FINANCE COMMITTEE

AGENDA

8th Meeting, 2002 (Session 1)

Tuesday 23 April 2002

The Committee will meet at 10.00 am in Committee Room 2 to consider the following agenda items:

1. **2003/04 Budget Process**: The Committee will consider the Scottish Executive Administration and Associated Departments’ 2003/04 budget proposals and take evidence from—
   - Graham Owenson, Finance Administration and Pay Policy;
   - Ian Walford, Director of Corporate Development;
   - Ingrid Clayden, Director of Pay and Personnel;
   - Paul Rhodes, Head of Accommodation Division;
   - Paul Gray, Director of IT;
   - Joanna Young, Head of Expenditure Policy.

2. **Proposed Amendment to Contingent Liability**: The Committee will consider Minute SE/2002/88 from the Scottish Executive Health Department concerning Scottish National Blood Transfusion Service Protein Fractionation Centre clinical trials.

3. **Covenant Between Local Authorities and the Scottish Parliament**: The Committee will consider a draft covenant between local government and the Scottish Parliament proposed by the Local Government Committee.

4. **Items in Private**: The Committee will decide whether to consider a paper on matters relating to its PFI/PPP Inquiry in private at its next meeting.

5. **PFI/PPP Inquiry**: The Committee will take evidence from Andy Kerr, Minister for Finance and Public Services.

6. **Cross-cutting Reviews (in private)**: The Committee will consider a paper on advisers for its cross-cutting reviews.
The papers for this meeting are:

**Agenda item 1**

*The Scottish Budget 2003-04* – Members are reminded to bring their own copy

**Agenda item 2**

Minute from the Scottish Executive Health Department (SE/2002/88)  
Paper by the Clerk

**Agenda item 3**

Letter from the Convener of the Local Government Committee

Draft Covenant between Local Government and the Scottish Parliament

Paper by Professor Midwinter

**Agenda item 6**

Paper by SPICe  
PRIVATE PAPER
Contingent Liability SE/2001/68
Amendment of table of clinical trials of blood products by the Scottish National Blood Transfusion Service

Background

In March 2001 the Committee approved a proposed contingent liability in relation to clinical trials of blood products being carried out under the auspices of the Scottish National Blood Transfusion Service. The Minute informing the Committee of the proposed liability contained a table of trials to be undertaken over the following twelve months. That period has now expired and the attached Minute (SE/2002/88) sets out a new table of trials for the period from 10 April 2002.

Contingent Liabilities

A contingent liability is one that is incurred only on a specific event whose occurrence or effect is not certain. The previous Finance Minister defined contingent liabilities for the Committee in accounting terms as either:

a) a possible obligation that arises from past events and whose existence will be confirmed only by the occurrence of one or more uncertain future events not wholly within the entity’s control; or

b) a present obligation that arises from past events but is not recognised because:

i) it is not probable that a transfer of economic benefits will be required to settle the obligation; or

ii) the amount of the obligation cannot be measured with sufficient reliability.

FIAG put particular importance on Parliamentary consideration of any proposed guarantees or indemnities in excess of £1m and the Scottish Ministers have undertaken to present any such proposals to the Finance Committee. The Committee will then consider the proposals within 20 days and has the power to either approve the proposal or propose an amendment. Any further disagreement between the Committee and the Scottish Ministers can be referred to the Parliamentary Bureau.

Minute SE/2002/88

The attached Minute is not a new liability. Instead, it updates the liability already approved by the Committee after taking evidence from the Deputy Chief Medical Officer and the Director of Finance at the Executive. There is no requirement for the Scottish Ministers to submit this to the Committee, but they have done so following a request from the Committee when considering the original liability.
The new trials which are set out in the attached table do not, in the Executive’s view significantly change the nature or amount of the liability. In addition, the Executive has informed us that, to date, no claims have been made under the liability.

Recommendation

In light of the fact that the new clinical trials represent no significant change to the existing liability, it is recommended that the Committee notes the new trials set out in the revised table and takes no further action.

