EXPLANATORY MEMORANDUM TO

THE EXPORT CONTROL (AMENDMENT) (NO. 3) ORDER 2010

2010 No. 2843

1. This explanatory memorandum has been prepared by the Department for Business, Innovation and Skills and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Export Control (Amendment) (No. 3) Order 2010 ("the 2010 Order") further amends the Export Control Order 2008 ("the 2008 Order"). The changes have the effect that pharmaceutical products for human use containing the active ingredient Sodium Thiopental are controlled for export to the United States of America.

3. Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 Sodium thiopental is an anaesthetic which is widely used in medicine in the UK and Europe but is also used in several US States to anaesthetise prisoners prior to execution. In two US States it is used in higher doses to execute prisoners. For several months, there has been a shortage of sodium thiopental in the US. This has caused at least one US State to seek supplies of the medicine from abroad.
- 3.2 On 28 October, a firm acting for one of the prisoners facing execution wrote to the Secretary of State inviting him to place controls on the export of sodium thiopental. Whilst affirming the United Kingdom's opposition to the death penalty in all circumstances, the Secretary of State declined to impose exports controls on sodium thiopental. His primary concern was that he should not take action which might cause delays in the export of a medicine which might be needed by patients in the US and elsewhere. The Secretary of State reaffirmed his decision on 12 November on the basis that there remained a possibility of significant legitimate trade in this important medicine and that it was unlikely that an order would prevent any execution.
- 3.3 On 22 November, the Court indicated that it would dismiss the Claimants' arguments that the Secretary of State was obliged by the EU Charter of Fundamental Rights or the Common Law to make an order controlling the export of sodium thiopental to the United States. It adjourned the hearing of the remainder of the Claimant's arguments until 29 November. In the meantime, the Department sought to clarify the extent of any possible lawful

trade in sodium thiopental. Having consulted US lawyers, they all agreed that, under applicable federal law, it is not currently lawful to import sodium thiopental into the United States for medical purposes. That meant that an order controlling the export of sodium thiopental should not have any adverse impact on patients in the US or on UK businesses. On Sunday 28 November, the Secretary of State decided, in the light of these new developments, to make an order under s. 6 of the Export Control Act 2002.

3.4 Given the sensitive context, the imposition of the new control is being treated as a matter of urgency. The Department has acted as soon as this new information came to light and it is considered necessary to bring the Order into force as soon as possible.

4. Legislative Context

- 4.1 This Order adds a new category of control to the 2008 Order. It is unusual for export controls to extend to medicines but there is nothing in the 2002 Act which prevents this. The control imposed by the new Article 4A is similar in nature to the controls imposed upon UK-controlled dual-use goods to certain destinations under Article 4 of the 2008 Order. Unlike the goods covered by Article 4, the good here is not "dual-use" within the meaning of that Order.
- 4.2 The Order is made under section 6 of the 2002 Act and will therefore cease to have effect on 28th November 2011.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 The Minister of State for Business and Enterprise has made the following statement regarding Human Rights:

In my view the provisions of the Export Control (Amendment) (No. 3) Order 2010 are compatible with the Convention rights.

7. Policy background

• What is being done and why

7.1 The purpose of the 2010 Order is to control the export of UK Sodium Thiopental to the US. Sodium Thiopental is used in a number of US states for the purposes of the death penalty. The United Kingdom firmly opposes the use of the death penalty in all circumstances. Because of the position under US federal law, this control will not impact on US patients or UK businesses.

• Consolidation

7.2 No consolidation of the 2008 Order is planned.

8. Consultation outcome

8.1 This is an urgent measure. There has been no time for general industry consultation although there have been discussions with the main trade associations.

9. Guidance

9.1 Comprehensive guidance on the 2008 Order is available on the BIS website (http://www.berr.gov.uk/whatwedo/europeandtrade/strategic-export-control/licensing-policy/index.html).

10. Impact

- 10.1 The impact on business, charities or voluntary bodies is limited.
- 10.2 The impact on the public sector is difficult to quantify.
- 10.3 An Impact Assessment is currently being prepared.

11. Regulating small business

11.1 The legislation applies to small business for the reasons given in the small firms impact test (see the Impact Assessment).

12. Monitoring & review

- 12.1 This Order will cease to have effect after 12 months. The Department will monitor the position in the US and the impact of the Order. It will then determine whether a further Order is required.
- 12.2 The explanatory memorandum to the 2008 Order contained the following commitment: "Within three to five years of the legislation coming into effect, we will review the legislation internally which may lead to further public consultation and, if appropriate, changes to the legislation."

13. Contact

13.1 Christopher Chew at the Department for Business, Innovation and Skills, Tel: 020 7215 8088 or email: christopher.chew@bis.gsi.gov.uk can answer any queries regarding the instrument.

Department for Business, Innovation and Skills

29 November 2010