

e-Cigarettes

How to consider e-Cigarettes under **EU-MDR (EU)**
2017/745 **and UK-MDR**

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1 Purpose

This procedure explains the process for handling proposals received by BSI Notified Body in respect of Delivery System (i.e., e-Cigarettes) for Nicotine Containing Product (NCP) which the manufacturer claims a medical application (i.e., Medical-NCP).

2 Scope

The scope of this procedure is limited to the Delivery System (i.e., e-Cigarettes) of the Nicotine Containing Product for which the manufacturer claims a medical application (i.e., Medical-NCP). In case the Delivery System for Medical NCP is sold as a separate device, it should meet the requirements laid down in the Medical Device Regulations.

This document clarifies the legislation related **Nicotine Containing Products (NCP)** and BSI's position on e-Cigarettes (or similar products), on how they are regulated and the role of the Notified Body in the regulation of the following products:

- Nicotine Containing Products (**NCP**)
- Electronic Cigarettes or e-cigarette

Electronic Cigarettes or e-cigarette means a product that can be used for consumption of nicotine-containing vapour via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. e-Cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single-use cartridges.

3 Legislation for Nicotine Containing Products (NCP)

Two EU-directives may apply in the regulation of Nicotine Containing Products (**NCP**):

- 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. (as published 29 April 2014) (**TPD**)
- DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use. (**MPD**)

However, only one of the two directives can be applied for the NCP. The appropriate directive will be determined by the manufacturer's claims and specifications.

3.1 DIRECTIVE 2014/40/EU - Tobacco Products Directive (TPD)

Nicotine as a chemical substance is not considered as a medicinal product provided the manufacture does not make any medical claims and the criteria set out below are satisfied:

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- a) nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2ml.
- b) the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.

If the criteria defined above are met **and** there are **no** medical claims, the (non-medical) NCP (and its delivery system) will fall under the TPD.

The EU Tobacco Products Directive has been revised by the "Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products" (as published 3 Nov 2022 and effective on 23 Nov 2022).

Introduction of a new 'Novel tobacco products' category into the TPD, which encompasses all tobacco products not falling under the one previously mentioned and that are placed on the market after May 19, 2014. Following the "Commission Delegated Directive (EU) 2022/2100 ", 'novel tobacco products' include 'Heated Tobacco Products,' which are defined as a product "that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s), and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking."

In addition, the European Commission is currently reviewing the Tobacco Products Directive, aiming to address issues such as further enforcement of the current regime for cross-border distance sales, emerging novel tobacco products, regulatory challenges posed by heated tobacco products and electronic cigarettes, new herbal products entering the market, and options to increase tobacco manufacturers' liability. According to the European Commission's Implementation Roadmap of Europe's Beating Cancer Plan, the Commission is expected to adopt a proposal for the revision of the Tobacco Products Directive sometime in 2024.

3.2 DIRECTIVE 2001/83/EC - Medicinal Product Directive (MPD)

In case one of the criteria of TPD is **not** met and/or there are medical claims for the **NCP (Medical-NCP)**, the Medical-NCP shall be considered a **medicinal** product under the MPD.

Addiction to a chemical substance is a medical condition and any product which claims to treat an addiction with supportive clinical data falls under this Medicinal Product Directive.

Examples of Medical Claims Include:

- [Product] relieves and/or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them.
- [Product] is indicated in pregnant and lactating women making an attempt to quit.

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3.3 UK's Legislation: The Tobacco and Related Products Regulations 2016 (TRPR)

The UK Tobacco and Related Products Regulations 2016 implemented the **TPD** in full.

The Tobacco and Related Products Regulations 2016 were subsequently amended by "The Tobacco Products and Nicotine Inhaling Products (Amendment)(EU Exit) Regulations" 2019 and 2020 to enable tobacco and e-cigarette regulation to continue to function following the UK's withdrawal from the EU.

The requirements main points are summarised below:

- restrict e-cigarette tanks to a capacity of no more than 2ml
- restrict the maximum volume of nicotine-containing e-liquid for sale in one refill container to 10ml
- restrict e-liquids to a nicotine strength of no more than 20mg/ml
- require nicotine-containing products or their packaging to be child-resistant and tamper evident
- ban certain ingredients including colourings, caffeine and taurine
- include new labelling requirements and warnings
- require all e-cigarettes and e-liquids be notified and published by the MHRA before they can be sold.

