MDR Article 117:

Drug-device combination products application process

Introduced by the European Commission under the Medical Devices Regulation (MDR), Article 117 requires manufacturers placing drug-device combination products onto the market as an integral device and marketing them as a "medicinal product" to seek a Notified Body Opinion (NBOp). The notified body then confirms whether the device is compliant with the relevant General Safety and Performance Requirements (GSPR) and provides an NBOp Report to the manufacturer to include in the Market Authorisation Application (MAA).

What is the role of a notified body?

A notified body, such as BSI, is designated by the Competent Authority to conduct a conformity assessment under the relevant EU regulations. For specific drug-device combination products, the conformity assessment requires a review of the relevant Technical Documentation provided by the manufacturer in support of the safety and performance claims for their medical device. The Technical Documentation is assessed against the GSPR of the EU regulations, taking into consideration the relevant guidance set out by the EU.

Focusing our attention on Article 117

BSI has formed a dedicated *Medicinal and Biologics* team to provide guidance on Article 117. The team has over 55 years' combined experience in drug development, Good Manufacturing Procedures (GMP) systems and controls, and Quality by Design (QBD). The team also has extensive experience in conformity assessments of medical devices with ancillary medicinal substances (MDR Rule 14) and substance-based medical devices (MDR Rule 21).

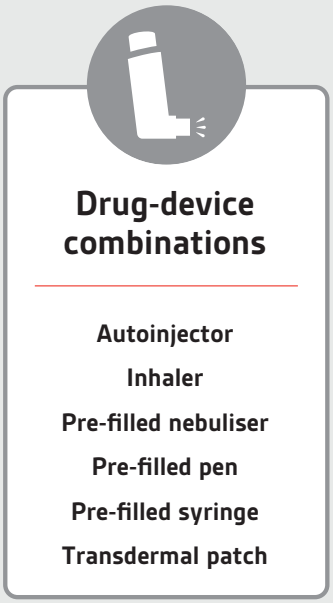
BSI was the first in the world to issue an NBOp to a manufacturer under Article 117 of the MDR. This is thanks to the incredible hard work of the team to provide this expertise to clients.

"The formation of a new, dedicated team will allow us to focus our attention on this challenging area of new EU regulation, delivering excellence to our clients."

Dr Jennifer Durrant

Global Head of Medicinal and Biologics, BSI

Examples of drug-device combination products requiring Notified Body Opinion



FAQs about the Article 117 process

Q: How long does the Article 117 process take?

The duration of the entire process depends on the quality of the documentation submitted by the manufacturer, the number of questions BSI needs to ask for each round, and the manufacture's responsiveness in answering questions. We have included an estimated timeline for Article 117 reviews on the next page. The process is typically expected to take between two and six months to complete, so the more time you factor into the process, the better.

Q: Is there an expedited service available?

There is no expedited service; however, our team will work closely with you to complete the reviews within the estimated timelines on the next page.

Q: Which documents do I need to supply?

Annex II of the MDR provides guidance on which documents are required. BSI has also produced an *MDR Documentation Submission Best Practice Guidelines* for further guidance. As part of the Article 117 process, there will be a thorough review of evidence of conformity to the GSPR; for this reason, supporting technical data will be required.

Q: What is the output of the process?

BSI will issue an NBOp Report providing a recommendation on conformity of the drug-device combination product to Article 117 of the MDR. To avoid any duplication of the reviews, this report will be detailed enough to demonstrate to the Competent Authority what data have been reviewed and to assure them conformity has been appropriately assessed.

Q: What is the role of BSI during the question stage of the MAA process?

On rare occasions, there might be questions from the Competent Authorities for the Notified Body during the MAA process. BSI will be available to answer these, mindful of the fact that there is a clock stop.

Q: How much clinical data is required?

The safety and efficacy of the medicinal substance is reviewed by the Competent Authority. As a Notified Body, BSI will need sufficient data to demonstrate the device performs as intended in the clinical setting. Clinical data may be required if there are specific device-related clinical claims or safety concerns.

Q: I'm making a change to an already marketed drug-device combination product. Does this require an NBOp?

Substantial changes to your product that could affect the performance and safety characteristics of the medical device will require an NBOp as part of the variation process. As an independent Notified Body, BSI is not able to advise or provide consultation to manufacturers on whether specific changes require an NBOp.

Estimated timeline for Article 117 reviews

Pre-review tasks

- Application submission
- Quote issued and signed
- Contract review completed
- Scheduling
- Complete documentation submission
- Documentation completeness check

Medicinal review conducted; NBOp summary passed on to technical specialists

Working days
BSI timeline by task
20
Total BSI timeline
20

BSI 1st review round and questions sent to client

Working days
BSI timeline by task
20
Total BSI timeline
40

Clock stops

Client responds to BSI

BSI 2nd review round and questions sent to client

Working days
BSI timeline by task
20
Total BSI timeline
60

Clock stops

Client responds to BSI

BSI 3rd review round and questions sent to client

Working days
BSI timeline by task
10
Total BSI timeline
70

Clock stops

Client responds to BSI

Final BSI NBOp report issued to client

Working days
BSI timeline by task
10
Total BSI timeline
80

BSI finalizes NBOp Report and makes submission for decision making

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