



# **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**



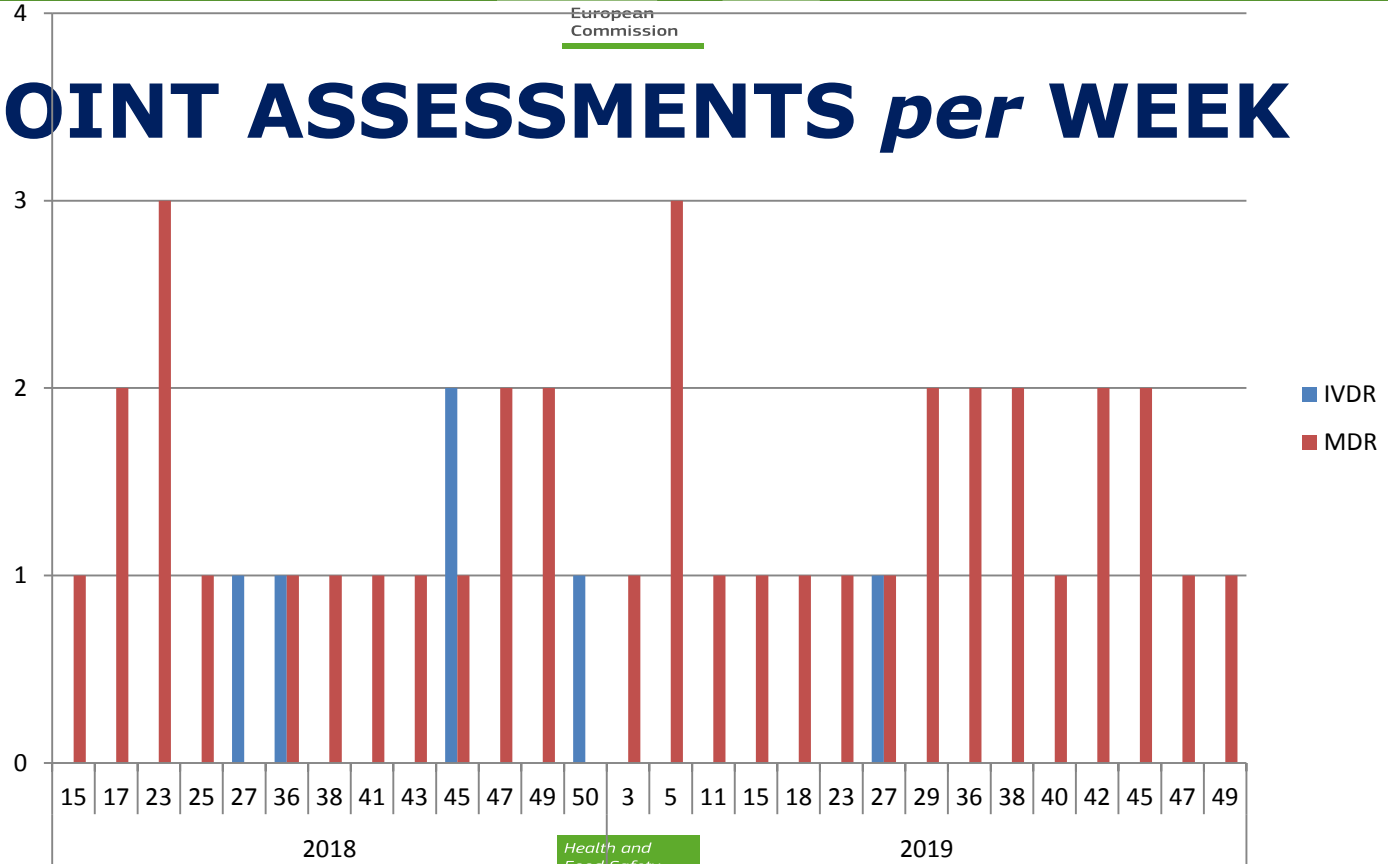
## 46 ON-SITE ASSESSMENTS

		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