Response ID ANON-ZAJJ-78HN-M

Submitted on 2015-01-08 14:01:40.718328

Responding to the call for evidence

Confidentiality

About the MHRA

Your Details

What is your name?

Name:
Charles Lowe

What is your email address?

Email:
charles.lowe@dhaca.org.uk

What is your organisation?

Organisation:
Digital Health & Care Alliance (www.dhaca.org.uk)

Your Category

Would you categorise your response as from

None of the above

If none of the above please state here.:
Cross-sector organisation dedicated to improving UK health & care systems

If your response is from an umbrella organisation representing a wider membership, please indicate the number of members consulted and the number of responses received

Please submit your response here.:
DHACA currently has some 340 members, split approximately 40:40:10:10 across the public, private, academic and third sectors. A significant portion of our members have an interest in medical devices, particularly medical apps. We have an active Special Interest Group working in this space, as well as wider regular membership get-togethers. We have recently consulted the whole membership for the EC Green Paper response, and, because time was pressing, a cross-section only for both the Personalised Health to 2020 and the NICE Triennial review. As we have only foundout about this MHRA review three days before it is due to close, this response is based on comments already received from members in previous consultations.

What interactions/relationship you have with the MHRA?

Please submit your response here.:
DHACA's members principally interact with the MHRA over certification of medical devices. As the full process for bringing medical apps to market is opaque, currently there is more interaction than there need be.

DHACA itself interacts both to ask questions on behalf of its members, and to draw MHRA attention to potential dangerous uncertified apps that appear to meet the MEDDEV 2.1/6 definition of Medical Devices.

Call for Evidence Questions

Performance, capacity and capability

Question 1

How would you rate the performance of the Agency?

Average

Please briefly explain your answer.:
DHACA's interest is solely in its responsiveness and helpfulness specifically regarding EU Medical Device (& to a lesser extent In Vitro Device) legislation.

The staff that are there are extremely helpful, however there are very few of them, they are not capable of being proactive because they are seriously overworked, and because they are scattered round the Agency, not in a single team do not appear to an outsider to be as effective as a single team might be.

Finally we do not sense that there is a good understanding of the hand-off between the MHRA and NICE, with some Agency staff quite critical of NICE's involvement.

Question 2

Where do you think the Agency performs particularly well or needs to improve?

Please submit your response here.:
The professionalism and dedication of Agency staff is hugely impressive.

The principal areas for improvement are:

1) to improve the responsiveness of the agency so it is able to cope with the increasingly rapid changes in the demand for its services as new health & care technologies emerge

2) to improve the interface with NICE where some Agency staff are currently very dismissive.

Question 3

How well does the Agency respond to relevant public health issues, e.g., safety issues with products, product defects, or new priority concerns?

Please submit your response here.:
As mentioned earlier, the Agency is very short staffed in the Medical Device area so has no been proactive in closing down medical apps that meet meet the MEDDEV 2.1/6 medical device definition and that are not appropriate CE certified. We have notified the MHRA of a few examples, which to date they have used the excuse of not having enough information on to go chase them up - needless to say that all they had needed to do was ask for that info!

Question 4

How effectively does the Agency balance risk/benefit decisions?

Please submit your response here.:
DHACA is in no position to take an overall view. However we worry greatly that a big risk of patient death/permanent harm is being taken in the medical apps area, particularly with uncertified dosage calculator apps.

Question 5

How well does the Agency negotiate and influence nationally and internationally? How might it exploit further opportunities?

Please submit your response here.:
No experience/views

Question 6

How well does the Agency support innovation and what more could be done?

Please submit your response here.:
There is a pressing need for an innovation architecture crossing the MHRA, NICE NHS England etc. which is not there just now. As is also the case with NICE, the Agency does not appear to be responsive to changes in health & care technology and so appears flat-footed when new technology needs Agency attention.

The agency would undoubtedly benefit from an innovation advisory board that ensured it was repositioning its scarce resources in anticipation of the emergence of new technologies, not after they had already been implemented.

Question 7

How well does the Agency communicate and engage with its stakeholders?

Average

Please briefly explain your answer:
In the medical devices area it really struggles due to overwork. However when we do get attention, the staff are unfailingly helpful and keen to participate in ensuring a good understanding of how the Agency works.

Question 8

How would you measure the performance of the Agency?

Please submit your response here.:
1) number of pharmaceuticals and medical devices receiving appropriate approvals (note there is currently no record kept of Class I medical devices receiving CE certification, so a change would be needed there).
2) Number of uncertified pharmaceuticals and medical devices removed from the market.

Question 9

How effectively do the various elements of the Agency work together? Are there more synergies that could be achieved?

