Add value.
Inspire trust.

Notified Body perspective

Independent Scientific Opinion for CE Mark or Early Dialogue for HTA: A Unique Expert Panel for Both?

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Regulatory Strategy Principal

- Notified Body TÜV SÜD since 2020
- Chair of NBCG-Med (formal coordination group of EU NBs)
- Vice-president Team-NB (EU NB association)

- Before TÜV SÜD:
  - Regulator & Legislator in NL Government (*20 years*)
    - pharma (scientific advice)
    - medical devices (international policy & legislation)
  - Big medtech industry (*7 years*)
  - Professional Societies and Expert Groups (*throughout career*), e.g.
    - RAPS EU/US Convergence & DIA Euromeetings
    - RAPS Global Board of Directors
  - Pharmacist by training

This presentation is based on information available as of today and prepared to my best knowledge as subject matter expert.
This presentation presents my personal understanding of medical device regulation in Europe and is not necessarily reflecting the view of TÜV SÜD.

Notified Body perspective

- Notified bodies as ‘extended arm’ of authorities
- NB interactions with EU COM and NCAs
- Clinical Evaluation Consultation Procedure & Expert Panels
- “Scientific Advice” vs. expert panels
- Conclusion

Notified bodies: “extended arm” of authorities

- Concept of “Notified body” common in EU product legislation (New Approach)
  - Applied in EU legislation for medical devices and IVDs
- Notified Bodies are private organisations
- Notified Bodies have to fulfill extensive requirements, stipulated in applicable legislation, on e.g.
  - Expertise, experience and competencies of staff
  - Authorization and continous training of staff
  - Internal organization
  - Content, organization and frequency of audits and inspections of manufacturers and subcontractors
  - Impartiality
- Notified Bodies are (strictly) controlled and monitored by authorities
  - Designation, re-assessment and regular audits
- Designation under a specific regulation entitles a Notified Body to take decisions on market access of product covered by that legislation
- In EU medical device/IVD legislation, NB involvement is required for mid- and high risk class devices

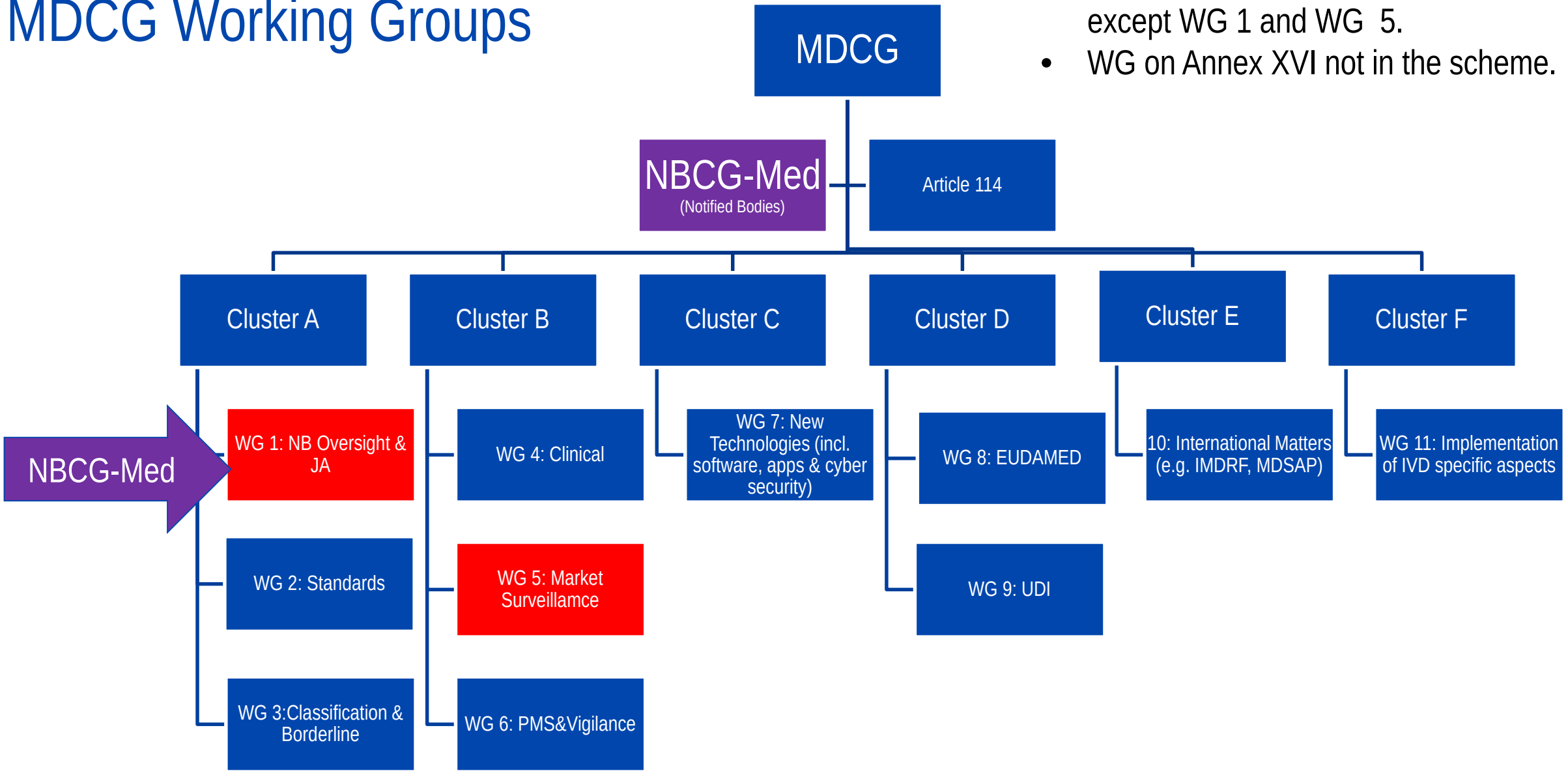
Notified Bodies interactions with EU Commission & National Competent Authorities (NCAs)

