CHC SUBMISSION TO PRODUCTIVITY COMMISSION INQUIRY INTO COST RECOVERY - EXECUTIVE SUMMARY

The Commission's Issues Paper sets out the range of issues well, raising most of CHC's concerns. CHC's experience with cost recovery relates to the cost recovery regime implemented by the Therapeutic Goods Administration (TGA).

The TGA is required by the Government to recover from Industry the full cost of its operations. Few Commonwealth agencies are required to do this. Many seek fees for direct services actually provided eg. surveys, publications, reports, passports, visas etc. In essence the Council considers that Industry should not be paying for the full cost of TGA, that the arrangements are inequitable and inefficient, and that they lack accountability. The Council's key concerns may be summarised as follows:

Full cost recovery and Community Service Obligations

- The justification for having a TGA and regulation is the protection of public health and safety. TGA does not provide a service to Industry; it manages a regulatory framework imposed by the Parliament. The monopoly services provided are requirements of the law.

- Industry pays TGA for a range of Community Service Obligations eg. supporting the Government, Minister and Parliamentary Secretary with briefings and policy advice; international and bilateral consultations with organisations; enforcement and prosecution; responding to requests for information and advice from the' public; laboratory analysis.

- These activities have nothing to do with Industry and should not be paid for by Industry. They are in no way a service provided for a fee or charge.

TGA accountability and performance standards

- Even though Industry is directed to pay for many activities it does not have any interest or involvement in, TGA is not accountable to Industry for its budget, expenditure, program activities or performance standards.

- For proper accountability there should be a direct correlation between the corporate plan, costings and deliverables, with measurable performance indicators specified for each sector appropriate to cost recovery.

Lack of discipline

- Full cost recovery imposes few disciplines on an organisation. As the agency does not receive Parliamentary appropriations there is no imperative for scrutiny by Government or Parliament.

- Shortfalls in revenue one year are made up with increases in fees the next year. CPI increases are added on. There are no Productivity Dividends required by the Government.

Contestability of services

- Many TGA activities could be contested by the private sector. For example, the Australian Register of Therapeutic Goods (ARTG) is a database of information, much of which appears on product labels and could be managed by a range of licensed service providers. Laboratory analysis of substances could be carried out by NATA accredited laboratories. Manufacturing facilities in Australia and overseas could be audited out by local auditors. At the very least contestability would benchmark TGA performance.

Fees are a Tax

- Fees being charged which do not relate to a direct service being provided may be unconstitutional as they are in fact taxes which are not supported by taxing legislation.

Consumer perceptions

- While Industry is concerned at the lack of accountability, consumers are concerned that full cost recovery will give Industry undue influence on activities which are Community Service Obligations

In conclusion, the Council strongly opposes full cost recovery. The Council is of the view that the full cost recovery model implemented by the TGA demonstrates the need for clear and strong guidelines for Government agencies imposing cost recovery, guidelines which will ensure an equitable, efficient, accountable and transparent system that appropriately balances Government obligations to the community, and Industry obligations to pay for services provided.

CHC SUBMISSION TO PRODUCTIVITY COMMISSION INQUIRY INTO COST RECOVERY

INTRODUCTION

The Complementary Healthcare Council (CHC) is the peak Industry body representing the overall Complementary Healthcare Industry in Australia. The CHC is recognised nationally and internationally as the principal body for the Complementary Healthcare Industry in Australia. The Council includes in its Membership over 70% of companies sponsoring Complementary Healthcare Products (CHPs) on the Australian Register of Therapeutic Goods (ARTG), in turn representing over 80% of the retail market for CHPs.

Complementary healthcare products cover a diverse range of products including vitamin, mineral and nutritional supplements, special purpose foods, herbal and aromatherapy products, homoeopathics and natural cosmetics.

The CHC is a professional organisation whose core membership represents the amalgamation of the two respected organisations - the Australian Council for Responsible Nutrition (ACRN) and the Nutritional Foods Association of Australia (NFAA). Historically the ACRN focussed essentially on increasing consumer awareness of nutritional supplements, whilst the NFAA's main focus has been a collaborative approach with Government to provide appropriate regulation for complementary healthcare products.

The Council welcomes this Productivity Commission Inquiry. This Submission draws on the experience of the Council and its Members in working within a 100% cost recovery regime managed by the Therapeutic Goods Administration (TGA). It argues that full cost recovery on the model provided by the TGA demonstrates the need for clear and strong guidelines for Government agencies imposing cost recovery, guidelines which will ensure an equitable, efficient, accountable and transparent system that appropriately balances Government obligations to the community, and Industry obligations to pay for services provided.

COST RECOVERY AND THE COMPLEMENTARY HEALTHCARE INDUSTRY

For ease of reading and consistency, this Submission addresses the issues raised and questions posed in the Commission's Issues Paper in the order they appear in the Paper.

