Health and Community Care Committee

12th Meeting, 2001

Wednesday 25 April 2001

The Committee will meet at 9.30 am in Committee Room 1

1. **Items in Private:** The Committee will consider whether to take items 5 and 6 in private.

2. **Budget 2002/03:** The Committee will take evidence from—

   The Scottish Executive

3. **Subordinate legislation:** The Committee will consider the following negative instruments—

   The National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2001 (SSI 2001/67)

   The National Health Service (Dental Charges) (Scotland) Amendment Regulations 2001 (SSI 2001/69)

   The Miscellaneous Food Additives (Amendment) (Scotland) Regulations 2001 (SSI 2001/103)

   The Feeding Stuffs (Sampling and Analysis) Amendment (Scotland) Regulations 2001 (SSI 2001/104)

   The National Assistance (Assessment of Resources) Amendment (No2) (Scotland) Regulations 2001 (SSI 2001/105)

   The National Health Service (General Medical Services) (Scotland) Amendment Regulations 2001 (2001/119)

4. **Petitions:** The Committee will consider a report on petitions.

5. **Petitions:** The Committee will consider draft Reporter's report on petition—

   PE 217 by Glenorchy and Innishail Community Council on single GP practices

6. **MMR Report:** The Committee will consider outcomes following the publication of the report.

Jennifer Smart
Clerk to the Committee
Room 2.5
email jennifer.smart@scottish.parliament.uk

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The following papers are attached for this meeting:

Agenda Item 2
Questions for Scottish Executive

HC/01/12/1

Agenda Item 3
The National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2001 (SSI 2001/67) – previously circulated

HC/01/12/2

The National Health Service (Dental Charges) (Scotland) Amendment Regulations 2001 (SSI 2001/69) – previously circulated

HC/01/12/3

The Miscellaneous Food Additives (Amendment) (Scotland) Regulations 2001 (SSI 2001/103) – previously circulated

HC/01/12/4

The Feeding Stuffs (Sampling and Analysis) Amendment (Scotland) Regulations 2001 (SSI 2001/104) - previously circulated

HC/01/12/5

The National Assistance (Assessment of Resources) Amendment (No2) (Scotland) Regulations 2001 (SSI 2001/105) – previously circulated

HC/01/12/6

The National Health Service (General Medical Services) (Scotland) Amendment Regulations 2001 (2001/119) – previously circulated

HC/01/12/7

Abridged Subordinate Legislation Committee14th Report, 2001

HC/01/12/8

Abridged Subordinate Legislation Committee 15th Report, 2001

HC/01/12/9

Agenda Item 4
Petitions Report

HC/01/12/10

Agenda Item 5
Report on PE 217 by Glenorchy and Innishail Community Council on single GP practices

HC/01/12/11

Agenda Item 6
Report to follow

Agenda item 3

Health & Community Care Committee

25 April 2001

Subordinate Legislation Committee

14th Report, 2001

ABRIDGED

Subordinate Legislation

The Committee reports to the Parliament as follows—

1. The Committee met on 27th March 2001 and determined that the attention of the Parliament need not be drawn to the instruments listed at Annexe A. The Committee draws the attention of the Parliament to the instruments listed at Annexe B.

2. The report is also addressed to the following committees as lead committees for the instruments specified:

Health and Community Care	SSI 2001/70
	SSI 2001/72
	SSI 2001/85
	SSI 2001/86
	SSI 2001/103

Negative Instruments

The Miscellaneous Food Additives (Amendment) (Scotland) Regulations 2001, (SSI 2001/103)

Agenda item 3

Health & Community Care Committee

25 April 2001

The Scottish Parliament

Subordinate Legislation Committee

ABRIDGED

15th Report, 2001

Subordinate Legislation

The Committee reports to the Parliament as follows—

1. The Committee met on 3rd April 2001 and determined that the attention of the Parliament need not be drawn to the instruments listed at Annexe A. The Committee draws the attention of the Parliament to the instruments listed at Annexe B. The Committee draws the attention of the Parliament and lead committee to the Executive's response to a question from the Committee at Annexe C.

2. The report is also addressed to the following committees as lead committees for the instruments specified:

Health and Community Care	SSI 2001/67
	SSI 2001/69
	SSI 2001/104
	SSI 2001/105
	SSI 2001/119

Negative Instruments

The National Health Service (General Medical Services) (Scotland) Amendment Regulations 2001, (SSI 2001/119)

Negative Instruments

The National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2001, (SSI 2001/67)

1. The Committee raised a range of points with the Executive on this instrument.

Point 1

2. The Committee noted that these Regulations are the 22nd set of amendments to the principal Regulations and that the equivalent English Regulations were consolidated last year. The Committee therefore asked when a similar consolidation would be made for Scotland.

3. In its reply, reprinted at Appendix A, the Executive regretted that it has not been able to consolidate these Regulations but it is working towards consolidation and continues to do so as time and resources allow. The Department is committed to consolidating the Regulations and will do so as soon as reasonably possible.

4. The Committee appreciates the Executive's position but nevertheless observes that consolidation of these Regulations requires some degree of priority. As the Committee has noted recently, it is particularly important that regulations such as these are readily accessible and understandable to the public.

5. **The Committee therefore draws the attention the Parliament and lead committee to the particular need for consolidation of these Regulations and to the Executive's response on the point.**

Point 2

6. The Committee noted that regulation 2(2) contains a definition of the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) Regulations 1988. As these Regulations are referred to only once in the principal Regulations in the terms defined, namely in the amendments effected by the current Regulations, and are otherwise referred to in full the Committee asked why this provision was considered necessary.

7. In response, the Department agreed that it would have not been appropriate to include a definition where the term was referred to just once in the instrument. The Department nevertheless noted that the instrument makes a reference to the term in each of paragraphs (10)(b), (14)(b)(ii) and (14)(c)(i) of Regulation 8 of the principal Regulations.

8. Whilst aware of the references in the amendments made by these Regulations, the Committee observes that the substantive point is that the Charges Regulations will now be referred to in two different ways in the principal Regulations. It would have been better, in the Committee's view, if it was considered desirable to include a definition of the Charges Regulations, to have completed the exercise and included a provision translating all existing references to the Charges Regulations to the new form.

9. While, in the Committee's view, the instrument, cannot be considered defectively drafted on this point, it reinforces the need for speedy consolidation of these Regulations.

Point 3

10. The Committee noted that a footnote is missing from the reference to the 1983 Rules in regulation 2(3)(a) and requested an explanation.

11. The Department replied that the purpose of the amendment made by regulation 2(3)(a) is to correct an error in the title of the rules as referred to in SSI 2000/396, which itself contained a footnote. The Department accepts, however, that it would have been appropriate to include a footnote in this instrument and has apologised for the omission.

12. The Committee notes that, as a point of form, footnote references should be provided for all references to legislation whether the reference is free standing or forms part of a provision making a textual amendment to other legislation.

13. **The Committee therefore draws the attention of the Parliament and lead committee to this point as defective drafting** not, however, affecting the substance of the instrument.

Point 4

14. The Committee was unclear as to how the new paragraphs added to regulation 8 of the principal Regulations interact with paragraph (6) of that regulation as amended and asked the Executive for explanation.

15. The Department explained that the new paragraphs added to regulation 8 interact with paragraph (6) by setting out the procedure to be followed for seeking repayment and the time limits within which such claims for repayment shall be submitted. Paragraph (7) applies specifically to payments made after 1 April 2001, where the other qualifying conditions of paragraph (7) apply, and, in respect of those payments, the qualifying period for entitlement to claim a refund is extended by paragraph (9) to cover the whole period of validity of the certificate. Whereas, in respect of payments prior to 1 April 2001, or where the other qualifying conditions set out in paragraph (7) are not met, the qualifying period is one month from the date on which the pre-payment certificate became valid.

