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Outcome of Medical device Expert Panels Workshop (May 2024)

Potential additional roles for the Expert Panels

15 October 2024 – Working document





- During the Medical Device Coordination Group (MDCG) meeting on 13-14 May 2024, a discussion on current and potential future activities for the Expert Panels was held.
- The outcome of the session was analysed by the EC and EMA. As an output, a list of future roles was proposed taking into account the impact on the sector and the feasibility for implementation.
- The proposals that are considered feasible have been categorised in the following 3 groups:
 - Group 1: Short term implementation (<1 year):
 - ✓ Extension of scientific advice to IVDs classes D and C and all implantable devices (beyond class III)
 - *Support to **paediatric devices**: already included and prioritised*
 - *Support to **integral combination products** (device component): already included; alignment of scientific advice with pharma component may take longer than 1 year but is kept in this group for clarity*
 - ✓ Advice to the MDCG, with a focus on vigilance matters
 - Group 2: Medium-long term implementation (>1 year):
 - ✓ Innovative device support to manufacturers and/or NBs
 - ✓ Orphan IVD support to manufacturers and/or NBs
 - ✓ Development of standards and common specifications
 - ✓ Participation in the COMBINE project
 - Group 3: Timing to be determined
 - ✓ Training curriculum for stakeholders on Expert Panels activities
 - ✓ Horizon scanning

- The outcome of each of the 3 breakout sessions of MDCG meeting in May 2024 was analysed and the output was gathered in themes/groups of topics since many topics were overlapping from each session.
- Proposed future roles were extrapolated from the themes, reviewed and listed according to the following multifactorial criteria:
 - Potential impact on the medical devices sector
 - Feasibility: considering the amount of effort (i.e. based on existing guidance/processes) and resources required.
- Legend:
 - High impact/ high feasibility
 - Low impact/ low feasibility





✓ Group 1:

✓ Short term implementation (<1 year)



Proposed additional activity for the Expert Panels	Impact & feasibility	Early start possible (< 1 year)
Extension of scientific advice to: <ul style="list-style-type: none"> • IVDs classes D and C • All implantable devices (beyond Class III) 		Yes
<i>Support to paediatric devices</i>	<i>Already prioritised in both 61(2) and orphan pilots</i>	Yes, already done
<i>Support to integral combination products (device component)</i>	<i>Already included for standalone advice</i>	- Yes, already done for standalone advice - TBD for alignment of scientific advice with pharma component
Advice to MDCG, with a focus on vigilance matters		Yes

✓ Group 2

✓ Medium-long term implementation (>1 year)

Proposed additional activity for the Expert Panels	Impact & feasibility	Early start possible (< 1 year)
Innovative device support to manufacturers and/or NBs		No
Orphan IVD support to manufacturers and/or NBs		No
Development of standards and common specifications (1-2 per year)		No
Participation in the COMBINE Project		No

- ✓ Group 3
- ✓ Timing to be determined

Proposed additional activity for the Expert Panels	Impact & feasibility	Early start possible (< 1 year)
Training curriculum for stakeholders on Expert Panels activities		No
Horizon scanning		No

< 1 year

	Description
Additional role	<p>Extension of scientific advice for manufacturers to:</p> <ul style="list-style-type: none">• IVDs classes D and C• All implantable devices (Class III are already included).
Context	<ul style="list-style-type: none">• IVDs: provide support to IVD manufacturers.• Implantable devices: as, per Art 61(4) MDR, all implantable devices in principle require a clinical investigation, this is an activity that will help medical device manufacturers during the transition period.
Impact & Feasibility	<ul style="list-style-type: none">• High impact: similar levels of support to more MD and IVD developers/manufacturers• Alignment with overall goals to help manufacturers with the transition to the MDR and IVDR• Effort for implementation considered medium, without the need to establish a new procedure or run a new pilot.
Notes	<ul style="list-style-type: none">• Support to paediatric devices already prioritised in both 61(2) and orphan pilots• Support to integral combination products (device component) already included for standalone advice. Alignment of scientific advice with pharma component is addressed in the next slide.

