



Navigating Article 117

*Practical and Insightful Compliance
Guidance for Combination Products*

16 July 2026

Thank you for joining our webinar

- An opportunity to understand some key aspects of the MDR through the vision of a full scope NB and UK Approved Body.

A couple of details

- Your microphones are on mute
- **Any question?** During the webinar you can ask your question in the chat, writing in the box on the right of your screen
- We will try to answer at the end



No questions yet

Questions from your attendees will appear here.

 **Submit a question** 

Enter your question

Our speakers today

Theresa Jeary



*Global Head of Medicinal &
Biologics, Regulatory Services - BSI*

Pilar Maldonado



*Business Development Manager –
BSI*

BSI



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Software as Medical
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Active

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Orthopaedic and Dental

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LEAD TIME & CAPACITY

[bsi-md-nb-capacity-lead-times-en-gb.pdf](https://www.bsi.com/bsi-md-nb-capacity-lead-times-en-gb.pdf)





Leading Notified Body for the provision of MDR Article 117 Notified Body Opinion (Nbo)

- First NB to issue NBO
- 75% of total NBO released





Time to Hear from You ?





Navigating Article 117

Practical and Insightful Compliance
Guidance for Combination Products

Theresa Jeary, Global Head Medicinal & Biologics Team
2026-16-07



Welcome & Introduction

Notified Body Opinion (NBOp)
Process

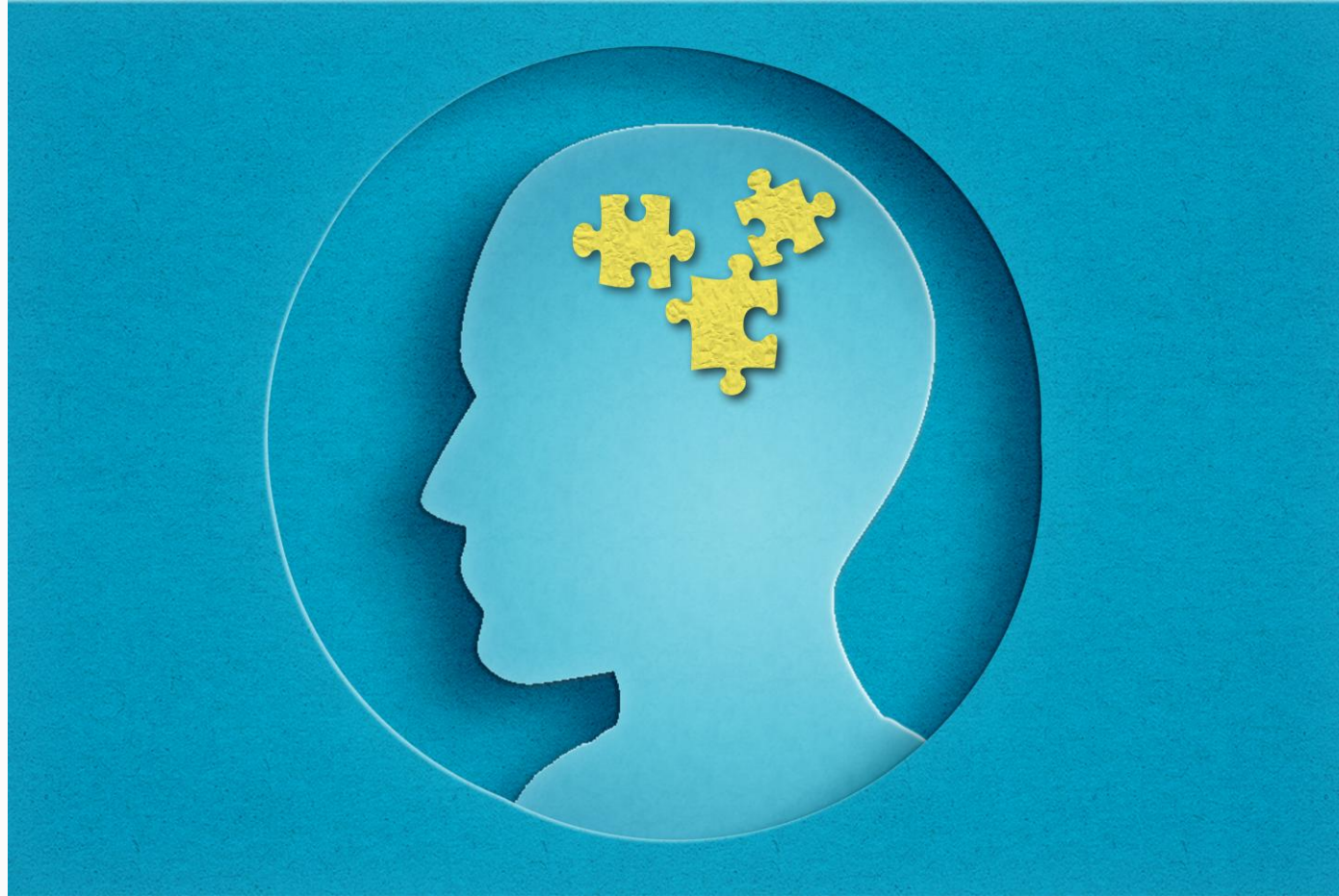
Understanding Article 117
under EU MDR

Best Practices & Compliance
Strategies