The 2020 Regulations sets out the requirements for new products to be notified from 1 January 2021.

This will mean that:

Producers placing products on the Northern Ireland market will be required to notify using the EU Common Entry Gate (EU-CEG) system for the notification of tobacco and e-cigarette products.

The Tobacco and Related Products Regulations 2016 do not cover nicotine-containing products that are authorised as medicines.

4 Electronic Cigarettes regulated under Medical Device Legislation

4.1 EU-Medical Device Legislation

In case the delivery system (i.e., the e-cigarette) for the Medical-NCP will be marketed as a separate product, the delivery system requires CE certification under the Medical Device Directive [Directive 93/42/EEC (MDD)] or Medical Device Regulation [(EU) 2017/745 (MDR)].

Note, the EU-MDD has been repealed by the EU-MDR on 26 May 2021. The requirements as listed in the repealed MDD continue to be applicable under the UK per UK-MDR-2002 (Part II).

Single integrated product (combination product)

Where the device and the medicinal product such as one-piece disposable e-cigarettes form a single integrated product designed to be used exclusively in the given combination and which is not refillable the whole product will be regulated as a medicinal product and require a marketing authorisation. However, the 'device' elements will need to meet the relevant General Safety and Performance Requirements of Annex I of EU Medical Devices Regulation ((EU) 2017/745).

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4.2 UK-Medical Device Legislation

Impact of medical device regulations for TPD placed in the UK

Product consisting of separate parts.

Where the e-cigarette device and the nicotine-containing medicinal product are separate entities and the device may be re-used or re-filled, for example an e-cigarette that has separate cartridges, then the device will need to be CE / UKCA (as applicable) marked as a medical device under the appropriate legislation.

Single integrated product (drug-device combination product).

In addition, where the device and the medicinal product form a single integrated product designed to be used exclusively in the given combination and which is not refillable the whole product will be regulated as a medicinal product and require a marketing authorisation. The device elements of the combination product will need to meet the relevant Essential Requirements of Annex I of the Medical Device Directive 93/42/EEC transposed through the UK Medical Devices Regulations 2002 (SI 2002 No 618) as amended (in the form that they exist on 1 January 2021). This transposes the three repealed EU Directives on Medical Devices (i.e., the Medical Devices Directive (93/42/EEC) and AIMDD (90/385/EEC) and IVDD (98/79/EC) into UK law.

Moreover, it is important to note that the demonstration of conformance of Essential Requirements under Annex I of MDD will be done in the manufacturer's Marketing Authorisation Application (**MAA**) and is outside the remit of Notified Bodies.

From 26 May 2021 the EU Medical Devices Regulation ((EU) 2017/745) fully applies in Northern Ireland and the EU. The 'device' elements must meet the General Safety and Performance Requirements as set out in Annex I of this regulation for purposes of the Northern Ireland market and apply to applications for UK wide marketing authorisations. In that case it is not necessary to separately comply with the Essential Requirements of the Medical Devices Directive.

5 Process

5.1 Role of the manufacturer

The manufacturer should submit an application for market authorization of a Medical-NCP to the Competent Authority because approval for market authorization of the NCP is within the remit of the Competent Authority, e.g., UK MHRA or NL's Medicines Evaluation Board (**MEB**) which is part of the Dutch Ministry of Health, Welfare and Sport [In Dutch: College ter Beoordeling van Geneesmiddelen (**CBG**) part of Ministerie van Volksgezondheid, Welzijn en Sport (VWS)].

In case the delivery system (i.e., the e Cigarette) for the Medical-NCP is to be marketed as a separate product it:

- Requires **EC**-certificate under the MDD from a MDD designated Medical Devices Notified Body as issued prior to May 2021. Because the MDD was repealed May 2021, an existing EC-Certificate cannot be renewed, or
- requires a valid **EU**-Certificate under the EU-MDR from a MDR designated Medical Devices Notified Body. Hence, the manufacturer should submit an application for **EU**-Certification under MDR for the e Cigarette to a Notified Body,

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- For the time being, for existing products (separate delivery devices/separate parts) that are CE marked [based on a valid EC-Certificate] are accepted in the product registration process in the UK.

For new products with separate delivery device (i.e., separate parts), an application should be submitted to a UK Approved Body for UKCA Certification of the separate parts of the device.

