



Notified Bodies Survey on certifications and applications (MDR/IVDR)

MDCG & Stakeholders

18 October 2021

Survey on certifications and applications

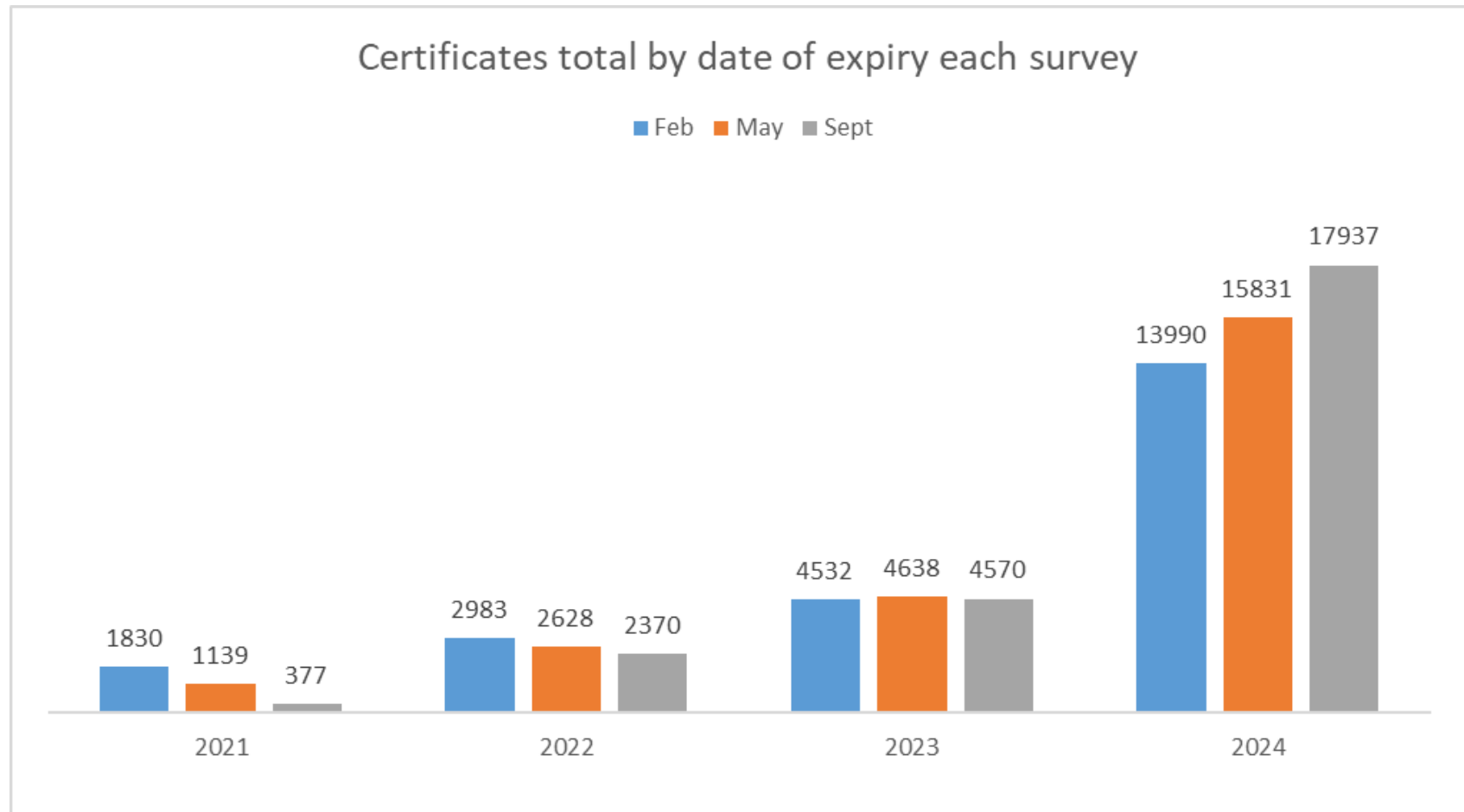
MD Notified bodies replies received – September 2021

- MDD/AIMDD: **51 replies received – out of 52 notified bodies** designated under the MDD (all notified bodies designated under the AIMDD replied)
- MDR: **23 replies received – out of 23 notified bodies** designated under the MDR

Survey on certifications and applications

MDD/AIMDD Certificates by year of expiring comparison Feb/May/Sept 2021

MDD/AIMDD Data (1)