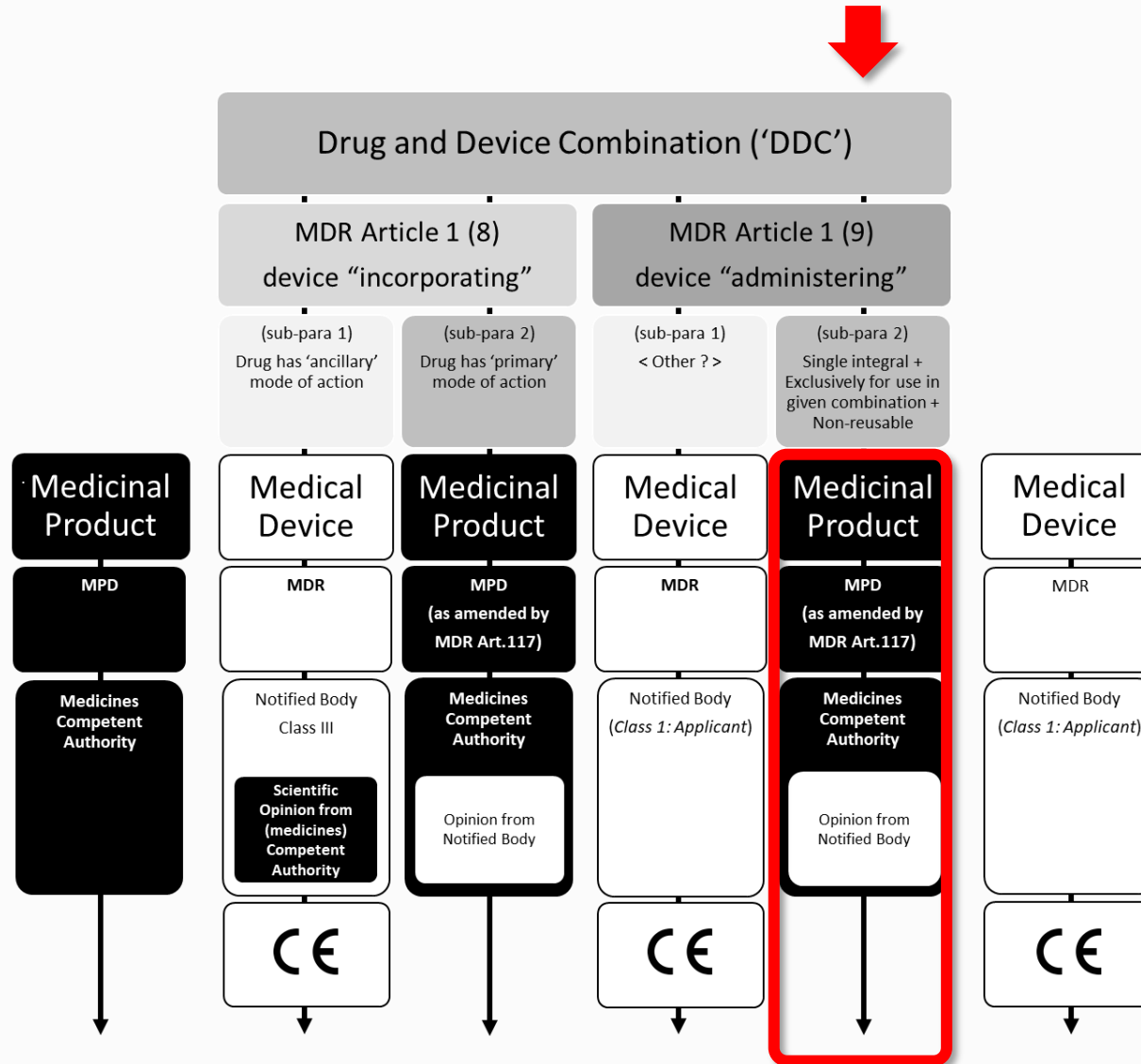
Key Regulatory Requirements

Q&A

Time to Hear from You ?



Session Focus



Staked-needle Pre-filled Syringe



- ✓ • *Single integral*
- ✓ • *Intended exclusively for use in the given combination*
- ✓ • *Non-reusable*



Understanding Article 117 under EU MDR





Article 117

Amendment to Directive 2001/83/EC

In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

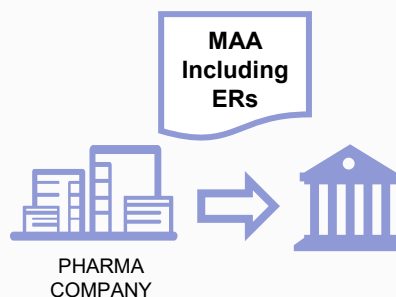
- ‘(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council (*), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer’s EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.

A117 – A key change in ways of working

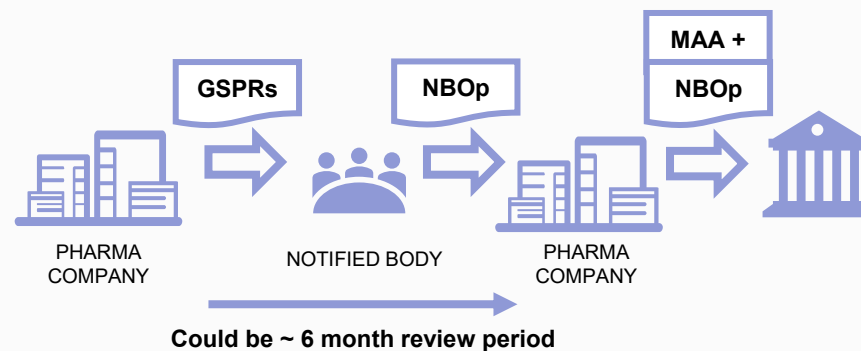
MDD Process

- MAA submitted directly to Competent Authority
- MDD Annex 1 Essential Requirements (ERs) self certified checklist



MDR Process

- MAA to be submitted with a Notified Body opinion (NBOp)
- MDR Annex 1 General Safety and Performance Requirements (GSPRs)





Article 117 Products

- MDR Article 1(9):
- Product governed by 2001/83/EC but relevant GSPRs shall apply.



Single
integral

- Medicine and device integral at point of use

Not
reusable

- Single dose
- Multi dose possible if not refilled

Exclusively
for use

- Device not also used for alternate medicine



Background to Article 117

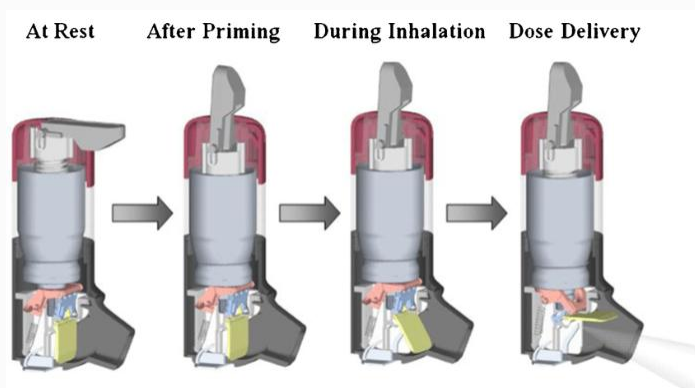
- Concerns with the gap in legislation of such products:
 - Technological advancements in the device area
 - MDD stated the device must meet applicable ERs as per Annex I of 93/42/EEC, but not included 2001/83/EEC
 - Competent Authority expectations for the device component were not clearly defined & divergence approaches seen





