

HOUSE OF LORDS

Secondary Legislation Scrutiny Committee

11th Report of Session 2017–19

**Draft Pharmacy (Preparation
and Dispensing Errors -
Registered Pharmacies)
Order 2018**

**Draft Sub-national Transport
Body (Transport for the
North) Regulations 2017**

Includes 2 Information Paragraphs on 3 Instruments

Ordered to be printed 28 November 2017 and published 30 November 2017

Published by the Authority of the House of Lords

Secondary Legislation Scrutiny Committee

The Committee was established on 17 December 2003 as the Merits of Statutory Instruments Committee. It was renamed in 2012 to reflect the widening of its responsibilities to include the scrutiny of Orders laid under the Public Bodies Act 2011.

The Committee's terms of reference are set out in full on the website but are, broadly, to scrutinise —

(a) every instrument (whether or not a statutory instrument), or draft of an instrument, which is laid before each House of Parliament and upon which proceedings may be, or might have been, taken in either House of Parliament under an Act of Parliament;

(b) every proposal which is in the form of a draft of such an instrument and is laid before each House of Parliament under an Act of Parliament,

with a view to determining whether or not the special attention of the House should be drawn to it on any of these specified grounds:

(a) that it is politically or legally important or gives rise to issues of public policy likely to be of interest to the House;

(b) that it may be inappropriate in view of changed circumstances since the enactment of the parent Act;

(c) that it may inappropriately implement European Union legislation;

(d) that it may imperfectly achieve its policy objectives;

(e) that the explanatory material laid in support provides insufficient information to gain a clear understanding about the instrument's policy objective and intended implementation;

(f) that there appear to be inadequacies in the consultation process which relates to the instrument.

The Committee may also consider such other general matters relating to the effective scrutiny of secondary legislation as the Committee considers appropriate, except matters within the orders of reference of the Joint Committee on Statutory Instruments.

Members

Baroness Blackstone

Lord Haskel

Lord Sherbourne of Didsbury

Lord Faulkner of Worcester

Rt Hon. Lord Janvrin

Rt Hon. Lord Trefgarne (Chairman)

Baroness Finn

Lord Kirkwood of Kirkhope

Baroness Watkins of Tavistock

Lord Goddard of Stockport

Baroness O'Loan

Registered interests

Information about interests of Committee Members can be found in the last Appendix to this report.

Publications

The Committee's Reports are published on the internet at www.parliament.uk/seclegpublications

The National Archives publish statutory instruments with a plain English explanatory memorandum on the internet at <http://www.legislation.gov.uk/uksi>

Information and Contacts

Any query about the Committee or its work, or opinions on any new item of secondary legislation, should be directed to the Clerk to the Secondary Legislation Scrutiny Committee, Legislation Office, House of Lords, London SW1A 0PW. The telephone number is 020 7219 8821 and the email address is hseclegscrutiny@parliament.uk.

Eleventh Report

INSTRUMENTS DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

Draft Pharmacy (Preparation and Dispensing Errors - Registered Pharmacies) Order 2018

Date laid: 13 November 2017

Parliamentary procedure: affirmative

Summary: This Order makes a change to the legislation governing the way pharmacists who make a mistake are prosecuted by making certain new defences available to them. Currently they face “triple jeopardy” from their professional regulator, health legislation and, potentially, criminal law (for manslaughter). As health law currently stands, breaches of sections 63 and 64 of the Medicines Act 1968 are “strict liability” offences, which means that the prosecution does not have to prove intention, recklessness or negligence on the part of the defendant for the prosecution to succeed. This results in a “fear factor” amongst pharmacy professionals, who are therefore reluctant to admit errors. This Order is based on the premise that reducing the risk of prosecution will increase the number of errors reported. Over time, learning from a greater number of error reports should lead to improvements in training and practices, which should in turn reduce the number of errors made. The Department of Health states that the consultation responses have confirmed that this logic (creating a virtuous cycle of reporting, learning and improving) and the assumptions underlying it are realistic and likely to make a significant reduction in the level of errors. We found this to be a well-supported argument set out in a particularly clear Explanatory Memorandum. Strict safeguards are maintained for deliberate or negligent adulteration, but the Department of Health proposal, that reducing the penalties on those who report genuine mistakes will lead to common errors being identified and reduced, is persuasive.

