

## Health law, Brexit and medical devices

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# **Health Law, Brexit and Medical Devices: a question of legal regulation and patient safety**

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## **Abstract:**

Brexit is already posing many major challenges for those concerned with health and social care. This paper explores one area, that of the regulation of medical devices which has been fundamentally underpinned by EU law and asks what Brexit means for future regulation in the UK. The paper provides the first detailed legal examination of the impact of Brexit for medical devices regulation. Section two of the paper outlines the current EU regulation of medical devices. It explores questions such as the role of the normative bodies, the problems of lack of central regulation and the role of vigilance processes. Section three explores the options for medical device regulation post Brexit in the light of the ongoing reform of the law in this area and the implementation of new EU Regulations. It considers the prospects for reciprocity and for alignment in the future. The paper concludes by arguing that while the new system for regulation of medical devices in the EU is not perfect it nonetheless provides an important opportunity for restructuring device regulation and providing greater opportunities for facilitating safety. It is important to ensure that as far as possible we do not lose such an opportunity at domestic level post Brexit.

## I. INTRODUCTION

Medical devices are one of the relatively unsung categories of medical miracles with a huge impact on patient lives. From cardiac pacemakers to hip prostheses to pregnancy tests the technology has improved and greatly facilitated individual health<sup>1</sup>. However over the last decade some medical devices have been at the heart of major health controversies. The PiP silicone breast implant scandal provides one such notable example<sup>2</sup>. Poly Implant Prothese (PiP), a French company manufactured breast implants. These were sold directly, or in some instances through intermediaries, having been rebranded across some 65 countries. PiP used industrial grade silicone rather than medical silicone in the production of breast implants. A high level of ruptures of the implants subsequently took place.

In March 2010 the Agence Francaise de Securite Sanitaire des Products de Sante decided to recall the implants from the market. They also suspended further market placement, distribution or use. The following month the EU Commission informed Member States about the situation and asked them to put measures in place to prohibit market placement, distribution or use of PiP implants and to inform relevant health care professionals. Subsequently civil litigation and prosecutions followed.<sup>3</sup>

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<sup>1</sup> To the extent to which that some devices can be seen as part of the evolution of integrated human beings and machines see M.Quigley and. Ayihongbe “Everyday Cyborgs: On Integrated Persons and Integrated Goods”[2018] 26(2) *Medical Law Review* 276.

<sup>2</sup> It should be noted that PiP was not the first scandal concerning silicone breast implants- see generally C. Greco “The Poly Implant Prothese breast prostheses scandal: Embodied Risk and Social Suffering” (2015) 147 *Social Science and Medicine* 150, Department of Health, *Poly Implant Prothèse (PIP) breast implants: final report of the Expert Group* (Department of Health, June 2012): M. Latham “If it aint broke don’t fix it”: Scandals, Risk and Cosmetic Surgery” [2014] 22(3) *Medical Law Review* 384.

<sup>3</sup> “French breast implant firm PIP’s founder jailed” *The Guardian* 10<sup>th</sup> December 2013. BBC News “PIP implant scandal: German firm ordered to pay damages” 14th November 2013.

More recently reports have highlighted the risks of and potential harms from the use of metal on metal hip implants.<sup>4</sup> Initially when these were marketed the National Institute of Health and Clinical Excellence (NICE) in the UK stated that clinicians who were advising patients on this should ensure that patients “understand that less is known about the medium to long term safety and reliability of these devices or the likely outcome of revision surgery than for conventional hip replacements.<sup>5</sup>” Subsequently safety concerns have been raised regarding their reported higher failure rates of the De Puy minnacle metal on metal hip implants. There were also allegations of “metal poisoning.<sup>6</sup>” Litigation is currently ongoing in the UK regarding these implants. In June 2017 the Medicines and Healthcare Products Regulatory Agency issued guidance on follow-up and patient management with the aim of ensuring swift detection of problems.<sup>7</sup> Recent controversy also relates to the use of vaginal mesh implants, called by some “the new Thalidomide”.<sup>8</sup> These have been used as a means of attempting to address incontinence problems caused after childbirth but it is alleged that this led to major complications with disintegration of the plastic mesh or it cutting into organs. Common side effects have included chronic pain infections, loss of sexual intimacy and also in some cases women have been left unable to stand or walk properly. This area is currently under review by both the Scottish and English governments and in July 2018 it was announced that use of vaginal mesh implants in England was suspended.<sup>9</sup> What these incidents graphically illustrate

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<sup>4</sup> C.Heneghan, D.Langton and M. Thompson “Ongoing Problems with metal on metal hip implants “(2012) 344 *British Medical Journal*.

<sup>5</sup> National Institute for Clinical Excellence *The Clinical Effectiveness and the Cost Effectiveness of metal on metal hip resurfacing*” NICE (2000).

<sup>6</sup> See the discussion and call for future research in Scientific Committee on Emerging and Newly Identified Health Risks *Opinion on The Safety of Metal-on-Metal joint replacement with a particular focus on hip implants*” Adopted at plenary of 24-25<sup>th</sup> September 2014.

<sup>7</sup> Medicines and Healthcare products Regulatory Agency ‘Medical Device Alert: All metal-on-metal (MoM) hip replacements: updated advice for follow-up of patients’ (29 June 2017) at <https://www.gov.uk/drug-device-alerts/all-metal-on-metal-mom-hip-replacements-updated-advice-for-follow-up-of-patients>.

<sup>8</sup> “Vaginal mesh to treat organ prolapse should be suspended, says UK health watchdog” *The Independent*, 15th December 2017.

<sup>9</sup> BBC News “ Mesh Implant Campaigners “Betrayed” by Reports Publication” 23<sup>rd</sup> March 2017, <http://www.bbc.co.uk/news/uk-scotland-39408064>; “Alison Britton to Report on the review of transvaginal mesh implants”, <http://www.scottishlegal.com/2017/05/19/alison-britton-to-report-on-scottish-governments-review-of-transvaginal-mesh-implants/>; *The Guardian* “Jeremy Hunt launches review into

is that safety of medical devices is clearly critical for patients. Consequently equally critical are the regulatory mechanisms which are put in place to ensure such safety along with the way in which clinicians make decisions regarding their use. Within this paper the focus is on the former issue.

Medical devices are one of the many areas of health law which will be impacted by the UK's withdrawal from the EU. Currently UK medical device regulation is structured through the prism of three EU Directives.<sup>10</sup> These are first, Directive 90/385/EEC which concerns implantable medical devices including such things as cardiac pacemakers. Secondly, Directive 93/42/EEC a general Directive which concerns medical devices from blood collection bags, hip prostheses and powered devices. Thirdly, Directive 98/79/EC concerns in vitro diagnostic devices such as pregnancy tests and tests for transmissible disease.