What does MDR A117 require

- Demonstration that the device part of the medicinal product meets MDR Annex 1 GSPRs
- NB Opinion required as part of the Medicinal product MA Application if
 - The device part does not bear the CE Mark
 - The device part has not got a Declaration of Conformity with MDR Requirements



NB Logo		NB Name and Address		NB Number	
Notified Body Opinion					
(Article 117 of the Medical Device Regulation (EU 2017/745))					
Compliance of device(s) incorporated into an integral drug-device combination product with Annex I (General Safety and Performance Requirements) Medical Device Regulation (EU 2017/745)					
Administrative reference number (including version number):					
Reviewer name and position:					
NB authorisation (signature):					
Issue Date of Notified Body Opinion: (YYYY/MM/DD)					

TS000-001 Not a Product Paper or a Proposal for a Notified Body Opinion Template Page 1/1

Scope of Article 117

In the Scope of Article 117

- Medicinal products that form an integral product with a medical device, where the action of the medicinal product is principal



Reference: Second subparagraph Article 1(9), MDR (EU) 2017/745

Out of Scope of Article 117

- Combined ATMPs – Regulation 1394/2007
- Non-Integral Combinations
 - Co-packaged devices with medicinal products
 - Cross-labelled products



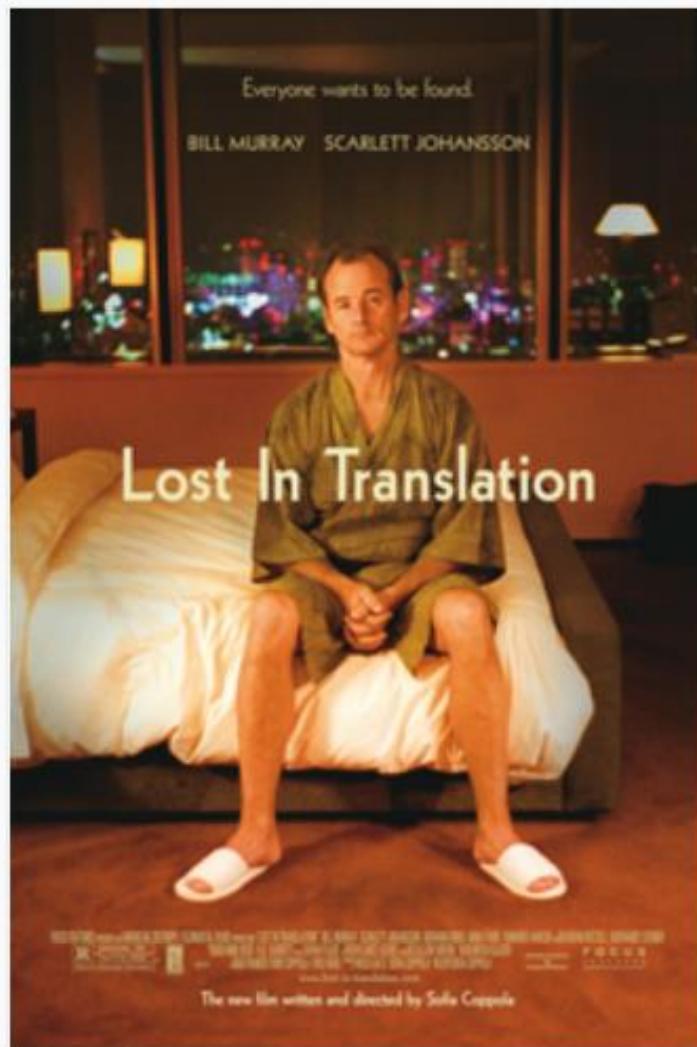
Why Article 117 ?

- Legislation governing medical devices is different to that for medicinal products
- **Proportional Vs Precautionary**
- It doesn't mean one set of legislation is superior to the other
- **Involvement of appropriate expertise in the process is key to ensure product safety**



MEDICINES ARE
FROM MARS

INTERNATIONAL BESTSELLER
MEN ARE
FROM MARS,
Women Are
from Venus
THE CLASSIC GUIDE TO
UNDERSTANDING THE OPPOSITE
SEX
JOHN GRAY, Ph.D.



Devices Are
from Venus



Acknowledgments: John Wilkinson, GMDN, 2020 Topra Symposium



Key Regulatory Requirements





**When is a NBOP
required ?**





Dry Powder Inhaler example



Single Integral ✓
Exclusively for use ✓
Not Reusable ✓



Single Integral ✗
Exclusively for use ?
Not Reusable ?



Multidose injection example



Single Integral ✓

Exclusively for use ✓

Not Reusable ✓



Single Integral ✗

Exclusively for use ?

Not Reusable ✗



Pre-filled syringe containing a dermal filler product and local anaesthetic pain relief drug?

Intended Use: A pre-filled syringe containing a dermal filler for facial reconstruction, containing Lidocaine

What is the purpose of the product

- A device that has a physical action and its action is supported by a medicinal product

Is the action of the Medicinal Product PRINCIPAL or ANCILLARY

- Ancillary. The drug supports the intended use of the

Does MDR Article 117 apply?

- No. MDR Article 52 applies (and Annex XVI)





What is a Notified Body and its Role





What is a Notified Body?

“A notified body is an organisation **designated** by an EU country to assess the conformity of certain products before being placed on the market.

These bodies carry out tasks related to **conformity assessment procedures** set out in the applicable legislation, when a third party is required...”¹