- Notified Bodies need to be designated
  - by NCA in Member State of their legal seat
    - after extensive assessment at EU level
    - by Joint Assessment Teams consisting of EU COM and other NCAs
  - Reassessment of designation every 3 years
  - Monitoring ´in between´ by NCA

- Medical Device Coordination Group (MDCG)
  - Consisting of EU COM and NCAs
  - Tasked with Coordination Activities for medtech sector
    - Medical Device Regulation (MDR) art 103
  - Several Subgroups (see next slide)
  - Notified bodies are ‘stakeholder’

MDCG Working Groups

- All MDCG WGs accept stakeholders, except WG 1 and WG 5.
- WG on Annex XVI not in the scheme.



New concept in MDR:
Clinical Evaluation Consultation Procedure (CECP)

- Basis: Additional check of NB clinical assessment by authorities
  - For certain high risk devices (certain class III and IIb)
  - By “Expert Panels” on behalf of authorities
    - Independent experts
  - NBs have to notify EU COM if they have assessed certain high risk devices
    - Include certain supporting documents in notification
  - EU COM forwards to the relevant expert panel
  - Expert panel decides: scientific opinion ‘yes’ or ‘no’
    i. If no: NB can proceed with certification
    ii. If yes: NB must await scientific opinion (60 days) and ‘shall give due consideration’ and ‘full justification where it has not followed the advice of the expert panel’
  - Up and running since Summer 2021 – managed by EU COM’s Joint Research Center (JRC) – via CIRCA-BC
  - NBs experience overall favourable – JRC doing a good job

- In summary:
  one extended arm of authorities (i.e. Expert panels) checks the work of another extended arm (i.e. Notified Bodies)

Expert Panels: additional task

- Manufacturers are allowed to consult expert panels (MDR art 61.2)
  - On the intended clinical development strategy and proposals for clinical investigation
  - Only for certain high risk devices (certain class III and IIb)
  - “The manufacturer shall give due consideration the views of the expert panel”
- Not available yet....