16. In the Committee's view, the Department's explanation amply illustrates the difficulties in untangling these provisions. The Committee observes that the explanation itself may not be wholly accurate insofar as the provisions of paragraph

(10) also appear to qualify the provisions of paragraph (6). Again, it seems possible that, had the principal Regulations been consolidated, the drafting of this provision might have been amended to make it clearer to the ordinary reader. **The Committee draws the Executive's explanation to the attention of the Parliament and lead committee.**

Point 5

17. The Committee noted a number of internal inconsistencies in the drafting of the new provisions and between the wording the Regulations and the principal Regulations. Paragraph (6) uses the phrase "sum prescribed under this regulation" but new paragraphs (7), (8), (11), (13) and (14) use the term "prescribed sum". In new paragraph (9) and (12) reference is made to an "application" under paragraph (6) whereas that paragraph refers to "claim" not "application". Except in new paragraph 10, reference is made to "paragraphs (13) to (15)" whilst paragraph (10) refers to "(13)-(15)". The Committee asked for clarification on these points.

18. In reply, the Department noted the elements of inconsistency in terminology identified by the Committee and apologised for these oversights. The Department considers that the nature of the inconsistent terminology is such that it is unlikely to confuse readers and will not affect the practical application of the provisions. The Department does, however, recognise the need to maintain consistency of terminology and has undertaken to correct this when consolidating the instrument. As for the differing style of references to paragraphs "(13) to (15)", the Department apologised for this inconsistency, due to an oversight, and will seek correction of the printed version of the instrument through the "printing points" procedure.

19. The Committee accepts that the inconsistencies in terminology are not such as to affect the application of the Regulations. Nevertheless, they are suggestive of insufficient care in the drafting of the Regulations.

20. **The Committee therefore draws the attention of the Parliament and the lead Committee to the instrument on the grounds of defective drafting as above.**

Point 6

21. The Committee asked for explanation as to how an application can be made "by" a person, as provided in new paragraph (7) inserted by regulation 4(3), given that the new provision only applies if the person has died. The Committee considered that a similar point might arise in relation to the reference to the "estate" in new paragraph (10) and asked for clarification on this point.

22. In reply, the Department explained that it had adopted a terminology consistent with that used at paragraph (6)(d). The Department accepts that in the context of paragraph (7), reference should correctly have been made to "by or on behalf of that person's estate". In paragraph (10), the Department accepts that reference should not have been made to "or his estate". These errors, for which the Department apologises, will not, in its view, affect the practical application of the provisions and, again, the Department undertakes to correct this when consolidating the instrument.

23. The derivation of the terminology, in the Committee's view, is plain. However, its use in paragraph (6) is unexceptionable. Paragraph (6) makes provision both in relation to the living and the dead. The defective drafting in this regulation points to the inadvisability of what may have been unconsidered copying of existing wording. Though the drafting may not affect the applicability of the provisions in question, except possibly in relation to paragraph (10), it is plainly defective. **The Committee therefore draws paragraphs (7) and (8) to the attention of the Parliament and lead committee on grounds of defective drafting**.

Point 7

24. The Committee asked for clarification of the references to paragraph (6) in new paragraphs (9) and (12). The Committee noted that applications under paragraph (6) are made in accordance with new paragraphs (13) to (15) by virtue of the amendment made by regulation 4(2) of these Regulations. While paragraph (13) appears not to be relevant for the particular purpose, paragraph (14) provides for four different periods within which applications can be made. In addition, paragraph (15) allows for an extension to these periods at the discretion of the Scottish Ministers. The Committee therefore asked the Executive for explanation of how the relevant periods for the purposes of paragraphs (7) and (12) will be calculated.

25. In reply, the Department draws the attention of the Committee to the response at point 4 above. The Department comments that the relevant qualifying period in paragraph (7) is the period beginning at the end of the period of one month from the date of issue of the certificate and ending at the end of the period of validity of the certificate itself. As for paragraph (12), the relevant period is the period beginning at the end of the period of one month from the date of issue of the certificate and ending at the end of the period of three months from that date.

26. The Committee does not see how the response to point 4 is relevant to the point at issue. Paragraphs (9) and (12) respectively prescribe the "relevant period" for the purposes of paragraphs (7) and (10) with reference to the month in which an "application" (undefined) under paragraph (6) may be made. Paragraph (6) provides for applications to be made in a number of different circumstances for which different periods for applications are prescribed in new paragraphs (14) and (15) as indicated above.

27. Though the Department has explained the policy intention, it is by no means clear that the Regulations have achieved this end. It would be simpler and clearer, in the Committee's view, if the Regulations spelt out the policy as above. Where legislation is of direct relevance to ordinary people, the Committee suggests that an extra effort should be made to ensure that it is expressed in plain English and is intelligible to the lay reader.

28. **The Committee draws the Department's explanation to the attention of the Parliament and the lead committee. The Committee also draws the attention of the Parliament and lead committee to the drafting as defective in that the meaning of the provisions remains obscure.**

Point 8

29. The Regulation breached the 21-day rule. The Committee was not satisfied with the explanation given and asked for further explanation of the breach.

30. The Department responded that it considered it important that the new charges applied from 1 April to ensure that the same charges apply throughout the 2001/2002 financial year. However, consideration within the Executive of the level of the increases for 2001/2002, including obtaining relevant information important to that consideration, resulted in it not being possible to announce the new charges and lay the instrument before 16 March. The Department apologises for the breach of the 21-day rule, a step that it did not take lightly.

31. The Committee has previously emphasised the need to make such instruments, impacting directly on the public, in good time not only to comply with the 21-day rule but also so that those affected by the instrument can become aware of its terms and make any representations they wish. **The Committee draws the Executive's response to the attention of the Parliament and lead committee.**

The Feeding Stuffs (Sampling and Analysis) Amendment (Scotland) Regulations 2001, (SSI 2001/104)

32. The Committee noted that the domestic rules in implementation of the relevant European legislation should have been in force by 1 September 2000. The Committee therefore asked, with particular reference to 57(2) of the Scotland Act, for explanation of the *vires* of the instrument in view of the late implementation of a Community obligation.

33. The Executive's response, reprinted at Appendix B, states that, in relation to section 57(2) of the Scotland Act, simply by virtue of being late the implementation measure (which in itself is within devolved competence) does not become *ultra vires*.

34. In the Committee's view, the difficulty arises with the clear wording of the Scotland Act in this respect. Section 57(2) states that " A member of the Scottish Executive has no power to make any subordinate legislation, …so far as the legislation …is incompatible with…with Community law". Furthermore, the wording is echoed throughout the Act, for example, in section 29 and Schedule 6. Where a date is specified by which implementation must be achieved, it appears to the Committee that, in the absence of any mitigating circumstances, a provision in domestic law that specifies a different or later date for implementation than that prescribed in Community legislation is *prima facie* incompatible with Community law.

35. This is not to say that every failure to comply with a programme for implementation set in Community legislation will breach the requirements of the Scotland Act. But it appears to the Committee that the interpretation of section 57(2) cannot be as wide as maintained by the Executive since the effect would be to deprive the section of all meaning.

36. **The Committee therefore draws the instrument to the attention of the Parliament and lead committee on the grounds that it is of doubtful *vires*. To that extent the instrument raises a devolution issue. The Committee also**

draws the response of the Executive to the attention of the lead committee and the Parliament, noting that the Committee intends to explore the matter, as regards the Scotland Act, further with the Executive.

The National Assistance (Assessment of Resources) Amendment (No.2) (Scotland) Regulations, (SSI 2001/105)

37. The Committee raised several points on this instrument with the Executive.

Point 1
38. The Regulations contained a drafting error in that they provided for the commencement of a regulation that did not exist. The mistake was, however, noticed by the Executive in advance of scrutiny by the Committee.

39. The Committee commended the Executive for alerting the Committee to the drafting error in the Regulations and welcomed its assurance that an amendment will be prepared in due course. The Committee asked the Executive for detail of its proposals to correct the defect identified.

40. The Executive's reply, reprinted Appendix C, states that it intends to correct the error by making new Regulations to revoke the above instrument in its entirety before it comes into force and to re-make it.