Note, applications for the Medical-NCP and the e Cigarette (supplied separately from the Medical-NCP) may be submitted simultaneously and Conformity Assessments activities can run in parallel.

5.2 Role of BSI as Medical Devices Notified Body

Note, the Notified Body has **no** involvement in the approval of the marketing authorization of a Medical NCP. However, where the intended purpose of the e-Cigarettes (if supplied separately from the Medical-NCP) will **not** be *cessation of addiction to nicotine* since the NCP is making this claim. The intended purpose of the e-cigarette will be to deliver the drug. Hence it is considered a drug delivery device

If supplied separately (without the Medical-NCP), the delivery part of the Medical-NCP - referred to as "e-cigarette" - will be regarded as a medical device and will require to be EU Certified under the Medical Device Regulation.

In addition, where the device and the medicinal product form a single integrated product (drug-device combination) designed to be used exclusively in the given combination and which is not refillable the whole product will be regulated as a medicinal product and require a marketing authorisation. The device elements of the combination product will need to meet the relevant General Safety and Performance Requirements of Annex I of EU Medical Devices Regulation ((EU) 2017/745) or Annex I of the Medical Device Directive 93/42/EEC transposed through the UK Medical Devices Regulations 2002 (SI 2002 No 618) (See section 4.3) whichever is applicable.

Those regulations also require the device components to have undergone an assessment by an EU Notified Body to demonstrate compliance with the General Safety and Performance Requirements of the regulation and that the assessment of the EU-designated Notified Body will need to be submitted with the MAA.

Refer to **MDP4566** (*Assessment of Medicinal Products with Integral Device Parts Under Article 117*) which describes the process for conformity assessment of medicinal products with integral device parts described in Article 117 of the Medical Devices Regulation (EU) 2017/745 (MDR).

5.2.1 BSI Policy of when to issue a CE certificate

The application for conformity assessment submitted to the Notified Body for the e-Cigarettes can take place in parallel to the marketing authorization application lodged with a Competent Authority for the medicinal product (NCP).

An **EU-certificate** for the separately sold delivery system, i.e., *e-cigarette* can be granted once all the applicable conformity assessments have successfully been completed.

As a part of the conformity assessment of the e Cigarette, the **Notified Body**

- should obtain from manufacturer:
 - evidence of the medical claim, or
 - a medicinal product licence for the NCP to be used with the Cigarettes, or

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- evidence that the manufacturer has applied for a medicinal product licence (e.g., PL number, CA letter).
- Complete the Notified Body's conformity assessment activities (incl. QMS Audits (Stage 1 & Stage 2) and Technical File Assessment).

An EU-certificate can be granted once all NB conformity assessment activities and Medicines Agency conformity assessment activities have successfully been completed.

5.3 Role of BSI as Medical Devices UK Approved Body

For UKCA certification process within BSI, please refer to MDP8900 (UKCA Certification Scheme Manual) for further guidance.

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Revision History

Rev No	Revision Date	Author	Sec. No	Brief Description of Change
0	Nov 2020	A Ahmed	all	- MDP4567 issued to replace MDP7001. Justification: Scope change: The requirements of the MDR are added to the procedure. As a consequence, the MDP7001 will be obsoleted since MDP7xxx is used exclusively for directives. The procedure will continue under MDP4567 (combining the procedure for Directive and Regulation) In comparison to MDP7001: - New Document Owner for MDP4567 - title of document includes MDR in addition to MDD
1	April 2024	A Ahmed	Title 1 3.2 3.3 5.3 Rev Hist Rel Docs	Change in subtitle Update to section 1 Purpose to include the following information: - Revision of the Tobacco Products Directive - UK only Legislation: The Tobacco and Related Products Regulations 2016 ((TRPR) - Impact of medical device regulations for TPD placed in the UK - Integral combination of medicinal product and medical device-one-piece disposable e-cigarettes Update to section 3.2 Role of BSI as Medical Devices Notified Body in relation to medicinal product and medical device containing one-piece disposable e-cigarettes Section 3.3 BSI Policy of when to issue a CE certificate renumbered to Section 5.2.1 New section 5.3. Role of BSI as a UK Medical Devices Approved Body referencing MDP8900 UKCA Scheme Manual Rev History moved to end of document per MDP2200 Related Documents section removed. References listed in associated GF070. This procedure does not include references to BSI Procedures and forms.

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