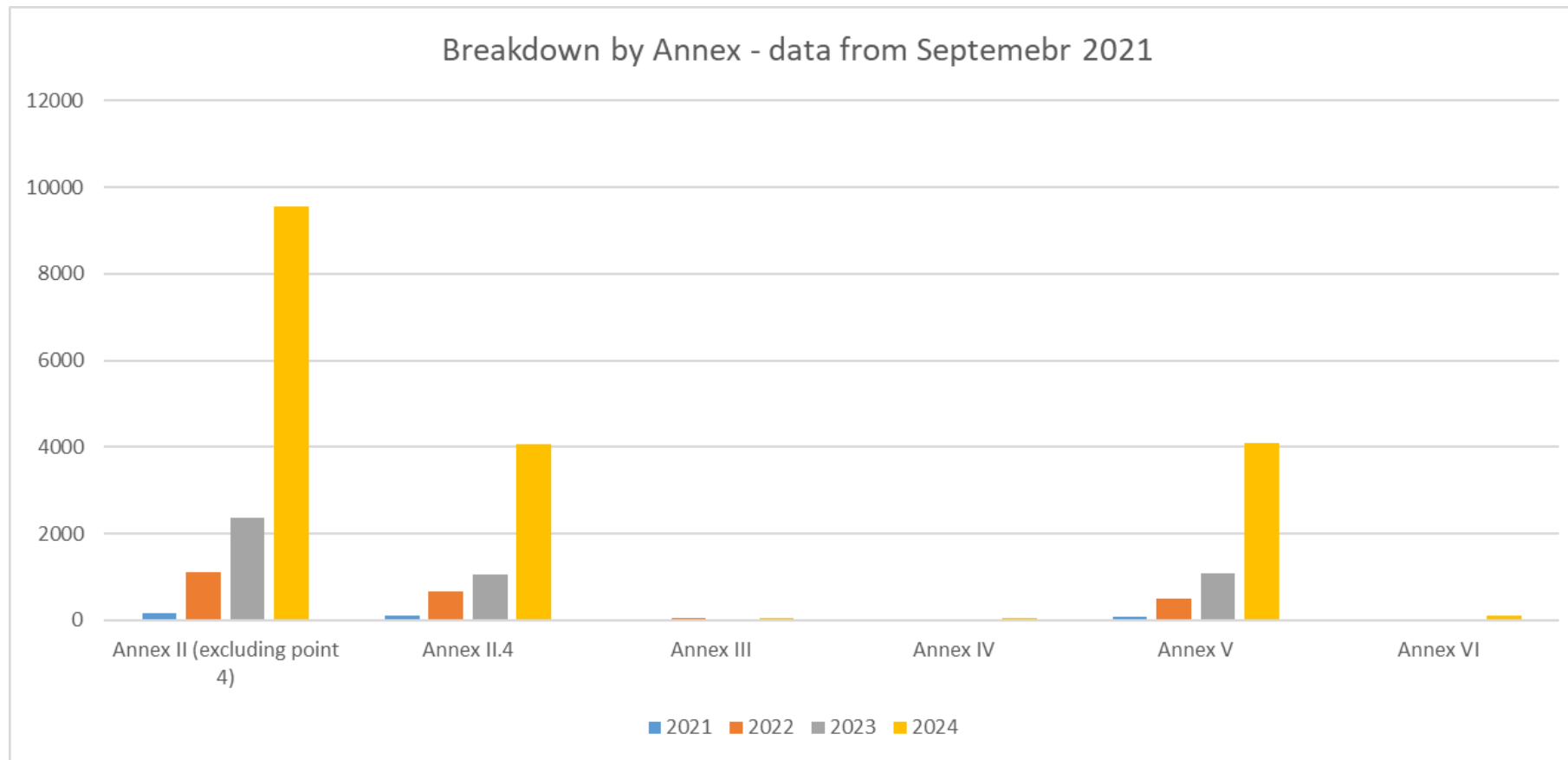


Tot. 25.254

Survey on certifications and applications

MDD/AIMDD Certificates – September 2021