¹ https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en

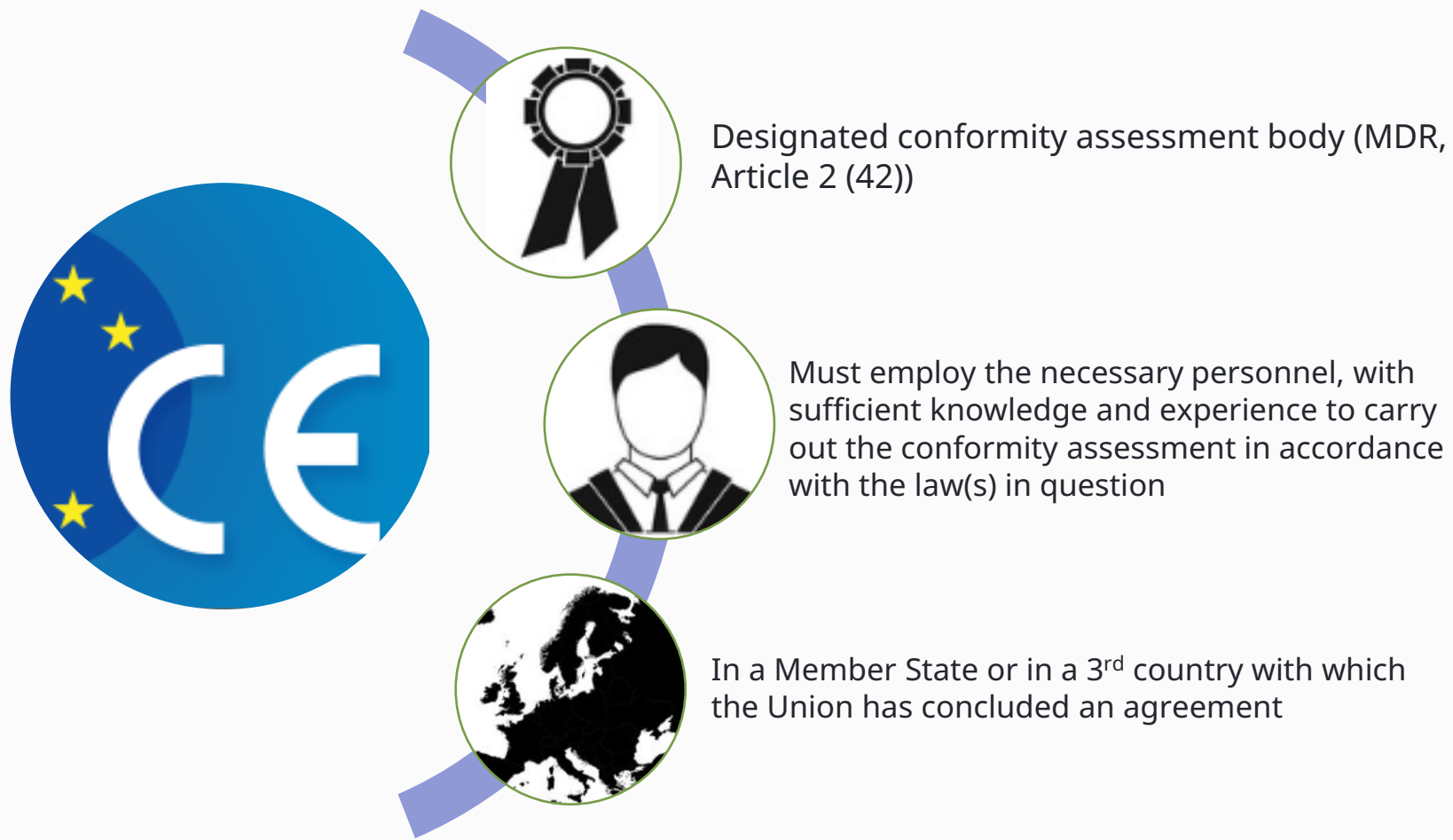


Role of the Notified Body

- Evaluate manufacturer's compliance to legislation that they are designated to
- Issue certification (EC) to permit CE marking of a device
- NBs range in size and scope
- NBs are not Government Agencies but private sector companies
- The Company chooses its NB body
 - Provided they are designated in that device area.
- NB fees vary depending on service required but are publicly available
 - Cost per Hour / Day.
 - Quality of submission will affect overall cost
- [NANDO \(New Approach Notified and Designated Organisations\) Information System](#) provides a list of designated NBs