Confidence in the regulation of medical devices at EU level was shaken by the PiP scandal. Nonetheless while PiP can be seen as a catalyst for reform in reality this scandal can be seen as part of what was and what remains a regulatory continuum. Review of EU law in this area was already underway from 2008 although it took almost a decade before two new EU Regulations finally came into force in 2017 to replace the three previous Directives. Implementation of the new Medical Devices Regulation is to be undertaken in 2020, while for the new In Vitro diagnostic devices Regulation implementation is 2022. It is perhaps

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handling of vaginal mesh scandal”, 21st February 2018, [https://www.theguardian.com/society/2018/feb/21/jeremy-hunt-launches-review-into-handling-of-surgical-mesh-scandal?CMP=Share\\_iOSApp\\_Other](https://www.theguardian.com/society/2018/feb/21/jeremy-hunt-launches-review-into-handling-of-surgical-mesh-scandal?CMP=Share_iOSApp_Other); BBC News “Vaginal mesh: England review into scale of harm” 30<sup>th</sup> January 2018. <http://www.bbc.co.uk/news/health-42871621> BBC News “Immediate Stop to NHS Mesh Operations”, 10<sup>th</sup> July 2018 <https://www.bbc.com/news/health-44763673>

<sup>10</sup> See further in relation to medical devices I. Vinck, F. Hulstaert, H.V. Brabandt, M. Nyet, S. Stordeur “Market Introduction of High Risk Medical Devices: Towards a Recast of the Directive Concerning Medical Devices” (2011) 18 *European Journal of Health Law* 477.

somewhat ironical that it is at the very time when the EU medical devices regulatory system is about to be tightened that there is a risk due to Brexit that the UK may end up bereft of such a regulatory structure.

Brexit is already posing many major challenges for those concerned with health and social care (see further papers in this volume).<sup>11</sup> This paper examines the implications of Brexit for UK patients and the NHS of the future regulation of medical devices. It provides the first detailed legal examination of the impact of Brexit for medical devices regulation. Section two considers current EU regulation of medical devices with specific focus upon general medical devices regulation. Section three explores the options for medical device regulation post Brexit, the prospect of a Bonfire of the Regulations and the new EU medical devices regulations and the impact of a “deal” or “no-deal scenarios”. The paper concludes by arguing that while the new EU system for medical devices regulation is not perfect it nonetheless provides an important opportunity for restructuring device regulation and for facilitating safety. It is important to ensure that as far as possible we do not lose such an opportunity at domestic level post Brexit.

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<sup>11</sup> See also N Fahy, T Hervey, S Greer, H Jarman, D Stuckler, M Galsworthy and M McKee, ‘How will Brexit affect Health and Health Services in the UK? Evaluating Three Possible Scenarios Against the WHO Health System Building Blocks’ (2017) 390 *The Lancet* 2110.

## II. REGULATING MEDICAL DEVICES FOR QUALITY AND SAFETY: THE ROLE OF THE EU

Prior to the EU's involvement in the area of medical device regulation the UK developed good manufacturing practice guidelines for industry in the 1980's.<sup>12</sup> In addition certain devices were also regulated as medicines including contact lenses and intra-uterine contraception.<sup>13</sup> It was however the involvement of the EU which provided the major drive for regulation with different types of medical devices being regulated through EU Directives since the 1990's<sup>14</sup>. Nonetheless there has long been a tension in this area between the pressures of the market place and those of safety.<sup>15</sup> As Hodges has argued the EU system

“can also be criticized on the ground that the jurisdictional basis of the legislation is that of the facilitation of trade rather than of safety. It is true that as with all New Approach legislation, the medical devices Directives state that the achievement of a high level of health and safety is mentioned in the preamble but this is not strictly {the}(SIC) legal basis on which the legislation is founded.”<sup>16</sup>

Similarly Flear has argued in the context of new health technologies that the approach undertaken by the EU can

“. . . narrow the meaning and framing of technological risk to being principally about product safety at different stages of product development and ultimately

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<sup>12</sup> See G.R. Higson *Medical Devices Safety: The Regulation of Medical Devices for Public Health* Institute of Physics Publishing (1998).

<sup>13</sup> Hodges at para 17.176.

<sup>14</sup> See T.K.Hervey and J.V.McHale *European Health Law Themes and Implications* Cambridge: CUP (2015) pages 366- 379.

<sup>15</sup> See eg C. Campillo- Artero “A full-fledged overhaul is needed for a risk and value based regulation of medical devices in Europe” (2013) 113 *Health Policy* 38.

<sup>16</sup> See C. Hodges “Do we need a European Medical Devices Agency”? (2004) 12(3) *Medical Law Review* 268.

marketing within the internal market. At the same time the techniques bracket off and marginalize the other kinds of harms or hazards to which risk might pertain.<sup>17</sup>

These tensions remain visible in the operation of the Devices regulatory system. This falls under the (DG GROW) rather than DG SANTE which concerns health.<sup>18</sup> The key factor in the regulation of medical devices is that of the award of a “C.E.” mark. This is needed to ensure conformity of safety standards. The precise approval process is dependent upon the perceived risk level of the Device. So for example, under the Medical Devices Directive there are different categories of devices.<sup>19</sup> Class I which concerns products which do not enter/interact with the body requires self-certification by the manufacturer. For three other classes a certificate of conformity is required from what is known as a “notified body”. These are Class IIa which includes such devices as contact lenses, dental bridges and crowns). Second, Class IIb comprises devices such as invasive/implantable device and those which interact with the body including maxillo-facial implants. Thirdly, Class III devices which are those which affect function of vital organs eg prosthetic heart valves. Medical implants will always fall under Class IIb or Class III. Critically important is the fact that these notified bodies are themselves private companies rather than state regulatory bodies. As we shall see below such an allocation of responsibility has long been very controversial.

In ascertaining whether quality standards are met there can be difficulties concerning which standard it is proposed to apply. Currently a manufacturer can select to be assessed by any standard including those national standards which are in conformity with harmonised EU

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<sup>17</sup> M. L. Flear, ‘Regulating New Technologies: EU Internal Market Law, Risk, and Socio-Technical Order’ in M Cremona, (ed.), *New Technologies and EU Law* (Oxford University Press: Oxford, 2016) at page77.

<sup>18</sup> See eg Professor A. Fraser *Evidence submitted to the Health Select Committee, House of Commons Implications of leaving the EU for the regulation of medical devices*, January 2018.

<sup>19</sup> See further generally C. Hodges “The Regulation of Medicinal Products and Devices” in J. Laing and J.V.McHale (eds) *Principles of Medical Law* (4<sup>th</sup> ed) (Oxford: OUP, 2017).



standards.<sup>20</sup> This gives rise to a real risk of problems arising due to the diversity in regulatory standards.