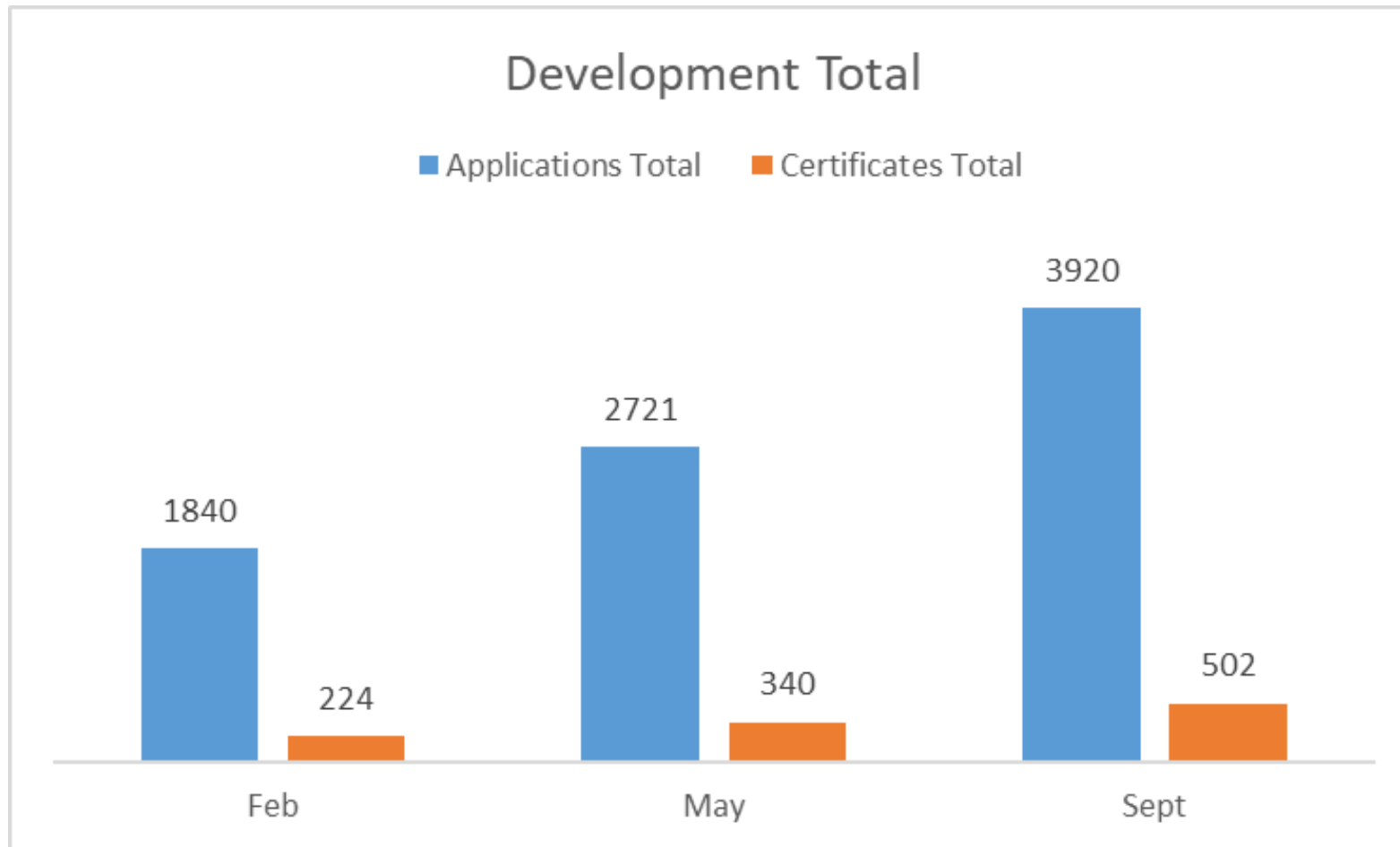
MDD/AIMDD Data (2)



Survey on certifications and applications

MDR Data (1)

