

- Based on EMA survey results EU SG discusses impact of COVID-19 on inspections.

- Majority inspectorates indicate to have resumed on-site inspections on national territory.
- Some inspectorates appear to be close to normal routine inspection planning, others indicate that they limit themselves to COVID-19 priorities.
- Third country inspections are uniformly on hold – inspectorates are using distant assessments.
- Distant assessments to verify GMP compliance, international collaboration with trusted authorities and pro-active engagement with developers are crucial to mitigate COVID-19 restrictions for verification of GMP compliance.
- Compliance with GMP is not waived. Early engagement between EMA, NCAs and developers is key.
- Large scale COVID-19 vaccine and medicine production in combination with upheld third country inspections presents potential oversight risk.

Bijgevoegd vinden jullie ter info:

- Vergaderagenda met aantekeningen
- Belangrijkste onderliggende vergaderstukken – waaronder ook twee presentaties van zijde industrie over respectievelijk vraag naar COVID-19 producten

De volgende bijeenkomst vindt plaats op 21 oktober 2020.

Voor meer informatie weten jullie mij te bereiken.

Met vriendelijke groet,

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