Transition from MDD to MDR - Expiration of Certificates

Scenario A: No application under the MDR, no preparation for transition
MDCG 2022-4 Rev. 1
-> NB should perform surveillance under MDD and verify implementation of relevant MDR requirements (PMS, Vigilance, Registration)

Sell off date deleted

Scenario B: MDR: Application is reviewed by the NB that has issued the MDD/AIMDD certificate
MDCG 2022-4 Rev. 1
--> Surveillance activities according to MDR by the NB

MDCG 2022-18: Application of Article 97 (1) and proposal: extension of validity of certificates

Extension of validity of certifiicates

Scenario C: Same NB for legacy devices and already certified devices (same, partially the same devices)
MDCG 2022-4 Rev. 1
--> Surveillance activities according to MDR by the NB

MDCG 2022-18: Application of Article 97 (1) and proposal: extension of validity of certificates

Extension of validity of certificates if conditions of (proposed) article 2 are met

No valid Certificates

Scenario XX: First Applicant

MDCG: 2022-14Position Paper: Notified Body capacity and availability of medical devices and IVDs:
....the MDCG calls on notified bodies to develop schemes in order to allocate capacity for SME manufacturers and first time applicants and ensure access of SMEs and first-time applicants to notified bodies for conformity assessment.

Have Patience

Scenario X: Several applications for MDR notified bodies

Under certain conditions: MDCG 2022-18: Application of Article 97 (1)

- the manufacturer is a SME and
- MDD/AIMDD certificate issued by a NB not (yet) designated under the MDR and
- The SME manufacturer can demonstrate the efforts to apply to a number of NB

Extension only: (proposed) article 2b) : application of Article 97 (1) (MDCG 2022-18)

Scenario D: Legacy devices and MDR devices certified by another NB (overlapping scope)
MDCG 2022-4 Rev. 1
--> Surveillance activities according to MDR by the NB (in case the MDD NB has a MDR Notification)
if not:
—> NB should perform surveillance under MDD and verify implementation of relevant MDR requirements (PMS, Vigilance, Registration)

No extension needed, sell off date deleted

Article 97 and MDCG 2022-18
Context: Placeholder for the proposed amendment of the regulations

Interpretation of applicability of article 97(1) of devices covered by the proposed article 2b): devices for which the CA has granted a derogation according to article 97(1)

Pre-conditions according to MDCG 2022-18 for conditions where the CA should consider to grant a derogation:
...in particular where the following conditions are all met: (i) the manufacturer is a SME, (ii) MDD or AIMDD certificate of that SME manufacturer had been issued by a notified body not (yet) designated under the MDR, (iii) the SME manufacturer can demonstrate that it has undertaken reasonable efforts to apply to a considerable number of relevant notified bodies and that their application has not been accepted due to limited notified body capacity.

Annex (Checklist) states: [In duly justified cases, the CA may waive the submission of the documentation referred to in the first two bullet points where the manufacturer is a SME and can demonstrate that it has undertaken reasonable efforts to apply to a considerable number of relevant notified bodies and that their application has not been accepted due to limited notified body capacity. In that case documentation to be submitted: rejection letters from notified bodies or other correspondence between manufacturer and notified bodies demonstrating frustrated efforts to submit application to notified bodies.]

MDCG 2022-4 Rev. 1 Guidance on appropriate Surveillance reg. the transitional provisions under article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2022-18 MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or MDR certificate expires before the issuance of a MDR certificate.