Please submit your response here.:
DHACA is only involved with Medical Device and In Vitro Device approvals - we do not see these other aspects of the MHRA in operation.

Question 10

Is there a continuing need for the functions undertaken by the Agency?

Yes

Please briefly explain your answer:
Particularly in the area where DHACA operates - medical standalone software - there is a pressing need for more MHRA involvement, because unapproved medical apps with the potential to do real harm are already in use and need the MHRA to remove them from the marketplace.

Question 11

Are there any functions that should be added, dropped, undertaken by another organisation, or which overlap with another organisation?

Please submit your response here.:
Approval of medical apps could be delegated ot another organisation - it is however doubtful id much - if any - money would be saved by so doing as the work would still need doing.

Question 12

How effectively does the Agency contribute to wider government policy? Are the Agency's activities effectively aligned with the rest of the health and social care system?

Please submit your response here.:
It's not clear to DHACA that the Agency's activities are indeed effectively aligned with the rest of the health & care sector. DHACA has for some time been seeking to encourage policing of the medical app area, without success. Perhaps more significantly, we rarely encounter MHRA staff in cross-sector discussions about changing the way care is delivered.

Form

Question 13

Do you think the Agency should

Remain in its current form (Executive Agency and Trading Fund)?

Please briefly explain your answer:
The obvious merger partner would be NICE, however it is important to separate out the functions of assessing safety and assessing efficacy, so DHACA does not consider such a merger would be in the best interests of the UK - it would be good perhaps if greater cooperation between the two parties could be encouraged though as gathering evidence of safety, with the right design, could also provide evidence of efficacy.

Question 14

If the Agency continues in its current form, are there opportunities for greater cooperation and joint working with other organisations?

Yes

Please briefly explain your answer:
As mentioned in answer to the last question, it would be good perhaps if greater cooperation between the MHRA & NICE could be encouraged, as gathering evidence of safety, with the right design, could also provide evidence of efficacy.

Efficiency

Question 15

How could the Agency reduce costs or improve performance through efficiencies?

Please submit your response here.:
DHACA is unaware of any such opportunities - the Agency currently appears to working efficiently although is greatly cash-constrained from respponding to innovative developments in the delivery of health & care.

Question 16

Are there any opportunities for the Agency to make more effective use of its assets and/or to increase commercial revenues?

Please submit your response here.:
A comment made also for the NICE review is that DHACA is unable to understand why both NICE & the MHRA seem unable to make commercial charges for their services: it seems entirely reasonable that if the MHRA incurs significant cost in reviewing the approval of a Class III device, then the cost of that review should be loaded on to the cost of the device - after all the notified body involved charges!

More challenging is how to charge for policing, which is desperately needed for medical apps - can fines be levied?

Question 17

The Agency applies a licence fee to fund its medicines' regulatory activities. Do you think devices' regulation should operate under a similar funding model?

Yes

Please briefly explain your answer:
Yes most definitely - see previous answer

Governance

Question 18

Does the Agency follow best practice governance arrangements?

Please submit your response here.:
We have no reason to believe it doesn't

Question 19

How effective are the Agency board and senior management team?

Please submit your response here.:
Well clearly a trick is being missed over medical device coverage & policing, with those working in this area being scattered all over the MHRA and not in one team, although whether that is a single isolated issue or part of an overall management failure we are not in a position to judge.

Question 20

How well are risks and opportunities identified and managed?

Please submit your response here.:
Again the risk of uncertified medical devices (specifically medical apps, such as dosage calculators) causing death or serious injusry, and the opportunity for early encouragement of compliance have both been missed by the MHRA. We understand that a solution has been suggested of encouraging Royal Colleges/Colleges to instruct their members not to use uncertified devices which would be disastrous if it happened because most apps used by clinicians do not need certification as they are not medical devices; deciding, at this late stage, which do and so cannot be used because they are uncertified, and which don't, so can be used, will be a non-trivial problem that would have been far easier to deal with had the MHRA wised up to the problem initially.

Other comments

Are there any other issues or evidence you think the review team should take into account?

Please submit your response here.:
There is a crying need, as mentioned earlier, for a common approach to innovation - what others refer to as an 'innovation architecture' - amoung DH agencies. Te reality is that the provision of health & care is changing far faster than the MHRA (or NICE) are, resulting in potentially dangerous unreviwed/unsafe services that, because they appear clearly beneficial to users, will still get used irrespective of the MHRA's behaviour otherwise - we have even heard a senior NHS Director tell people not to look to hard into medical apps otherwise they might get classified as medical devices which would slow everything down!!!