This Order is drawn to the special attention of the House on the ground that it gives rise to issues of public policy likely to be of interest to the House.

This Order has been laid by the Department of Health (DH) under provisions of the Health Act 1999. It is accompanied by an Explanatory Memorandum (EM) and an Impact Assessment (IA).

Background

1. This Order makes changes to the Medicines Act 1968 (“the 1968 Act”) by providing new defences to pharmacy professionals who commit an offence by making inadvertent dispensing errors:
 - Section 63 (adulteration of medicinal products) of the 1968 Act concerns changing the composition of a medicinal product in a way that is injurious to health. Most medicines dispensed from a registered pharmacy are manufactured away from the pharmacy, but, where registered pharmacy professionals have to make up (compound) a medicine from individual ingredients, errors may occur if, for example,

an ingredient is omitted or inadvertently added which ‘adulterates’ the medicine.

- Section 64 (protection of purchasers of medicinal products) concerns the sale or supply on prescription of medicinal products that are not of the nature or quality ordered.
 - Under Section 67(2) of the 1968 Act, people who contravene sections 63 or 64 are guilty of an offence the penalty for which can be a fine or imprisonment for up to two years, or both.
2. The 1968 Act does not only apply to registered pharmacists. Someone who was involved in the ordinary retail sale of medicines such as standard painkillers could, for example, be prosecuted for breach of section 64. However, in the case of a registered pharmacy professional who makes an error, the matter may also be referred to the appropriate pharmacy regulator, for example the General Pharmaceutical Council, to consider whether their fitness to practice is impaired and their permission to practice should be suspended or withdrawn. In the most serious cases, often where the dispensing error leads to the death of a patient, prosecution is and will continue to be possible under the general criminal law – for example for manslaughter. Registered pharmacy professionals therefore face “triple jeopardy” where they commit a preparation or dispensing error.

The “fear factor”

3. In the UK in 2015-16 over a billion prescription items were dispensed (approximately 90% by community pharmacies). The IA states that there were 20,820 reported dispensing errors in the UK in 2016 (paragraph 66) but estimates that the number of unreported dispensing errors for that year was around 499,651 (paragraph 69): the IA concludes that about 20% of the under-reporting is attributable to the fear of prosecution.
4. That fear of prosecution is in part because breaches of sections 63 and 64 are “strict liability” offences (notwithstanding that they are already subject to limited defences in sections 64(3) and (4), 121 and 122 of the 1968 Act). This means that the prosecution does not have to prove a “mental element” – intention, recklessness or negligence – on the part of the defendant for the prosecution to succeed. This makes prosecution easier and in turn makes pharmacists reluctant to admit errors.

Reducing errors by learning

5. Although prosecutions have been rare, generally only being brought where the error has resulted in death, DH states that the evidence included in the IA demonstrates that the “fear factor” persists. This Order is based on the premise that reducing the risk of prosecution will increase the number of errors reported. Over time, learning from a greater number of error reports should lead to improvements in training and practice, which should in turn reduce the number of errors made. The DH states that the consultation responses confirmed that this logic (creating a virtuous cycle of reporting, learning and improving) and the assumptions underlying it are realistic.
6. This Order therefore proposes new defences that may be used in relation to offences under both sections 63 and 64: the defendant must show that they were a pharmacy professional (or a supervised student) acting in the

course of their profession at a registered pharmacy, and the product has been sold or supplied in pursuance of a prescription. The defence then relies on the pharmacy professional, supervised student, or pharmacy owner who becomes aware of an error promptly taking all reasonable steps to ensure that the patient is notified.

7. This final element of the defence – notification of the patient – builds on the “duty of candour” of health care professionals where they make a mistake, and the corporate “duty of candour” of pharmacy owners. DH state that this is a key part of the new thinking: registered pharmacy professionals will move from a position of having a reason not to report their errors (fear of prosecution) to a position of having a clear additional reason to report them (helping to make a possible defence to a prosecution).

Anticipated impact of the change

8. The IA estimates that 62% of errors can be corrected by increasing the reporting of errors (paragraph 74) and estimates a 30% decrease in errors over a four year period, if learning is enabled (paragraph 79). As well as suggesting considerable patient benefits from these proposals, there are financial benefits estimated to be a saving of £871,000 over the ten year period set out in the IA. This is composed of:
 - one off familiarisation costs estimated at £392,000,
 - the net cost of impact of changes in error reports £4,707,000,
 - cost savings resulting from reductions in the handling of dispensing errors £5,404,000, and
 - net cost savings from reduced risk of criminal prosecution £566,000.

