

EMA/701495/2021 24th November 2021

Agenda – 7th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines.

1st December 2021, C.E.T.: 13:00-17:00 virtual meeting: WebEx

Chair: Alberto Gañán Jiménez

Item	Preliminary Draft Agenda
1.	Welcome / Introductions
2.	Info on repurposing pilot from EMA
3.	Update on Implementation of IRIS Marketing Status
	Coffee break
4.	Use of master data and IDMP implementation
5.	An update on EC pilot on Intent to launch of Orphan and Oncology Medicinal products
6.	Working Parties project implementation
	Coffee break
7.	Measures taken to help the EU regulatory network coping with increased workload. How can industry support?
8.	Changes to Pre-Submission Meeting activities
9.	Derogation of the Gaelic as an official EU language in January 2022
10.	Summary of follow-up items