41. **The Committee draws the instrument to the attention of the Parliament and lead committee on the grounds of defective drafting, acknowledged by the Executive. The Committee notes the Executive's reply and its undertaking to revoke and re-make the instrument, which it draws to the attention of the Parliament and the lead committee as providing the explanation requested by the Committee**.

Point 2
42. In view of the number of substantive amendments that have now been made to the principal Regulations, the Committee asked the Executive if it has any proposals for consolidation.

43. The Executive explained that time and resources have not permitted consolidation to take place before now. However, the Committee's comments will be borne in mind.

44. The Committee is aware of the pressure on the resources of the Executive. However, the Committee has repeatedly emphasised the importance in its view of consolidation of legislation particularly where the legislation is directly relevant to the general public. **The Committee draws the attention of the lead Committee and the Parliament to the instrument, and to the Executive's response, on the grounds of the need for consolidation of the Regulations.**

Point 3
45. As a minor technical point, the Committee noted that a description of the subject matter of Schedule 4 is missing from the first line of regulation 5.

46. The Executive noted the Committee's comment on the omission of the description of the subject matter of Schedule 4 of the principal Regulations and undertakes to correct the error in the new instrument. **The Committee therefore**

draws the Executive's response to the attention of the lead Committee and the Parliament.

The National Health Service (Dental Charges) (Scotland) Amendment Regulations 2001, (SSI 2001/69)

1. The Committee asked for further explanation of the Executive's breach of the 21-day rule in the laying of the instrument.

2. In its reply, reprinted at Appendix E, the Department stated that it considered it important that the new charges brought in by the instrument applied from 1 April to ensure that the same charges have effect throughout the 2001/2002 financial year. However, consideration within the Executive of the level of the increases for 2001/2002, including obtaining relevant information important to that consideration, resulted in it not being possible to announce the new charges and lay the instrument before 16 March. The Executive apologised for the breach of the 21-day rule, a step, it states, that it did not take lightly.

3. **The Committee draws the Department's response to the attention of the Parliament and lead committee** and reiterates its comment regarding SSI 2001/67 that, where an instrument is of direct relevance to the general public, the Executive should make particular efforts to avoid breach of the 21-day rule.

THE NATIONAL HEALTH SERVICE (CHARGES FOR DRUGS AND APPLIANCES) (SCOTLAND) AMENDMENT REGULATIONS 2001, (SSI 2001/67)

On the 27th March 2001 the Committee asked:

"2. The Committee notes that these Regulations are the 22nd set of amendments to the principal Regulations and that the equivalent English Regulations were consolidated last year. The Committee therefore asks when a similar consolidation will be made for Scotland.

3. The Committee notes that regulation 2(2) contains a definition of the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) Regulations 1988. As these Regulations are referred to only once in the principal Regulations in the terms defined, namely in the amendments effected by the current Regulations, and are otherwise referred to in full the Committee asks why this provision was considered necessary.

4. The Committee notes that a footnote is missing from the reference to the 1983 Rules in regulation 2(3)(a) and requests an explanation.

5. The Committee is unclear as to how the new paragraphs added to regulation 8 of the principal Regulations interact with paragraph (6) of that regulation as amended and asks the Executive for explanation.

6. The Committee notes that Paragraph (6) uses the phrase "sum prescribed under this regulation" but that new paragraphs (7), (8), (11), (13) and (14) use the term "prescribed sum". In new paragraph (9) and (12) reference is made to an "application" under paragraph (6). The Committee notes that paragraph (6) refers to "claim" not "application". The Committee observes that except in new paragraph 10 reference is made to "paragraphs (13) to (15)", whilst paragraph (10) refers to "(13)-(15)". The Committee asks for clarification on these points.

7. The Committee asks for explanation as to how an application can be made "by" the person as provided in new paragraph (7) inserted by regulation 4(3), given that the new provision only applies if the person has died. The Committee considers that a similar point may arise in relation to the reference to the "estate" in new paragraph (10) and seeks clarification on this point.

8. The Committee asks for clarification of the references to paragraph (6) in new paragraphs (9) and (12). The Committee notes that applications under paragraph (6) are made in accordance with new paragraphs (13) to (15) by virtue of the amendment made by regulation 4(2) of these Regulations. While paragraph (13) appears not to be relevant for the particular purpose, paragraph (14) provides for four different periods within which applications can be made. In addition, the Committee notes that paragraph (15) allows for an extension to these periods at the discretion of the Scottish Ministers. The Committee therefore asks the Executive for explanation of how the relevant periods for the purposes of paragraphs (7) and (12) will be calculated.

9. The Committee asks for further explanation of the Executive's breach of the 21-day rule."

The Scottish Executive Health Department responds as follows:

1. In response to point 2 above the Department regrets that it has not been able to consolidate these Regulations but it is working towards consolidation and continues to do so as time and resources allow. The Department is committed to consolidating the Regulations and will do so as soon as reasonably possible.

2. In response to point 3 the Department agrees that it would have not been appropriate to include a definition where the term was referred to just once in the instrument but the Executive notes that this instrument makes 3 references to the term, those being in paragraphs (10)(b), (14)(b)(ii) and (14)(c)(i) of Regulation 8 of the principal Regulations.

3. In response to point 4 the Department notes that the purpose of the amendment made by regulation 2(3)(a) was to correct an error in the title of the rules as they were referred to in S.S.I. 2000/396 which itself contained a footnote. The Department accepts that it would have been appropriate to include a footnote in this instrument and apologises for the omission.

4. In response to point 5 the Department comments that the new paragraphs added to regulation 8 interact with paragraph (6) by setting out the procedure to be followed for seeking repayment and the time limits within which such claims for repayment shall be submitted. Paragraph (7) applies specifically to payments made after 1 April 2001, where the other qualifying conditions of paragraph (7) apply, and in respect of those payments the qualifying period for entitlement to claim a refund in extended by paragraph (9) to cover the whole period of validity of the certificate, whereas in respect of payments prior to 1 April 2001, or where the other qualifying conditions set out in paragraph (7) are not met, the qualifying period is one month from the date on which the pre-payment certificate became valid.

5. In response to point 6 the Department notes the elements of inconsistency in terminology highlighted by the Committee. The Department apologises for these oversights. The Department notes that the nature of the inconsistent terminology is such that it is unlikely to confuse readers and will not affect the practical application of the provisions. The Department does, however, recognise the need to maintain consistency of terminology and will correct this when consolidating the instrument. As for the differing style of references to paragraphs "(13) to (15)" the Department apologises for this inconsistency, due to an oversight, and will seek correction of the printed version of the instrument through the printing points procedure.

6. In response to point 7, the Department adopted a terminology consistent with that used at paragraph (6)(d). The Department accepts that in the context of paragraph (7), reference should correctly have been made to "by or on behalf of that person's estate". In paragraph (10) the Department accepts that reference should not have been made to "or his estate". These errors, for which the Department apologises, will not affect the practical application of the provisions and again, the Department will correct this when consolidating the instrument.

7. In response to point 8, the Department draws the attention of the Committee to the response at paragraph 4 above. The Department comments that the relevant qualifying period in paragraph (7) is the period beginning at the end of the period of one month from the date of issue of the certificate and ending at the end of the period of validity of the certificate itself. As for paragraph (12), the relevant period is the period beginning at the end of the period of one month from the date of issue of the certificate and ending at the end of the period of three months from that date.

8. In response to point 9, the Department considered it important that the new charges applied from 1 April to ensure that the same charges apply throughout the 2001/2002 financial year. However, consideration within the Executive of the level of the increases for 2001/2002, including obtaining relevant information important to that consideration, resulted in it not being possible to announce the new charges and lay the instrument before 16 March. The Department apologises for the breach of the 21 day rule: A step which it did not take lightly.