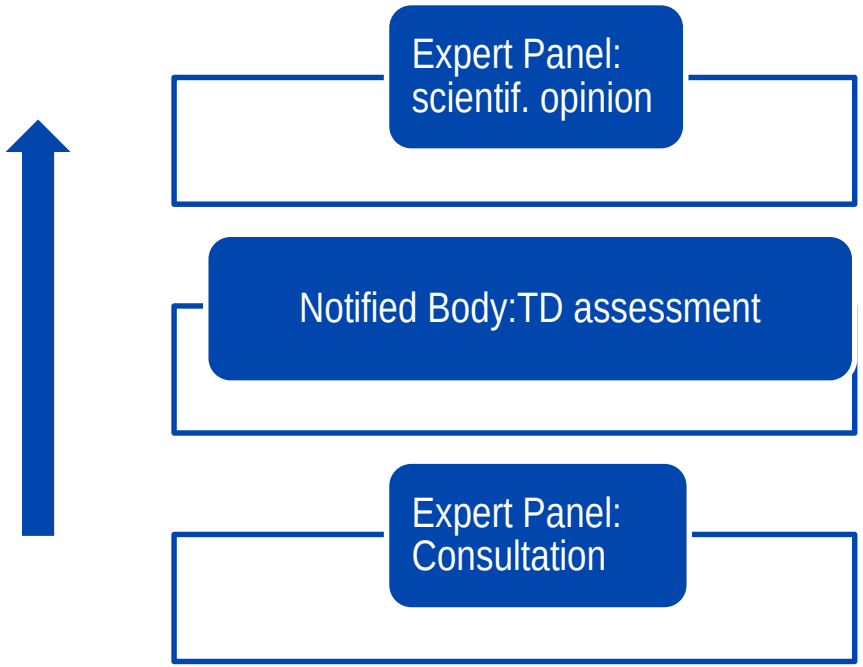
Sounds familiar?

- Could we see ‘consultation of expert panels’ as the device-equivalent of ‘scientific advice’?
- ‘yes’ and ‘no’

“Scientific advice”

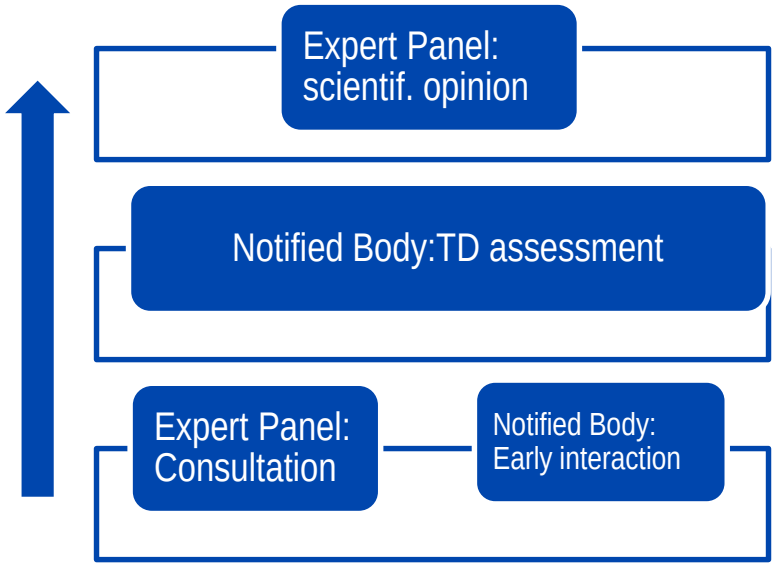
- In the pharma sector “scientific advice” has been an established concept since decades
  - On CMC, preclinical, clinical (regulatory)
  - NCA-level
  - EMA-level
  - EMA-EUnetHTA-Joint Consultations
- Concept: same authority body provides scientific advice (with disclaimer...) and later MAA assessment

- In the device sector different situation
  - NCA-level: in general not available
  - EU-level: in future ‘consultation of expert panels’
  - Not same authority body, but “sandwich of extended authority arms”
    i. Bottom layer: Expert panel
    ii. Middle layer: Notified Body
    iii. Top layer: Expert panel



Gaps in “consultation of expert panels”

- Only for high risk devices
- Only for clinical (not for quality, technical, biocomp etc aspects)
- Gap for lower risk devices and other aspects than clinical
- How to fill this gap?
  - ‘Consulting’ by NBs not allowed
  - Consulting ≠ scientific advice
  - Currently no possiblity for “early meaningful interactions” between NBs and manufacturers
    - Possible in future???
      - Expert panel and notified body in parallel?
        - Manufacturer could go to NBs for aspects not covered by Expert Panel?



Synergy between Expert Panels and HTA?

- In principle: yes
- Criteria for decision scientific opinion by expert panel ‘yes’ or ‘no’ might need to be adapted to ‘HTA-aspects’
- Some other legal impediments/restictions might need to be removed
- In addition:
  - Gaps need to be filled
    - Early meaningful interaction between Notified Bodies and manufacturers
  - Overlap should be avoided
  - Synergies between other parties and Notified Bodies should be optimized

Thanks for your attention!

Questions?