HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Notified Bodies – Designation Process

AUT-G0149-1
26 November 2017
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

ABBREVIATIONS

CAB	Conformity assessment body
CAPA	Corrective and preventative plan
HPRA	Health Products Regulatory Authority
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU
JAT	Joint assessment team
MDCG	Medical Device Coordination Group
MDR	Regulation EU 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC
NANDO	New approach notified and designated organisations
PAR	Preliminary assessment report

1 SCOPE

This document is intended to provide guidance to conformity assessment bodies and notified bodies currently designated under the existing medical devices and *in vitro* diagnostic medical devices Directives when making designation applications to the HPRA under article 38 of Regulation (EU) 2017/745 on medical devices[1] (hereafter MDR) and corresponding articles in Regulation (EU) 2017/746 on *in vitro* Diagnostic Medical Devices[2] (hereafter IVDR). For the purposes of these Regulations, the HPRA is the authority responsible for notified bodies as outlined in Article 35.1 of Regulation (EU) 2017/745.

2 DESIGNATION APPLICATION

When applying for designation, the conformity assessment body (CAB) should use the relevant application form provided on the HPRA website. The application should be accompanied by the supporting documentation as requested within the form and any other documents considered necessary to support the application. The HPRA requests applicants to include a summary document outlining the overall organisational structure of the CAB, including subsidiaries and a full listing of quality system processes and procedures. A Declaration of Completeness form must also be read, signed and submitted by the applicant. Applications must be accompanied by the associated fee, details of which can be found on the HPRA website.

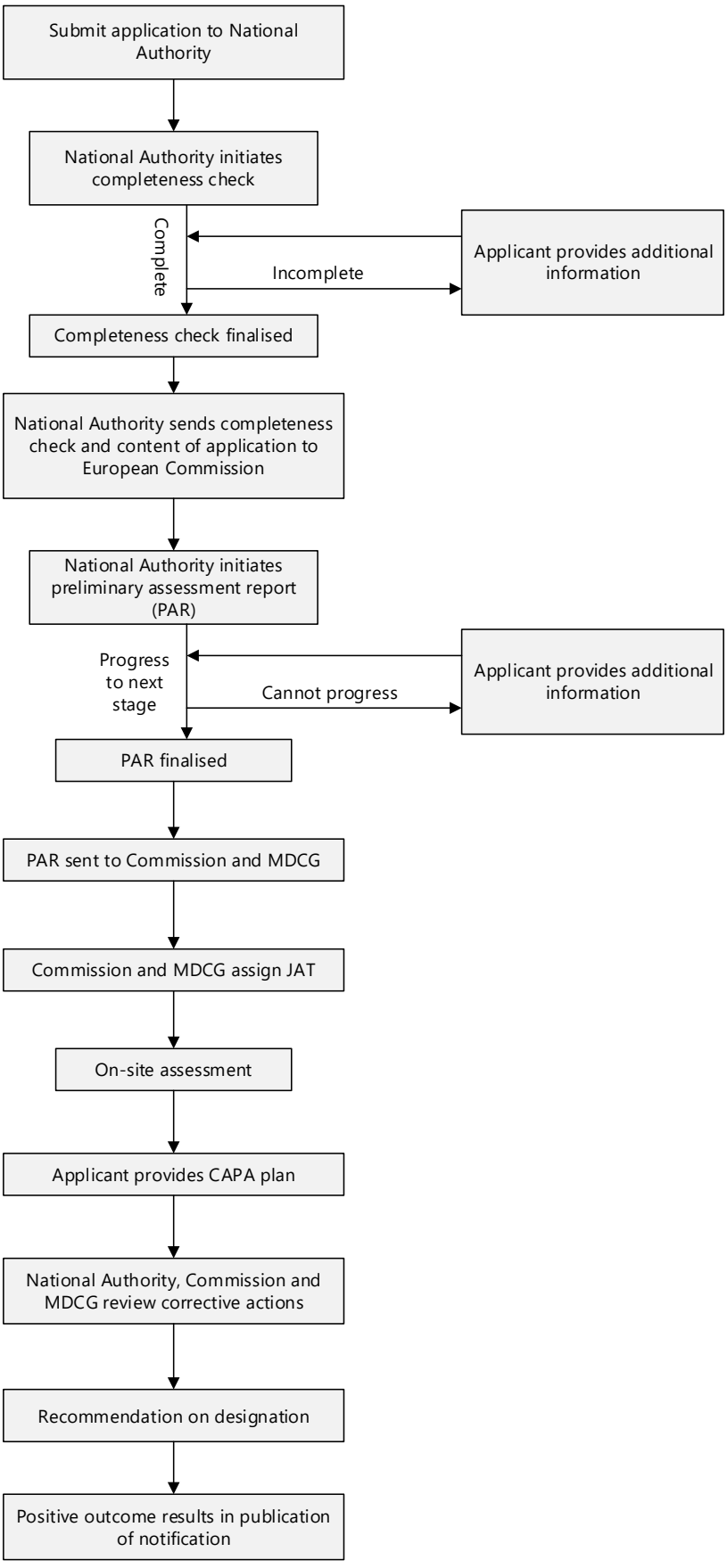
From the 26th November 2017, a CAB can submit an application to the HPRA to seek designation under the Regulation(s) as a notified body in Ireland. The HPRA anticipate that the minimum expected time it will take to complete the European designation process will be 18 months, therefore, notified bodies should consider this in determining when to submit their applications.

