

Telecare Soapbox: Complicity between UK telehealth commissioners and providers

If 'ignorance of the law is no excuse' telehealth commissioners and providers have a responsibility to make sure that in matters of medical devices all regulations - many of them legal requirements - are being adhered to. Failure to do so on one side or the other implies a willingness to be complicit in their breaking and it unfairly tilts the market against those companies that abide by the rules.

This Soapbox item is timely given that there is due to be a big push for telehealth in the UK on the back of the WSD programme results. It is written by an experienced professional in the telehealth field who, because of his or her position cannot reveal his or her identity. It will also become obvious to readers why he or she cannot name the 'guilty parties'. However, there are questions at the end which service commissioners should now use to identify whether they are dealing with a company that is breaking the regulations.

There is now no excuse for either the companies involved not to correct the situation or for commissioners to continue to put their investment of public money at risk.

Steve Hards, Editor

While the world holds its breath waiting for the imminent final revelation of the Department of Health's Whole System Demonstrators (WSD) results, the global mass of telecare and telehealth manufacturers, distributors, resellers and newcomers are revving up their trucks full of boxes and briefing their marketing departments - all believing that a 'tsunami of sales' are just around the corner!

Storm brewing...

Potentially there is a storm brewing in the UK with the policing of Quality Assurance and Regulatory Affairs (QA-RA) of the technologies and software used in the remote monitoring of a person with a long-term or other health care condition, wherever this person is located.

To highlight this point:

- The legal responsibility of QA-RA lies with the manufacturer, the distributor and reseller, but who in the UK is responsible for monitoring the Commissioners of Telehealth and Telecare?
- Commissioners are not asking pertinent QA-RA questions on tenders (and often not aware that some of the kit they are buying could be illegal, i.e. not in compliance with EU medical device directives. Some manufacturers are confused as to whether the technology is a medical device or not (and if so, which Class of device it is!) and patient safety is potentially put at risk if a non-compliant product is used.
- The Government Procurement Service, The Telecare, Telehealth and Telecoaching framework agreement (previously PASA/Buying Solutions) appear not to be asking for

copies of evidence of CE marking for telehealth and telecare medical devices for products and services used within the Telecare Framework!

- Medical devices sold in the UK need to be CE marked either by a Notified Body or be registered with the MHRA if a low risk Class I device. It is illegal to sell a medical device without an appropriate CE marking in the UK but this does not appear to stop the NHS or other providers from buying such devices!
- Customs and Excise unknowingly allow these devices to be imported!
- Trading Standards Officers are unaware that such devices are sold in their area!
- Trade bodies and associations are often not aware that European Directives, regulations and national laws exist and are not educating and/or reinforcing such issues with their members.
- UK centres of excellence for Telehealth, Telecare and Telemedicine do not appear to be monitoring this issue or addressing this locally either!

Key regulations

The MHRA publication *Guidance Note 20: Borderlines with Medical Devices*, Updated March 2011, advises the following useful information:

- The word 'manufacturer' in the context of the medical device directive means the person or company who is placing the product on the market or into service in their own name. It does not necessarily mean the physical manufacturer of the devices concerned. If a company is an 'own brand labeller' then they take on full legal responsibility as the manufacturer of the product as defined in the Regulations.
- Software may be considered to be medical devices provided that the purpose fits the definition of a medical device. The revised definition of a medical device includes standalone software in the definition of a medical device and includes the fact that when software is used in combination with a device which is 'intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes' that it will be considered to be a medical device.

Other published advisory information:

- Software that performs a medical intended purpose today as given in the MDD 93/42/EEC should be treated as an active medical device. This is not a change in regulation on software but merely a clarification and reinforcement of an existing requirement to treat stand-alone software as an active medical device. Any stand alone custom software must be MDD CE marked.
- Clinical Trial requirements:
 - For software that qualifies as a medical device but is not yet CE-marked or is a new version that is not covered by the previous CE mark (for example, because it is an update to remedy a flaw that caused an incident), a manufacturer is prohibited from running that software in human tests outside of an approved clinical trial setting. This rule may appear obvious, but it is, in practice, a frequent source of confusion and mistake on the part of manufacturers.

