco products*". By significantly expanding the obligations for tobacco manufacturers, notably regarding the costs to be borne by tobacco manufacturers that move their goods within and through Belgium, there would be a difference between the costs borne by tobacco manufacturers pursuing activities in Belgium, on the one hand, and by tobacco manufacturers pursuing activities in another EU Member State, on the other hand. The extra costs would not be incurred for the same activities in other EU Member States.

The increased costs to be borne by tobacco manufacturers, encroach on and restrict certain freedoms guaranteed within the EU internal market and enshrined in the EU treaty. Belgium's envisaged amendments should notably be considered in light of the free movement of goods within the EU internal market.

Articles 34 and 35 of the TFEU provide that quantitative restrictions on imports and exports and all measures having equivalent effect are to be prohibited between EU Member States. The CJEU has rather broadly defined "*measures having an effect equivalent to quantitative restrictions*" as "*All trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade*".[19]

By expanding the obligations imposed on tobacco manufacturers, contrary to what is foreseen under Article 15(7) of the TPD, the proposed amendments of the Royal Decree could be considered as constituting a **measure having an effect equivalent to quantitative restrictions** and could, therefore, violate Articles 34 and 35 of the TFEU. This system would increase the operating costs and reduce the ability of tobacco manufacturers to have seamless logistics and supply chains within the EU given that, when and if their products are distributed through Belgium, the additional costs incurred because of the application of the proposed measure would make the use of Belgium as a hub prohibitive or no longer tenable. Tobacco manufacturers would face higher costs and would likely need to change their distribution processes and paths, thereby negatively impacting the free movement of goods across the EU, notably by avoiding manufacturing and/or shipping goods through Belgium.

3.2.4 Linking the Unique Identifier with the list of validated products creates a barrier to trade

The new proposed requirement that, in order to obtain a Unique Identifier, tobacco products must figure on Belgium's list of validated products, would pose problems for products not intended for the Belgian market but being intended to be manufactured and/or shipped through or from Belgium.

The measure by which products that do not figure on the list of validated products may not obtain a Unique Identifier could be considered a market barrier. While, in theory, this requirement could be complied with for products destined

[19] Case C-8/74 Dassonville.

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for the Belgian market, as these products must figure on the list of validated products on the basis of Article 4(11) of Belgium's *Royal Decree relating to the manufacture and marketing of tobacco products and herbal smoking products*, it could create a significant problem for products manufactured in Belgium and being shipped through Belgium, but destined for other EU Member States' markets or exported to third country markets, products which would not or not necessarily figure on the list of validated products and for which it would become impossible to comply with the mandatory TPD requirements.

Furthermore, paragraph 1 of Article 4 of *Commission Implementing Regulation (EU) 2018/574* on '*Competent ID issuers for generating and issuing unique identifiers*' defines the competent ID issuer as follows:

> *"For tobacco products manufactured in the Union, the competent ID issuer shall be the entity appointed for the Member State in which the products are manufactured.*
>
> *By derogation to the first subparagraph, the competent ID issuer shall be the entity appointed for the Member State on whose market the products are placed, where such a requirement is imposed by that Member State."*

Thus, it is unclear how the proposed requirement to link the issuance of the Unique Identifier with the list of validated products for Belgium could be complied with even for products intended to be place on the Belgian market for which: (i) Unique Identifiers are obtained by an ID issuer in another EU Member State on the basis of the first sub-paragraph Article 4(1) of *Commission Implementing Regulation (EU) 2018/574*; or (ii) Belgium has appointed an ID issuer by derogation on the basis of Article 4(1), second sub-paragraph, in case the ID issuer is not a Belgium-based legal entity. Thus, it remains unclear on what legal basis the business activity of such entities based outside of Belgium, whose activities as ID issuers are regulated by the local legislation in the respective EU Member States, would be conditioned with respect to the requirements related to the list of validated products in Belgium, given that there would be no such requirement neither in the EU track and trace legislation nor in the local legislation of any other EU Member State. If implemented, Belgium's draft Decree would cause significant operational issues on the EU internal market.