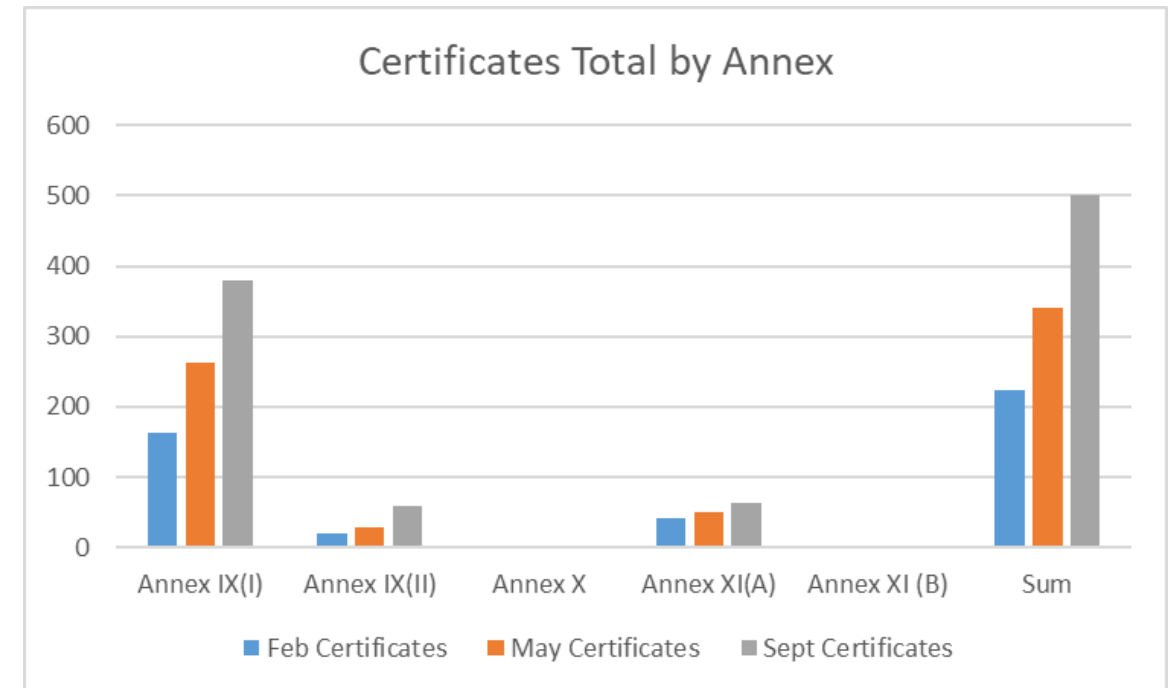
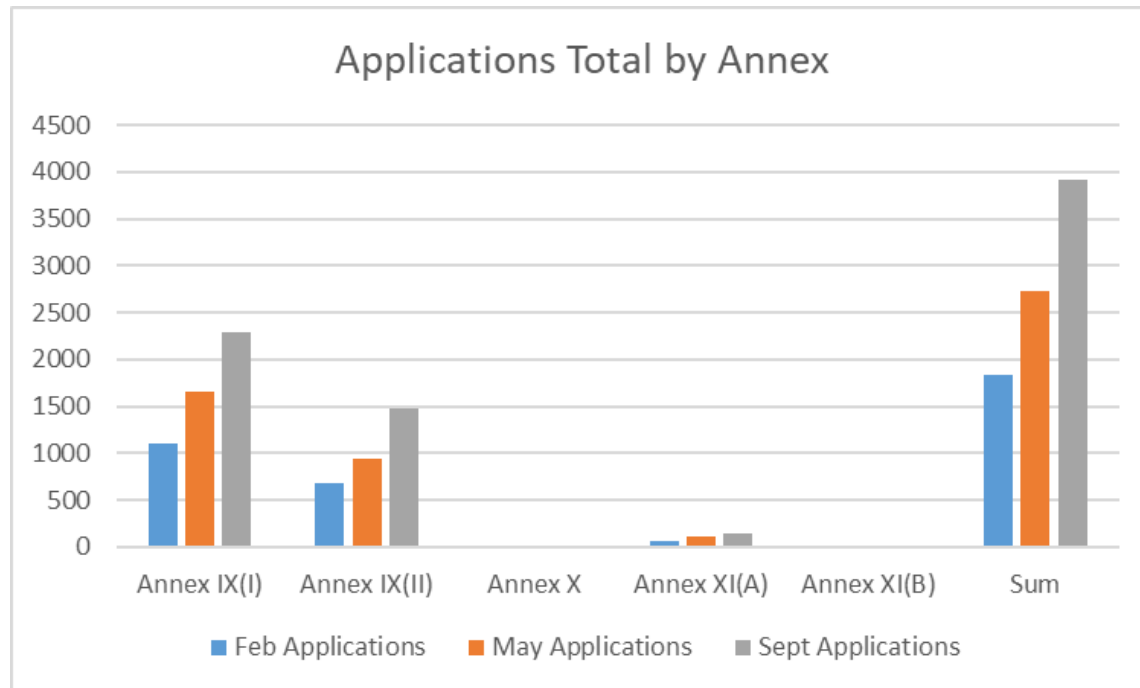
MDR Certificates and Applications - total