David McGill
18 April 2002
MINUTE FROM THE SCOTTISH EXECUTIVE HEALTH DEPARTMENT

CONTINGENT LIABILITY (SE/2001/68): REVISED TABLE OF CLINICAL TRIALS OF BLOOD PRODUCTS PRODUCED BY THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE PROTEIN FRACTIONATION CENTRE

1. Minute SE/2001/68 (copy attached) informed the Parliament of the contingent liability for the clinical trial of blood products produced by the Scottish National Blood Transfusion Service. The Finance Committee considered the minute at its meetings on 6 and 13 March 2001 and the Convener subsequently wrote to the Minister confirming that the Committee had approved the terms of the minute. A table detailing the proposed trials for the 12-month period to March 2002 was attached. The table was subsequently amended by Minute SE/2001/127, which was also approved by the Committee.

2. We would now like to draw the Committee’s attention to the attached updated table detailing the trials proposed during the 12 month period to March 2003. It is not anticipated that the revised programme will significantly change the nature or amount of the liability.

Scottish Executive Health Department
April 2002

SE/2002/88
MINUTE FROM THE SCOTTISH EXECUTIVE HEALTH DEPARTMENT

CONTINGENT LIABILITY: CLINICAL TRIAL OF BLOOD PRODUCTS PRODUCED BY THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE PROTEIN FRACTIONATION CENTRE

1. When a Department of the Scottish Executive proposes to undertake a contingent liability in excess of £1m, for which there is no specific statutory authority, it is appropriate to report the circumstances to the Scottish Parliament. This minute gives particulars of such a liability and explains the circumstances. Under arrangements between the Finance and Audit Committees and the Scottish Executive on in year changes to expenditure allocations, the Finance Committee should approve, or propose an amendment, within 20 days. Accordingly the Scottish Executive undertakes to take no action during this time.

2. Clinical trials of new and safety-enhanced products produced by the Scottish National Blood Transfusion Service’s (SNBTS) Protein Fractionation Centre is an essential part of the process for the SNBTS to obtain a licence for each product. In 1993, the Scottish Home and Health Department informed the Westminster Parliament that it intended to enter into a contingent liability (with prior Treasury approval) to pay any legal and other costs of those medical staff working on the clinical trials approved by the Department unless there was negligence on the part of these staff or it was demonstrated that they had not followed the written protocol for the trial. The resulting liabilities encompassed the cost of any damages claims from patients arising from the said clinical trials of the said new products. It is not possible to quantify the costs, which might arise from these liabilities. A total of 30 clinical trials have been approved since 1993 and 125 letters of indemnity have been issued. No claims have so far been received.

3. Clinical trials form an inescapable part of SNBTS business. Scottish Ministers are of the view that such trials could not proceed without indemnification. In terms of the Scotland Act 1998, functions in relation to supplies of blood (and blood products) have devolved to the Scottish Ministers. Accordingly, the Scottish Ministers consider that the 1993 Westminster Minute is no longer relevant. It is now appropriate to inform the Scottish Parliament that contingent liabilities of this type will be entered into.

4. The purpose of this Minute is therefore to make Parliament aware of the liability and to provide details of the trials proposed during the next twelve months (see attached Annex) for which indemnities may be granted. Departmental approval for the trials of new products will be given on a product by product basis on an assessment of the need for the product and the risk of any ill effect. All of the trials will have prior approval from the Medicines Control Agency under the Clinical Trials Exemption Scheme and are also subject to Ethics Committee approval. The indemnity is of a standard type given in the course of trials conducted on behalf of pharmaceutical companies.