Hamish Wilson
For the Scottish Executive Health Department
29th March 2001

THE FEEDING STUFFS (SAMPLING AND ANALYSIS) AMENDMENT (SCOTLAND) REGULATIONS 2001, (SSI 2001/104)

On 27th March the Committee asked:-

"The Committee notes that the domestic implementing rules should have been in force by 1 September. With reference to 57(2) of the Scotland Act, the Committee asks for explanation of the *vires* of the instrument in view of the late implementation of a Community obligation."

The Food Standards Agency responds as follows:-

In relation to section 57(2) of the Scotland Act, it is considered that, simply by virtue of being late, the implementation measure (which in itself is within devolved competence) does not become *ultra vires*.

COLIN FORSYTH

for the Food Standards Agency
29th March 2001

THE NATIONAL ASSISTANCE (ASSESSMENT OF RESOURCES) AMENDMENT (No 2) (SCOTLAND) REGULATIONS (SSI 2001/105)

On 27th March 2001 the Committee asked:

2. The Committee commends the Executive for alerting the Committee to the drafting error in the Regulations and welcomes its assurance that an amendment will be prepared in due course. The Committee asks the Executive for detail of its proposals to correct the defect identified.

3. In view of the number of substantive amendments that have now been made to the principal Regulations, the Committee asks the Executive if it has any proposals for consolidation.

4. As a minor technical point, a description of the subject matter of Schedule 4 is missing from the first line of regulation 5.

The Scottish Executive Health Department, Community Care Division responds as follows:

The drafting error in the above instrument is that Regulation 1(1) thereof makes reference to Regulation 5(2), which provision does not exist. The Executive intends to correct that error by making new Regulations which revoke the above instrument in its entirety before it comes into force and to re-make it.

Time and resources have not permitted consolidation to take place before now. However, the Committee's comments will be borne in mind.

The Committee's comment on the omission of the description of the subject matter of Schedule 4 of the principal Regulations will be incorporated into the new instrument.

Date 29th March 2001

Thea Teale
for Community Care Division
Scottish Executive Health Department

THE NATIONAL HEALTH SERVICE (DENTAL CHARGES) (SCOTLAND) AMENDMENT REGULATIONS 2001, (SSI 2001/69)

On the 27th March 2001 the Committee asked:

"1. The Subordinate Legislation Committee today considered the above instrument and requests an explanation of the following matter.

2. The Committee asks for further explanation of the Executive's breach of the 21-day rule.

The Scottish Executive Health Department responds as follows:

1. The Executive considered it important that the new charges applied from 1 April to ensure that the same charges apply throughout the 2001/2002 financial year. However, consideration within the Executive of the level of the increases for 2001/2002, including obtaining relevant information important to that consideration, resulted in it not being possible to announce the new charges and lay the instrument before 16 March.

2. The Executive apologises for the breach of the 21 day rule: A step which it did not take lightly.

Hamish Wilson
For the Scottish Executive Health Department

29 March 2001

Agenda item 4

Health & Community Care Committee
25 April 2001

Health and Community Care Committee

25 April 2001

Petitions

Background

1. The petitions shown in Annexe A have been circulated to members for comment. Petition cover sheets only are attached to this report as members have already received all relevant papers. Should members require background papers to any of the petitions, please request them.

2. The current position regarding petitions which have been considered by Committee are attached at Annexe B. Responses received to enquiries over some petitions are also attached. A draft report on PE217 will be considered under a separate agenda item.

3. A new petition (PE348) is attached in full at Annexe C. This has been passed to Members for information only.

Recommendations

4. The Committee's views are sought on the new petitions that have received comments.

5. The Committee is asked to note the current position regarding petitions shown in Annexe B.

6. The Committee is also asked to note the petition in Annex C for information

Jennifer Smart
Clerk

ANNEXE A

Health and Community Care Committee

NEW PETITIONS

Number	Petitioner	Petition	Comments received	Recommendation
PE 320	John Watson on behalf of World Development Movement	Calling for the Health and Community Care Committee of the Scottish Parliament to examine the possible implications for health policy in Scotland of the World Trade Organisation's liberalisation of trade in services.	JMc – Hold and inquiry RS – call for a debate in Chamber.	
PE 283	SORRO (Scottish Organisation Relating to the Retention of Organs	Calling for the Scottish Parliament to initiate a public inquiry into the practice of organ retention at post-mortem without the appropriate parental consent.	RS – Committee should examine review group report & comment. J Mc – seek info on the reaction to the report & the Executive's view on it.	

PETITION PE320: John Watson on behalf of World Development Movement (WDM)

Signatures: 588 (210 electronically)

Date Received: 6 December 2000

Subject: Implications of the liberalisation of trade in services

Background: Petition calling for the Health and Community Care Committee of the Scottish Parliament to examine the possible implications for health policy in Scotland of the World Trade Organisation's liberalisation of trade in services.

The petition was hosted on the International Teledemocracy Centre e-petitioner web site for a period of three weeks during November 2000. Background information has been provided by the ITC and is also attached. This includes details of comments made on the site on the issues raised in the petition.

The petitioners are concerned that the World Trade Organisation is pushing for greater liberalisation of trade in services and that the outcome will be legally binding on the Scottish Parliament. In particular, the petitioners are concerned about the impacts of this liberalisation on health provision in Scotland.

Members may be aware that motion S1M-617 lodged by Linda Fabiani on Health Provision in Scotland, which calls for the Parliament to debate this issue, has attracted 53 names of support.

Suggested Action: It is suggested that the Committee may wish to agree to refer the petition to the Health and Community Care Committee for further consideration.

Public Petitions Clerk
13 December 2000

PETITION PE283: Geraldine MacDonald on behalf of the Scottish Organisation Relating to the Retention of Organs (SORRO)

Signatures: 13500

Date Received: 6 October 2000

Considered by PPC: 24 October 2000

Subject: Organ Retention

Background: Petition calling for the Scottish Parliament to initiate a public inquiry into the practice of organ retention at post-mortem without the appropriate parental consent.

Members are aware of the Executive's decision to establish an independent review group to review past practice and the legislative position in relation to the matter referred to in the petition.

As members were informed at the PPC meeting on 24 October, the Clerk has written to the Executive, asking officials to provide the Committee with the background to this decision, with particular reference as to why this approach was favoured over a public inquiry. Information on the remit of the review group and the likely timescale for its report was also been requested. **A response has now been received from the Executive, and a copy is attached.**

The response indicates that the Health Minister has met with a range of parents organisations, including the Stillbirth and Neonatal Deaths Society (SANDS), the Association for Children with Heart Disorders, the Scottish Cot Death Society, and SORRO, who are, of course, the petitioners. The letter goes on to say that from discussion in these meetings and from correspondence from individual parents, it was clear – in the Executive's view – that a full public inquiry would be disproportionate and distressing.

The letter also provides details of the remit of the independent review group which is to consider this matter. It will review past practice in the matters of post-mortem consent, organ retention and the disposal of organs at hospitals across Scotland. It will also develop guidance in the form of a Code of Practice, and report on all of these aspects of its work by the end of January 2001. It will consider later the current law in relation to consent, removal and retention of organs and the ownership of human tissue – with recommendations announced in autumn 2001.

The Minister believes that the approach adopted is appropriate, proportionate and sensitive to the range of parental views already expressed.

Suggested Action: The Committee will need to reach a view on whether any further action should be taken in respect of the petition in the light of the Executive's response. This is an extremely emotive issue. It would

appear that the Minister has had to balance the differing views of different parents and parents organisations before deciding to establish an independent review group. It is clear that whatever decision she reached on this matter not all of those involved would be content.

The difficulty for the Committee is that should it decide to ask the Health & Community Care Committee or the Executive to consider whether a public inquiry should be initiated as requested by the petitioners, this would clearly be unacceptable to other parents organisations who do not support such action. It would therefore seem inappropriate for the Committee to pursue such a course of action.

Members are invited to consider whether it should respond to the petitioners on these terms, or whether it should pass the matter to the Health & Community Care Committee for further consideration.

A copy of the Executive's response should also be passed to the petitioner.