In the case of some devices which are specifically “custom made” for the sole use of a particular patient CE authorisation is not needed but further specific criteria are required including retention of documentation for the competent authority. In addition the manufacturer must retain documentation for the competent authority. Confirmation of compliance with essential requirements must be based on clinical data typically the compilation of relevant scientific literature or an appropriate written report with critical evaluation. In some instances a clinical investigation itself may be required and where this is the case this would need to be undertaken subject to research ethics committee requirements. An example here would be the introduction of a completely new form of device into clinical practice where the components are previously unknown.

One concern regarding the medical devices approval process relates to that of transparency. Since 2007 in the USA there has been a requirement that trial studies and results concerning medical devices must be published by the US Food and Drug Administration (FDA). However there is no such requirement under the Medical Devices Directive. The level of information required for device approval is also very different than that needed by pharmaceutical regulatory processes. In evidence submitted to the House of Commons Science and Technology Select Committee review of medical devices regulation in 2016 by the Centre for Evidence Based Medicine it was stated that the amount of clinical evidence needed for approval “could be minimal” and that moreover the fact that existing studies

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<sup>20</sup> See note 19 *supra* Hodges, para 17.159.

published in the literature were accepted “are one of the main drivers of poor quality under-researched devices on the market today.”<sup>21</sup> Similarly the Faculty of Pharmaceutical Medicine of the Royal College of Medicine expressed concern about the use of equivalence data and that unpublished safety issues could have arisen concerning devices already certified. Devices may be produced with “subtle differences” but not requiring new authorisation meaning that certain safety/effectiveness issues may not as a result be explored. In addition as the Faculty commented

“as time goes on each iteration of a device rests its case on a previous iteration, each a little different to the next one, after several years devices may be approved that are very different to the original marketed devices.”<sup>22</sup>

Oversight of the operation of the Directives is provided in each member state by a “competent authority”, which in the UK is the Medicines and Healthcare Products Regulatory Agency.<sup>23</sup> The MHRA’s role includes implementation of the Directives’ provisions, designating notified bodies, undertaking assessment and authorisation of clinical investigation of those devices which are non CE marked. In addition the MHRA has the task of investigating adverse events and addressing safety matters such as the recall of devices. Since 2015 the MHRA has had its own Devices Expert Advisory Committee.<sup>24</sup> In contrast to pharmaceuticals however there is no general overarching central approvals process from a central European Agency such as the European Medicines Agency nor is there a decentralised process operational at member state level as is currently operated by the MHRA in relation to pharmaceuticals. Instead as noted above the actual authorisation of medical devices themselves is entrusted to the “notified bodies”. The use of notified bodies and their

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<sup>21</sup> House of Commons Science and Technology Committee *Regulation of Medical Implants in the EU and UK*, 5<sup>th</sup> Report of Session 2012-3, HC 163 at para 26 for similar criticisms see C.Campillo- Artero n 16 above.

<sup>22</sup> Note 21 *supra* at para 26.

<sup>23</sup> <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

<sup>24</sup> <https://www.gov.uk/government/groups/devices-expert-advisory-committee>

operation has long been a very controversial aspect of the Directives.<sup>25</sup> It is effectively providing regulation via a commercial company operating expressly for this purpose. There are clearly dangers in such processes not least the question of effective oversight and accountability.

At present there is some engagement at EMA level between devices and medicines regulation. This is first because the EMA does have the role of providing scientific opinions regarding the quality and safety of medical devices which include medicinal substances where these can have an ancillary action on the patient's body. In these cases the notified body is required to consult the EMA for a scientific opinion. Secondly, there is also an ad hoc European Medicines Agency/Committee for Advanced Therapies and Medical Devices Notified Body (EMA/CAT-NB) Collaboration Group concerned with facilitation of some parts of Regulation (EC) No. 1394/2007 which deals with advanced-therapy medicinal products (ATMPs).<sup>26</sup> Such products may be gene therapy medicinal product, a somatic cell therapy medicinal product or a tissue engineered product.<sup>27</sup>

What could appear to be an obvious solution would be to totally align the processes for pharmaceuticals and for medical devices<sup>28</sup>. This would provide the EMA with oversight and this could be matched by independent oversight from the competent authority at member

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<sup>25</sup> See note 19 supra.

<sup>26</sup> [http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CAT/people\\_listing\\_000086.jsp&mid=WC0b01ac058029021c](http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CAT/people_listing_000086.jsp&mid=WC0b01ac058029021c). See also *the European Commission Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products* Brussels, 22.11.2017 C (2017) 7694 final.

<sup>27</sup> See Regulation (EC) No 1394/2007 of the European Parliament and the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

<sup>28</sup> See eg Professor A. Fraser *Evidence submitted to the Health Select Committee, House of Commons Implications of leaving the EU for the regulation of medical devices*, January 2018.

state level- for the UK the MHRA. However those involved in the medical device industry have been strongly opposed to this. It is the case that there are some practical distinctions between drugs and devices which inevitably impact upon the precise manner in which their safety is reviewed. So for example, it can be argued that clinical trials concerning drugs are simply and inevitably practically different- put bluntly it is easier to stop a participant taking a trial drug than to remove an implant. Moreover as devices are designed to last several years follow up of a device during a trial would take considerable some time. In contrast the MHRA have commented that the use of notified bodies use needs to be seen in the context of the sheer scale of the medical devices market with at that time there being some 400,000 devices across the EU.<sup>29</sup> The MHRA also saw an advantage in that notified bodies could “specialise in certain areas and react to market demand adding expertise and capacity when required which would not be possible for public sector bodies.”<sup>30</sup>

While the use of notified bodies can be seen as a practical compromise nonetheless concerns have been rightly identified over many years as to the lack of conformity in approach taken by such bodies across jurisdictions. The number of such bodies varies between member states. That is not by itself necessarily a problem given that this may be reflective of different demands for approval from state to state. More worrying is that evidence has emerged over time of a lack of consistency in decisions taken by oversight bodies and questions as to the effectiveness of the oversight of such bodies. In addition manufacturers have the ability to “shop around” between notified bodies. They are able to select which body to approve their device rather than approval being entrusted to a national regulator. This practice is made

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<sup>29</sup> See note 21 *supra*.