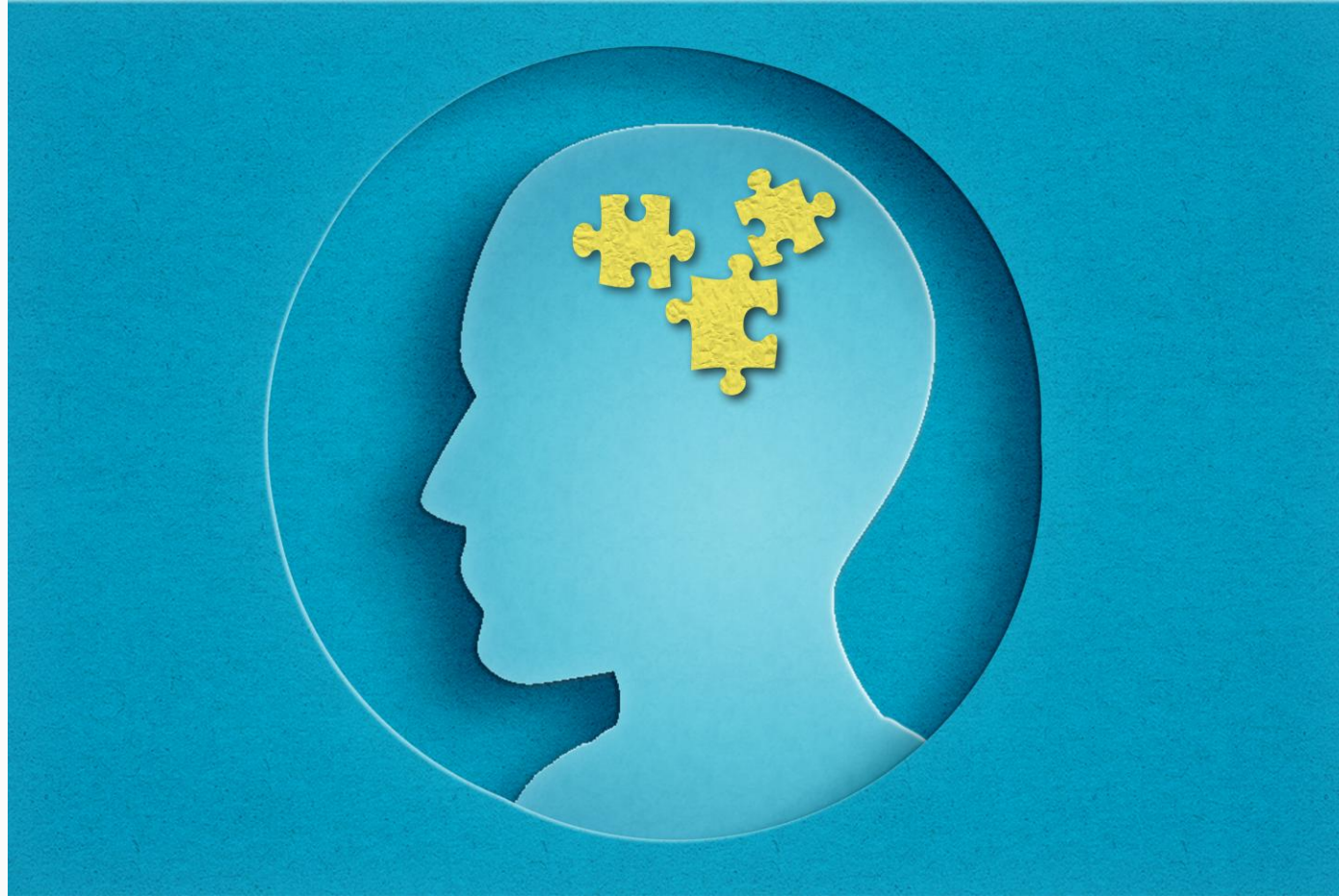
Notified Bodies for Medical Devices



¹ https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en



Time to Hear from You ?





**What documentation
and level of evidence
is needed ?**





Technical Documentation Requirements

- How much information should I provide
- What format should I use?
- [BSI Article 117 Guidance Document](#)
- [MDR Article 117 Brochure](#)





MDR Annex I, General Safety and Performance Requirements

**Chapter 1:
General
Requirements**
(GSPRs 1-9)



**Chapter 2:
Design and
Manufacture**
(GSPRs 10-22)



**Chapter 3:
Information
Supplied with
the Device**
(GSPR 23)





MDR Annex I – General Safety and Performance Requirements

- | | | | | | | | | |
|----|--|---|-----|--|---|-----|--|---|
| 1. | Safe, Perform as Intended, State of the Art |  | 10. | Chemical, Physical & Biological Properties |  | 17. | Electronic programmable systems |  |
| 2. | Risk reduction as far as possible | | 11. | Infection & Microbial Contamination |  | 18. | Active devices and devices connected to them |  |
| 3. | Risk Management |  | 12. | Devices incorporating a medicinal product and devices composed of substances that are absorbed by or locally dispersed in the human body | | 19. | Requirements for AIMD | |
| 4. | Risk Control | | 13. | Devices incorporating materials of biological origin | | 20. | Protection against mechanical and thermal risks |  |
| 5. | Risk of Use Error | | 14. | Construction and interaction with the environment |  | 21. | Protection against the risks posed to the patient or user by supplied energy or substances |  |
| 6. | Lifetime |  | 15. | Devices with a diagnostic or measuring function |  | 22. | Protection against the risks posed by medical devices intended for use by lay persons | |
| 7. | Packaging, Transport, Storage |  | 16. | Protection against radiation |  | 23. | Information Supplied |  |
| 8. | Undesirable side-effects minimised & Risks < Benefits | | | | | | | |
| 9. | Annex XVI “no risk at all” or “no more than the maximum acceptable risk” |  | | | | | | |



Documentation Expectations

Notified Body expectations for Art.117 submission?



- ✓ Product 'road-map' document
- ✓ Comprehensive GSPR checklist
- ✓ All 'evidence' cited against applicable GSPRs
- ✓ Searchable, pdf file

The European Association Medical Devices - Notified Bodies		
Editor :	Team-NB	Adoption date : 01/04/2020 Version 1
Team-NB Position Paper on Documentation Requirements for Drug Device Combination Products Falling in the Scope of Article 117 of MDR 2017/745.		

Topic 1: Requirements on the submission file's documentation (structure)

Each Notified Body is a separate, non-governmental organization and thus offers its own specific organizational setup. This organizational setup includes specific processes and specific interfaces on client interaction.

In consideration of this organizational setup of Notified Bodies, the requirements on the submission file format should only focus on general documentation related requirements, i.e. the structure and contents as well as the format related to the documentation submitted. The way of documentation submission to the respective Notified Body, the way of documentation handling, storage and archiving at the respective Notified Body are out of scope.

According to the second subparagraph of Article 117 (Regulation (EU) 2017/745 on medical devices (MDR)), the opinion issued by a notified body applies to "the conformity of the device part with the relevant general safety and performance requirements set out in Annex I (GSPRs) to that Regulation" ("that Regulation" being the MDR).

For medical devices being solely governed by the MDR, the documentation requirements related to the GSPRs are described in Annex II Technical Documentation (MDR, Annex II; in specific section 4). These documentation requirements should also be considered for the documentation of the device part.

A) Structure and content of the submission file of the device part

I. Contains a *description of the device part* covering

- a general description of the device part including its intended purpose and intended users
- the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings (for the integral product/ single integral product)
- principles of operation of the device part and its mode of action, scientifically demonstrated if necessary
- a description of the accessories for a device part, other devices and other products that are not devices, which are intended to be used in combination with it
- a general description of the device part's key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams



Requirements on Article 117 documentation

Annex II

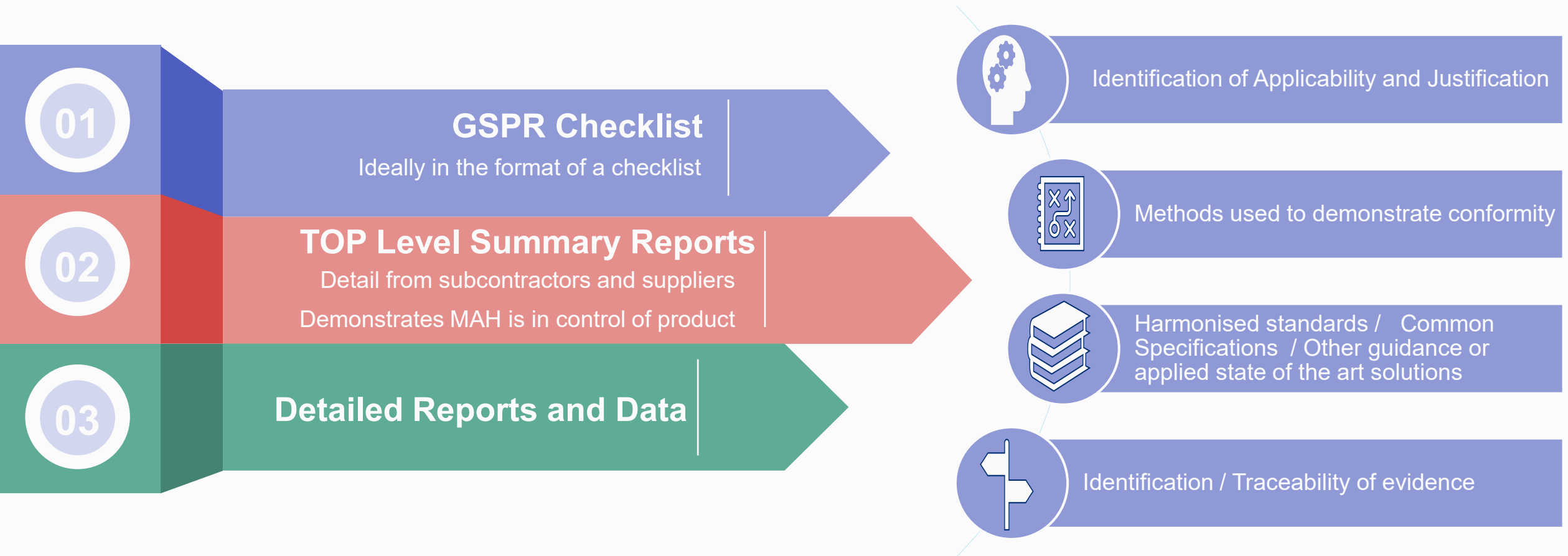
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

