

# The Welsh Government's Supplementary Legislative Consent Memorandum (Memorandum No. 2) on the Medicines and Medical Devices Bill

December 2020

## 1. Background

### The Bill

1. The UK Government's Medicines and Medical Devices Bill<sup>1</sup> (the Bill) was introduced to the House of Commons on 13 February 2020. It is sponsored by the Department of Health and Social Care.
2. The Bill moved to the House of Lords on 24 June 2020.

### The Welsh Government's Legislative Consent Memorandum

3. On 8 July 2020, the Minister for Health and Social Services, Vaughan Gething MS (the Minister), laid before the Senedd a Legislative Consent Memorandum<sup>2</sup> (LCM) in respect of the Bill.

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<sup>1</sup> Medicines and Medical Devices Bill 2019-21

<sup>2</sup> Welsh Government, [Legislative Consent Memorandum, Medicines and Medical Devices Bill](#), July 2020



**4.** We reported on the LCM on 22 October 2020 (first report).<sup>3</sup> The first report sets out in more detail the background to the Bill. The first report also summarises the purpose and extent of the Bill.

## The Welsh Government's Supplementary Legislative Consent Memorandum

**5.** Since the publication of the LCM, the Bill was amended during its passage through the House of Lords. The Lords Committee Stage concluded on 19 November 2020.

**6.** On 2 December 2020 the Minister laid before the Senedd a Supplementary Legislative Consent Memorandum<sup>4</sup> (Memorandum No. 2) (LCM No. 2) in respect of the Bill.

**7.** The Business Committee agreed that the Legislation, Justice and Constitution Committee (the Committee) and the Health, Social Care and Sport (HSCS) Committee should report on LCM No. 2 by 11 January 2020.<sup>5</sup>

**8.** At the time of writing this report, the Minister has not yet responded to our first report. However, paragraphs 14 and 15 of LCM No. 2 provide a 'Follow up from recent Senedd Committee reports' on the LCM.<sup>6</sup> This is discussed further in the 'Our view' section below.

### Provision for which the Senedd's consent is required

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**9.** Paragraphs 6 to 8 of LCM No. 2 provide an update on the Bill since the publication of the LCM.

**10.** Paragraph 7 restates the Welsh Government's position that it is supportive of the Bill's purpose subject to some concerns about aspects of former clause 16 of the Bill (now clause 18) which relates to the introduction of a medical device information system.

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<sup>3</sup> Legislation, Justice and Constitution Committee, [Report on the Welsh Government's Legislative Consent Memorandum on the Medicines and Medical Devices Bill](#), October 2020

<sup>4</sup> Welsh Government, [Supplementary Legislative Consent Memorandum \(Memorandum No. 2\), Medicines and Medical Devices Bill](#), December 2020

<sup>5</sup> Business Committee, [Timetable for consideration of the Supplementary Legislative Consent Memorandum \(Memorandum No. 2\) on the Medicines and Medical Devices Bill](#), December 2020

<sup>6</sup> Welsh Government, LCM No. 2, paragraphs 14 and 15

**11.** LCM No. 2 states:

“The concerns included the absence of a specific requirement to consult the devolved administrations (DAs) on the medical device information system (MDIS), the need for four nation oversight of the system, the costs to the Welsh Government and NHS in Wales of participating in the initial stages of the MDIS and ownership of the data and access to the raw non-Welsh data for comparative analyses.

As the Bill is enabling legislation, the details of how it will be implemented will be determined by UK regulations. Officials of the DAs have developed a series of principles to which the regulations should conform for discussion with the Department of Health and Social Care (DHSC) and NHS Digital.”<sup>7</sup>

**12.** Paragraphs 9 and 10 of LCM No. 2 set out the changes that have been made to the Bill since the publication of the LCM for which consent is sought. LCM No. 2 states:

“... a UK Government amendment to the medical device provisions tabled by Lord Bethell on 17 November was agreed in relation to the DAs which is within the Senedd's competence. This amendment is to clause 41 (now clause 43) which replaces the former general power to consult with a statutory requirement that the DAs are consulted before any regulations under clause 16 (now clause 18) are made irrespective of whether the proposed regulations are seen as relating primarily to supporting specific device safety matters or supporting the wider healthcare system.”<sup>8</sup>