<sup>30</sup> See note 21 *supra* at para 11.

easier by the fact that no central database which records approvals.<sup>31</sup> This gives rise to the very real risk that if some bodies are less rigorous than others certain less scrupulous manufacturers may decide to target them. In addition there is some evidence that some notified bodies have been prepared to act as consultants to companies to assist them to get approval when in fact they are not allowed to do this.<sup>32</sup>

In the wake of the PiP scandal investigations a Joint Action Plan was established between the EU Commission and the EU member states in 2012<sup>33</sup>. This focused upon the functioning of notified bodies, market surveillance co-ordination in relation to vigilance and transparency and communication.<sup>34</sup> Member states were requested to reinforce market surveillance<sup>35</sup> and also to better co-ordinate their activities.<sup>36</sup> Voluntary joint audits were undertaken of notified bodies by teams drawn from member states and the Commission. While some good practice was identified, concerns were also raised as to the operation of notified bodies.<sup>37</sup> These included notable variation in internal audits and follow ups, limited or no procedures to deal with conflicts of interest,<sup>38</sup> evidence of poor documentation and delays<sup>39</sup> inadequate information supplied to the Commission<sup>40</sup>, and diversity in the nature of liability insurance required.<sup>41</sup>

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<sup>31</sup> See discussion in Campillo-Artero n. 16 *supra* at page 40.

<sup>32</sup> See further n. 16 above at page 40.

<sup>33</sup> Commission Staff Working Document *Implementation of the Joint Plan for Immediate Action under the existing Medical Devices legislation* Brussels 13.6.2014 SWD (2014) 195 final.

<sup>34</sup> Note 21 *supra* at para 1.4.1.

<sup>35</sup> Note 21 *supra* at para 1.4.2.

<sup>36</sup> Note 21 *supra* at para 1.4.3.

<sup>37</sup> See “Restoring Confidence in medical devices. Action Plan after PIP scandal tightened control in Europe. European Commission Press Release, 20<sup>th</sup> June 2014.

<sup>38</sup> Note 23 *supra* at para 4.3.1.

<sup>39</sup> Note 23 *supra* at para 4.1.

<sup>40</sup> Note 23 *supra* at para 4.2.

<sup>41</sup> Note 23 *supra* at para 4.3.1.

Subsequently the number of such bodies has dropped from some 80 to 56.<sup>42</sup> Some certificates already awarded were as a result withdrawn. Measures were introduced with the aim of addressing some of the problems highlighted in this audit process. In 2013 a Commission Implementing Regulation was introduced intending to clarify the criteria which were required by notified bodies.<sup>43</sup> Joint audits are now mandatory for new designations and for resignations of notified bodies. The Commission introduced monthly vigilance teleconferences with member states. In addition trends concerning safety related incidents are now under examination by the EU Commission's Joint Research Centre in Ispra. As we shall see below the new EU medical devices Regulations will further tighten the regulatory processes but real concerns regarding the fact that that the approvals themselves are left to private sector bodies in this way remain.

Finally, one common method of EU regulatory oversight is the use of databases enabling pertinent information to be made available across member states to facilitate safety vigilance processes. In the context of medical devices the current database, "EUDAMED", was established in 2010 and became operational from 2012 with Member States being required to enter all data into this by that date.<sup>44</sup> Information stored in the database includes that relating to manufacturers, authorised representatives and also certificates. It also contains some basic data on vigilance and clinical investigations in the form of the title of the protocol and the primary objective. This provides an important source of information though as the PiP scandal demonstrates its operation does depend upon effective co-operation by notified bodies.

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<sup>42</sup> D. Cohen "Medical devices face tougher premarket testing under new EU laws" (2017) 357 *British Medical Journal*.

<sup>43</sup> Regulation (EU) No 920/2013.

<sup>44</sup> Commission Decision 2010/227/EU of 19th April 2010 on the European Databank on Medical Devices (Eudamed) Official Journal L 102, 23<sup>rd</sup> April 2010, 45-48.

The UK regulation of medical devices is thus underpinned by EU law; however various aspects of this regulatory process can be seen as problematic at present. Could Brexit with its prospect of decoupling from EU regulatory regimes provide potential opportunities with the development of a new specific UK based scheme or would Brexit itself cause potential risks to patient safety in this area in the future? We consider these issues below.

### **III. MEDICAL DEVICES REGULATION AND THE BREXIT EFFECT**

At the time of writing and following the Article 50 notification issued by the UK to the EU in 2017 the UK is due to leave the EU at 11 pm GMT on 29<sup>th</sup> March 2019. There has already been considerable concern expressed by those working in this area as to the impact that Brexit may have on the operation of medical device regulation in the future. Medical devices and the industry around it have clearly been seen as a matter of some importance by the Government.<sup>45</sup> However as with many issues concerning Brexit its precise impact remains a matter of considerable uncertainty. This section considers the effect of the possible legal alternatives flowing from Brexit. A number of issues are examined in turn. Will this in principle be seen as an area for continued regulatory alignment or one for a “Bonfire of the Regulations”? Secondly, if continued and future alignment is sought then how can this be achieved? Here the new EU devices Regulations which will be fully implemented in 2020

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<sup>45</sup> So for example, medical devices were included in the list of case studies published by DexEU in 2017 <https://commonslibrary.parliament.uk/economy-business/economy-economy/brexit-impact-58-sectors-assessed/>

and 2022 respectively are discussed in relation to the impact of a “deal” or “no deal” scenario between the UK and the EU.

### **A Bonfire of the Regulations?**

Is it likely that the area of medical devices is one which is subject to a “bonfire of the regulations”? As with other aspects of Brexit this may be viewed by some as a very real opportunity to decouple from EU regulatory processes. In the past there have been suggestions by some UK Government ministers that certain EU Regulations in the area of health care can be seen as inhibitors of scientific development for example in the context of clinical trials.<sup>46</sup> In an article in the British Medical Journal (BMJ) it was reported that George Freeman, the UK Life Sciences Minister whose brief includes the Medicines and Healthcare Regulatory Agency had written to Carlos Moedas who is the EU Research, Science and Innovation Commissioner. He asked him to “tackle the increasingly precautionary ‘anti-science’ trend in EU legislation” and this could be seen as deterring investment. Concerns as to such an approach were highlighted in the same BMJ paper by Professor Martin McKee, Professor of European Public Health at the London School of Hygiene and Tropical Medicine and a leading international authority on EU health regulation who stated that

“Once again the European Union is prioritising patient safety over the narrow interests of industry, protecting us from the policies pursued by our own government. We give up this protection at our peril,”<sup>47</sup>

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<sup>46</sup> See eg Michael Gove in the *Daily Telegraph* 20th Feb 2016.

<sup>47</sup> D. Cohen “UK minister lobbied EU for lighter regulation of drugs and devices” (2016) 353 *British Medical Journal*, published 15<sup>th</sup> June 2016.



Subsequently other Government ministers have been somewhat more conciliatory and saw greater potential for regulatory alignment. In July 2017 Jeremy Hunt, the then Secretary of State for Health and Greg Clark the Business Secretary writing in the *Financial Times* newspaper about pharmaceutical regulation commented that there was a need to both place the safety of patients at the heart of regulation and in addition to

“provide certainty and long-term stability. Our focus is on supporting initiatives across Europe that will be vital to developing the next generation of products — big data, genomics and ever greater support for medical research and scientific collaborations”<sup>48</sup>.