Conclusion

9. We found this to be a well-supported argument set out in a particularly clear EM. Strict safeguards are maintained for deliberate or negligent adulteration, but the DH proposal, that reducing the penalties on those who report genuine mistakes will lead to common errors being identified and reduced, is persuasive.

Draft Sub-national Transport Body (Transport for the North) Regulations 2017

Date laid: 16 November 2017

Parliamentary procedure: affirmative

Summary: This instrument establishes Transport for the North (TfN) as the first Sub-national Transport Body and sets out the functions it will exercise in relation to a transport strategy and its delivery in the North of England. An accompanying report sets out the funding proposals.

These Regulations are drawn to the special attention of the House on the ground that they give rise to issues of public policy likely to be of interest to the House.

10. These Regulations are laid by the Department for Transport (DfT) under Part 5A of the Local Transport Act 2008 (“the 2008 Act”) as inserted by section 21 of the Cities and Local Government Devolution Act 2016. The instrument is accompanied by an Explanatory Memorandum (EM). In accordance with section 102T(3) of the 2008 Act, the Secretary of State has also laid before Parliament a report explaining the effect of the Regulations and why he believes it is appropriate to make them.¹

Background to Sub-national Transport Bodies

11. This instrument establishes Transport for the North (TfN) as the first Sub-national Transport Body (STB) and sets out the functions it will exercise in relation to a transport strategy and its delivery in the North of England. Section 102E(1) of the 2008 Act empowers the Secretary of State to establish a STB if he considers that its establishment would facilitate the development and implementation of transport strategies for the area, and the objective of economic growth in the area would be furthered by the development and implementation of such strategies. This instrument is the first use of these powers.
12. The EM notes that DfT expects more areas to come forward with proposals for STB status, in the first instance from Midlands Connect and England’s Economic Heartland (Oxford to Cambridge arc), but indicates that these instruments are unlikely to be laid in Parliament before 2020. It also states that TfN, and other STBs, will operate at a sub-national level above local and combined authorities, filling the gap that exists between planning for local transport projects and the largest scale national transport schemes. They will “leverage regional and local knowledge to plan and prioritise transport interventions aimed at yielding an economic boost.” (EM paragraph 7.7)

Function of TfN

13. A number of reports in 2014-15 supported the idea of a body which would allow the North of England to “speak with one voice” on transport issues in their area and boost growth. This became known as the “Northern Powerhouse” initiative. TfN estimates that long term economic growth in

¹ See Legislation.gov.uk, *Secretary of State Report on the Sub-national Transport Body (Transport for the North) Regulations 2017*: http://www.legislation.gov.uk/ukdsi/2017/9780111161593/pdfs/ukdsiod_9780111161593_en.pdf [Accessed 29 November 2017].

North could be worth an additional Gross Value Added of £97 billion per year and an extra 850,000 jobs by 2050.²

14. TfN was created in October 2014 as a partnership of the 19 Constituent Authorities (six Combined Authorities, three County Councils and 10 Unitary Authorities) listed in the Regulations.³ In March 2015 the Government and TfN published the first Northern Transport Strategy, which will be used to advise the Secretary of State on transport matters for the area. The TfN will begin the statutory requirement to conduct public consultation on the strategy as soon as these Regulations formalising the TfN as a STB are made.
15. The long term strategy aims to “connect the north, create a single economy and allow northern towns and cities to pool their strengths”. It includes the introduction of new road and fast rail links to connect northern cities, and integrated rail ticketing across the whole region. This new approach requires the Department to create bespoke governance mechanisms for TfN that can align to the relevant investment processes – Road Investment Strategy for Roads, High Level Output Specification (HLOS) and Rail Upgrade Plan (RUP) for rail. The report states that being recognised formally inside these processes will afford TfN an opportunity to influence central government decision-making to deliver the needs of local communities.