- (a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;
- (b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;
- (c) the harmonised standards, CS or other solutions applied; and
- (d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.



Documentation Learning Points





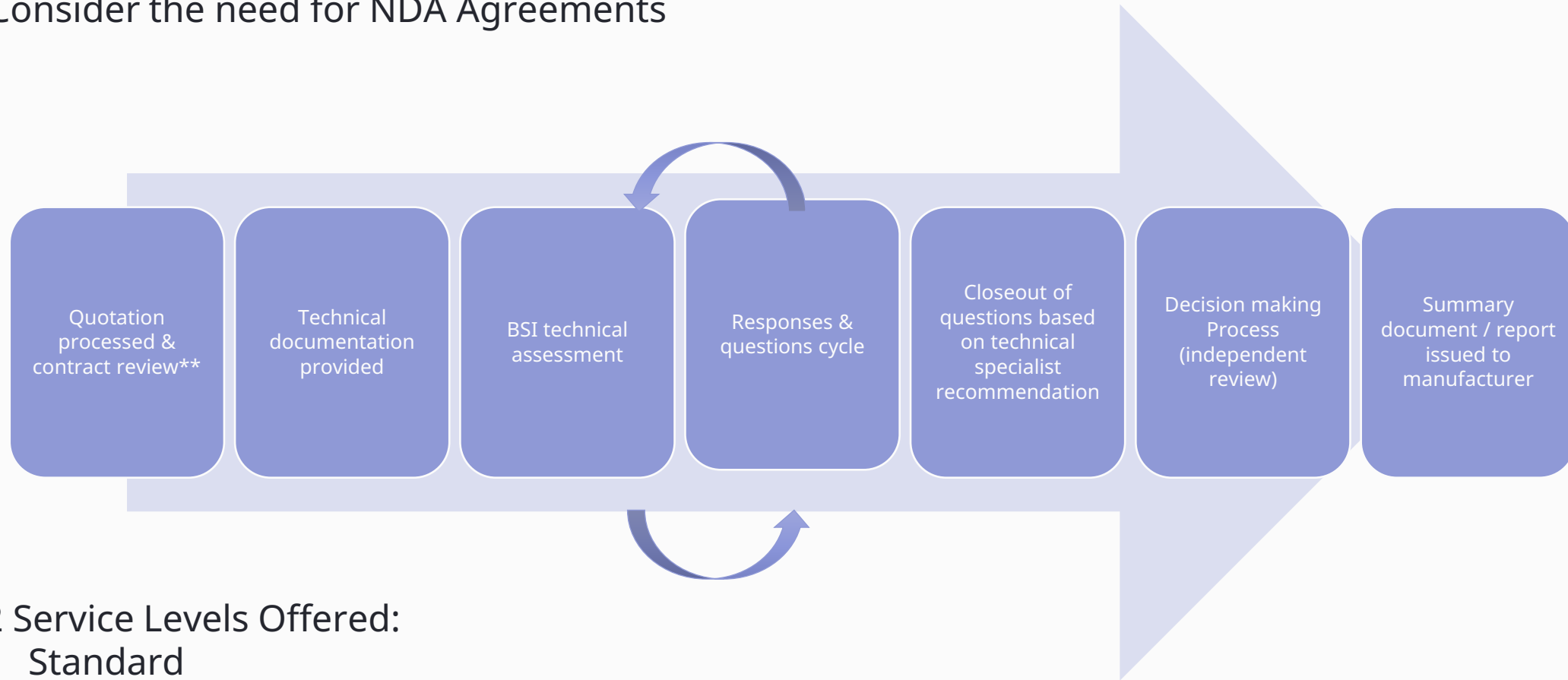
Notified Body Opinion (NBOp) Process





Notified Body Assessment Process and Key Stages

**Consider the need for NDA Agreements



2 Service Levels Offered:

- Standard
- Dedicated for an interactive assessment



Notified Body Opinion

- Will take the form of a report
 - Clear which version of the device has been evaluated
 - Clear to Competent Authority what has been looked at
 - Sufficient detail to avoid duplication/ overlap
 - Sufficient detail to give confidence
 - Any gaps clear to Competent Authority

 Your partner
in progress

MDF4566

Notified Body Opinion Report
Revision 3 (October 2024)

Notified Body Opinion Report

MANUFACTURER NAME

Medicinal Product Name

Reference A117#

Notified Body Opinion
Article 117 of the Medical Devices Regulation (EU) 2017/745

Compliance of device(s) intended to administer a medicinal product, placed on the market with the medicinal product as a single integral product, with Annex I (General Safety and Performance Requirements) Medical Devices Regulation (EU) 2017/745

BSI Approval: **BSI signature**

Date:

BSI- NL: Notified Body BSI Group The Netherlands B.V. (NB 2797) is part of BSI Regulatory Services (Medical Devices). BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

The contents of this document are confidential to BSI Group
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Common challenges and how to address them ?