2.1 Completeness check

Following submission, the HPRA will perform an initial review of the application to verify the completeness of the designation application form and the supporting documentation. There is a legislative requirement that the completeness check shall be completed within 30 days after receipt of a validated designation application. If information is missing or incomplete, the HPRA will request additional information from the CAB within this 30 day timeframe.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC.
[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

If additional information is required to ensure the application is complete, the HPRA will request this information to be made available within 14 days. It should be noted that any delays in the initial completeness check review phase due to missing information may result in subsequent delays in the overall designation process.
Once the application is considered complete, the HPRA must submit the completeness check to the European Commission including the application with all supporting documentation that were submitted by the CAB.


Submit application to National Authority
National Authority initiates completeness check
Complete
Incomplete
Applicant provides additional information
Completeness check finalised
National Authority sends completeness check and content of application to European Commission
National Authority initiates preliminary assessment report (PAR)
Progress to next stage
Cannot progress
Applicant provides additional information
PAR finalised
PAR sent to Commission and MDCG
Commission and MDCG assign JAT
On-site assessment
Applicant provides CAPA plan
National Authority, Commission and MDCG review corrective actions
Recommendation on designation
Positive outcome results in publication of notification

2.2 Preliminary assessment report

In addition to the completeness check, the HPRA will complete a preliminary assessment report. There is no legislative timeframe for completion for the preliminary assessment report, the HPRA will aim to complete the report within 4-6 weeks beyond the finalisation of the completeness check. The time taken to complete the preliminary assessment report will depend on the response time from the CAB, in relation to requests for additional information and clarifications from the HPRA. The assessment shall take into consideration all of the applicable requirements of the Regulations. When completed, the preliminary assessment report will be submitted to the European Commission and the outcome of the report will be the basis for whether an on-site assessment will be scheduled. To assist with scheduling, at this point, the CAB will be requested to inform the HPRA of dates to indicate availability and non-availability for the on-site assessment.

Scheduling of the on-site assessment is managed by the European Commission in conjunction with the authority responsible for notified bodies and the selected Joint Assessment team who will be performing the on-site assessment.

3 ON-SITE ASSESSMENT

3.1 Overview

The on-site assessment is conducted at the premises of the applicant CAB and will be performed and led by the national authority responsible for notified bodies in the Member State where the applicant is based. The on-site assessment will be conducted together with an EU Joint Assessment Team (JAT).

The European Commission appoints the JAT in conjunction with the Medical Device Coordination Group (MDCG). The JAT will include one expert from the European Commission and two experts from a pool of national experts selected from European designating authorities. The purpose of the JAT is to assist in the assessment of designation applications and to provide an opinion to the EU Commission and the regulatory network on the proposed designation of a notified body.

The HPRA will work with the European Commission in the scheduling of the on-site assessment and communicate with the CAB regarding the assessment dates. On-site assessments will normally be scheduled for four to five days. If further time is required to complete the on-site assessment, the CAB will be informed. A formal announcement letter will be sent to notify the CAB that the on-site assessment has been scheduled. The on-site assessment plan will be sent to the CAB in advance of the on-site assessment.

3.2 Conduct of the on-site assessment

The on-site assessment will cover all of the designation requirements laid down in the MDR or the IVDR.

The assessment will be conducted in line with the assessment plan and will be led by the national authority. An opening meeting will be held to outline the basis for the on-site visit and how the assessment will be managed, giving consideration to the normal operating hours of the CAB. The JAT will actively participate as part of the overall assessment team.

3.3 Closing meeting

Where requirements of the Regulations are not met, non-compliances will be raised by the assessment team. Non-compliances will be classified as major or minor in line with HPRA procedures. Observations or comments may also be included as part of the assessment. At the end of the assessment, the HPRA will aim to provide the CAB with a list of non-compliances in writing. A timeline will be discussed for the CAB to provide a corrective and preventive action (CAPA) plan to the HPRA.

4 CAPA PLAN

The CAB shall submit its CAPA plan within the deadline defined and communicated by the HPRA during the closing meeting. This must provide sufficient levels of information on the root cause and resultant corrective and preventative actions. The HPRA and JAT will assess whether the CAPA plan appears satisfactory to address the non-compliances identified. Further clarifications will be sought where necessary.

5 DECISION ON DESIGNATION

The time for designation decision will vary depending on the number and nature of issues identified, and the extent of work required for the CAB to implement the corrections and CAPAs. The HPRA will verify the progress on the implementation of all CAPAs and confirm whether non-compliances can be considered closed.

Further on-site assessments and verification of closure of the non-compliances may be required.

The HPRA will then submit a final report along with its decision on the recommended scope of designation of the applicant CAB. A report shall also be provided by the JAT. Both reports will be submitted to the EU Commission and the MDCG to allow Member States to review and where necessary raise objection to a proposed designation.

After a successful designation, the notification will be published to the NANDO [3]website.

The designation then becomes valid the day after the notification is published on the NANDO website and notified bodies can then begin to certify devices to the requirements of the applicable Regulation.

It should be noted that specific timelines are provided for within the Regulations to allow for review of the designation decision by a national authority and consensus amongst the Member States, JAT and the European Commission. This may impact on the time to designation decision and notification to the NANDO website.

[3] Weblink to NANDO