Scottish Executive Health Department
February 2001
# List of Planned SNBTS Studies (as amended 10 April 2002)

<table>
<thead>
<tr>
<th>Product</th>
<th>1.1 Study Title/ clinical area / Rationale</th>
<th>Details of Study</th>
<th>Planned start date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fibrin Sealant</strong> (unlicensed)</td>
<td><strong>FS-015 – Influence of Fibrin Sealant on biliary leakage after Liver Surgery for hepatic malignancy</strong>&lt;br/&gt;Clinical Studies have already been conducted on this product.</td>
<td>Aim to Recruit 90 patients&lt;br/&gt;Expected Duration: 3 years&lt;br/&gt;Location Dundee only</td>
<td>June 2002&lt;br/&gt;Protocol endpoints being altered in light of new clinical information</td>
</tr>
<tr>
<td><strong>Fibrinogen Concentrate</strong> (unlicensed)</td>
<td><strong>FB-006 - A Pilot Study To Compare SNBTS Human Fibrinogen Concentrate With Cryoprecipitate In Patients With Acquired Hypofibrinogenaemia</strong>.&lt;br/&gt;This small pilot study is being set up to obtain preliminary data on the safety, tolerability and efficacy of Human Fibrinogen concentrate (compared with current treatment which has no virus inactivation steps) in patients with acquired hypofibrinogenaemia. The data obtained in this study will allow a full scale study to be designed.</td>
<td>Aim to recruit 20 patients&lt;br/&gt;Expected Duration 12-15 months&lt;br/&gt;Location: Edinburgh Only</td>
<td>June 2002</td>
</tr>
</tbody>
</table>
### VID-001 - A Study To Examine The Pharmacokinetics Of An Intramuscular Preparation Of Low pH Treated Human Anti-D Immunoglobulin Manufactured By The Scottish National Blood Transfusion Service (SNBTS) Compared To The Existing Non- Low pH Treated SNBTS Human Anti-D Immunoglobulin.

- **Study Aims**: This study aims to compare the pharmacokinetic profile of low pH treated SNBTS Human Anti-D Immunoglobulin with non-low pH treated SNBTS Human Anti-D Immunoglobulin in healthy volunteers to show that the addition of the virus inactivation step does not harm the product.
- **Study Design**: 16 volunteers will receive the current licensed product and 16 volunteers will receive the improved product which contains a virus inactivation step during manufacture.
- **Recruitment**: Aims to recruit 32 volunteers and follow up for 6 weeks.
- **Study Location**: To be carried out by a contract organisation in Guildford.
- **Expected Duration**: April 2002

### SCIG-001 A study to assess the efficacy and safety of pH4 treated Human Normal Immunoglobulin preparation manufactured by the Scottish National Blood Transfusion Service when administered by the subcutaneous route.

- **Study Aims**: To assess the efficacy and safety of SNBTS pH4 Treated Human Normal Immunoglobulin administered by the subcutaneous route in patients with primary immunodeficiency syndromes.
- **Study Design**: Patients will receive regular infusions over the 6 month period and will have their trough serum IgG levels monitored and wellbeing assessed throughout. They will also be monitored for adverse events and followed up for virus safety.
- **Recruitment**: Aims to recruit 25 patients and follow up for 6 months.
- **Expected Duration**: 18 months
- **Study Location**: To be carried out across the UK

### Awaiting updated clinical trial guideline from the Committee for Proprietary Medicinal Products (CPMP) before the protocol can be revised.
<table>
<thead>
<tr>
<th>Product Description</th>
<th>Study Description</th>
<th>Protocol Status</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Thrombin (unlicensed)</td>
<td>Study of the use of SNBTS Human Thrombin in the treatment of Pseudoaneurysm</td>
<td>Study protocol under development</td>
<td>Q3 2002</td>
</tr>
<tr>
<td>Previous clinical trials have been conducted on this product</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ultra violet treated 20% Albumin (unlicensed)</td>
<td>Protocol under development</td>
<td>Study protocol under development</td>
<td></td>
</tr>
<tr>
<td>Improved version of a licensed product – includes an additional virus inactivation step during manufacture</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>High Yield Liberate (unlicensed)</td>
<td>Protocol under development</td>
<td>Study protocol under development</td>
<td></td>
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<tr>
<td>Improved manufacturing process of Licensed product, also including an</td>
<td></td>
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<td></td>
<td>Protocol under development</td>
<td>Study protocol under development</td>
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<td></td>
</tr>
<tr>
<td><strong>High Yield Anti-D Immunoglobulin (unlicensed)</strong></td>
<td>Improved manufacturing process of Licensed product, also including an additional virus inactivation step currently being trialled.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ultra violet treated Intramuscular Immunoglobulin (unlicensed)</strong></td>
<td>Improved manufacturing process of Licensed product, also including an additional virus inactivation step currently being trialled.</td>
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</tr>
</tbody>
</table>
Mr Des McNulty MSP  
Convener  
Finance Committee  
The Scottish Parliament  
Edinburgh  
EH99 1SP