Under Article 36 of the TFEU, Belgium would need to justify any such restrictions, but it is not clear to what extent, if at all, the proposed amendments are necessary to achieve the relevant objectives of the overall measure, namely those of addressing illicit trade and the related threats to public health, and how they could be justified. Given that the currently used system (*i.e.*, based on the SPOC and the provision of the equipment through reimbursement) can be considered as a reasonably available alternative that is less trade restrictive and that has so far adequately contributed to the fulfilment of the objective of preventing illicit trade, it would be difficult for Belgium to demonstrate that the proposed measure is indeed needed and justified.

3.2.5 Freedom to conduct a business

Article 16 of the Charter of Fundamental Rights of the EU on '*Freedom to conduct a business*' provides that:

> "*The freedom to conduct a business in accordance with Community law and national laws and practices is recognised*".

The freedom of individuals and enterprises to engage in economic activity, to enjoy freedom of contract and to compete freely in the market is, therefore, protected as an EU fundamental right.

The proposed amendments would **infringe on tobacco manufacturers' freedom to engage in economic activity**, as they would require tobacco manufacturers to reimburse the costs of doing business incurred by other economic operators, notably by extending the reimbursement obligation also to staff costs, as well as with respect to equipment maintenance, software development or licenses, or other software and hardware parameters. Given the way that the SPOC system has been conceptualised, tobacco manufacturers are not party to the contracts between

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economic operators and the suppliers of the hardware and the software, which prevents them from being able to negotiate these costs as a matter of freedom of contract. The amendments proposed by Belgium would **fundamentally interfere with the usual business conduct**.

The proposed amendments look poised to significantly impact the business decisions by tobacco manufacturers. When deciding where and how to conduct business activities, businesses naturally consider a multitude of factors, such as logistical, geographical, and fiscal aspects. While tobacco manufacturers could still decide to establish or maintain a distribution centre in Belgium, they would then see their freedom to conduct business significantly curtailed by the additional costs entailed by doing business in Belgium, due to the different rules on the elements covered by the reimbursement obligation.

Additionally, the new obligations imposed on tobacco manufacturers with respect to the reimbursement of costs associated with the operation of the traceability system (i.e., *inter alia*, staff costs, equipment renewal and maintenance costs, and software costs) would interfere with the current compensation system under the SPOC.

3.2.6 Negative implications for market competition

It should also be noted that the proposed amendments would likely create a situation where manufacturers dealing with a single distributor (or fewer distributors) incur significantly lower traceability related costs compared to those that supply many wholesale customers. This would constitute a **direct interference with the competition on the EU market** and a potential distortion of the EU single market.

Additionally, the disproportionate obligations on tobacco manufacturers operating in Belgium could deter manufacturers from other EU Member States from entering (or staying in) the market, reducing market competition and limiting consumer choice.

3.3 Conflicts with international trade rules – Barriers to trade

The amendments foreseen to Belgium's Royal Decree should also be considered in view of Belgium's and the EU's international trade commitments, notably as certain elements of the proposed rules could be perceived as technical regulations posing unnecessary barriers to trade.

3.3.1 The draft Royal Decree is a technical regulation that should be notified to the WTO and WTO Members

The draft Royal Decree contains technical regulations within the meaning of Annex 1 paragraph 1 of the World Trade Organization's Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement) because the proposed Article 3(1) establishes a product characteristic by requiring that each unit packet of tobacco products placed on the Belgian market must bear a Unique Identifier and because compliance with that requirement is mandatory for the tobacco products to be placed on the market.

