



JOINT ASSESSMENTS – PROGRESS REPORT

Update – 2 October 2019

LIVE APPLICATIONS

- Sent to SANTE/F:
 - 40 – MDR
 - 11 – IVDR
- 51**
- Scope coverage: overall,
the entirety of MD and IVD
codes

PRELIMINARY ASSESSMENT REPORTS

- Received by SANTE/F:
 - 38 – MDR
 - 8 – IVDR
- 46**
- **90% of applications**



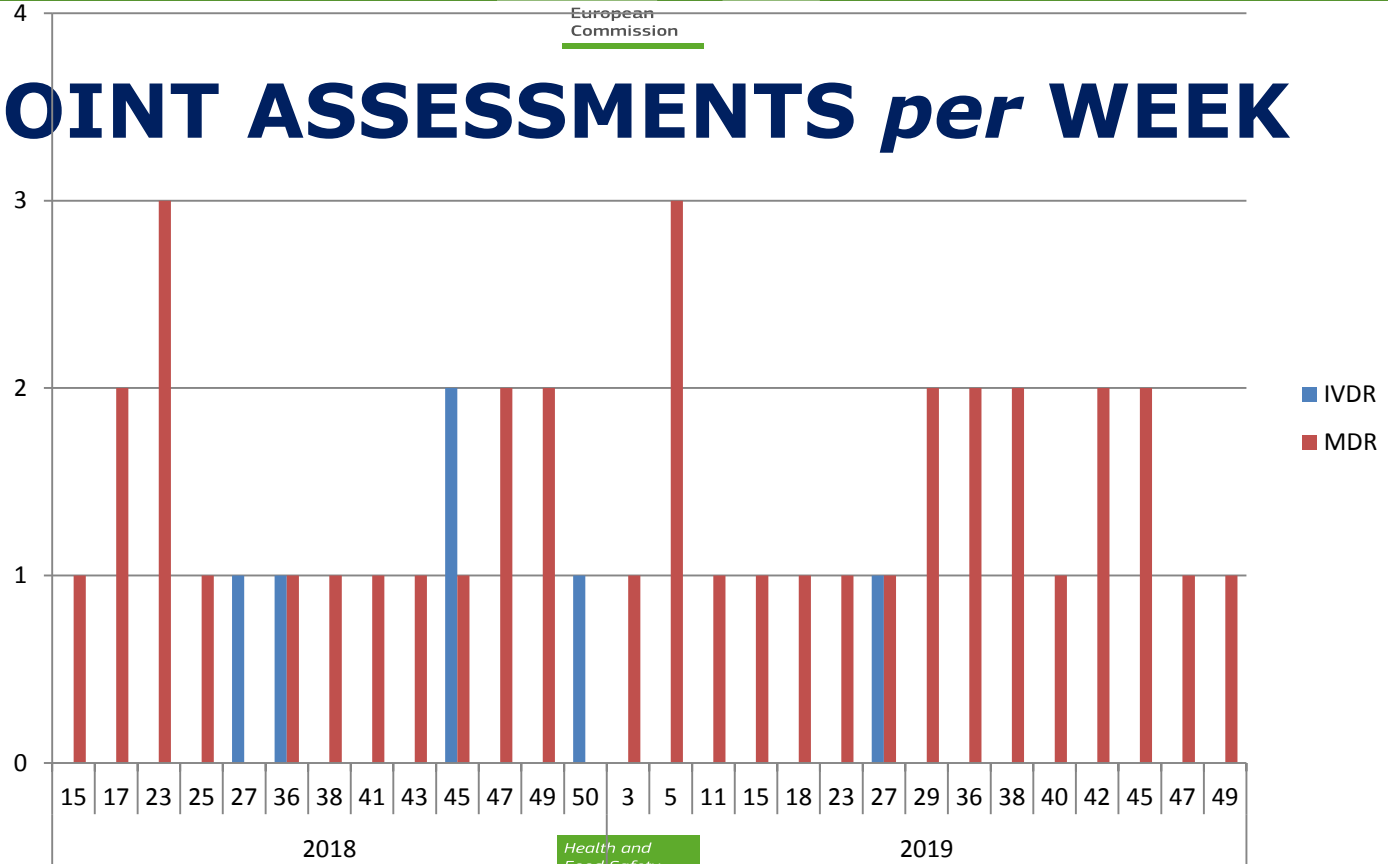
46 ON-SITE ASSESSMENTS

		MDR	IVDR
Completed	2018	16	5
	2019	15	1
Scheduled - 2019		7	-
Pending		-	2



European
Commission

JOINT ASSESSMENTS *per WEEK*



POST-ASSESSMENT ACTIVITIES

- **23** CAPA plans received by SANTE/F
 - **3** JAT reviews under preparation
 - **20** JAT reviews issued
- **9** DA final reports
- **9** JAT final opinions
- **9** MDCG recommendations