Proposed checklist to release the clinical evaluation report

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Aurora, Illinois May 2, 2022 (Issuewire.com**)** - A well-researched clinical evaluation report gives regulators, patients, clinicians, and competent authorities the assurance that medical devices have been evaluated using strict guidelines. This ensures that there are no potential risks to their use. To ensure a consistent approach among manufacturers and notified bodies (NBs) participating in conformity assessment procedures, MDR Article 61 was used.

Article 61 mandates the creation and regular updating of a Clinical Evaluation Report for Medical Devices. This report reviews and analyzes data about a medical device to verify its clinical safety and performance. Medical device manufacturers must prove that their products meet the 2017/745 general safety and performance requirements (GSPR). Medical device manufacturers must evaluate existing data to develop a CER according to MDR Article 61. Annex XIV covers post-market surveillance data that includes post-market clinical follow-up data.

The CE Marking process is incomplete without the clinical evaluation report. Both are linked together. The CE Marking process for a device must include CER. CE marking must be maintained to market a device in the European Union. The EU MDR stresses CER's importance and includes general safety requirements, documentation, and clinical evaluation review.

A detailed CER must be included in the technical file to obtain CE Certification. Specific requirements are outlined in EU 2017/745 for data analysis and documentation of medical device clinical evaluation

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These are the things that should be considered before a report on clinical evaluation is released:

- Is the report easy to understand by a third party? Does it contain enough detail to allow them to comprehend the data, assumptions, and conclusions?
- Are all clinical data generated by the manufacturer mentioned in the report and properly summarized?
- If equivalence has been claimed,
- Is the report complete with a demonstration of equivalence?
- Does the report detail all differences between the device under review and the equivalent device?
- Does it explain why these differences aren't expected to impact this device's clinical performance or safety?
- Is the product on the European market or elsewhere? Have the most recent PMS/PMCF data been considered, and have they been summarized and referenced within the report?
- Concerning current knowledge/the state of the art
- Is the report up-to-date?
- Is the current knowledge/state of the art summarized and well supported by literature?
- Is the report following current knowledge/state of the art?
- Is the report able to explain the acceptable side-effects and the risk profile of this product in light of current knowledge/ state-of-the art?
- Are there sufficient clinical data and conclusions if the report includes multiple models, sizes, settings, and clinical situations?
- All the devices?
- All sizes, models, and settings. (Including the smallest/largest size, highest/lowest dose, etc.
- Each medical indication?

(As per the IFU/not excluded with contraindications as the IFU).

- The whole target population?

(Pre-term infants through old age, for males or females, if the IFU does not limit them)

- All forms, stages, and severity of medical conditions, as applicable.

(Including the most severe/most benign forms, acute/chronic stage, if not exempted in the IFU).

- All users intended?

(Laypersons included, if not exempted by the IFU and any other unusual user group).

- The product's entire duration, including repeated exposures? (as permitted by the IFU).
- Are there any discrepancies in the above?
- Are all the discrepancies in the report's conclusions identified?
- Are the information materials provided by the manufacturer following the contents of this report? If not, are any discrepancies identified within the report's conclusions.
- Are there any residual risks or uncertainties that the report does not address?

- Is the report current?
- Is the report correct regarding the qualifications of the evaluators?
- Is the manufacturer able to provide a copy of the CV and declarations of interest of all the evaluators?

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