Supplier Information

- Device part usually manufactured by supplier and therefore supplier has expertise and documentation on the device part
- Supplier control and agreements shall be in place and well defined
- If IP issues, supplier data can be shared only to NBs
- Who takes manufacturer's responsibilities in DDC?



Identification when a NBOp is needed

- NBs see requests for NB Opinions where a DoC or CE Certificate for the device exists
- NBs aware if CAs requesting NBOp where a Declaration of Conformity exists
- The device part is reusable and should obtain CE Certification as a medical device, but NB Opinion requested & *vice versa*

Article 117

Amendment to Directive 2001/83/EC

In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

'(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council (*), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.



Technical Documentation Expectations

- NB needs to see the evidence and scientific data that demonstrates how the GSPR has been met
- Difficult to prescribe the requirements given the wide range and difference in device complexity that may require a NBOp
- Pragmatic approach taken by NBs and flexibility built in to allow the MAA determine the information applicable to their relevant product and applicable GSPRs
- Accept that there may be some overlap in the data assessed by NB and CA but remember the differing perspectives involved



Management of Changes



- MAH to have in place a process for the review and management of changes
 - Expert on the medicinal product as a whole
 - Best placed to make the determination of impact of change
 - Should take a risk-based approach to determine if a new NBOp needed
 - MAH to justify approach taken
- Difficult to have a prescribed list of changes given the range and potential complexities of the device part
- Not all variation submission may need a revised NBOp
- Document your decision and you can discuss with the NCA/EMA



Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746)

2.6. How does Article 117 of the MDR impact currently authorised DDCs? **Rev. June 2021**

Annex I to Directive 2001/83/EC, point 12 of section 3.2, as amended by Article 117 of MDR, is not intended to apply retrospectively to DDCs already authorised or to those MAAs that have been already submitted prior to 26 May 2021.

However, if after the granting of the marketing authorisation there is a change to the design or intended purpose of the device (part), or a new device is introduced, any required declaration of conformity / EU certificate / notified body opinion should be submitted as part of the appropriate regulatory procedure to EMA/NCA (see also Q2.7).

As for any other changes, the MAH should determine whether there is a potential impact on quality, safety and/or efficacy of the DDC. If the MAH determines that the change impacts the registered information, a variation application according to the variation guideline will be required. If the change does not impact the registered information but the MAH concludes that there is an impact on the quality, safety and/or efficacy of the DDC, a variation application must also be submitted. In cases where the need for a variation and/or the category of the change is unclear, it is recommended that the medicines competent authority that issued the marketing authorisation be consulted.

In line with the advice provided in the EMA Q&A for [Post-authorisation procedural advice for users of the centralised procedure](#), given the relatively short timelines for variations procedures, the (new/updated) EU declaration of conformity / EU certificate issued by a designated notified body / notified body opinion for medical devices should be provided at the time of submission of the application to avoid any delays of the procedure.

2.7. Will I need to provide a (new or updated) EU declaration of conformity/EU certificate issued by a notified body/notified body opinion if there are changes to the device (or device part) after the initial marketing authorisation of the Drug Device Combination? Rev. June 2021

Article 117 requirement applies post-authorisation to all marketing authorisations, irrespective whether already compliant with Annex I to Directive 2001/83/EC, point 12 of section 3.2, as amended by Article 117 MDR at the time of the initial MAA, in case of changes that may affect the safety and performance of the device part or the intended use of the device. Contractual agreements between the MAH and the medical device manufacturer should ensure appropriate level of communication and action as regards changes to the device part. There are two situations where a (new or updated) EU declaration of conformity / EU certificate issued by a notified body / notified body opinion must be submitted in a post-authorisation setting of the medicinal product.

a) Addition or full replacement of the device or device part

Where a device (or device part) is replaced or a new device is added, a new EU declaration of conformity/ EU certificate issued by a notified body / notified body opinion must be provided as part of a variation or extension application.

b) Changes to the device or to a device part

Where the medical device manufacturer plans to introduce changes that may affect the safety and performance of the device part or the conditions prescribed for the intended use of the device part, there are three possible situations:

- **For devices covered under a manufacturer's EU declaration of conformity only (no involvement of a notified body):** the device part manufacturer is responsible to ensure compliance with the MDR, including changes to the device part. The EU declaration of conformity should be updated accordingly, if necessary.
- **For devices covered under an MDR EU certificate issued by a notified body:** if the assessment of changes leads to the issuance of a new/supplemented EU certificate according to the requirements established in the relevant annexes (Annexes IX, X, XI) of the MDR, the EU certificate must be provided as part of an appropriate post-authorisation regulatory procedure.
- **For devices holding a notified body opinion:** if the assessment of changes lead to the issuance of a new notified body opinion, the new notified body opinion must be provided as part of an appropriate post-authorisation regulatory procedure.



Best Practise & Compliance Strategies





Preparing Robust Submissions & Common Challenges

User Information

- Why does the NB want to see this ?
- What information would you provide ?
- What challenges do you see with this request ?
- It is recognised the labelling must comply to the Medicinal Product Directives and GSPR 23 subparts are not relevant
- Often see labelling referenced as evidence of compliance to GSPRs
- Necessary to see labelling relating to
 - use of the device,
 - dosing accuracy,
 - safety and communication of risks



Preparing Robust Submissions & Common Challenges

Product and Design Specification

- Why does the NB want to see this ?
- What information would you provide ?
- What challenges do you see with this request ?
- The NB wants to see that design requirements have been identified and documented in accordance with the intended use, safety and performance requirements, risk assessments.
- Design information with respect to the final combination product, function, performance, lifetime, shelf life, packaging, labelling, regulatory requirements, usability and packaging etc is expected.



Preparing Robust Submissions & Common Challenges

Manufacturing Information

- Why does the NB want to see this ?
- What information would you provide ?
- What challenges do you see with this request ?
- To identify any special or proprietary processes, and any subcontracted processes.
- The manufacture of the device parts and information on the assembly of the device parts into the final product, including in-process and device related product testing



Preparing Robust Submissions & Common Challenges

Shelf Life

- Why does the NB want to see this ?
- What information would you provide ?
- What challenges do you see with this request ?
- The stability of the medicinal product is under the remit of the Competent Authority; however, evidence of the stability of the device components is required for the NBOp (SPR 7).
- Evidence should be provided to support device-function related aspects of the final product only.
- Stability protocol and Reports should be provided
- Shelf-life may be justified with reference to accelerated data. However, clear justification with reference to ICH guidelines should be provided



Preparing Robust Submissions & Common Challenges

Risk Management

- Why does the NB want to see this ?
- What information would you provide ?
- What challenges do you see with this request ?
- Expect to see a thorough design and process Risk Management assessment conducted for the entire lifecycle of the device (from initial design concept up to and including disposal). (SPRs 1, 2, 3, 4, 5, 8)
- How are risks assessed, mitigated and reduced
- Have appropriate controls (design out then protective measures) have been applied to all risks.
- Do risk mitigations introduce new risks
- Do the benefits outweigh all the residual risks when the device is used as intended.