Finance and funding

16. **A key theme from the set-up consultation was that funding for TfN should not come from current local authority budgets and TfN should not be able to draw down statutory contributions from its members. Although the report notes that TfN’s constituent authorities can make voluntary contributions, the amount will require unanimous agreement by TfN’s constituent members.**
17. TfN is therefore to be funded directly by grants from the Secretary of State for the spending period ending in 2020 with:
 - £50 million up to 2020 core funding
 - £150 million for Smart Ticketing
 - £60 million for Northern Powerhouse Rail.
18. The report concludes that, although the Department has committed to funding the administration of TfN up to 2020, any future funding decisions will always remain the responsibility of the Government at the time.

2 Transport for the North, *Northern Powerhouse Independent Economic Review: Final Executive Summary Report*, June 2016: <http://www.transportfornorth.com/wp-content/uploads/Northern-Powerhouse-Independent-Economic-Review-Executive-Summary.pdf> [Accessed 27 November 2017].

3 Blackburn with Darwen BC, Blackpool BC, Cheshire East, City of York, Cumbria CC, North East CA, East Riding of Yorkshire, Greater Manchester CA, Kingston Upon Hull, Lancashire CC, Liverpool City Region CA, North East Lincolnshire BC, North Lincolnshire BC, North Yorkshire CC, Sheffield City Region CA, Tees Valley CA, Warrington BC, West Yorkshire CA.

INSTRUMENTS OF INTEREST

Draft European Union (Definition of Treaties) (Partnership and Cooperation Agreement) (Turkmenistan) Order 2017

Cm 9537 Partnership and Cooperation Agreement Establishing a Partnership between the European Communities and their Member States, of the one part, and Turkmenistan, of the other part

19. This Order declares the Partnership and Cooperation Agreement between the European Communities and their Member States and the Republic of Turkmenistan signed at Brussels on 25th May 1998 (the “Agreement”) to be an EU Treaty as defined in section 1(2) of the European Communities Act 1972. This designation allows subordinate legislation to be made to give effect to the provisions of the Agreement. As well as seeking to strengthen existing economic ties and contribute to the process of economic reform and development in Turkmenistan, the Agreement also sets out that democratic and human rights principles must play their part. The delay in ratification of the Agreement arose because of concerns about the human rights record of Turkmenistan. The Explanatory Memorandum states that the Government now consider that, on balance, the entry into force of the Agreement would allow a closer relationship with Turkmenistan and potentially greater scope to encourage progress on its human rights and good governance.

Childcare Payments (Eligibility) (Amendment) Regulations 2017 (SI 2017/1101)

20. On 15 November 2017, Mel Stride, MP, Financial Secretary to the Treasury, made a Written Ministerial Statement, giving a “Childcare Service Update”.⁴ This included an acknowledgement that “applications for Tax-Free Childcare accounts have been lower than expected. We want to encourage more parents to take up the offer they are entitled to and now the service has improved, we will undertake activity to raise awareness of Tax-Free Childcare amongst parents.”
21. The Childcare Payments (Eligibility) (Amendment) Regulations 2017 (SI 2017/1101), laid by HM Revenue and Customs (HMRC), clarify certain aspects of eligibility for these payments, by amending an earlier set of Regulations.⁵ We asked HMRC whether SI 2017/1101 was a response to the low level of applications for Tax-Free Childcare. In July of this year, we published information about the Tax Credits (Claims and Notifications) (Amendment) Regulations 2017 (SI 2017/597), in which we noted that we had asked HMRC to ensure that guidance for parents was updated and communicated without delay. We also asked HMRC if this had been done.
22. HMRC has told us that SI 2017/1101 addresses minor changes designed to provide greater clarity and improve the customer experience, rather than increase the take-up of the scheme. It has said that low take-up rates are due to two factors: slower than planned rollout; and lack of parent awareness. As set out in the Written Statement of 15 November, the Government have opened the scheme to under-six-year-olds, from 24 November 2017. As regards guidance to parents to minimise the number that apply for Tax-Free

4 Parliament.uk, ‘Written Statements’: <http://www.parliament.uk/business/publications/written-questions-answers-statements/written-statements/?page=1&max=20&questiontype=AllQuestions&house=commons%2clords&keywords=childcare> [Accessed 22 November 2017].

