

Minutes of a meeting of the Medical Devices Information session, organised by Central Procurement and Supplies Unit of the Ministry of Health, on behalf of MCCA Bellavista Conference Centre, Qawra on Friday 24th May at 8.30-11.30am.

Panel:

Central Procurement & Supplies Unit (CPSU)

Ing. Karl Farrugia, Managing Director (Sourcing and Supply)

Dr. Alison Anastasi, Head of Operations (Procurement)

Mr Donald Attard, Charge Nurse, Technical Compliance Unit

Ms Josette Sciberras, Head of Quality

Mr Joseph Xuereb, Senior Principal, Contracts policy and compliance

Malta Consumer Competition Affairs Authority (MCCA)

Ms Ingrid Borg, Director, Regulatory Affairs Directorate, Technical Regulations Division

Audience:

Industry

Central Procurement & Supplies Unit (CPSU)

Malta Consumer Competition Affairs Authority (MCCA)

Medicines Authority (MA)

Ing Karl Farrugia welcomed the attendees and thanked all for their continuous collaboration.

Ms Ingrid Borg started off with a presentation (attached) to update the audience with respect to updates on the new directives of medical devices implementation. She emphasised the fact that since this is a regulation the directives that apply in the EU will apply directly to the National legislation. Any derogation will be tackled on an individual case by case basis by MCCA as the competent authority. However, there will be no postponement on implementation of new directives. There is no derogation on Protective Personal Equipment.

Discussion:

1. Major companies have been proactive and have recertified notifying bodies
2. There are other companies who are awaiting the timeline date to recertify
3. Other manufacturers do not give the relevant feedback to the local suppliers
4. Besides BSI shifting to Netherlands, TUV has also shifted to Germany
5. The importance for the current competent authority and the new competent authority to meet up with the relevant stakeholders such as but not limited to GRTU, COC etc. to implement it locally
6. The main concern is with respect the hearsay of registration;
 - a. Issue of registration fee
 - b. How will cost impact current tenders
7. CPSU in agreement with MCCA and MA agreed to the industry's suggestion and confirmed that there will be public consultations with relevant economic operators and other stakeholders to balance access, quality and safety

8. MCCA explained that medical devices are already being registered in EUDaMED
9. The discussion went on agreeing that no new registration mechanism or fee should impact treatment access so that there is no further burden and added bureaucracy especially when one considers all the limitations involved.
10. Besides having public consultations, there should be a stepwise approach and a process set when one considers the number of medical devices including anything within the legislation which is really voluminous per company.
11. CPSU advised that the department's objective and current processes are going for pay per use cycles or complete service cycles to include consumables, service and maintenance up to lifetime of the machine.
12. The importance of the Declaration of Conformity (DOC) was pinpointed again. MCCA explained that the declaration is not rectifiable by their end. Only the manufacturer can rectify it and only when the product is changed. They also advised that PPEs and anything electrical, that is anything with a CE marking has a DOC.
13. Forging the declaration of conformity is a criminal act and as per current scenario there will be legal consequences. If the document is MS Word it is implied as clear forgery.
14. CPSU launched the fact that from the 1st of June 2019 the declaration of conformity will be part of a self-assessment questionnaire besides the usual upload of the declaration. The self declaration is being linked to blacklisting and exclusion as per PPR (2016) if the DOC is not as per declaration.
15. The industry advised that the answers for the assessment should include the not applicable option just in case the item would not need a DOC and CPSU agreed to amend the relevant question to include. For the query where there is 1 lot with 300 reagents - the assessment needs to be filled generically and all the applicable DOCs uploaded. It was agreed to issue a memo on the website to alert everyone with the new template update.
16. The industry was also reminded regarding the February/March data collation mitigation exercise so that they do a review of the medical devices list and see what is needed for the current scenario to keep on supplying the items to the NHS. It was explained that they need to list any medical device including spare parts and see which notifying body/alternative route is being applied for access. The only exclusion is where there is a service, however, companies were still invited to seek assistance if needed. It was re-clarified that data collation is to be used solely for CPSU to take stock of what are the issues that will impact the market and how the department can assist. The MCCA who will be leading the implementation of the new directives are collaboratively assisting in the exercise.