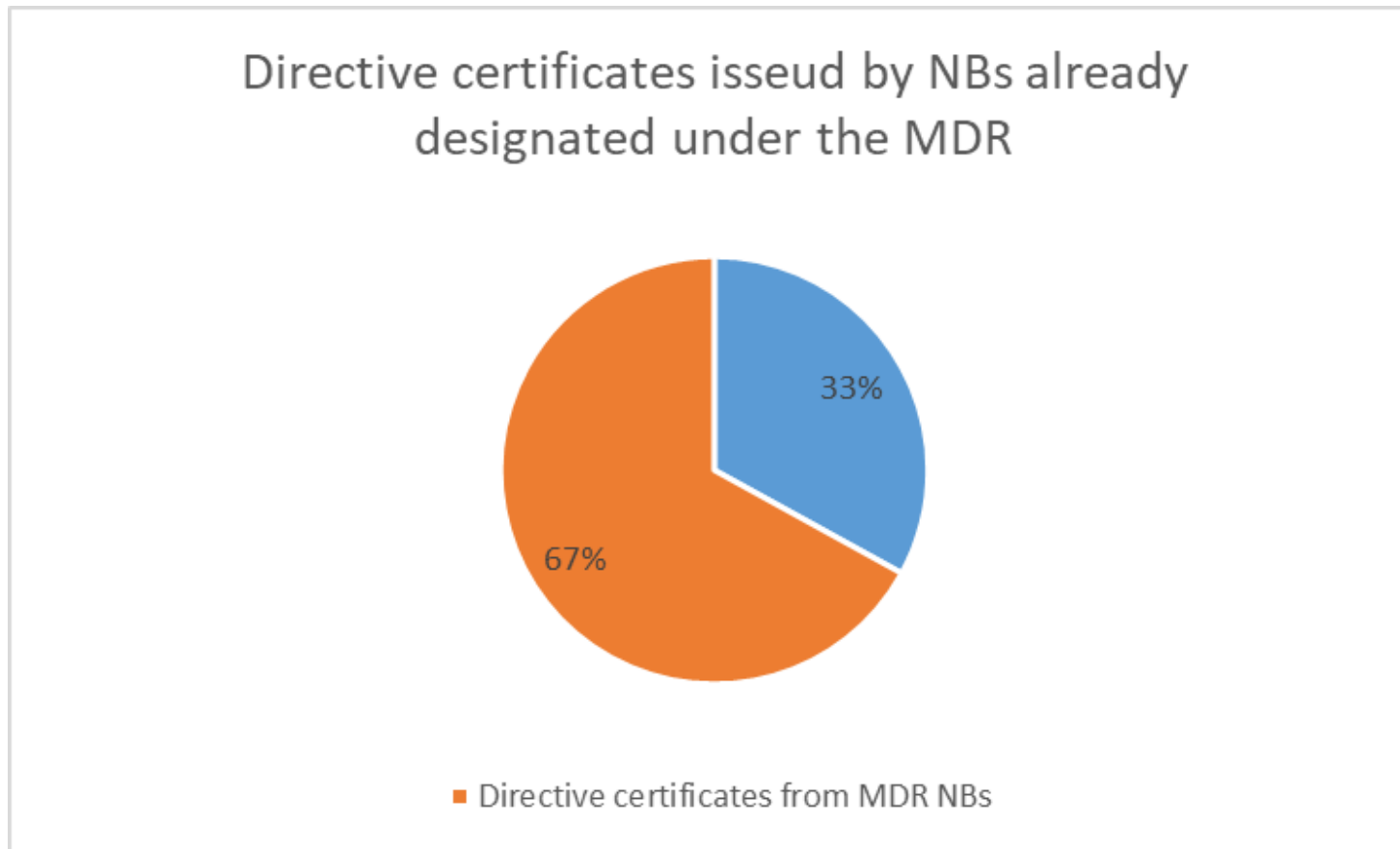
Survey on certifications and applications

MDR Data (2)

MDR Certificates and Applications by Annex – Comparison Feb/May/Sept 2021



Survey on certifications and applications



Survey on certifications and applications

IVD Notified bodies replies received – September 2021

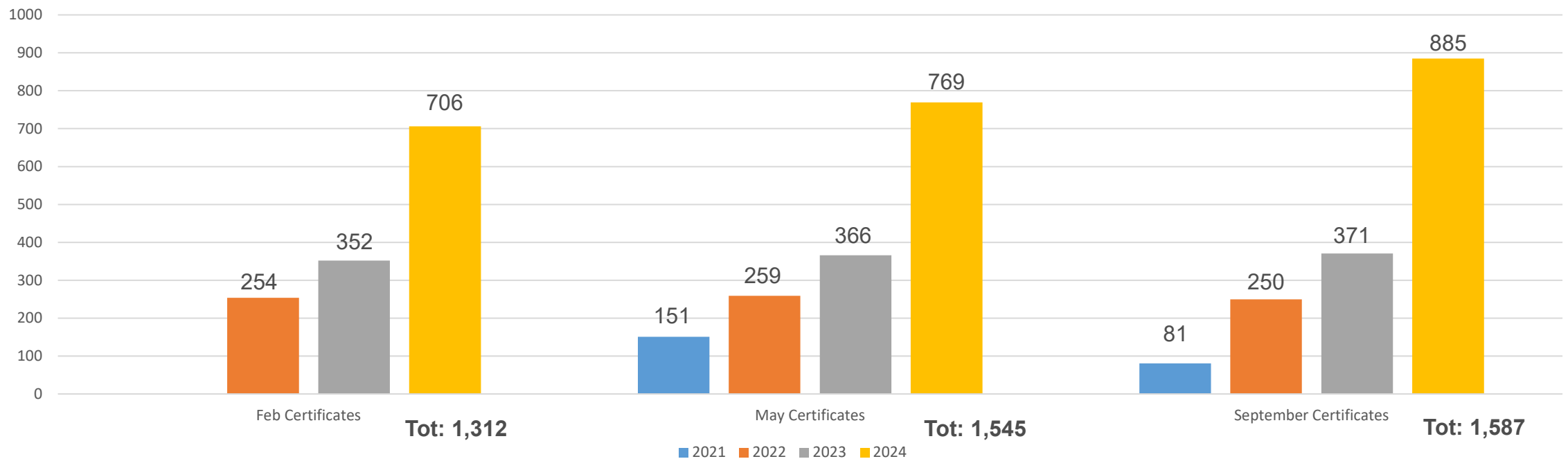
- IVDD: **18 replies received – out of 18 notified bodies** designated under the IVDD
- IVDR: **6 replies received – out of 6 notified bodies** designated under the IVDR