Timing to be determined

	Description
Additional role	As part of extension of scientific advice: align more closely the processes for scientific advice (pharma and device components) for manufacturers of integral combination products.
Context	Integral combination products are a unique challenge and would benefit from a better integrated pathway for scientific advice, i.e. parallel advice on the clinical strategy for both the pharma and device components.
Impact & Feasibility	<ul style="list-style-type: none">• Frequently requested by manufacturers• Needs the development of an internal process for alignment.

< 1 year

	Description
Additional role	Provide advice to the MDCG, with a focus on vigilance matters.
Context	Expert panels can be asked to support the MDCG on any topic regarding the implementation of the MDR or the IVDR. Although vigilance activities are handled individually by MSs, the need to consult the Expert Panels on specific matters has been identified.
Impact & Feasibility	<ul style="list-style-type: none">• High impact, MSs often refer to the need to have this additional support from the Expert Panels• Direct impact on the MDR/IVDR implementation• Low implementation effort as process for MDCG requests already in place.

> 1 year

	Description
Additional role	Provide support to manufacturers of innovative “breakthrough” devices or notified bodies in the conformity assessment phase.
Context	Support to innovation is asked by stakeholders (e.g., MedTech Europe). Other regulatory regions (e.g. USA or Japan) have dedicated pathways to support innovative medical devices. This support can be provided in a voluntary way similar to the one set up for the orphan devices, by confirming the innovative status of the device and/or giving advice to the manufacturers or to the notified bodies on the clinical development strategy.
Impact & Feasibility	<ul style="list-style-type: none">• The EU is one of the few large regulatory regions that does not have a dedicated support for innovative devices: high impact on the EC, MS, and Expert Panels’ reputation• Medium effort for implementation: it possibly requires the development of a new guidance from EC/MSs, and a new pilot.

> 1 year

	Description
Additional role	Provide advice to manufacturers/NBs for orphan IVDs (similar to orphan device support).
Context	IVDs are currently out of scope of the orphan guideline but will be included in an updated/new version of the guideline that the MDCG orphan device Task-Force will soon start to develop.
Impact & Feasibility	<ul style="list-style-type: none">• High impact• Medium implementation effort as it would mirror orphan device support; however, it requires the development of a new guidance from EC/MSs.

> 1 year

	Description
Additional role	Provide advice to the MDCG on standards and/or Common Specifications (CS).
Context	The Expert Panels can contribute to standards/CS and guidelines per MDR. This process has not been established.
Impact & Feasibility	<ul style="list-style-type: none">• Impactful activity• Medium effort to implement; needs to be adapted to the Expert Panels work rules - very different from current work• Complex procedures with long development.

> 1 year

	Description
Additional role	TBC – Provide early scientific clinical advice to sponsors of combined studies for device aspects.
Context	Combined studies pose a unique challenge, and some sponsors could benefit from scientific input to such studies.
Impact & Feasibility	<ul style="list-style-type: none">• The topic of advice was raised in the COMBINE analysis phase. Specific needs to be further explored and confirmed• High effort to align on the procedural timetables from all areas• Some actions are already being undertaken as MS's responsibilities.

Timing to be determined

	Training curriculum for stakeholders on Expert Panels activities	Horizon scanning
Additional role	Provide a training curriculum to relevant stakeholders, e.g. NBs, manufacturers, HCPs	Providing support in horizon scanning activities
Context	Several stakeholders could benefit from potential trainings from the Expert Panels & its secretariat	Horizon scanning can support the panels in detecting new technologies and better prepare for their opinion/advice
Impact & Feasibility	High effort as a full curriculum needs to be developed	Complex activities, currently not undertaken in a systematic way in the EU



Any questions?

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