The House of Commons Health Select Committee in their 2018 Report<sup>49</sup> called for the Government “to look to secure, as a priority in the next round of negotiations, the closest possible regulatory alignment with the EU”.<sup>49</sup>The Government White Paper published in July 2018 sets out the case for “an economic partnership” which will include “participation by the UK in those EU agencies that provide authorisations for goods in highly regulated sectors”. It envisages that this would include the European Medicines Agency. There is emphasis upon the “deep and special relationship” and the need to protect patients and support the UK life science industry.<sup>50</sup> While there is no specific reference to medical devices in this document the tone of the document is particularly interesting and relevant given the relationship between drugs and devices regulation.

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<sup>48</sup> *Financial Times*, July 4<sup>th</sup> 2017.

<sup>49</sup> House of Commons *Health and Social Care Select Committee Brexit: medicines, medical devices and substances of human origin* Fourth Report of Session 2017–19, para 18.

<sup>50</sup> HM Government *The United Kingdom’s exit from and new partnership with the European Union* Cm 9417 (2018) para 37.

## **The new Medical Devices Regulations and the potential implications of deal or no deal**

If alignment is sought with EU medical devices regulatory processes then how can this be achieved? The UK Government is seeking a transition period as part of its Withdrawal agreement. Initially it indicated that they want such an agreement with the European Union which would include a 2 year transition period.<sup>51</sup> However the EU took a slightly more restrictive approach and currently the transitional period is due to end in December 2020<sup>52</sup>. If that remains the case and forms part of the final agreement then the UK during this period will remain subject to existing EU law and furthermore need to comply with new EU law which is to be implemented during transition. This raises important practical issues due to the fact that a new EU Medical Devices Regulation is due to be fully implemented in 2020 which is discussed below. Moreover as will become obvious full compliance will require reciprocity which will require an agreement to be reached with the EU.

First, the aim of the European Union (Withdrawal) Act 2018 is to transpose existing EU law into UK law. Thus legal continuity is intended to be assured and medical devices regulation within the UK itself would appear to be able to continue as at present undertaken by notified bodies. The 2018 Withdrawal Act only translates certain provisions and by itself cannot address a number of practical problems which are likely to emerge in such a situation.

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<sup>51</sup> “Theresa May asks EU for two-year Brexit transition period” *The Guardian*, Friday 22<sup>nd</sup> September 2017, <https://www.theguardian.com/politics/2017/sep/22/theresa-may-asks-eu-for-two-year-brexit-transition-period>.

<sup>52</sup> BBC News “EU agrees Brexit 'transition' negotiation guidelines” 29<sup>th</sup> January

2018.<http://www.bbc.co.uk/news/uk-politics-42861496> and see *Annex to the Council Decision supplementing the Council Decision of 22 May 2017 authorising the opening of the negotiations with the United Kingdom of Great Britain and Northern Ireland for an agreement setting out the arrangements for its withdrawal from the European Union - Supplementary directives for the negotiation of an agreement with the United Kingdom of Great Britain and Northern Ireland setting out the arrangements for its withdrawal from the European Union, XT 21004/18 ADD 1 REV 29<sup>th</sup> January 2018.*

Unless there are specific sectoral agreements being made with the EU the UK will be unable to participate in those parts of the Devices Directives and subsequently Regulations in the future which require reciprocity and cross- EU collaboration. Indeed the existing Withdrawal agreement expressly precludes the UK's participation in EU computer databases post Brexit<sup>53</sup>. Without a special agreement the UK would be unable to access EURAMED.<sup>54</sup> We would be excluded from existing vigilance systems. The decisions made by notified bodies would no longer be automatically recognised in other EU member states as we would have third country status at that point. Thus attaining an additional specific agreement concerning medical devices is likely to be of great importance.

Secondly, there is the question of compliance with new EU law provisions during the transition period. This is a major concern regarding medical devices and it is likely to come into sharp relief because two new EU Regulations have come into force to replace the existing Devices Directives. The new EU Regulations which are due to be implemented post March 2019 are Regulation EU 2017/745 of the European Parliament and the Council of 5<sup>th</sup> April 2017 on medical devices<sup>55</sup> and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices<sup>56</sup>. If we move into transition then we will have to comply with the medical devices Regulation which is due to be implemented in 2020. In contrast the In Vitro regulation does not have to be implemented

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<sup>53</sup> Article 7 Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community highlighting the progress made (coloured version) in the negotiation round with the UK of 16-19 March 2018.

[https://ec.europa.eu/commission/sites/beta-political/files/draft\\_agreement\\_coloured.pdf](https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf)

Origin:

<sup>54</sup> Article 7 of the Draft Withdrawal Agreement will exclude the UK from EU computer databases- and this will apply unless there is a specific agreement.

<sup>55</sup> Regulation EU 2017/745 of the European Parliament and the Council of 5th April 2017 on medical devices amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

<sup>56</sup> Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

until 2022. But if we were within a transitional period we would be expected to comply with the Regulations as will become evident without a specific agreement with the EU concerning the devices Regulations we will not be able to be fully compliant with them. A specific deal concerning devices therefore becomes critically important.

First what are the differences between the existing Directives and the new Regulations? What is notable is that they build upon the approach taken by the Directives while at the same time evolving and tightening the regulatory processes. As with the Directives the final form of the Regulations can be very much seen as a compromise between considerations of business as well as regulation. The Commission stated in the proposal that such regulation

“Should be supportive of innovation and the competitiveness of the medical device industry and should allow rapid and cost- efficient market access for innovative medical devices, to the benefit of patients and healthcare professionals<sup>57</sup>.”

In some ways the new Regulations are as striking for what they do not change as what they do. As was seen above there have been concerns as to the lack of an overarching body at EU level providing regulation for medical devices. Such a role could have been given to the EMA thus combining both pharmaceuticals and medical devices. This approach would have been welcomed by many health professionals, academics and those from the patient community. It could have facilitated safety oversight which is something of particular importance given recent controversies such as PiP. However such a new role for the EMA was strenuously opposed by industry and the notified bodies themselves. It was argued that as approval once given by a notified body for a medical device was valid across the whole of Europe then the need for approval by a central body as in the case of the centralised drug

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<sup>57</sup> European Commission, *Proposal for a Regulation on Medical Devices, and amending Directive 2001/ 83/ EC, Regulation (EC) No 178/ 2002 and Regulation (EC) No 1223/ 2009*, COM(2012) 542 final, at 2

approval procedure operated through the EMA was unnecessary. Moreover detailed central regulation would have also involved considerable de-coupling from private actors and also extensive investment at EU level in the process of medical devices oversight- something which as we shall see below appears not to be entirely forthcoming.