Survey on certifications and applications

IVDD Certificates by year of expiring comparison Feb/May/Sept 2021

IVDD Data (1)

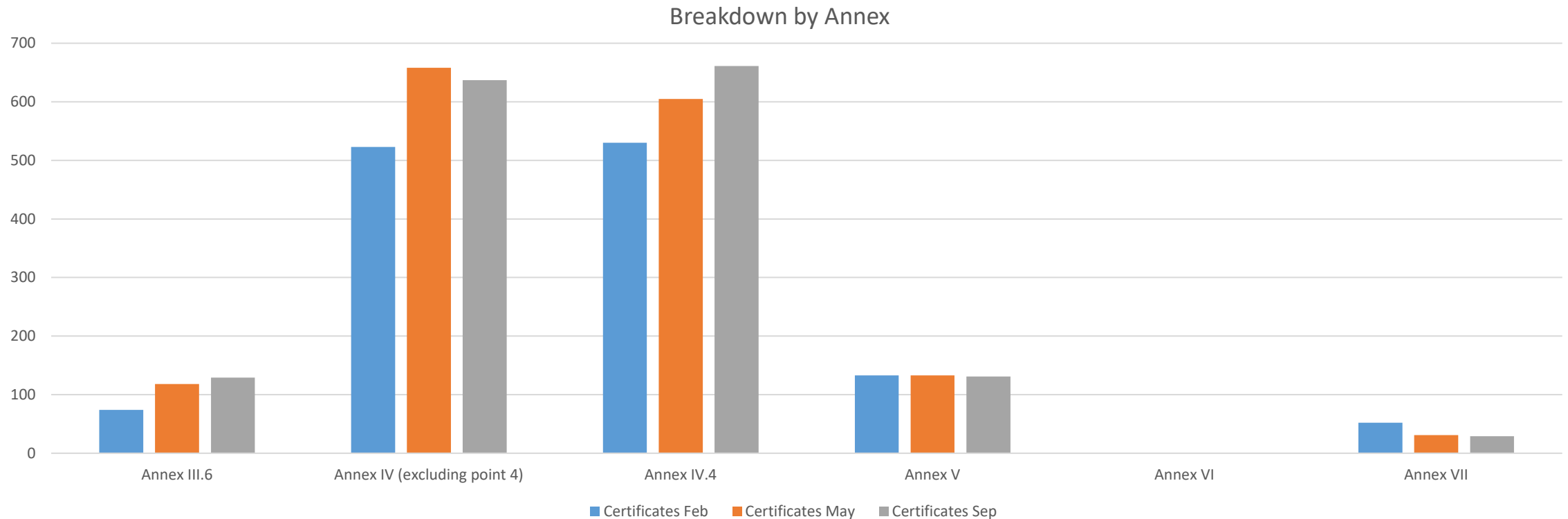
Certificates by year of expiry total



Survey on certifications and applications