6 March 2002

Dear Des

**Covenant between local government and the Scottish Parliament**

You may recall that the report of the Commission on local government and the Scottish Parliament (The McIntosh Report) recommended, amongst other things, the establishment of a covenant and joint standing conference between local government and the Scottish Parliament.

Since the establishment of the Parliament, representatives of COSLA, on behalf of local government, and the Local Government Committee have been working towards the establishment of such a Covenant and joint standing conference. I am pleased to say that the attached draft document, which has resulted from that work, has now been endorsed by COSLA on behalf of its member councils and has also been passed for information to those councils who are currently not in membership. The draft text has been approved by the Parliament’s Legal Office.

The Local Government Committee agreed some time ago that once it had been signed off by representatives of local government, the Parliament’s subject committees together with the Procedures Committee should be invited to consider and, if appropriate, comment on the draft document. Thereafter, it is intended that the Covenant should become a topic for committee business in the Chamber, with an accompanying motion that the Parliament approves the Covenant.

I would be grateful if you would arrange for your committee to consider the draft document, and make comments on it if you wish to do so. Comments should be made in writing to Eugene Windsor, Clerk to the Local Government Committee, before **Friday 26 April**.

cont/
Copies of this letter go to Carol Devon, Director of Clerking and Reporting, Ann Nelson, Director of Legal Services, Elizabeth Watson, Head of Committee Office, Ken Hughes, Head of Chamber Office and the Clerks to the Committees referred to.
Yours sincerely

Trish Godman
Convener – Local Government Committee

cc:
Carol Devon, Director of Clerking and Reporting
Ann Nelson, Director of Legal Services
Elizabeth Watson, Head of Committee Office
Ken Hughes, Head of Chamber Office
Jennifer Smart, Clerk to the Committee
THE SCOTTISH PARLIAMENT AND LOCAL GOVERNMENT WORKING TOGETHER

"THE COVENANT"

COVENANT DEFINING WORKING RELATIONSHIPS AND THE ESTABLISHMENT OF A STANDING JOINT CONFERENCE
INTRODUCTION

1. This Covenant which has been adopted by the Scottish Parliament and Local Government is founded upon a recommendation from the McIntosh Commission which stated that:

   the Parliament and the 32 councils should commit themselves to a joint agreement – which we call a Covenant – setting out the basis of their working relationship; and that they should set up a standing Joint Conference to be a place where parliamentarians and local government representatives may hold a dialogue on a basis of equality.

BACKGROUND

2. Councils, like Parliament, are democratically elected and consequently have their own legitimacy as part of the whole system of governance.

3. It is therefore essential and entirely in keeping with the power sharing and participation principles of devolution that the Parliament should develop a working relationship directly with local government.

4. Based on parity of esteem and the principles underlying the European Charter of Local Self Government, (text of the Charter is annexed) this Covenant sets out the understanding of, on the one hand the Scottish Parliament and on the other local government, of the principles that will underlie relations between them.

5. The arrangements acknowledge the need for the parties to work together in an atmosphere of mutual trust and respect, recognising the value and legitimacy of the role that both have to play in the governance of Scotland.

6. This Covenant does not constitute a legally enforceable contract or create any rights or obligations that are legally enforceable. It is intended to be a broad guidance document, binding in honour only and not an exhaustive text of those issues that might arise.

