# Medical Device Coordination Group

**11 October 2023**

## Agenda point 5.1: Document for endorsement - New Work Item Proposal: Guidance for manufacturers and notified bodies on the application of clinical evaluation requirements to orphan devices in view of their certification in accordance with the MDR

Dear MDCG Members,

Under this agenda point, you are asked to endorse the draft New Work Item Proposal (NWIP) for the development of guidance for manufacturers and notified bodies on the application of clinical evaluation requirements to orphan devices in view of their certification in accordance with the MDR.

The draft NWIP is included in the annex below.

At its meeting on 6 and 7 September 2023, the MDCG orphan device taskforce endorsed the draft NWIP. The draft NWIP was then sent to the NBO and CIE subgroups with deadline for possible comments by 15 September 2023. One comment was made by a NBO representative, namely to delete the word 'safety' in the second bullet point under the heading 'scope' ("*clarification of the level of clinical ~~safety~~ evidence considered sufficient*"), which has been taken into account.

Development of the proposed guidance is considered a key priority for the MDCG.

Should you have any questions on the above, please write to SANTE-MED-DEV@ec.europa.eu or raise them during the meeting.

**Annex**

# MDCG New Work Item Proposal (NWIP)

## Proposed new work item:

Guidance for manufacturers and notified bodies on the application of clinical evaluation requirements to orphan devices in view of their certification in accordance with the MDR.

## Initiator:

MDCG

## Proposed MDCG sub-group(s) or MDCG task-force:

MDCG taskforce on orphan devices (ODTF) with involvement of MDCG CIE Working group.

## Purpose and scope:

Purpose

In its position paper MDCG 2022-14, the MDCG stated:

> "The MDCG considers that, in particular for safe and effective legacy devices, including orphan devices, the complexity of conformity assessments should be reduced and more pragmatism ensured with regard to the demonstration of compliance with the applicable requirements. For this purpose, the MDCG commits to undertake the following actions with highest priority:
>
> […]
>
> 18. The MDCG acknowledges the specific situation of 'orphan devices' and will pursue work with a view to providing a definition for 'orphan devices' and suggesting specific guidance or other means of assistance for those products to be able to meet the legal requirements. Sustainable solutions are also needed in the mid- and long-term for orphan devices. [*actors: MDCG TF on orphan devices*]"

The ODTF confirms that generating sufficient clinical data for devices for orphan devices is challenging due to the epidemiology of the disease or condition to be treated (small patient populations). Meeting the clinical evidence requirements set out in the MDR within an appropriate time will be too burdensome or not even feasible for orphan devices.

Scope

The guidance should address the following:

- definition of 'orphan device' for the purpose of the guidance and clarification of the scope of the planned guidance, including whether it should also apply to 'orphan indications' for devices intended for broader patient populations;
- clarification of the level of clinical evidence considered sufficient for demonstrating conformity with the relevant general safety and performance requirements. This should include clarification of what may constitute acceptable gaps in clinical evidence and of strategies to address those gaps within an appropriate time after certification by using suitable PMCF methodologies, which could be specified as conditions/provisions linked to the certification, building on the general framework

**END**