Public Petitions Clerk
3 November 2000

ANNEXE B **Ongoing Petitions**

Number	Petitioner	Petition	Current Position
PE 192	Mr Alex Doherty	Calling for the Scottish Parliament to order the Mental Welfare Commission to a) regard all of their records as Health Records and b) to comply with the Act by allowing access to those who the act defines as being eligible for access	12 December: Committee noted correspondence from MWC and forwarded it to Millan Commission. Milan Report published in January.
PE 214	Mrs Anne Dundas on behalf of various patients, friends and relatives of the Scottish Cardiac Transplant Unit	Calling for the Scottish Parliament to investigate the current recruitment crisis in the Cardiac Transplant Unit at Glasgow Royal Infirmary and establish what action will be taken to re-establish the cardiac transplant service as soon as possible.	Noted. Update from Executive on current position is attached.
PE 45 and PE 185	West of Scotland Group of the Haemophilia Society and Thomas McKissock	Haemophilia and Hepatitis C	Report published by Executive on 22 October 2000 and considered by the Committee on 25 October. Haemophilia Soc and Scottish Blood transfusion Service gave evidence on 21 March. Further info is being sought and the Minister has been invited to attend 23 May 2001.
PE 145	Mr Bill Welsh	Vaccinations/Autistic Spectrum Disorder	Mary Scanlon appointed reporter at 21st meeting. Report published 6 April.
PE 123	Warm Homes Campaign	Fuel poverty	Dorothy Grace Elder will report on 25 April.
PE 217	Glenorchy and Innishail Community Council	Calling for the Scottish Parliament to take account of the workload and general circumstances of a single General Practitioner in the Parish of Glenorchy and Innishail and appoint an additional part-time partner.	Margaret Jamieson will report to Committee under a separate item.
PE247	Epilepsy Association of	Calling for the Scottish Parliament to ensure there are co-ordinated health and social services that will	Agreed on 12 December to await Acute Services Review. (As at 19

	Scotland	benefit the 30,000 people in Scotland with epilepsy.	April, not yet complete).
PE223	Mr and Mrs A McQuire	Calling for the Scottish Parliament to ensure that Multiple Sclerosis sufferers in Lothian are not denied the opportunity to be prescribed Beta Interferon.	Agreed on 12 December to await NICE report. SPICe have prepared Research Note RN 01-38 - attached.
PE148	Mr William Brian Anderson	Calling for the Scottish Parliament to investigate various issues relating to specialist referral and diagnosis of exposure to organophosphate chemicals	Agreed on 12 December to take no further action but only <u>on the understanding that this is being reviewed in Westminster.</u> **UK Department of Health representative confirmed that recommendations were made to the NPIS[1] as a result of the Royal College of Physicians report in 1998.** **A report by the Committee on Toxicology in 1999 reported that a link between Organophosphate exposure and illness was 'not proven' and recommended more research.** **A research proposal will shortly be agreed between the UK Dept. of Health and MAFF.** **Further information from petitioner attached – please would members indicate preferred action.**

[1] National Poisons Information Service – provide advice to for GPs

Health Department

St Andrew's House
Regent Road
Edinburgh EH1 3DG

Telephone: 0131-244 5086
Fax: 0131-244 5076
Ian.turner@scotland.gsi.gov.uk
http://www.scotland.gov.uk

Ms J Hardy
Assistant Clerk
Health & Community Care Committee
The Scottish Parliament
EDINBURGH
EH99 1SP

23 March 2001

Dear Ms Hardy

PE214: FRIENDS OF CARDIAC TRANSPLANT UNIT

Thank you for your letter of 6 March asking, on behalf of the members of the Health & Community Care Committee, for an update on progress in relation to the Scottish Heart Transplant Unit.

The Health Minister's letter of 27 November 2000 made the point that the key to resumption of the full heart transplant service in Glasgow is the development of a fully-staffed multi-disciplinary team, and that has been the main focus of activity in the intervening period. The Minister would like to assure the Committee that good progress is being made, and that the North Glasgow University Hospitals NHS Trust, in conjunction with the Scottish Executive Health Department, are actively planning for the resumption of all aspects of heart transplantation in Glasgow.

The Minister shares the Committee's view that the main concern must be the interests of the patients who depend on the full spectrum of services provided by the Unit. She understands that, as she requested them to do, the Trust has taken steps to keep patients regularly informed of developments, and that both the patients themselves and the Friends of the Cardiac Transplant Unit have been supportive of those developments.

The Minister intends to make a full statement about the work of the Unit in the near future, and will make sure the Committee is aware of its terms.

Yours sincerely

IAN TURNER
Health & Community Care Committee
Liaison Officer

Research Note for the Health and Community Care Committee **01/38**
26 March 2001

MEDICINAL DRUGS: LICENSING, COST EFFECTIVENESS AND TREATMENT FOR MULTIPLE SCLEROSIS

MURRAY EARLE

This note provides background information on the processes by which a medicinal drug is developed, licensed, marketed and eventually prescribed. It then outlines the method by which the actual cost of drugs is arrived at before considering the process by which the cost-*effectiveness* of each drug is determined. Thereafter, it considers how Health Boards use the concept of the Quality Adjusted Life Year to decide whether a particular drug will be made available on the NHS within that Health Board area, as well as the implementation of formulae for Numbers Needed to Treat with a particular drug. By way of example, Beta Interferon for sufferers of multiple sclerosis will be used, because this note is also intended to provide background information on the issues surrounding Petition PE223 from Mr and Mrs A McGuire *calling for the Scottish Parliament to ensure that Multiple Sclerosis sufferers are not denied the opportunity to be prescribed Beta Interferon.*

MEDICINAL DRUGS

The System of Licensing

Product and manufacturer's licences control the manufacture of and dealing in medicinal products. Licences are required unless dealing in medicinal products falls within the scope of the exemptions[2] provided by the Medicines Act 1968. Thereafter, the medicinal product may be used or dealt with only in ways covered by the terms of the licence. Ministers have the power to prohibit the sale, supply or importation of any medicinal products or animal feeding stuffs containing medicinal products likely to cause serious danger to human or animal health.[3]

The Granting of Licences

Licence applications are made to the licensing authority. If the authority is satisfied as to the safety of a product,[4] a licence may be granted without extensive investigation. Alternatively, the matter may be referred to one of the committees established under the 1968 Act, the most important of which is the Committee on the Safety of Medicines.[5] The onus of establishing product safety is on the applicant for a licence. The Committee also

[2] These cover clinical trials and the prescription and manufacture of drugs by doctors and pharmacists.
[3] Medicines Act 1968 s 105(1).
[4] For the factors which the authority must consider, see the Medicines Act 1968, s 19. As to considerations of safety, see s 132(2).
[5] This committee was established under s 4, by the Medicines (Committee on Safety of Medicines) Order 1970, SI 1970/1257.

monitors adverse drug reactions, passed to the committee by doctors and dentists observing reactions in their patients, often due to a condition in the licence requiring practitioners to notify the Committee.

Suspension and revocation of licences

Product licences may be suspended, revoked, or varied.[6] Grounds for so doing include making a false or incomplete application and contravening the provisions of the licence. Considerations of safety may also lead to suspension or revocation.

New Products

The manufacture of products for medicinal use requires a licence.[7] The granting of a full product licence depends on safety and efficacy. Applications must be supported by data which will satisfy the authority on these grounds.[8] An animal testing process, in which matters such as toxicity may be assessed, takes place initially, followed by clinical trials to test the effects on human volunteers. Legal regulation aims to ensure: the prevention of irresponsible tests, and, in the case of clinical trails, the safety of participants.

Clinical Trials

These involve the administration to test subjects of medicinal products, by a medical practitioner, where there is evidence that the product may be beneficial to patients. The aim is to test that hypothesis.[9] Sale, supply, manufacture or assembly of a product for the purposes of a clinical trial requires a product licence authorising that trial, as does importing a medicinal product for that purpose. Doctors and dentists are exempted from these restrictions if the medicinal product is specially made up to his or her[10] order.