7. The Covenant is therefore founded upon mutual Respect, with a “Code of Operational Practices” covering Recognition and Relationships, while a Standing Joint Conference will monitor Review and Renew the arrangements as appropriate.

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1 In this document, the "Scottish Parliament" means the Scottish Parliament and the powers devolved to it in terms of the Scotland Act 1998, and "local government" means the councils constituted under the Local Government Acts and COSLA as the representative organ.
RESPECT AND RECOGNITION

8. In furtherance of the European Charter of Local Self Government the Parliament recognises the need to secure and maintain a strong and effective system of local government based on their parity of esteem and the principal of subsidiarity, underlying the European Charter of Local Self-Government. The parties also acknowledge and respect each other’s roles and functions, which are distinct and complementary:

- Within the powers conferred by the Scotland Act 1998 the Parliament has responsibility for determining the powers and duties of local government, while the Executive has responsibility for setting the national framework for local service provision.

- Councils have a democratic mandate to ascertain the needs of their communities and the priorities of their electorates; to plan, co-ordinate and ensure the delivery of local services accordingly, within the legal framework laid down by Parliament.

9. It is inherent in the McIntosh report that the Parliament, Executive and local government have a shared responsibility to serve the people of Scotland; and it is the clear intention of the report’s recommendations that so far as possible these several institutions should work in partnership towards this common objective.

10. The parties agree that for the relationship to be effective and meaningful it has as the core objective the establishment of operational arrangements which ensure that local government is fully engaged in all relevant aspects of the Parliament’s work and that working together, sharing information, experiences and views is integral to the whole process.

11. Noting that Her Majesty’s government has signed and ratified the European Charter of Local Self-Government, the parties also agree to work within the framework established by the Charter.

12. The parties agree to work to the Code of Operational Practice set out below.

13. The Covenant may be subject to review from time to time at the initiative of either party.

OPERATIONAL ASPECTS

14. This Code has at its core objective the establishment of clearly defined processes and procedures for engaging local government in all relevant aspects of the Parliament’s work.

ENGAGEMENT

15. Primarily through the Parliament’s committee arrangements there will be active involvement of local government on both the principle and practice of any proposals which impact upon local government.

CONSULTATION

16. The procedures adopted by the Scottish Parliament provide for a high level of consultation and discussion at all stages of the preparation and consideration of legislation, involving interested
bodies and individuals, the Executive and committees of the Parliament. Within that framework -

- The Parliament via its committee arrangements undertakes to facilitate consultation with local government on all proposals which affect or might affect the structure, role, functions and financing of local government. The financial effects of policy and legislative proposals on local government will be given specific attention; as will the impact of cross-cutting developments which span a number of service or policy areas.

- Local government undertakes to provide a considered, co-ordinated and timely response to issues on which it is consulted.

- The Parliament and Local Government undertake to respect confidentiality where that is required or requested; and otherwise to conduct their dialogue openly.

- Consultation with local government will involve both COSLA and individual councils, on the understanding that, where appropriate and applicable, COSLA will undertake to provide a co-ordinated response which takes account of the views of the individual councils. On certain specialised topics some councils will have an interest and others will not: in these cases COSLA will facilitate more targeted consultation.

- Local government will be invited to submit views on the likely costs associated with legislative and other changes which impact on the services provided by local government.

- There will be opportunities for local government to bring to the Parliament’s notice matters on which local government wishes to see legislation introduced or existing legislation amended.

- The parties will support arrangements where appropriate for secondments and/or regular job exchanges between local government officers and Parliamentary staff.

17. The working arrangements will require to evolve as the relationship between the Parliament and local government develops. However, the above represents the anticipated minimum level of participation of local government.

LOCAL GOVERNMENT COMMITTEE

18. The following arrangements will operate in relation to working arrangements between the Parliament’s Local Government Committee and local government, although they may also be taken up in whole or in part by any of the Parliament’s committees:

- observer status for the Committee at COSLA meetings, with an understanding that observers may be excluded where required at private meetings.