Rather than a wholly radical reframing of the law the Regulations build upon the current approach with continued requirements for CE marks<sup>58</sup>, the use of notifiable bodies and an oversight body for notifiable bodies at member state level. However in some respects they do expand the scope of regulation. Critically higher risk devices such as those in Class C III for medical devices will now be subject to much stricter pre-market review than was the case. For in vitro devices some 80-90% will now need to be subject to a conformity assessment<sup>59</sup>. Manufacturers will have to supply information drawn from systematic clinical investigations to Notified Bodies. These are required to identify the safety and the performance of the device and in addition have the task of establishing its “clinical benefit”. “Clinical benefit” is defined as being positive impact of a device on an individual’s health which is determined by reference to what are meaningful, measurable, and patient-relevant clinical outcomes. For some time there has been concern in relation to the safety of certain cosmetic procedures, notably the use of facial fillers. Certain new aesthetic devices which have the same risk profile and characteristics as medical devices are now included under the Regulations. Where products combine medicinal product and devices then these will also now need to be assessed under the marketing authorisation criteria for medicinal products.

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<sup>58</sup> Article 20.

<sup>59</sup> Annex VIII of the Medical Devices Regulation and In Vitro Devices Regulation.

In the past there has been concern in relation to the diversity in standards applied when assessing medical devices.<sup>60</sup> The Regulations are driving towards alignment of approach. The EU Commission is to establish panels of experts to advise on whether a high risk device should be approved who will be organised through the EU Joint Research Centre, a specialist EU research unit based in Ispra in Italy.<sup>61</sup> The expert panels will operate on an ad hoc basis and will be comprised of volunteers. Concerns remain as to whether sufficient resources will ultimately be devoted to this task and how effective these panels will be.<sup>62</sup> As Professor Alan Fraser commented in evidence to the House of Commons Health Select Committee in January 2018 the group in DG Grow (Directorate General for the Internal Market, Industry, Entrepreneurship and SMEs) concerned with devices and the staff at the Joint Research Centre are currently limited in number

“Together, however, these two groups have few staff dedicated to medical devices (recently the total was less than 15 whole-time equivalents, but it has been projected to increase to more than 30) and their number includes very few technical specialists (recently, there were only 2 medical doctors).”<sup>63</sup>

In addition while panel’s advice will be published it will not be binding- merely advisory. The Regulation also establishes a Medical Devices Co-ordination Group to work at EU level. It will be able to invite organisations to participate and can invite organisations representing medical professional bodies as observers. As the current arrangements for transition stand whether we even if the UK leaves in December 2020 from March 2019 itself it will be

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<sup>60</sup> See Hodges n.18 *supra*.

<sup>61</sup> See further A.G. Fraser “Medical Devices and Evidence-Based Clinical Practice” [Healthmanagement.org](http://Healthmanagement.org)

<sup>62</sup> See discussion in P. Szymanski, I. Leggeri, J. Kautzner and A.G. Fraser “The new European regulatory framework for medical devices: opportunities for engagement by electrophysiologists” (2017) *Europace* 1.

<sup>63</sup> See note 28 *supra*.

excluded from such agencies and expert bodies unless it is “exceptionally” invited to attend on a “case by case” basis<sup>64</sup>.

A new procedure has been developed to deal with cases where it is intended to undertake clinical assessments in more than one member state. This will work initially on a voluntary basis but seven years from the implementation of the Regulation will become binding. This will enable a single application to be made for assessment something which potentially will work towards greater centralisation and standardisation of processes concerning medical devices than exists at present. This would potentially provide the first steps towards aligning the structure of centralised processes for drugs and for devices.

The new Regulations also use common EU regulatory approach in the area of health law that of the “qualified person<sup>65</sup>. Manufacturers must ensure that a person is responsible for regulatory compliance, conformity and post market surveillance.<sup>66</sup> This person is required to have specific expertise including the requisite university level academic qualifications and scientific or regulatory experience.<sup>67</sup> In the case of very small businesses they will not have to have such a person on their staff but they will need to have access to them.<sup>68</sup> Alignment with EU standards would require such persons to be employed post Brexit. But if the UK

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<sup>64</sup> Article 7 Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community highlighting the progress made (coloured version) in the negotiation round with the UK of 16-19 March 2018. [https://ec.europa.eu/commission/sites/beta-political/files/draft\\_agreement\\_coloured.pdf](https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf). Article 12(4).

<sup>65</sup> C/f e.g. approach in relation to the regulation of pharmaceuticals, blood/tissue and cells/organs.

<sup>66</sup> Article 15.

<sup>67</sup> Article 15 (1).

<sup>68</sup> Article 15(3).

leaves the EU it is possible that some existing notified bodies in the UK may decide to relocate and as a result those individuals with highly specialised qualifications in this area may also decide to seek employment in notified bodies in other EU member states. This could adversely impact on the operation of such bodies and their business models.

A further concern raised in relation to the safety of devices is what would happen when things went wrong and the nature of liability of manufacturers for their devices, something brought into sharp focus with PiP and other ongoing litigation. The new devices Regulations introduce the role of the “sponsor” something which has been included in the scrutiny of clinical trials on medicinal products both in the original EU Clinical Trials Directive and also the new Clinical Trials Regulation<sup>69</sup>. The sponsor is a “back stop” in terms of liability and of accountability. The Regulations also require that there is the need for sufficient financial coverage in relation to manufacturers’ potential liability<sup>70</sup>. These are notable steps forward but they do not provide a panacea. There is no requirement for a Member State to set up a specific compensatory system in relation to the potential harms resulting from such medical devices. This is an issue which does require greater consideration at domestic and EU level<sup>71</sup>.

The Regulations include a range of other new safety related measures including requiring manufacturers to produce an annual safety report along with tighter reporting timescales for vigilance information<sup>72</sup>. Traceability is another common regulatory strategy utilised in

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<sup>69</sup> See T.K. Hervey and J.V. McHale *European Health Law: Themes and Implications* (Cambridge: CUP, 2015).

<sup>70</sup> Article 10 of the Medical Devices Regulation and In Vitro Devices Regulation.

<sup>71</sup> See further K. Watson and R. Kottenhagen “Medical Liability in Europe” in A.den Exter (eds) *European Health Law* (Maklu 2017).

<sup>72</sup> Chapter VII, Section 1 and 2 of the Medical Devices Regulation and In Vitro Devices Regulation.