IVDD Certificates by Annex comparison Feb/May/Sept 2021

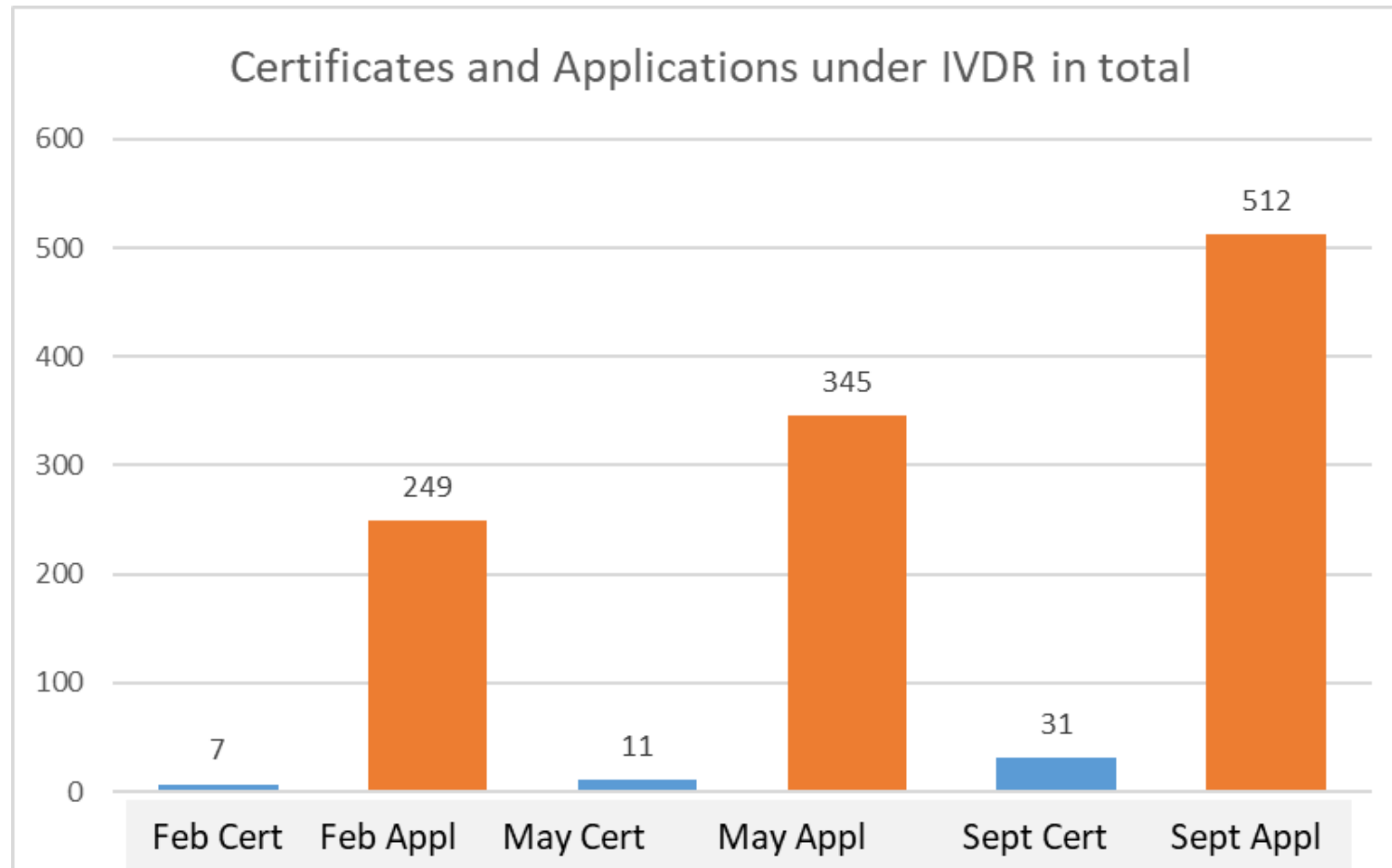
IVDD Data (2)



Survey on certifications and applications

IVDR Certificates and Applications - total

IVDR Data (1)



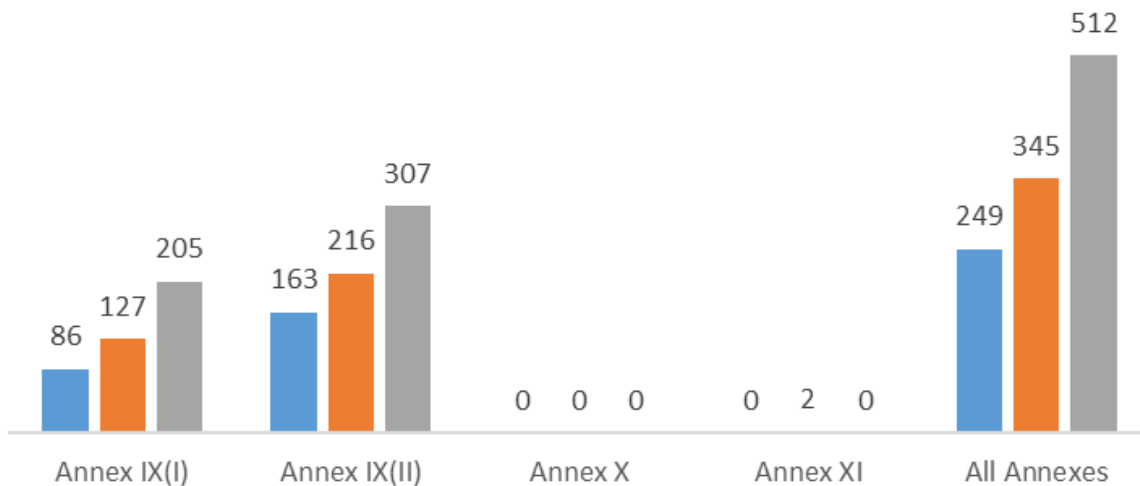
Survey on certifications and applications