Preparing Robust Submissions & Common Challenges

Clinical

- In what cases would the NB want to see this ?
- What information would you provide ?
- What challenges do you see with this request ?
- In most cases Clinical evaluation of the medicinal product will be carried out by the Competent Authority and the device is just aids the delivery of the medicinal product
- In cases where there are device claims relating to the device part e.g., 'less painful injection' or, where the device is novel or where there are clinical safety risks for the device part e.g., implants, the clinical evaluation will be required.
- If needed data to support the safety & performance claims made for the device part



Conclusions on A117 Implementation





Where are we today ?

- BSI have now issued over 280 NB Opinions for over 100 Companies
 - Majority are for Pre-Filled Syringes / Autoinjectors
- Applications continue to increase and starting to see more complex systems
- As a NB actively involved in EMA discussions and improvements to the system
- Member of the [COMBO Operational Group](#)

BSI issues first Article 117 Notified Body Opinion

News: 20 January 2020





Improvements to the A117 experience ?

Improve Communications

- NB point contact to discuss planned applications and potential changes on a regular basis and ensure project timelines and constraints are understood

Set Clear Expectations

- Publish additional guidance documents
- Internally align expectations and ensure consistency in approach and depth of review
- Limit the conduct of assessments to a specialised core group of A117 device experts

Improved Predictability of Service

- SLAs exist but ensure a clear timetable for all assessments is provided prior to assessment start
- Publish our SLA for change assessments analogous to variation timelines





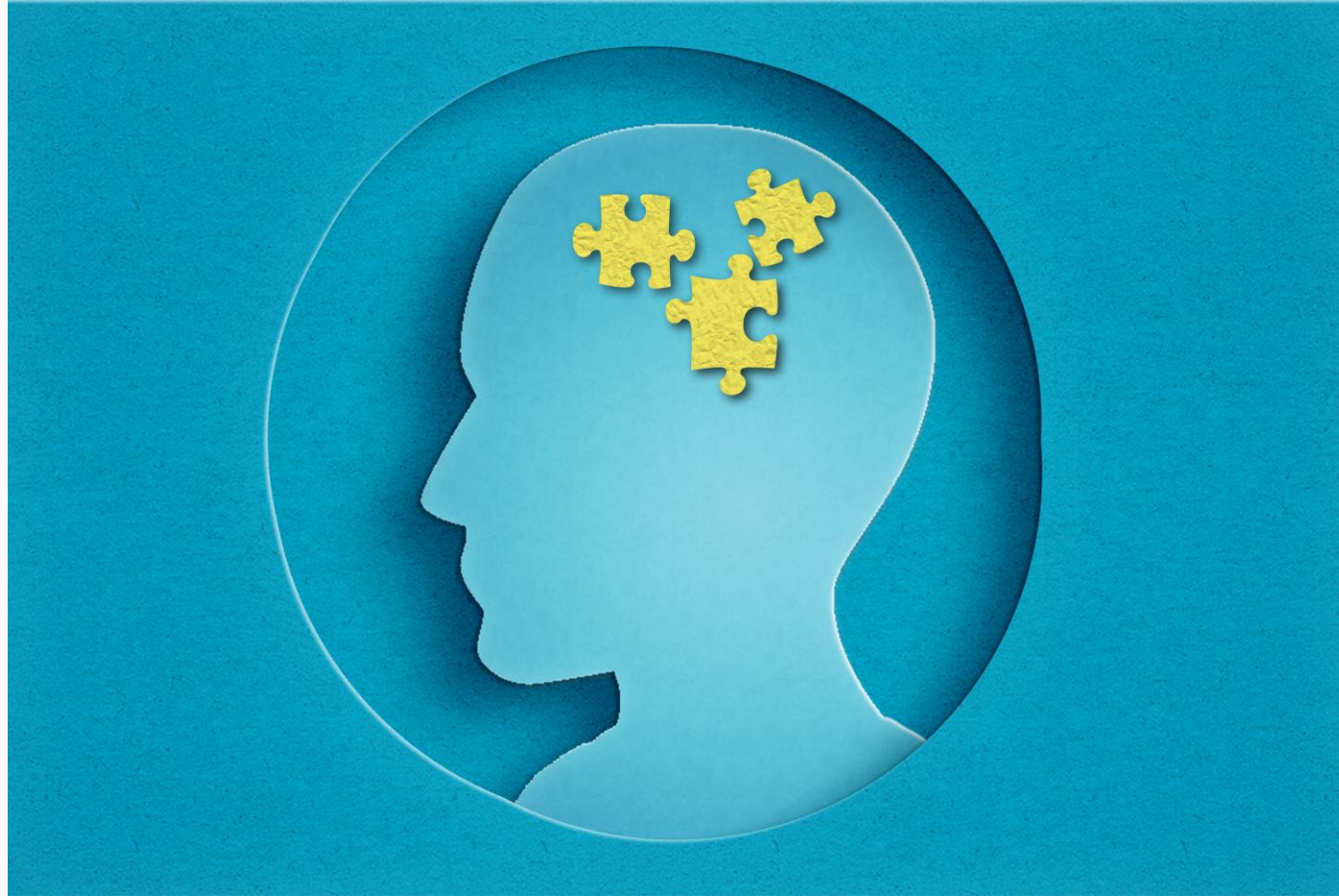
What have we learnt about A117 Implementation

- It has been challenging for all involved and has required lots of investment
 - Resources
 - Time
 - Commitment
- Interpretative challenges exist and remain pragmatic in approach
- Feedback is always appreciated as it helps us review and make improvements
- Important that all Stakeholders appreciate the differing perspectives that exist in this area





Time to Hear from You ?





Q&A Session





Interested in getting a A117 NBOp

Contact

For further information, please feel free to contact :

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Thanks for your participation.

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