**WRITTEN SUBMISSION TO HOUSE IN RESPECT OF LORDS AMENDMENTS**

**Memorandum for Public Bill Committee on the application of Standing Order No. 83L of the Standing Orders of the House of Commons relating to Public Business to Lords amendments to the Health Service Medical Supplies (Costs) Bill**

**Commons Consideration of Lords Amendments**

1. The following is the Department’s assessment of the Lords amendments to the Health Service Medical Supplies (Costs) Bill (“the Bill”) as first printed for the Lords (HL Bill 81).

**Summary[[1]](#footnote-1) and Territorial Extent of Bill**

1. Other than as set out in paragraphs 3 and 4 below, the provisions in the Bill would extend to England and Wales, Scotland and Northern Ireland.
2. Clause 7 of the Bill, which relates to the provision of information from those providing primary medical services or pharmaceutical services and the disclosure of the information, would amend the National Health Service (Wales) Act 2006 (“NHS (Wales) Act 2006”). Clause 7 would extend to England and Wales and apply to Wales only.
3. Subsection (1) of clause 8 of the Bill, which relates to the control of prices of medical supplies, would amend the National Health Service (Scotland) Act 1978 (“NHS (Scotland) Act 1978”). Subsection (1) would extend to Scotland only.

**Lords Amendment 1**

*Context and Purpose*

1. Lords amendment 1 would add a new clause to the Bill, and relates to the remuneration for persons providing pharmaceutical services in respect of special medicinal products.
2. Special medicinal products are medicines made to order for individual patients.
3. The new clause would amend section 164 of the National Health Service Act 2006 (“NHS Act 2006”), which relates to the remuneration for persons providing pharmaceutical services in England.
4. Subsection (8A) of section 164 of the NHS Act 2006, as amended by the new clause, would make clear that the Secretary of State could make regulations regarding remuneration for pharmaceutical services specifically with respect to special medicinal products.
5. Subsection (8B) would explain that the regulations made by the Secretary of State could relate to how the remuneration should be calculated and also that remuneration would not have to be provided in specified circumstances.
6. In terms of how the remuneration should be calculated, subsection (8C) would explain that this may include, for example, requiring a dispenser, health service body or a determining authority (which includes the Secretary of State or where authorised by the Secretary of State, NHS England or any other person) to make inquiries to ensure that remuneration is reasonable or estimating an amount of remuneration that is reasonable. Subsection (8C) would therefore allow for different payment arrangements to be established for special medicinal products compared to other products supplied through pharmaceutical services.
7. In terms of the circumstances in which remuneration would not have to be provided, subsection (8D) would explain that this may include, for example, circumstances where special medicinal products are provided to persons providing pharmaceutical services by a health service body or under an arrangement between a health service body and other person. This could include some form of central procurement for provision of special medicinal products, rather than the pharmaceutical provider purchasing the products.
8. Subsection (8E) would provide definitions for “health service body” and “special medicinal product”.

*Extent and Application*

1. In summary, the new clause added to the Bill by Lords amendment 1 would extend to England and Wales, and by virtue of section 271 of the NHS Act 2006, apply only to England.
2. Section 164 of the NHS Act 2006, which is amended by the new clause added by Lords amendment 1, extends to England and Wales (see section 278 of the NHS Act 2006).
3. Section 271 of the NHS Act 2006 makes clear that the functions of the Secretary of State under section 164 of the NHS Act 2006 are exercisable only in relation to England. Therefore, the new clause, as an amendment to section 164, would relate exclusively to England.

1. The new clause refers to a “health service body” as defined in section 9(4) of the NHS Act 2006. Some of the bodies listed in that provision exercise functions in relation to Wales, Scotland or Northern Ireland. However, section 164, as amended by the new clause, would still apply only to England. This is because the references to a “health service body” in the amendments to section 164 make up part of the description of the type of circumstances in which reimbursement will or will not be made to persons providing pharmaceutical services in England. Therefore, the operative part aspect of section 164 would still only relate to England.

*Legislative Competence*

1. The new clause inserted by Lords amendment 1 would be within the legislative competence of the National Assembly for Wales, Scottish Parliament and the Northern Ireland Assembly.
2. Indeed Lords amendment 2 would confer corresponding powers on Welsh Ministers by adding a new clause to the Bill which would amend section 88 of the NHS (Wales) Act 2006.

*Certification*

1. The Department considers that Lords amendment 1 should be certified as one to which the English Votes for English Laws procedure applies.

*Related Lords Amendments to Lords Amendment 1*

1. Lords amendment 18 relates to the extent of the new clause that would be added to the Bill by Lords amendment 1.
2. Lords amendment 18 would amend clause 9, which relates to the extent of the provisions in the Bill, and would specify that the new clause added by Lords amendment 1 would extend to England and Wales.
3. Clause 9 extends to England, Wales, Scotland and Northern Ireland.
4. Clause 9 includes other subsections which make provision relating to England, Wales, Scotland and Northern Ireland. Clause 9 would as a whole therefore continue to extend and apply to England and Wales, Scotland and Northern Ireland.