IVDR Data (2)

IVDR Certificates and Applications by Annex – Comparison Feb/May/Sept 2021

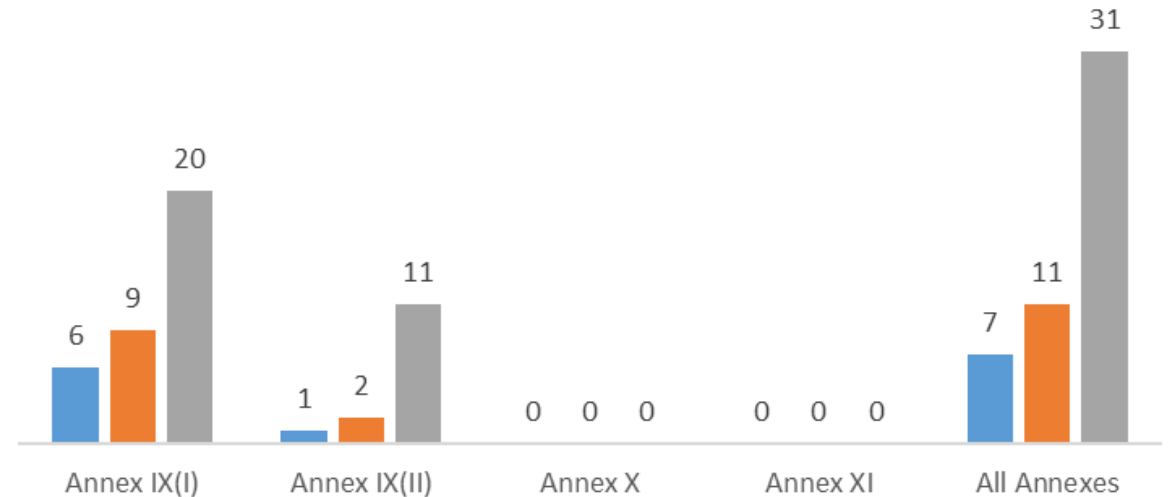
Overview Applications by Annex

■ Feb Applications ■ May Applications ■ Sept Applications



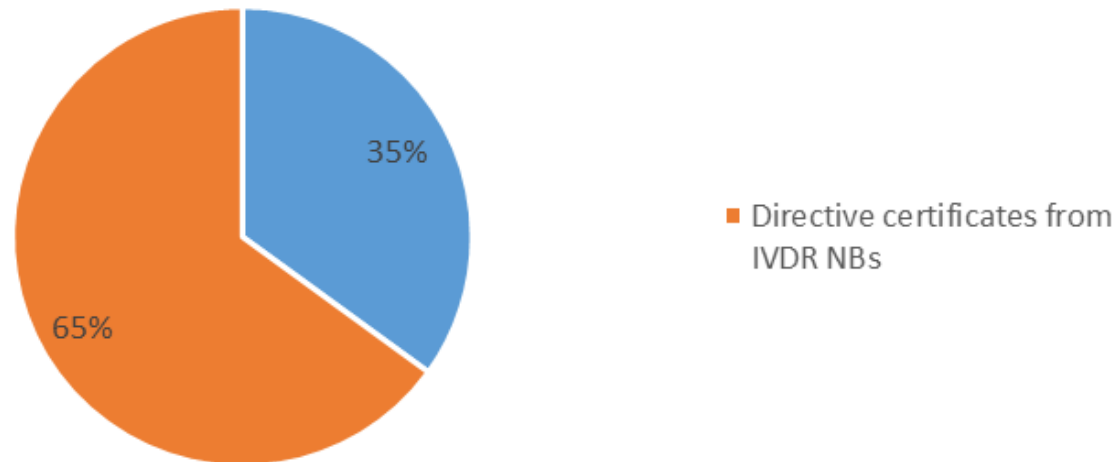
Overview Certificates by Annex

■ Feb Certificates ■ May Certificates ■ Sept Certificates



Survey on certifications and applications

IVDD Certificates issued by NBs
already designated under IVDR



Thank you



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