Restrictions on Sale and Supply

For these purposes there are three categories: the general sale list,[11] products sold only in pharmacies,[12] and those which require a prescription.[13] Products in this last group may be administered only by a practitioner or by a person acting in accordance with the directives of a practitioner.

As a general rule, once such a licence is in effect, a product may be prescribed on the National Health Service. However, each Health Authority will decide, on the basis of their annual budget, how resources are best utilised. In respect of medicinal drugs, this will involve cost utility analyses of treatments and available resources, which will be done by using the Quality Adjusted Life Year as a yardstick. This will also have to do with the cost and pricing of the medicinal product in question and the effectiveness of the drug itself.

CALCULATION OF COST AND UTILITY

Pricing and the Pharmaceutical Price Regulation Scheme (PPRS)

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[6] Medicines Act 1968 s 28(1)–(3) as amended.
[7] Medicines Act 1968 s 18(1).
[8] S19, particularly s19(5).
[9] Medicines Act 1968 (c 67), s 31.
[10] The rest of this note follows the Interpretation Act 1978, s 6 in that, unless the contrary is specified, words importing the male gender include the female, and *vice versa*.
[11] Medicines Act 1968 (c 67), s 51
[12] Medicines Act 1968, s 52
[13] Ibid. s58, as amended by the Medicinal Products: Prescription by Nurses etc Act 1992 (c28), s1.

The PPRS controls National Health Service medicine prices and costs.[14] It is an agreement between the government and the pharmaceutical industry, for the purposes of the Health Act 1999, to ensure safe, effective medicines for the NHS at reasonable prices and to promote the pharmaceutical industry in research and development. The scheme applies to all branded, licensed NHS medicines.

The guiding principle behind the scheme was first agreed in 1957 in an inquiry chaired by Lord Sainsbury and led to the Voluntary Price Regulation Scheme. That principle was one of limiting profits made on NHS medicines by 'identifying the relevant capital employed, restricting the associated costs and limiting the allowable return.'[15]

In the 1990s, the scheme was further modified to exclude generic medicines. This was to reflect, 'NHS developments such as GP fundholding, and the creation of enhanced financial incentives for prescribers, practices and hospitals to minimise medicine costs.'[16] The Health Act 1999 gave the Government reserve powers to intervene to control NHS pharmaceutical profits and prices. The other factor keeping costs down is the fact that companies are in competition with each other.

The PPRS imposes restraints in price rises and allows an average spend of only 7-8% of NHS income on sales promotion, including information aimed at helping practitioners keep up to date with developments in pharmacy. The revised PPRS applied from October 1999 for 5 years and covers all branded NHS medicines, including blood products, vaccines and medicines.

Companies with annual NHS sales of greater than £25m subscribe to the core reporting mechanism of the PPRS, known as the Annual Financial Return (AFR), which sets out costs, sales and profits, as well as capital employed. With this, the overall profitability is assessed when dealing with an application for a price increase.

While the PPRS sets a ceiling on profits, it does not guarantee them. This is set at a cap of 21%, measured against average historic capital employed. There is some flexibility (40% or 21%) on this cap, if a company has not received any product price increase that year. PPRS members may not increase the prices of their medicines without prior approval of the Department of Health, and will be disallowed unless profits have fallen below 8.5%. Manufacturers are allowed some flexibility in applying price cuts. This was subject to an overall reduction of 4.5% in 1999.

Certain allowances are made within the scheme. For research and development the allowance is 20% of total home NHS turnover. Account may also be taken of the costs of assets and manufacturing infrastructure in supplying the NHS, and a sales promotion allowance of 6% is permitted - but reduced to 3% when considering a price increase.

Broadly speaking, this outlines the principles and formula by which the cost of (pharmaceutical) interventions is arrived at. This should be seen in conjunction with the cost-*effectiveness* of any given intervention. For this, use is made of the Number Needed to Treat (NNTs) and the Quality Adjusted Life Year (QALYs).

The Number Needed to Treat (NNTs)

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[14] *The Pharmaceutical Price Regulation Scheme* can be found at www.doh.gov.uk/pprs.htm.
[15] *Understanding the PPRS.* Association of British Pharmaceutical Industries. 2000. p5.
[16] Ibid.

The NNT is used as a tool to express the effectiveness of interventions. This effectiveness may be expressed as the ratio between the Number Needed to Treat and the Number Needed to Harm (the NNT:NNH ratio). This will allow clinicians to use data which expresses the clinical risk/benefit ratio. NNH is therefore an expression of the safety issues in new interventions.

A NNT value of 1 indicates that every patient achieves the intended outcome. This represents an 'ideal' clinical outcome. Most interventions will have NNTs which are higher, being as those treatments are effective in some, though not all, of the population. NNTs are reciprocal to the absolute risk reduction (ARR). For example:[17]

> Assume that the rate of strokes in a normal population at high risk is 60%. A prophylactic agent given to prevent ischaemic stroke may reduce the number of strokes in this patient group to 50%. The difference in event rates (60% - 50%) is the ARR, which would be 10%.
> To calculate the NNT for this intervention, one would take the reciprocal of the ARR (or $^{1}/_{ARR}$).
> The NNT for preventing strokes through this intervention would, therefore, be 10 (or $.^{1}/_{0.1}$).

These results, however, should not be used in isolation, because in the context of the National Health Service as subdivided into Health Authorities, it is also important to take account of age, epidemiology, population needs, social factors and local priorities. One of the strengths of NNTs is that they can be used as a yardstick between and within therapeutic areas to determine the clinical effectiveness of treatments relative to one another. A weakness of the NNT calculation is that there is no standard unit of measurement in terms of time (one year or one month), unlike the Quality Adjusted Life Year (QALY). This is shown to be difficult in neurological conditions in which rates of relapse may differ as between patients. This in itself begs questions such as, 'should life-extending therapies have higher *acceptable* NNTs [for an intervention to become recommended]?'

The Quality Adjusted Life Year (QALYs)

The QALY is a device by which medical interventions can be compared with one another relative to both the quality and the quantity of life generated by each intervention. It is one device among others which is used to determine cost-effectiveness, being the arithmetic product of life expectancy as well as a measure of the quality of the remaining life years, due to the intervention in question.

A year of perfect health has a value of 1, and death has a value of 0 - though some states of (ill) health may be considered to be worse than death, so values less than zero are possible. Weight is therefore placed on time in different states of health, taking into account factors such as mobility, pain/discomfort, self-care, anxiety/depression, and usual activities.

Health State Valuations - some examples:[18]

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[17] Taken from *Implementing NNTs.* Hayward Medical Communications. 1998.
[18] Taken from *What is a QALY.* Hayward Medical Communications. 1998.

Health State	Description	Value
11111	No problems	1.000
11221	No problems walking about or self-care; some problems with performing usual activities; some pain or discomfort; not anxious or depressed.	0.760
21123	Some problems walking about; some problems washing or dressing self; unable to perform usual activities; moderate pain or discomfort; extremely anxious or depressed.	0.222
23322	Some problems walking about; unable to wash or dress self; unable to perform usual activities; moderate pain or discomfort; moderately anxious or depressed.	0.079
33332	Confined to bed; unable to wash or dress self; unable to perform usual activities; extreme pain or discomfort; moderately anxious or depressed.	-0.429

The formulae used may be demonstrated as follows:[19]

1. Calculating QALYs

Intervention A: 4 years in health state 0.75 = 3 QALYs
Intervention B: 4 years in health state 0.5 = 2 QALYs

Additional number of QALYs generated by A = 1 QALY
(It is then necessary to consider the cost per QALY)

2. Cost-Utility Ratio =

$$\frac{\text{Cost of Intervention A - Cost of Intervention B}}{\text{No. QALYs produced by A - No. QALYs produced by B}}$$

Combining the QALY with the absolute costs of interventions, produces a cost-utility ratio, which will indicate the (notional) cost involved to generate a year of perfect health (one QALY). This is used to make comparisons between interventions and to establish priorities for Trusts. These are made on a cost per QALY basis.