The definition of a medical device as defined by Article 2(2) of Directive 2001/83/EC is: *any instrument, apparatus, appliance, material or other article, whether used alone or in*

combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

With regard to mHealth and mobile phone telehealth solutions one medical device consultant advised:

"With respect to hardware, I suggest it is acceptable in this application for the tablet PC or Smartphone to be compliant with electrical safety standards other than IEC 60601-1, given there is no direct wired connection with the peripheral devices. However, the use of wireless Bluetooth comms raises the issue of any interference with data collection and transmission from each peripheral medical device, particularly when all the intended peripherals are connected wirelessly to the nearby communications unit at the same time (if that is possible)".

On asking about a specific mobile solution he said:

"I believe this product should be medical EMC (emissions and immunity) tested as a medical device system as part of the software CE process, as it is probably unrealistic to apply a CE mark to a standard tablet PC or Smartphone. There could also be a need to test for any cross-talk between adjacent peripheral devices effecting their operation."

NHS encouraged to use telehealth

In the recent publication *NHS Operating Framework for the NHS in England 2012/13*, Sir David Nicholson KCB DCE, NHS Chief Executive states: "Rapidly spreading changes that improve quality and productivity to all parts of the NHS will be crucial: a clear example is the use of telehealth to improve services for patients with long term conditions."

Section 2.22 of this report states:

Telehealth and telecare offer opportunities for delivering care differently but also more efficiently. Use of both of these technologies in a transformed service can lead to significant reductions in hospital admissions and lead to better outcomes for patients. Using the emerging evidence base from the Whole System Demonstrator programme, PCT clusters working with local authorities and the emerging CCGs should spread the benefits of innovations such as telehealth and telecare as part of their ongoing transformation of NHS services. They should also take full consideration of the use of telehealth and telecare as part of any local reconfiguration plans.

The move to a new NHS Commissioning Board (a special health authority) that will have the responsibility to provide leadership and to hold Clinical Commissioning Groups (CCGs) to account (from April 2013) is most welcome.

No policing

In the meantime, however, we are experiencing a wide range of commissioning of Telecare and Telehealth, procurement of such technologies and services by PCT's, FT's, NHS Direct, Social Care Organisations, Charities, Housing Associations, Local Authorities, Councils, Call Centres, Government Procurement Frameworks, Private Health Care Providers et al. This commissioning goes unabated, unchecked and perhaps unseen by higher authorities - in short, there appears to be no real policing of Telecare and Telehealth QA-RA compliance in UK procurement of such devices today!

The UK Telecare market is one of the world's largest in devices sold per head of population (but not necessarily implemented and installed in homes) - the traditional Telecare market is now worryingly migrating towards Telehealth as an area of potential growth and Social Care organisations are commissioning the procurement of Telehealth. Local Authorities, Councils and Housing Associations are commencing Telehealth programmes (often in partnership with a device manufacturer and their neighbouring PCT) and *often without the awareness of EU CE marking directives, national laws and registration concerning the use of medical devices*. The MHRA, as the UK's Competent Authority, needs to ensure that enforcement actions are taken and it must work with all stakeholders, especially the Department of Health and NHS to ensure that patient safety is protected and that only compliant products are placed on the rapidly increasing market.

In a *Medtech Business* publication, Issue 19 June 2011 (link at end), Trevor Lewis BSc(Hons), CEng, CPhys, MIEE, MInstP, MCIM, MInstD, medical device regulatory expert and Principal Consultant at Medical Device Consultancy (MDC) stated:

"If the regulatory system in Europe is to improve, a number of factors are needed. There has to be a mindset among all manufacturers to fully comply with or exceed the essential requirements of the directives. There is a need for more clinical investigations (both pre-and post-market), especially for higher-risk devices; and for greater transparency about the classification and presence on the market of all devices, especially higher-risk ones. The regulations should be enforced in an appropriate and proportionate way, with due regard to economic cost and the public health interest. Finally, all medtech industry representatives and other stakeholders need to work at improving the medical device directives...The current position that the medical device regulatory world finds itself in causes me much concern. The focus should be on making the current system more productive and more rigorously used and enforced, not reinventing it."

