

APPLICATIONS - 55

- **MDR - 44**
 - 3 new applicants (1 of them withdrew)
 - 40+1 out of 49 *current** bodies – **86%**
- **IVDR - 11**
 - 1 new applicant
 - 10 of 20 *current** bodies – **50%**

* *Designated under the Directives, excluding bodies from Turkey*

PRELIMINARY ASSESSMENT REPORTS

- Received by SANTE/F:

- 39+1 – MDR

- 9 – IVDR

49

- 89% of applications



49 ON-SITE ASSESSMENTS

		MDR	IVDR
Completed	2018	16	5
	2019	22	2
Pending in 2020		2	2

PROCESSING OF CAPA plans

- **45** on-site assessments completed
- 20 CAPA plans pending
- **25** CAPA plans submitted
- **24** live plans (1 withdrawn)
- 3 JAT reviews pending
- **21** JAT reviews issued

FINAL STAGE

- 8 DA final reports pending
- **13** DA final reports submitted
- **13** JAT final opinions
- **12** MDCG recommendations
- 3 notifications
- **9** designations in NANDO