Use of the QALY in resource allocation (in conjunction with NNTs) means that choices between patient groups are made explicit. It also means that so-called post-code prescribing is that much more apparent, as each intervention is measured against other interventions relative to their cost per QALY.

Cost-effectiveness

Analysis of cost-effectiveness has the aim of determining whether an intervention is viable from an economic point of view. For this, it is necessary first to distinguish *independent interventions* from *mutually exclusive interventions*. For the former, average cost-effectiveness ratios are sufficient; for the latter, incremental ratios are used (to maximise health-care effects relative to resources). Cost-effectiveness ratios are related to the size of the relevant budget to determine cost-effectiveness strategies.

Cost is calculated using direct costs (of drugs, transport, etc.) indirect costs (production losses and other uses of time) as well as opportunity costs (the value placed on using resources elsewhere) and intangible costs (pain, suffering and adverse effects). This, along with the QALY, produces cost-utility ratios, as discussed above.

Use of these calculations and formulae can be demonstrated by using the example of beta interferon for relapsing-remitting multiple sclerosis.

[19] Ibid.

MULTIPLE SCLEROSIS AND BETA INTERFERON

Multiple Sclerosis

While the cause of MS remains unknown, it may be described as a *neuro-degenerative* disease which is characterised by the gradual accumulation of focal plaques of demylenation.[20] Myelin may be likened to an insulating sheath around nerves which ensures the conductivity of the body's nervous system. Demylenation, therefore, is the loss of myelin which has the effect of impairing nerve conductivity. Peripheral nerves are not affected. Onset is usually between the ages of 20 and 30 with intermittent progression over an extended period. There is also a correlation between latitude and the incidence of the condition: it is for this reason that the number of sufferers North of the Border is proportionately higher than that south of the Border; indeed, is thought to be the highest in Europe.[21] This incidence has yet to be explained. It is not unusual for patients to suffer from a remitting-relapsing form of multiple sclerosis, in which there is change in the frequency and severity of relapses. These relapses affect the patient's motor function and may not assume the same form as the previous relapse.

In October 2000, in a publication entitled *Multiple Sclerosis*, [22] the Scottish Needs Assessment Programme reported that a national strategy should be drawn up to bring together the various disciplines involved in the diagnosis, treatment and management of the 10,400 sufferers of multiple sclerosis. The Report found services to be 'fragmented' and under-funded, with £80m being spent currently, which constituted an estimated shortfall of £20m.[23] It is also the case, however, that the Report avoids a discussion of 'postcode prescribing'.

Beta Interferon

The matter of treatment with beta interferon has been discussed in the Scottish Parliament on more than one occasion.[24] Much has been made in the political arena of the use of beta interferon for sufferers of relapsing-remitting multiple sclerosis. However, there are alternative interventions in Copaxone (Glatiramer Acetate)[25] and Mitoxantrone,[26] both of which are cheaper in absolute terms, although they may not be cheaper in QALY terms. QALY studies of these alternative treatments have not been done, and Mitoxantrone is not licensed for use in the United Kingdom.

Beta Interferon is indicated for prescription to sufferers of a relapsing-remitting form of multiple sclerosis, in order to reduce the severity and frequency of their relapses. There are three interferons: alpha (for treatment of leukaemias, other cancers and chronic hepatitis B), beta (which reduces frequency and intensity of relapses in multiple sclerosis) and gamma (in conjunction with antibiotics, prescribed for chronic granulomatous disease). There are several brand names such as Betaferon (Schering Health Care, Germany), Rebif (Ares-Serono, Switzerland) and Avonex (Biogen, USA) Of the interferon betas, two types exist -

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[20] http://www.graylab.ac.uk/cgi-bin/omd?query=multiple+sclerosis

[21] See note 21 below.

[22] http://www.gla.ac.uk/external/ophis/PDF/ms.pdf

[23] BBC News Online: http://news.bbc.co.uk/hi/english/uk/scotland/newsid_1013000/1013829.stm

[24] For example, on 5th October, 2000, S1M-1132 in the name of Tricia Marwick MSP.

[25] Johnson, KP et al. 'Sustained clinical benefits of glatiramer acetate in relapsing multiple sclerosis patients observed for 6 years.' (2000) 6 *Multiple Sclerosis* 255-266.

[26] Clegg A, Bryant J, Milne R, 'Disease-Modifying Drugs for Multiple Sclerosis: a Rapid and Systematic Review' *Health Technol Assess.* 2000;4(9):1-101

1a and 1b - both of which are, according to the *British National Formulary*, effective in reducing the frequency and intensity of relapses in multiple sclerosis.

Recent reports in the press have pointed out that the National Institute for Clinical Excellence (NICE) in England and the Health Technology Board (HTBS) in Scotland are currently investigating the cost-effectiveness of funding the prescription of interferon beta. NICE has 'drawn the preliminary conclusion that there is not enough evidence at the moment to support the general use of beta interferon.'[27] Indeed, the *British Medical Journal*[28] reported a cost-utility study of the drug and found that each Quality Adjusted Life Year (QUALY) would cost between £833,514 and £1,024,667, depending on the number of people treated, and hence that the benefits relative to the costs, are low. The actual cost per patient per year has been estimated at £10,000.[29]

The formula for calculating cost per QALY gained by treatment with interferon beta-1b in secondary progressive multiple sclerosis works like this:[30]

> Cost per QALY gained = net cost of treatment divided by number of QALYs gained, where Net cost of treatment = total cost of treatment costs averted (from reduced relapses and wheelchair dependence).
> Total cost of treatment = number needed to treat (NNT) × 30 months × unit cost of interferon beta-1b.
> NNT = Number needed to treat to delay time to wheelchair dependence by nine months

Drug and therapeutics committees advise clinicians on the clinical indications for using a particular drug within the therapeutic environment. The current advice on interferon beta has remained unchanged for some time: because it has been granted a licence, it is available for prescription if, in the opinion of a neurologist, it is indicated for the patient in question - in this case patients suffering from particular forms of multiple sclerosis. This means that the NHSiS will fund that prescription as it would with any other licensed drug. This is because once a product receives a licence, and unless the NHS says otherwise, it may be prescribed under the auspices of the NHS.[31]

The Health Technology Board for Scotland (HTBS) considers, among other things, the cost-effectiveness of drugs. The Board (and NICE, the equivalent in England) has recently been asked to consider interferon beta; indeed, it is the first medicine that the HTBS will consider. That report has not yet been completed, though as already stated, it does not look promising for sufferers of multiple sclerosis because, in a cash-strapped system, those treatments which are to be preferred will tend to be those that cost least and/or benefit most. A difficulty with drugs such as beta interferon, is that it is a drug which benefits a few people marginally, and does so at great cost. The use of the Quality Adjusted Life Year and the conversion of that figure into money, is done in order to be able to use money as an index with which to compare different treatments with one another - comparing unlike with unlike using a notional common denominator.

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[27] BBC News Online: http://news.bbc.co.uk/hi

[28] Raeburn B Forbes, et al 'Population based cost utility study of interferon beta-1b in secondary progressive multiple sclerosis.' (1999) 319 *British Medical Journal* 1529-1533.
http://www.bmj.com/cgi/content/full/319/7224/1529.

[29] Ibid.

[30] Ibid.

[31] Schedules 10 and 11 of the NHS GP Regulations 'blacklist' certain drugs.

To illustrate this mechanism, one can use the example of Viagra: [32]

> 'The mean incremental cost utility ratio of sildenafil (Viagra) was £3,639 per QALY in the first year and improved in the following years. This cost utility ratio is generally favourable, and suggested acceptable thresholds of cost utility vary between £8000 and £25 000. Moreover, many interventions with less favourable cost utility ratios are currently being funded, such as breast cancer screening (£5,780 per QALY) and kidney transplantation (£4,710 per QALY). Our analysis therefore suggests that the clinical effect (of sildenafil) is derived at reasonable costs.'