European Health law. Tracking and tracing is used in the context of tobacco regulation and in relation to tissue and cells through the Single European Code enabling identification of material<sup>73</sup>. This approach is now being introduced in relation to medical devices. Distributors and importers are required to co-operate with manufacturers in relation to the traceability of devices.<sup>74</sup> In addition there will be a unique device identification (UDI) system to enable the traceability of devices<sup>75</sup> linked to a new UDI database accessible to the public free of charge.<sup>76</sup> Manufacturers will be required to include devices, other than custom made devices, in this database<sup>77</sup>. Without a specific agreement the UK would not have access to this database.

The existing EUDRAMED approach will be continued and extended through an expanded computer database<sup>78</sup>. This will enable information to be added in relation to the registration of devices, economic operators, UDI's, notified bodies and clinical investigations etc. There will also be a new central registration database which will be inter-operable with the new Clinical Trials Database which is being introduced in 2019 as part of the implementation of the new EU Clinical Trial Regulation which is replacing the EU Clinical Trials Directive which currently regulates trials on medicinal products. This bringing together at least one further part of pharmaceutical regulatory approaches can be seen as symbolically very important. While devices for many years have been treated separately and while the EMEA is not a central regulator nonetheless this in the future may be regarded as an important step to bring the regulation of pharmaceuticals and devices together. Again the UK will not have

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<sup>73</sup> Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells, 9 April 2015.

<sup>74</sup> Article 25.

<sup>75</sup> Article 27.

<sup>76</sup> Article 28.

<sup>77</sup> Article 29. This is the same approach as has been taken in relation to tissue and cells via the Single European Code.

<sup>78</sup> Article 33.

access to these new databases without a specific agreement being negotiated to apply after we leave the EU.

One feature of pharmaceutical regulation has long been that of patient information. The Pharmaceutical Directives led to information being provided to patients via information sheets having to be included in marketed packs of medicines<sup>79</sup>. Greater information provision can be seen as a means of facilitating patient consent to treatment- something which at EU level is included as requirement in the EU Charter of Fundamental Rights.<sup>80</sup> This approach is now being developed in relation to medical devices through the requirement of the provision of an “Implant card”<sup>81</sup>. This will provide information regarding implantable medical devices for patients. It can be seen not only as following the trend in pharmaceuticals but also the lack of information provided in the past to patients with PiP implants. Patients will be given enhanced information regarding technical specifications including information in relation to the UDI, the serial number of the device, whether devices will be affected by security scanners and the life of the device itself. Information is to be made available in a comprehensible manner, updated as needed and will be available to patients via a website.

<sup>82</sup>This can be seen as a very important development for patients particularly also in the light of the recent confirmation from the Supreme Court in *Montgomery v Lanarkshire* that informed consent is part of English law and that a dialogue between doctor and patient is a necessary part of this<sup>83</sup>. It can be argued that disclosure of the risks of treatment should include such information in relation to technical specifications. The implant card can be seen

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<sup>79</sup> Directive 2001/83/EC, Articles 58-60.

<sup>80</sup> Article 3(2).

<sup>81</sup> Article 18.

<sup>82</sup> Article 18(1) (d).

<sup>83</sup> *Montgomery v Lanarkshire Health Board* [2015] UKSC 11; see further R. Heywood. “R.I.P. *SIDAWAY*: Patient-Oriented Disclosure- A standard worth waiting for?”(2015)23(3) *Medical Law Review* 455.

as something which can effectively be built into the consent process. The EU's engagement with and requirement of provision of such enhanced information to patients can be seen as framing in the future judicial understanding of what a responsible patient and what this particular patient would want to know about the implications of their medical treatment where that treatment includes a medical device. Both implementation of these provisions along with continued future alignment can be seen as particularly important to ensure that patient choice is facilitated in the future.

What will be the impact of Brexit upon UK implementation of these new EU Regulations? In the case of a Brexit transition period the UK would need to align and participate with these developments concerning the general Devices Regulation due to be fully implemented in 2020 though not the In Vitro Devices Regulation which will only be fully implemented after 2022. There is a further complexity here which is that at the present time the MHRA has already advised that as it is the case that the Regulations are in force, albeit full implementation is not for some time some firms may decide to have their devices approved under the new Regulations<sup>84</sup>.

This however only takes the implementation of medical devices so far. As we have seen unless there is a specific agreement either in relation to the transition period and /or subsequently then the UK stands to lose a range of benefits which it currently possess and which it would have normally have had access to through the implementation of the new Regulations.

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<sup>84</sup> <https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr>

What could then be done to address this issue? The July 2018 White Paper suggests the prospect of an ongoing Association Arrangement between the UK and the EU with provision for “regular dialogue between UK and EU leaders and ministers, commensurate with the depth of the future relationship and recognising the significance of each other’s global standing”. It is envisaged that in some situations the UK will remain part of a “Common rulebook” so that products should only have to be tested in one market –UK or EU to be recognised. The intention that this would be accompanied by adherence to compliance frameworks.”<sup>85</sup> The 2018 White Paper also makes reference to conformity assessments and necessary labels/marks which would it appears include the C.E. marking. It is also envisaged that conformity assessment bodies would be accredited and there would be adherence to manufacturing and quality assurance processes. The White Paper also proposes continued recognition of approvals completed before the end of the implementation period itself.<sup>86</sup>

This approach appears to be in line with that of “mutual recognition”. Switzerland provides one example of a non-EU member state where there is agreement to facilitate regulatory alignment in relation to medical devices. A mutual recognition agreement operates by setting out conditions under which the non EU country will accept conformity assessment results undertaken by EU conformity assessment bodies to show compliance with the non EU members country and vice versa.<sup>87</sup> Such agreements include relevant lists of designated laboratories, inspection bodies and conformity assessment bodies in both the EU and the third country. There are also mutual recognition agreement (MRA) for medical devices between the EU and Therapeutic Goods Administration (TGA) of Australia, and with New Zealand

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<sup>85</sup> Note 51 supra at para 28.

<sup>86</sup> Note 51 supra at para 31.

<sup>87</sup> Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment - Final Act - Joint Declarations - Information relating to the entry into force of the seven Agreements with the Swiss Confederation in the sectors free movement of persons, air and land transport, public procurement, scientific and technological cooperation, mutual recognition in relation to conformity assessment, and trade in agricultural products, OJ L 114, 30.4.2002, p. 369–429.

and Canada. This does depend upon negotiations and consequent financial agreements reached in relation to access. It remains uncertain as to whether the EU will be prepared to support this type of agreement. Nor does it seem aligned with the approach currently sought by the UK which appears to be a sectoral deal hybrid approach which would enable us to retain involvement with the EMA and consequent participation in EU databases etc. Thus while the UK appears to be moving in this direction as to how it wants to proceed in negotiations whether this option will prove realistic to attain is very unclear.

