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Faculty of Pharmaceutical Medicine submission to the MHRA public consultation on the revision of European legislation on medical devices

21.01.13

Many of the members of the Faculty of Pharmaceutical Medicine work in the development of medical devices. A small group of these experts form the 'Medical Devices Special Interest Network' of the Faculty, who have been responsible for developing this consultation submission. We hope that you find our comments below to be useful in your consultation.

1 Agree. "Ancillary" will require careful definition to avoid liberal (relaxed) interpretation.

2 We believe that these products should be covered by 'combination' guidelines as per the US FDA. They are not adequately covered by either device or medicines regulation alone. Any product that will be 'administered' and distributed by the body should not be considered a device.

However, we have concerns that some device related issues/defect in a drug/device combination might not be captured especially if there is no drug related problem e.g. if there is a problem with drug delivery device (too low delivery/too high delivery) but patient improves anyway.) So there is no adverse event but there is an adverse device deficiency. This will not be captured because of the exclusion.

3 Agree except for ex-vivo sterilization equipment.

4 Agree. Cosmetic indication should be included as a medical purpose.

5 We believe that all implanted/invasive products should be regulated whatever their purpose. However, we think that piercings should be excluded but that other cosmetic devices, such as dermal fillers and breast implants should not be excluded.

6 Agree

7 Agree - the term "software" needs to be defined so that it does not include laptops that algorithms sit on.

8 Including software could be problematic - all sorts of validation issues, stability, platform dependent issues. This might be better dealt with in a separate regulation.

9 Agree

10 Agree, "in-house" IVDs are often abused and are widely used so should have a clinical evaluation.

11 All Classes should be regulated. Otherwise, how can you ensure the tests are properly valid - particularly if (potentially far reaching) clinical management decisions are taken on the basis of the results? Waivers could be granted for single institution tests while they are brought up to standard.

12 Agree

13 Agree

14 Agree

15 Agree, but need clarification on how different individuals can share qualifications.

16 Agree.

17 No experience to the exact cost. QP can be hired contractually or sessionally to minimise cost by small and medium sized manufacturers and manufacturers of Class 1 devices.

18 One member suggested requiring QP review of all safety reports and design history files to ensure patient safety.

19 Yes - but should encourage consistency across/within EU - and avoid reuse of devices. Reprocessing of single used devices is not routinely done but happens occasionally, which can compromise the safety and effectiveness of the device.

Clarification of the definition of single use devices was raised – one device per patient or one device per clinical session

20 Agree - if it goes in the direction of allowing some member states to reuse, there should be closer vigilance and there should be provision for a post-marketing safety study before approval. However, we require clarification as to what counts as single use - one device on one patient, or one device on one clinical session?

21 Yes. Single card though - written in plain language with details of how/who to contact if a problem.

22 Agree

23 No. Devices should be considered 'in total'. If a part is replaced with a part that changes the way the device works - the whole device with the new part should be reassessed. Getting CE marks for individual parts sounds too complex and unworkable - a single screw could dramatically alter the way a device works - and what if a replacement part is incorrectly used - is it the part, the device or the operator who is at fault?

24 No suggestions

25 Agree

26 No suggestions

27 Agree. Long overdue. Bar coding and serial numbers are normal practice in commerce & retail so why not for medical devices?

28 Initial set up - but once running smoothly minimal extra cost. However monitoring and vigilance against frauds may need to be increased.

29 Agree

30 Suggest similar structure and detail as SmPC for drugs; little additional burden since all information should be available, just needs to be collated. Should include device deficiencies as well as adverse effects.

31 Agree

32 Strongly suggest that audit includes review of evidence to support positive decisions to CE mark, not just audit of procedures and processes. Preference is for central body providing oversight of NBs rather than just national competent authorities. We believe that there should be inclusion of an industry representative in NB oversight.

33 Agree

34 No suggestions

35 Agree

36 Agree - may force higher fees that will hurt small manufacturers, or devices for very small markets which would be unfortunate. Can a sliding scale of fees be proposed?

37 Agree in principle, but should have clear guidelines on the audit process (for consistency) and the audits should be made public (for transparency).

38 Agree

39 Agree

40 Agree

41 Suggest that patient safety is more important than manufacturers' burdens and so err on the side of caution when classifying devices

42 Agree

43 Device novelty does not suggest itself as a prime determinant of patient safety (such as misdiagnosis) so suggest not adding it

44 Agree but noted that this will be administratively burdensome for manufacturers

45 Agree

46 Yes. Will the NBs do the sterility testing themselves or subcontract to approved independent third parties? If internal - who certifies their competence and quality? If third party - how are those parties chosen and regulated?

47 Agree

48 Disagree: expertise can be imported into the MDCG if needed; some NB decisions regarding positive CE mark decision seem shocking as they are based on very little evidence, so suggest that these decisions do need to be policed. Alternative is that the CA that designated the NB checks some of the Class III decisions as suggested, as CAs have expertise.

49 Agree. MHRA should also audit past approvals with safety issues which later on have safety issues and implement measures which can prevent these from happening again.

50 Agree

51 Agree, since IVDs can do significant harm so proper evaluation is critical and the additional burden should not deter the implementation of this. The evaluation of devices must be for as long as the device remains in use in all classes.

52 Agree but feel that a six-day approval time is very short. We encourage public disclosure of all medical device trials.

53 Agree

54 Agree

55 Agree

56 Agree

57 Agree

58 Agree

59 Agree

60 Agree

61 Agree

62 Agree

63 Agree

64 Yes

65 Agree

66 Agree. Payment of fees to NBs should NOT be linked (or scaled) to outcome of assessments and preferably not paid to NBs anyway (currently they are for profit organizations which leads, potentially, to conflict of (financial) interests).

67 Yes but agree that timelines could be shortened

68 Agree