- observer status for COSLA at meetings of the Local Government Committee, with an understanding that observers may be excluded where required at private meetings.

- regular meetings between the Committee and Council Leaders to consider issues of mutual interest.
• regular programme of visits to councils by the Committee or their representatives, although specific ground rules need to be set out and agreed for arranging and reporting back on visits.

**MONITORING THE AGREEMENTS**

**REVIEW AND RENEW**

19. In recognition of the key role that local government plays in the governance of Scotland, a Standing Joint Conference will be established with equal numbers (not more than 16 from each side) of representatives from Parliament and local government.

20. The Parliamentary membership of the Conference may include conveners of the Parliament’s Committees and local government membership will be selected annually so that each council will be directly represented during a three year period and the selection process will have regard to the political balance of councils and geographical spread.

21. The main functions of the Conference are to:

- **Review** how the procedures set out within the Covenant are operating in practice and make proposals to **renew** the arrangements where appropriate.

- **Review** how the Partnership Agreement between the Executive and local government is operating in practice and make proposals for changes / improvements where appropriate.

- **Renew** and work towards the promotion of excellence in Government as a whole by improving governance and public service standards across the board. Exploit the opportunity for Parliament and local government to exchange ideas, review existing policy, discuss future policy and consider the impact of legislative changes. Consider views of a strategic nature as well as those of more immediate interest.

22. The Conference will develop its own set of agreed working practices, including the establishment of a clear work programme, procedures and protocols, however the following specific arrangements will apply:

- **Conference meetings** will be jointly chaired and will be serviced by a secretariat drawn from the Scottish Parliament and Local Government

- **Conference meetings** will be held on at least 2 occasions per year (provisionally April and October) with arrangements being made for special meetings as required

- **Members of either side** can initiate a special meeting of the Conference by presenting a notice of motion signed by at least 5 members of the Conference.

- **Policy issues impacting upon local or central government services** may be placed on the agenda by either side

- **With agreement of the joint chairs any Minister, MSP, council or relevant body or person with a specific interest, has the right to submit papers on agenda items, or to be invited to attend and address the Conference**
THE SCOTTISH PARLIAMENT AND LOCAL GOVERNMENT

“THE COVENANT”

OPERATIONAL ASPECTS CODE OF OPERATIONAL PRACTICES

RECOGNITION

FOUNDATION OF COVENANT

RELATIONSHIPS

RESPECT

REVIEW

RENEW

MONITORING THE COVENANT STANDING JOINT CONFERENCE
Covenant between local government and the Scottish Parliament

Comments on the Covenant

I have three comments which highlight matters relevant to the Finance Committee’s remit. These are –

**Paragraph 16**

This states that ‘COSLA will undertake to provide a co-ordinated response which takes account of the views of individual councils’. On finance, COSLA has attempted to provide ‘a local government view’, but this can reflect either partisan or territorial interests. Moreover, the party group system can work to conceal disagreement. In short, it is important where a range of views exist, particularly over finance, that these are made known to the Parliament for consideration – not just the majority position.

**Paragraph 18**

Refers to the need for ‘regular meetings’ between the Committee and council leaders. Is this in addition to the two conference meetings referred to in Para 22? At the moment, the LGC takes oral evidence from COSLA and a sample of authorities on budget consultation. Perhaps this should be formalised as part of the Covenant to ensure all councils have the opportunity to give oral evidence (once in five years) as well as the opportunity to submit written evidence annually.

**Paragraph 22**

The formal approval of the local government finance settlement is a key stage in the process. It would be helpful if the April meeting could take place on a date which ensures councils have had the opportunity to consider the AER; and the October meeting on a date which allows discussion of the proposals in the LGF settlement prior to the Executive seeking parliamentary approval.

These three topics would assist the Finance Committee (and the Parliament) in the scrutiny of the Executive’s budget proposals.

Professor Arthur Midwinter