Article 2.9 of the TBT Agreement requires WTO Members to notify other WTO Members of a proposal to introduce or amend a particular technical regulation and to "*allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account*". The TPD and *Commission Implementing Regulation (EU) 2018/574* have both been notified to the WTO TBT Committee. However, it appears that, despite containing technical regulations, **Belgium's draft Royal Decree has not been notified to the WTO**, thus not informing other WTO Members of the draft Royal Decree and depriving them of their right to submit comments and try to minimise the trade restrictive and disproportionate features or effects of the proposed measure.

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3.3.2 Linking the Unique Identifier with the list of validated products creates unnecessary obstacles to trade

On the substance, under Article 2.2 of the TBT Agreement, WTO Members must "*ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade*".

Belgium's draft Royal Decree unjustifiably exceeds the requirements of the TPD and of *Commission Implementing Regulation (EU) 2018/574* by providing that tobacco products must appear on the list of validated products in order to obtain a Unique Identifier. This provision implies that, if a tobacco product is not validated and has not been added to the list, it may not be legally placed on the market, as it would not be able to obtain the Unique Identifier. The requirement for Unique Identifiers also concerns products manufactured in Belgium but destined for other EU Member States' markets and for products manufactured in the EU and later exported from the EU to third country markets, with those products not necessarily figuring on the list of validated products. For instance, a product manufactured in Belgium and destined for the US market with specific characteristics (e.g., ingredients) not allowed for the Belgian market, would not figure on the list of validated products, would not be eligible to obtain a Unique Identifier and would, therefore, not be able to be shipped within and exported from the EU.

Therefore, the measure, notably that tobacco products must appear on the list of validated products in order to obtain a Unique Identifier, **creates unnecessary obstacles to international trade contrary to Article 2.2 of the TBT Agreement**. When adopting technical regulations, Belgium is required to ensure that they are not more trade-restrictive than necessary to fulfil the stated objective in order not to create unnecessary obstacles to international trade. The word "*necessary*" requires a test of proportionality regarding the trade-restrictiveness of the measure; as the track and trace system has been functioning well in Belgium until now, the new requirement cannot be considered as proportionate for these purposes.

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Appendix: Brief overview of the functioning of the Single-Point-Of-Contact (SPOC)

Article 15(7) of the TPD requires tobacco manufacturers to provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported, or otherwise handled.

This requirement has been transposed into the local legislation of EU Member States. In the absence of any applicable procedure on how this requirement is to be implemented and complied with, the manufacturers of tobacco products have established the Single Point of Contact (SPOC) as an EU-wide, joint industry reimbursement model, which has been operating since 2019.

SPOC is a model that is open for the entire tobacco manufacturing industry and, currently, 25 tobacco manufacturers across Europe (18 of which in Belgium) participate. The single objective of SPOC is to provide an efficient way for manufacturers to fulfil their legal obligations under the TPD and national EU Member States' law to the benefit of eligible economic operators who are able to receive sufficient financing to equip themselves with the equipment of their choice required to comply with their traceability obligations for tobacco products.

SPOC provides economic operators with the possibility to submit claims for reimbursement for equipment through an easy-to-use and entirely online process on the *OnTrack* website. The portal is operated by SGS as an independent third-party provider, thus ensuring a professional and objective approach. The model considers the business needs of each applicant while applying the same reimbursement principles to all operators in the EU in a transparent and fair manner. The reimbursement is provided to the requesting economic operators at once from all participating manufacturers instead of operators having the need to reach out to each individual tobacco manufacturer. The same equipment can be used to scan all products irrespective of their type or manufacturer, which requires the cost for the equipment to be shared among manufacturers. While the applicable legislation does not give an answer to the question how this should be done in practice, the SPOC model offered a solution for manufacturers to comply with the law and for economic operators to receive their reimbursement.

To date, the SPOC model has been successfully utilised by nearly 14,000 economic operators, which is estimated to represent over 90% of the relevant economic operators across the EU. By making monetary payments, SPOC provides economic operators with maximum flexibility to choose their preferred suppliers of equipment including with regard to different conditions related to the software for the operation of the equipment.

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