> 'The main benefit of a healthcare intervention should be greater "health." A potential measure of "health" is the quality adjusted life year (QALY).[33] To calculate a QALY, the duration of health state (in years) is multiplied by a factor representing the quality ("utility") of that health state. The quality (or utility) value for economic evaluation is usually derived from a health index. In health indices, health is rated along an interval scale, where 1 equals perfect health and 0 represents dead. It is also possible to rate health states with a negative value that is worse than death. Values for health states are usually derived using time-trade off methods or standard gamble techniques. Studies which calculate the cost per QALY gained from an intervention are called cost utility analyses.

> 'Values for the cost per QALY gained across a range of different interventions can be used to inform resource allocation decisions. There are arguments for limiting access to interventions which have a very high cost per QALY, as there may be alternative uses for those funds which are more efficient for example, they provide benefits to more people. Conversely, fewer restrictions might be placed on interventions that have a low cost per QALY gained.'

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[32] Stolk et al, 'Cost utility analysis of sildenafil compared with phentolamine injections.' (2000) 320 *British Medical Journal* 1165: http://bmj.com/cgi/content/full/320/7243/1165

[33] From Forbes et al, 'Population based cost-utility study of interferon beta 1b in secondary progressive multiple sclerosis.' (1999) 319 *British Medical Journal* 1529-33: http://bmj.com/cgi/content/full/319/7224/1529).

POSTCODE PRESCRIPTION

'Postcode prescription' has become a term used by the media and politicians alike to denote the availability of a particular treatment within a certain area, where that treatment is denied to patients with similar medical conditions in another area. This occurs because decisions on expenditure and prioritisation are made at Health Authority level. These decisions are made using the same NNT and QALY studies, using them relative to one another and using them relative to the prevalence of particular conditions with the boundaries of each health authority.

This, in turn, leads to postcode prescribing, because one health authority may adopt different priorities than another as regards the treatments they will provide. They will do this on the basis of their budget, QALY studies, and the implementation of NNT studies. This is both due to and reflected in their budgets.

In respect of beta interferon, the problem comes to the fore in the following scenario. Interferon beta may be prescribed only by a neurologist. Neurologists work within Health Authorities. Assume a neurologist feels that it is medically appropriate to prescribe interferon beta to a particular patient. There would be nothing against this at present and indeed the NHSiS would in principle pay for the prescription. However, if the Health Authority has deemed it outwith their budget due to the formulae set out above, they may disallow it. Given the figures above, this is the most likely scenario at this stage, pending the outcome of reports by the HTBS and NICE; that is the impasse with which the HTBS is currently dealing. However, this is not necessarily an impasse with which health authorities *need to* deal - at least until the results of the NICE / HTBS reports have been published.

Indeed, the Queen's Bench Division of the High Court in England has dealt with the supposed impasse in *R v Derbyshire Health Authority,* ex parte *Fisher*,[34] which was a judicial review of a decision taken by the authority. It was held that the health authority had acted unlawfully in denying a patient with multiple sclerosis treatment with interferon beta, even although the basis of this denial was that the authority had already overspent its earmarked £50,000 on beta interferon by that time. The Health Authority was ordered to reconsider Mr Fisher's clinical case to determine whether he would benefit from the drug.

The rationale of the judgement was that the health authority had effectively placed a 'blanket ban' on the drug, despite a NHS circular which made it available through hospitals. The ground of the 'ban' was cost / QALY, which caused the health authority (unlawfully) to adopt a policy restricting use of the drug to clinical trials only. It was argued at the time (1997) that the case would have ramifications for cash-strapped health authorities and would 'boost the case for a separate NHS fund to pay for expensive new drugs coming on the market as a result of biotechnological advances.'[35] This has not as yet turned out to be the case.

Cannabis and 'Postcode Prosecution'

Given the contents of the preceding pages, it has been argued by organisations such as Alliance for Cannabis Therapeutics (ACT) that the use of cannabis as a palliative for

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[34] [1997] 8 Med LR 327.

[35] Clare Dyer. 'Ruling on interferon beta will hit all health authorities.' (1997) 315 *British Medical Journal* 143: http://www.bmj.com/cgi/content/full/315/7101/143/g

conditions such as multiple sclerosis ought to be allowed.[36] Indeed, the House of Lords Select Committee on Science and Technology recommended[37] allowing the use of cannabis for therapeutic purposes and berated the Medicines Control Agency for their tardiness in conducting research into its medicinal properties and for not considering 'cannabis based medicines in a properly balanced way.' The House of Lords' Report *Therapeutic Uses of Cannabis* also alleges the existence of what the Committee called 'postcode prosecution' of those using and cultivating cannabis for medicinal use. At the same time, the Committee commended the Home Office for 'showing the first signs of adopting a genuinely pragmatic and expeditious approach to the issue of cannabis-based medicines.'

If you have any comments or questions about this Research Note, please contact Murray Earle on extension 85364 or Murray.Earle@scottish.parliament.uk.

[36] And other conditions such as anorexia (loss of appetite), glaucoma, bronchial asthma, pain, other muscle spasticity, hypertension and mood disorders. See *Therapeutic Uses of Cannabis. British Medical Association. 1997.*

[37] 14.03.2001: http://www.publications.parliament.uk/pa/ld200001/ldselect/ldsctech/50/5001.htm

ANNEXE C

Petition for information

PETITION PE348: Mr James A Grant

Signatures: 1

Date Received: 13 March 2001

Subject: Psychiatric care in the NHS in Aberdeen

Background:

Petition calling for the Scottish Parliament to implement a pilot study of the manner and methods of psychiatric care and treatment in the NHS in Aberdeen City during the past 25 years.

The petitioner makes a number of recommendations regarding the Millan Committee Report on the Review of the Mental Health (Scotland) Act 1984. He suggests that the Parliament might be better informed in responding to this report if it was aware of the experiences of patients and carers under the present legislation. He requests that to facilitate this process a study of the methods of psychiatric care and treatment of the NHS in Aberdeen during the last 25 years should be conducted. The petitioner's concerns arise out of his own 25 years of experience of working with mental health professionals in relation to the care of his daughter, who has a manic depressive illness.

The petitioner recommends the collation of appropriate statistics including those to do with the types of admittance, staffing levels and available finance. The petitioner also makes a plea for a more sensitive and sophisticated approach to diagnosis involving not only medical practitioners but also in consultation with families.

The petitioner has also submitted substantial documents which relate to his own individual case and details involvement he has had with the Mental Health Commission for Scotland, The Health Service Commissioner for Scotland, the NHS Complaints Procedures as well as MP's and MSP's. These documents are available for members in PHQ Room 5.16.

The Millan Committee presented its review of mental health legislation in Scotland to the Scottish Executive on 25 January 2001. The report recommends a new Mental Health Act to replace the current Act - which dates back to 1984. Among the key recommendations of the Committee are:
- The new Act should incorporate a statement of basic principles;
- Compulsory care and treatment should only be used as a last resort, and be linked to a plan of care for the patient;
- It should be possible for some patients to be compulsorily treated in the community rather than hospital;
-There should be a new independent tribunal, replacing the role of the sheriff court in considering compulsory measures;
- The rights of carers should be clarified and strengthened;
- There should be reforms to the system for dealing with mentally disordered offenders, including new arrangements for discharge of restricted patients;
- New legislation will require to be accompanied by adequate resources for mental health services if it is to succeed.

Suggested Action:

It is suggested that it would not be appropriate for the Parliament to conduct the study into the practices of the NHS in Aberdeen as requested by the petitioner. The Millan Committee Report has been presented to the Executive, not the Parliament.

It is recommended that it should be suggested to the petitioner that It would be more appropriate if he were to direct his request to the Executive to be taken into account as part of its response to the Millan Committee's Report. The Parliament would, of course, become involved in the scrutiny of a new Mental Health Act, should the Executive accept the recommendation in the Report that the current Act should be replaced. It is also suggested that no further action should be taken.

Public Petitions Clerk
22 March 2001