There are as have been outlined a myriad of remaining uncertainties dependant not only on the negotiations but also on the willingness of the UK Government to continue to align longer term with the regulatory standards in this area. Medical devices regulation is currently undergoing major revision. The UK can unilaterally if it chooses align with various parts of the new EU medical devices regulations. However without an agreement the UK will be excluded from the EU networks, databases and mutual recognition processes and agreements between the EU and UK will be need to cover both transition and post transition for this to be the case. It remains of course uncertain whether such an agreement will be possible. Of course some though may see Brexit as an opportunity for regulation to enable the establishment of new approaches in this area in the future. The concluding section examines whether Brexit could provide potential for a new regulatory approach.

## IV. CONCLUSIONS

The implications of Brexit for health law in the UK in general and on medical devices in particular are riven with uncertainty<sup>88</sup>. Nonetheless there is a possibility that some may see the withdrawal from the EU as an opportunity to reframe medical devices regulation and indeed rather than reduce regulation see this as having potential to provide more rigorous scrutiny than that currently applied. As noted above the medical devices regulation is complex and its effectiveness is a matter of controversy and while reforms are being introduced it can be argued that they do not yet go far enough. If there was a “no-deal scenario” this could potentially allow the UK to introduce quite major reforms at domestic level. The UK Government could decide that in the light of the complexity of the regulatory system and the concerns in relation to safety thrown up by the PiP, metal hip implants and vaginal mesh controversies that what is needed is a radical revision of the system. They could decide to move away from the current de-centralised system with its myriad of private “notified bodies and to instead move towards a centralised regulation system. This was rejected when the EU considered reform of the various medical devices directives but the UK could decide to take this forward at domestic level. Either a new Medical Devices public regulatory body could be established<sup>89</sup> or alternatively this role could be entrusted to the existing Medicines and Healthcare Products Regulatory Agency. Were the MHRA to be

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<sup>88</sup> See also the other papers in this Special Edition.

<sup>89</sup> The notion of a separate EU device regulator was considered by Hodges in 2004 – see note 16 *supra* but this would develop that idea of a specialist regulator but simply at domestic level.

given this role it would of course need to be accompanied with enhanced staffing and financing. Giving this task to the MHRA would have the advantage that decisions regarding approvals of medical devices were entirely entrusted to an independent regulator rather than a commercial company which could help to restore public trust. While this would clearly involve fairly extensive costs, particularly in the initial establishment phase, it could be argued that these could be seen as appropriately proportionate in terms of ensuring safety in relation to medical devices. The new Agency could take forward beneficial aspects of the existing EU schemes such as the implant card and tracking and tracing of products. This would not however address the question of reciprocity. Unless there is a separate sectoral agreement then the UK would still be excluded from cross-EU recognition of device approval and from the ability to share information as part of vigilance activities. Whether access would be allowed to the full EU databases themselves remains questionable at present. A new UK regulatory scheme could also address the concerns noted above in relation to compensation for medical devices. It could for example establish a specific no fault compensation scheme in this area, but in reality given the unwillingness to introduce such schemes generally in the UK with very limited exceptions this is unlikely to be taken forward at least in the near future<sup>90</sup>

While such an entire reframing of medical device regulation itself may provide an effective solution in the long term there are several reasons why this particular option is very unlikely to be taken forward by the UK Government. The first is clearly that of time- unless the clock is stopped on Article 50 and/or unless there is a much longer transitional period negotiated than currently envisaged by either of the parties to the negotiations then the UK Government's role in relation to regulation up to Brexit will be concentrated on firefighting

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<sup>90</sup> See further the Vaccine Damage Compensation Act 1979.

across a range of fronts. As we have seen in relation to devices and this is a problem across all other sectors- not simply health- there are a huge range of matters which will need to be resolved before we leave to ensure effective operations of systems which cannot be resolved by the European Union (Withdrawal) Act 2018 itself. This is simply not the time for a calm and considered thorough domestic overhaul of the medical devices regulatory system. What the Government have indicated in the technical notices published in August 2018 in preparation for a no-deal scenario is that they are currently working on contingency plans for supply of such devices.<sup>91</sup> It has indicated that in the case of a no-deal arrangement the UK will continue to recognise CE marked devices approved for the EU market at least initially and there will also be consultation “in due course” as to what happens after this initial arrangement<sup>92</sup>. Moreover the MHRA would not be able to provide oversight for notified bodies as at present. It is intended the MHRA would take over national decisions as to post market surveillance. The intention seems very much for an approach at least initially of a holding operation and continuity.

Secondly, even if time were not the issue it currently is there would be a further practical problem here. There has been a steady trend over the last two decades by UK Governments to reduce the number of Arms Lengths bodies as a means of reducing cost<sup>93</sup>. This current Government has shown no signs of reversing this trend, nor is it noted for taking forward the introduction of new regulatory regimes in the area of health care, in contrast to the previous Labour Government with e.g. its introduction of ground breaking regulation in the area of

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<sup>91</sup> Department of Health and Social Care Guidance Medicines Supply Contingency Planning Programme : Guidance for marketing authorisation holders in the event of a no-deal Brexit, 23<sup>rd</sup> August 2018, <https://www.gov.uk/guidance/medicines-supply-contingency-planning-programme>

<sup>92</sup> Department of Health and Social Care *Guidance How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal* August 23<sup>rd</sup> 2018. <https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal> accessed 7th September 2018.

<sup>93</sup> Department of Health *Liberating the NHS Report of the Arm's Length Bodies Review* (DOH, 2010).



human material through the Human Tissue Act 2004. Without the necessary political will the prospect of the creation of alternative regulatory bodies and bespoke new innovative regulatory structures in relation to medical devices is likely to simply remain within the pages of academic journals and not to enter the statute books.

The best case scenario at present to help to reduce future risks to patient safety will be for the UK to align with the new Medical Devices Regulations. This will require active continued alignment during the transitional period in relation to the General Devices Regulation. In the subsequent period after transition it would be necessary for the UK to ensure compliance with the new In Vitro Regulation which is due to be in force in 2020. In addition the UK government should explore the prospect for a sectoral deal relating to devices and pharmaceuticals. Given the existing EU negotiation strategy this may be prove ultimately impossible or if that is unsuccessful a mutual recognition agreement. It should also attempt to ensure ongoing liaison with the Joint Research Centre and Expert Working Groups developing standards in this area and seek an observer role on the new Medical Devices Coordination Group which the EU is establishing. Such proactive steps to facilitate regulation are critical. As we have seen in relation to PiP, vaginal mesh and metal hip implants we simply cannot afford to be complacent about the risks that medical devices can pose to patients. The recent EU initiatives demonstrate there is a real need to ensure that standards are not reduced. As elsewhere patient safety is a critical factor in a healthy Brexit.

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