**Lords Amendment 2**

*Context and Purpose*

1. Lords amendment 2 would add a new clause to the Bill, and relates to the remuneration for persons providing pharmaceutical services in respect of special medicinal products.
2. Special medicinal products are medicines made to order for individual patients.
3. The new clause would amend section 88 of the NHS (Wales) Act 2006, which relates to the remuneration for persons providing pharmaceutical services in Wales.
4. Subsection (8A) of section 88 of the NHS (Wales) Act 2006, as amended by the new clause, would make clear that Welsh Ministers could make regulations regarding remuneration for pharmaceutical services specifically with respect to special medicinal products.
5. Subsection (8B) would explain that the regulations could relate to how the remuneration should be calculated and also that remuneration would not have to be provided in specified circumstances.
6. In terms of how the remuneration should be calculated, subsection (8C) would explain that this may include, for example, requiring a dispenser, health service body or a determining authority (which includes the Welsh Ministers or so far as authorised by the Welsh Ministers to exercise the functions of determining authorities, any Local Health Board or other person appointed by them in an instrument) to make inquiries to ensure that remuneration is reasonable or estimating an amount of remuneration that is reasonable. Subsection (8C) would therefore allow for different payment arrangements to be established for special medicinal products compared to other products supplied through pharmaceutical services.
7. In terms of the circumstances in which remuneration would not have to be provided, subsection (8D) would explain that this may include, for example, circumstances where special medicinal products are provided to persons providing pharmaceutical services by a health service body or under an arrangement between a health service body and other person. This could include some form of central procurement for provision of special medicinal products, rather than the pharmaceutical provider purchasing the products.
8. Subsection (8E) would provide definitions for “health service body” and “special medicinal product”.

*Extent and Application*

1. In summary, the new clause added to the Bill by Lords amendment 2 would extend to England and Wales (see section 209 of the NHS Wales Act), and by virtue of section 202 of the NHS Act (Wales) Act 2006, apply only to Wales.
2. Section 88 of the NHS Act (Wales) 2006, which the new clause added by Lords amendment 2 would amend, extends to England and Wales.
3. Section 202 of the NHS Act (Wales) Act 2006 makes clear that the functions of the Welsh Minister under section 88 of the NHS Act 2006 are exercisable only in relation to Wales. Therefore, the new clause as an amendment to section 88 would relate exclusively to Wales.

1. The new clause refers to a “health service body” as defined in section 7(4) of the NHS Act (Wales) 2006. Some of the bodies listed in that provision exercise functions in relation to Wales, Scotland or Northern Ireland. However, section 88, as amended by the new clause, would still apply only to Wales. This is because the references to a “health service body” in the amendments to section 88 make up part of the description of the type of circumstances in which reimbursement will or will not be made to persons providing pharmaceutical services in Wales. Therefore, the operative part aspect of section 88 would still only relate to Wales.

*Certification*

1. The Department considers that as the new clause inserted by Lords amendment 2 relates exclusively to Wales, the amendment should not be certified as one to which the English Votes for English Laws procedure applies.

*Related Lords Amendments to Lords Amendment 2*

1. Lords amendments 18 and 21 relate to the new clause added by Lords amendment 2. As Lords amendment 2 should not, in the Department’s view, be certified as one to which the English Votes for English Laws procedure applies, Lords amendments 18 and 21 should not, in the Department’s view, be certified as such either.

**Lords Amendment 3**

1. Lords amendment 3 would add a new clause to the Bill, regarding factors which the Government must have regard to when seeking to secure best value for money in the purchase of medicines and medical supplies.
2. The factors include promoting and supporting a growing life sciences sector in the UK and ensuring that patients have rapid access to NICE approved medicines.
3. The new clause appears to extend to the UK, though part of it may only apply to England.

**Remaining Lords Amendments**

1. The remaining Lords amendments would not change the extent or application of the clauses in the Bill as first printed in the Lords.

**Territorial Extent and Application of the Lords Amendments in the United Kingdom**

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| **Provision** | **Extends to E & W and applies to England?** | **Extends to E & W and applies to Wales?** | **Extends and applies to Scotland?** | **Extends and applies to Northern Ireland?** | **Would corresponding provision be within the competence of the National Assembly for Wales?** | **Would corresponding provision be within the competence of the Scottish Parliament?** | **Would corresponding provision be within the competence of the Northern Ireland Assembly?** | **Legislative Consent Motion needed?** |
| LA 1 – new clause | Yes | No | No | No | Yes | Yes | Yes | No |
| LA 2 – new clause | No | Yes | No | No | N/A | N/A | N/A | Yes (W) |
| LA 3 – new clause | Yes | Yes | Yes | Yes | N/A | N/A | N/A | Yes (NI) |
| LA 4 – 7 - Clause 5 | Yes | Yes | Yes | Yes | N/A | N/A | N/A | Yes (NI) |
| LA 8-10 - Clause 6 | In part | In part | In part | In part | N/A | N/A | N/A | Yes, in part (W, S, NI) |
| LA 11-14 – Clause 7 | No | Yes | No | No | N/A | N/A | N/A | Yes (W) |
| LA 15 – 16 –Clause 8 | Yes | Yes | Yes | Yes | N/A | N/A | N/A | Yes, in part (NI, W and S) |
| LA 17 – Clause 8 | No | Yes | No | No | N/A | N/A | N/A | Yes (W) |
| LA 18 -20 – Clause 9 | Yes | Yes | Yes | Yes | N/A | N/A | N/A | Yes (NI, W, S) |
| LA 21 -24 – Clause 10 | Yes | Yes | Yes | Yes | N/A | N/A | N/A | Yes, in part (NI,W,S) |

1. **References in this statement to a provision being within the legislative competence of the Scottish Parliament, the National Assembly for Wales or the Northern Ireland Assembly are to the provision being within the legislative competence of the relevant devolved legislature for the purposes of Standing Order No. 83J of the Standing Orders of the House of Commons relating to Public Business.** [↑](#footnote-ref-1)