**13.** The Welsh Government supports the Lords' amendment to clause 41 (now clause 43), as it ensures that the devolved administrations will have an opportunity to engage in the discussions on the design and operation of the MDIS and to highlight specific arrangements it would like to see reflected in the regulations that would be made by UK Ministers.<sup>9</sup>

**14.** LCM No. 2 states:

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<sup>7</sup> Welsh Government, LCM No. 2, paragraphs 7 and 8

<sup>8</sup> Welsh Government, LCM No. 2, paragraph 10

<sup>9</sup> Welsh Government, LCM No. 2 paragraph 11

“The emerging proposals on the design of the MDIS envisage a partnership arrangement between the NHS, patients, regulators, device manufacturers, clinicians, DAs and Department of Health and Social Care (DHSC) and the form and nature of the system is likely to be unclear until early drafts of the regulations are available. The DAs have been given assurances by the UK government of places on the working groups that will design and implement the MDIS, including on the project’s steering group and there are also proposals for a four nation working group to look at the MDIS regulations.”<sup>10</sup>

**15.** Paragraph 13 of LCM No. 2 notes that discussions between the Welsh and UK Governments continue and the Welsh Government will set out more detail on its position as the situation develops and further information becomes available.<sup>11</sup>

**16.** As set out in paragraphs 17 and 18 of LCM No. 2, the Welsh Government has concluded that, while supportive of the policy behind the Bill, concerns about aspects of clause 16 (now clause 18) remain. LCM No. 2 states:

“Much of the concern relates to the absence of firm information on the form and nature of the proposed information system and how it will operate. This reflects the absence of draft regulations and firm views on its form and operations. UK Ministers have emphasised that the DAs views on the regulations will be carefully considered when shaping the new arrangements and the DAs, including Welsh Government and the NHS in Wales, have been offered places on the working groups.

The benefits of a UK wide MDIS are recognised and set out in the first Legislative Consent Memorandum on the Bill. The Cumberlege Report also recently emphasised the importance of introducing such a system.”<sup>12</sup>

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<sup>10</sup> Welsh Government, LCM No. 2, paragraph 12

<sup>11</sup> Welsh Government, LCM No. 2 paragraph 13

<sup>12</sup> Welsh Government, LCM No. 2 paragraphs 17 and 18

## 2. Committee consideration

**17.** We considered LCM No. 2 at our meeting on 7 December 2020.<sup>13</sup>

### Our view

**18.** Our conclusions and recommendations for further action are detailed in the following paragraphs. Our report on LCM No. 2 should be read alongside our first report on the Bill.

**19.** With regards to LCM No. 2, we note that it is the view of the Welsh Government that clause 41 (now clause 43) of the Bill requires the Senedd's consent. We also note the Welsh Government's reasons as to why, in its view, making provision for Wales in the Bill is appropriate.

**20.** In our first report, we acknowledged the Welsh Government's concerns regarding clause 16 (now clause 18) and noted that a relevant amendment had been tabled at Committee stage in the House of Lords that would require the Secretary of State to consult the devolved governments before making regulations in devolved areas under clause 16.

**21.** While it is not this amendment that was agreed to by the Lords, we acknowledge that the amendment that was made to clause 41 (now clause 43) replaces the former general power to consult with a statutory requirement that the Welsh Government is consulted before any regulations under clause 16 (now clause 18) are made by UK Ministers.

**22.** While the Minister has not yet formally responded to our first report, we welcome the fact that the views we set out in that report (and the report of the HSCS Committee<sup>14</sup>) are acknowledged in LCM No. 2.

**23.** Finally, we note that discussions between the Welsh and UK Governments continue and that the Welsh Government has said it will set out more detail as the situation develops and further information becomes available. As such, we recognise that a further supplementary legislative consent memorandum may be required.

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<sup>13</sup> [Legislation, Justice and Constitution Committee, 7 December 2020](#)

<sup>14</sup> Health, Social Care and Sport Committee, [Report on the Legislative Consent Memorandum: Medicines and Medical Devices Bill](#), October 2020