5 The Childcare Payments (Eligibility) Regulations 2015 (SI 2015/448).

Childcare by mistake when seeking to apply only for DfE's 30 hours free childcare scheme, HMRC has told us that it has continued to update the on-screen warnings and messaging to minimise the number of parents that make applications by mistake. However, HMRC says that this has been less effective than hoped so far, and cases continue to arise; that, where necessary, it has used the Commissioners' powers of payment and management of tax credits to prevent parents from losing out; and that it continues to improve warning messages and to monitor the position.

23. **It seems clear that many parents continue to find it hard to understand both the details of Tax-Free Childcare accounts, and the process of applying for them. We urge HMRC to be vigilant for ways of further improving the intelligibility, and ease of operation, of the system.**

INSTRUMENTS NOT DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

Draft instruments subject to affirmative approval

Draft Combined Authorities (Mayoral Elections) Order 2017

Draft European Union (Definition of Treaties) (Partnership and Cooperation Agreement) (Turkmenistan) Order 2017

Draft European Union (Definition of Treaties) (Enhanced Partnership and Cooperation Agreement) (Kazakhstan) Order 2017

Draft Local Authorities (Mayoral Elections) (England and Wales) (Amendment) Regulations 2017

Draft Policing and Crime Act 2017 (Maritime Enforcement Powers: Code of Practice) Regulations 2017

Draft instruments subject to annulment

Draft Test Valley (Electoral Changes) Order 2018

Draft Tewkesbury (Electoral Changes) Order 2018

Instruments subject to annulment

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| Cm 9534 | Geneva Act of the Hague Agreement concerning the International Registration of Industrial Designs |
| Cm 9537 | Partnership and Cooperation Agreement Establishing a Partnership between the European Communities and their Member States, of the one part, and Turkmenistan, of the other part |
| Cm 9538 | Minamata Convention on Mercury |
| Cm 9539 | Agreement between the Government of the United Kingdom and the Government of the Republic of Panama for the Establishment and Functioning of Private International Schools of Excellence in the Republic of Panama |
| SI 2017/1064 | Central Securities Depositories Regulations 2017 |
| SI 2017/1070 | Environmental Impact Assessment (Miscellaneous Amendments Relating to Harbours, Highways and Transport) Regulations 2017 |
| SI 2017/1071 | United Nations and European Union Financial Sanctions (Linking) (Amendment) (No. 2) Regulations 2017 |
| SI 2017/1073 | Infrastructure Planning (Compulsory Acquisition) (Amendment) (No. 2) Regulations 2017 |
| SI 2017/1076 | Coroners and Justice Act 2009 (Alteration of Coroner Areas) (No. 2) Order 2017 |
| SI 2017/1084 | Teachers' Pensions Schemes (Miscellaneous Amendments) Regulations 2017 |

- SI 2017/1086 Traffic Signs (Amendment) (England and Wales) Regulations and General Directions 2017
- SI 2017/1090 General Anti-Abuse Rule Procedure (Amendment) Regulations 2017
- SI 2017/1094 Venezuela (European Union Financial Sanctions) Regulations 2017
- SI 2017/1096 Childcare Payments (Amendment) Regulations 2017
- SI 2017/1100 Patents and Patents (Fees) (Amendment) Rules 2017
- SI 2017/1101 Childcare Payments (Eligibility) (Amendment) Regulations 2017
- SI 2017/1115 Insolvency (England and Wales) and Insolvency (Scotland) (Miscellaneous and Consequential Amendments) Rules 2017
- SI 2017/1119 Insolvency (Miscellaneous Amendments) Regulations 2017

APPENDIX 1: INTERESTS AND ATTENDANCE

Committee Members' registered interests may be examined in the online Register of Lords' Interests at <http://www.parliament.uk/mps-lords-and-offices/standards-and-interests/register-of-lords-interests>. The Register may also be inspected in the Parliamentary Archives.

For the business taken at the meeting on 28 November 2017, Members declared the following interests:

Draft Pharmacy (Preparation and Dispensing Errors - Registered Pharmacies) Order 2018

Lord Kirkwood of Kirkhope

Chair of General Pharmaceutical Council's ad hoc Advisory Committee on Fitness to Practise

Attendance:

The meeting was attended by Baroness Blackstone, Lord Faulkner of Worcester, Baroness Finn, Lord Goddard of Stockport, Lord Janvrin, Lord Kirkwood of Kirkhope, Baroness O'Loan, Lord Trefgarne and Baroness Watkins of Tavistock.