From the same publication, an article titled Benefits of the European regulatory system from the ABHI states:

"ABHI has for many years operated a Code of Business Practice, which was comprehensively revised in 2008 in conjunction with the revision of a similar Code of Practice operated by Eucomed. These codes lay down, in strict terms, the way in which manufacturers and suppliers should interact with health professionals and purchasers of medical technology."

It is a condition of membership of both ABHI and Eucomed that members adhere to these Codes, which are aimed at establishing and maintaining high standards of business ethics.

NHS and Social Care Commissioners and UK trade bodies and associations representing the telecare, telehealth and telemedicine industries should take note of the ABHI Code of Practice!

The DALLAS police?

The Technology Strategy Board (TSB) are in the process of evaluating DALLAS bids that could see over the next three years, the deployment of 'tens of thousands' of devices and solutions starting April 2012, the question should be asked: 'who is policing the various TSB Community Seeds submitting these plans to ensure their trade partners have legitimate and legal CE marked medical devices/products'? - In addition: are there any existing funded ALIP projects that fall foul of QA-RA and EU laws/CE issues?

With devolved Governments in Scotland, Wales and Northern Ireland all serious about telehealth implementation in 2012, there is the issue over the existing legacy telehealth and telecare systems already sold throughout the UK to Health and Care organisations and programmes and used by patients that are not CE marked as a medical device! Will an audit be undertaken regionally or nationally of such solutions already deployed in the market place? And if found to be illegal - what will these organisations actually do about the kit in daily use in patient's homes? Who would the policeman be in this scenario - the MHRA?

Existing illegal devices

With respect to the CE marking of a medical device, the question arises where illegal and legacy telehealth systems/devices are found to exist in the UK market place, as to whether these devices will be officially recalled under an MHRA ruling? Strictly speaking, you cannot retrospectively CE mark a product.

From a commercial perspective, companies that are compliant and follow EU legislation together the significant time and investment associated with the CE marking of medical devices are facing competition in tenders and potentially being disadvantaged by suppliers winning contracts with non CE compliant solutions. There is also the very British reticence it would seem, that 'whistle blowing isn't the done thing' so as not to be ostracised and or 'blackballed' by Commissioners!

Finally, if such an organisation were found to have sold product(s) and or services that included non-compliant solutions that potentially put a healthcare organisation, their patients and healthcare professionals at risk, what sanctions would be applied to that provider or supplier - locally and/or nationally - and would the embarrassed commissioning body, having potentially spent tax payers' money unwisely, 'sweep the issue under the carpet' so as not to be exposed for incompetence? Again, who would be the policeman be 'issuing the ticket'?

'Dr Concerned'

6 December 2011

Questions Telehealth Commissioners should ask their suppliers

Is the product CE marked to Article 12 of the Medical Device Directive 93/42/EC?

If 'yes', please provide evidence.

If 'yes', is the Medical Device registered with the MHRA?

If 'no', is the telehealth system software CE marked independently?

If 'yes', please provide evidence as to what classification.

If the software is CE marked independently, are the medical peripherals also CE marked independently and to what classification?

Please provide a list of, and evidence of, all medical devices' CE certificates

Have you sold products and/or services using the product, in the UK market prior to CE marking of the product by a Notified Body?

Is the product (or service using the product) registered on the Government Procurement Service's Telecare Framework RM 748?

If yes, in which Lots?

Supporting documentation (PDF downloads)

The pre-market clinical evaluation of innovative high-risk medical devices. KCE reports 158C

http://ta-images.s3.amazonaws.com/images/pdfs/kce_158c_innovative_high-risk_medical_devices-2.pdf

Medtech Business Issue19 June 2011

http://ta-images.s3.amazonaws.com/images/pdfs/Medtech_Business%20Issue19_June_2011-1.pdf

Electrical and Electronic Safety in Medical Devices – Human Factors, Software and Electromagnetic Compatibility. Lewis and Armstrong *Medical Device Manufacturing And Technology* 2006

<http://ta-images.s3.amazonaws.com/images/pdfs/ElecSafetyMD.pdf>

Other links

<http://www.medicaldeviceconsultancy.co.uk/?id=4>

<http://www.cherryclough.com>

www.clinica.co.uk