To: 5.1.2e)[5.1.2e @minvws.nl]
Cc: 5.1.2e [5.1.2e @bsigroup.com]; 5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e .[5.1.2e @igj.nl]
From: 5.1.2e
Sent: Fri 3/13/2020 3:58:29 PM
Subject: RE: MDSAP - Issues - COVID 19
Received: Fri 3/13/2020 4:00:39 PM
image006.png

5.1.2e

Thank for adding to 5.1.2e feedback this is a real concern we had a call with other MDSAP Ao's this p,m they all share the same problem and are wanting to have a similar approach as with ISO 13485 we will take this up again with the FDA and Health Canada.

It will be good if we can keep each other posted.

Have a good weekend 5.1.2e

From: 5.1.2e) < 5.1.2e @minvws.nl>
Sent: 13 March 2020 11:26
To: 5.1.2e < 5.1.2e @bsigroup.com>; 5.1.2e < 5.1.2e @bsigroup.com>
Cc: 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e . < 5.1.2e @igj.nl>; 5.1.2e 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e 5.1.2e) < 5.1.2e @igj.nl>
Subject: RE: MDSAP - Issues - COVID 19

Dear 5.1.2e

Covid-19 is indeed keeping us all busy. Something to add to the stress of developments within the Medtech sector.
I can imagine BSI as a worldwide organization is feeling its impact hard.

It is good to hear from you that the European directives and regulations leave some room for dealing with this challenge, even though the whole situation is not optimal.

Thank you for flagging this issue with MDSAP. Just this week the European Commission announced the set-up of a special taskforce about the effect of the Coronavirus on notified bodies. 5.1.2e will represent the Netherlands in this Taskforce. We will ask him to flag this issue within this taskforce.
Obviously, many notified bodies will encounter the problem you describe.

If there are other concrete steps we can take at the moment, or at a later stage, please let us know.

Kind regards,

5.1.2e

5.1.2e
Directie Geneesmiddelen en Medische Technologie
Ministerie van Volksgezondheid, Welzijn en Sport |
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5.1.2e

Van: 5.1.2e < 5.1.2e @bsigroup.com>
Verzonden: donderdag 12 maart 2020 15:28
Aan: 5.1.2e) < 5.1.2e @minvws.nl>
CC: 5.1.2e < 5.1.2e @bsigroup.com>
Onderwerp: MDSAP - Issues - COVID 19

Dear 5.1.2e

I hope you well in these difficult times and you and your team manage to avoid the current health threat we are all concerned about.

Relating to COVID 19 BSI is looking to get some cross regulator support to help with a problem we have run into with the MDSAP Program (Run by the US FDA and Health Canada) not only in Category 1 countries but in other increasing geographies with travel restrictions.

Just to reassure we have business continuity procedures in place to cover EU CE and EU QMS requirements ...

MDD /ICD MDR and IVDR:	Certification (under your jurisdiction) most of this is Conformity Assessment activity desktop and remote and therefore less of a challenge and we can also cover the regular Technical audit requirements remotely.
Unannounced Audits:	BSI will have to defer the Unannounced audits where travel does not permit, however, we do not fell this will adversely effect patient safety or product market access as numbers are lower as a result of the once in 5 year cycle requirements.
ISO 13485 QMS:	QMS onsite audits are more challenging, however, for the EU requirements we are following IAF guidance under IAF ID3:2011 which contains a force majeure procedure that allows for remote audit and deferral up to six months in the case of a number of major acute crises including Pandemic. From this we are meeting the audit requirements for ongoing surveillance Audit under ISO 13485 (agreed with RVA (NL)/UKAS (UK) and SCC (North America)) by delivering audits in closed geographies in the main remotely with a much smaller number of deferred recertifications.

Our issue is...

MDSAP FDA/Health Canada:	Their approach is not to allow remote audit with their preferred proposed solution being to defer where we cannot deliver due to restrictions with no extension of certificates. Our view is the resulting lack of oversight will increase patient risk and it seems to us the IAF approach is far more pragmatic. We fully recognise at a remote audit is not exactly comparable to us being onsite, however, it can cover the majority of the requirements and maintains a good degree of manufacturing oversight.

The other reason for mail is this could directly affect European patients and Industry in several ways ...

1. Large numbers of deferred audits will challenge all NB's after the resolution of the COVID 19 crisis as we could be in catch up mode. Delivery increase just for BSI alone could be between 5000 -10,000 audit days, as you are aware there is little or no capacity in the system to flex to accommodate this spike in demand (The MDR had already stretched resources). This market disruption would result in deferred EU ISO 13485 Audits and CE Conformity Assessment. We estimate in the worst case BSI could take 2 years or more to catch up with audit demand (if we ever do) and this would inevitable impact both ISO 13485 Audits and MDR /IVDR certification potentially putting EU patients at risk.

2. EU companies wanting to access Canada (MDSAP is mandatory) / US , Japan and Australia would not be compliant during this period and could either place product in the market without compliance (as certificates will lapse) or stop supplying product directly affecting patient risk or patient care.

We are looking as I mentioned for cross regulator support to help convince the MDSAP authorities to put patients first and mirror the IAF approach. We are of course speaking directly to the MDSAP organisation and other regulators as well as industry groups.

I would appreciate your thoughts and support.

Kind regards – 5.1.2e

5.1.2e
5.1.2e

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