REASONS FOR COST RECOVERY

As noted by the Commission, until relatively recently, most government activities were largely funded from general taxation revenue. Increasingly, however, governments have been recovering some or all of the costs of particular government services by other more direct means including, but not limited to, user charges. Commonwealth agencies' cost recovery measures can include charges, fees, levies and specific purpose, earmarked taxes.[1]

The Commission notes that charges may be levied for a number of reasons including:

- to ration government services or prevent excessive, frivolous or vexatious use of government services;
- to provide resources for government activities additional to those available from government appropriations;
- to provide incentives to improve the efficiency of government services provision; and
- to improve the equity of the distribution of the costs of government services.

To this the Council would add a further reason, namely, *to pay for the costs the Government has itself freely incurred when it decided to impose regulation on an Industry*.

Governments imposes - Industry pays

In most other countries, CHPs are not regulated as pharmaceutical products, but as foods or dietary supplements, or as a separate category of goods between pharmaceutical products and foods. The costs of regulation borne by the CHP Industry in Australia are not imposed in most other countries. The Government has chosen to regulate these low risk products as if they were pharmaceutical drugs; the 'service' it is providing in exchange for a fee is a monopoly 'service' imposed by law.

NATURE AND EXTENT OF COST RECOVERY

This section addresses the questions posed in Section 3.1 of the Commission's Issues Paper.

What type of cost recovery arrangements have been implemented? To what activities do they apply?

[1] Productivity Commission *Cost Recovery Issues Paper* October 2000, p.6

- For CHPs, fees and charges are levied at ten activities (or intervention points) where Industry is required by regulation to interact with the TGA in order to gain and maintain approval for selling or marketing a product.

These intervention points are:

1) Listing a new product on the ARTG. This provides a unique identification, or Listing Number, on the ARTG.

2) Maintaining that product Listing on the ARTG.

3) Changing the details of the Listing of the product on the ARTG (a 'Variation'). There are both marketing and safety reasons why a Sponsor would wish to vary the classification of a product.

4) Gaining approval for the use of an ingredient not already approved for use in therapeutic goods ('new substances').

5) Gaining approval for advertising of product in mainstream media.

6) Gaining approval for a Registrable product including high level advertising claims.

7) Licensing of facilities in Australia and overseas for Good Manufacturing Practice.

8) Regular audit of facilities in Australia for Good Manufacturing Practice.

9) Export certification. Because CHPs are regulated as if they were pharmaceutical drugs, there is a requirement that a Government certificate be obtained indicating that the products are deemed to be of appropriate quality and safety for export.[2]

Where else might cost recovery justifiably be implemented?

- The Council considers that there are no other points of intervention where cost recovery is justified. Indeed, some of the current points are not justified. For example, it is hard to justify an annual fee to maintain a Listing on the ARTG. There are no costs involved - or there should not be if the database was efficient

How much of the costs of particular activities is recovered? How much of the agency's overall costs is recovered?

[2] This is a pharmaceutical issue, arising from international discussions in the 1970s and 1980s about the sale of substances manufactured in developed countries (such as DDT or dieldrin) to developing countries, when those substances were banned for public health and safety reasons in the developed countries. CHPs are traded in most countries as foods.

- The full cost of particular TGA activities is recovered. In addition that full cost is augmented by a premium to ensure that the full cost of running the TGA is recovered from fees and charges. There are many TGA activities which are not subject to specific fees and charges eg. overseas travel, policy advice, support to the Minister, training of staff, investigation and enforcement, Commonwealth/State consultations, international activities. The actual fees and charges are set in order to cover the full estimated running cost of the agency which includes these activities which are not a separate service to Industry.

What is the legal authority for the cost recovery arrangements?

- the Council understands that fees and charges are collected in pursuance of the Therapeutic Goods Act 1989 and Regulations.

What guidelines were used in their design and implementation? What outside assistance was sought in the design and implementation of the arrangements?

- The Council is not aware of what if any guidelines were used. The TGA / Industry Consultative Council provides a forum for exchange of views on fees and charges.

Have the arrangements changed substantially since their introduction? How? Why?

- When imposed by Government, fees and charges were set at recovering 50% of TGA's operating costs. That has progressively moved through 75% to 100% at present.

How do cost recovery arrangements in Australia compare generally with arrangements in other countries?

- The Council is not aware of any similar regimes for CHPs in other countries, most of which regulate these products under food law with minimal intervention - there is no requirement for evaluation and premarket approvals and no manufacturing licensing required therefore no associated fees and charges., no evaluation or registration requirements, and no fees or charges.

For cost recovery arrangements with which you are familiar, do those arrangements differ substantially from the arrangements implemented in other countries for similar services?

- As noted above, the Council is not aware of any similar regimes in other countries, most of which regulate CHPs under food law with minimal intervention.

Do the overseas examples recover more or less of the cost of providing services? For what reasons?

- As noted above, the Council is not aware of any similar regimes in other countries, most of which regulate CHPs under food law with minimal intervention.

Beyond cost recovery

The cost recovery regime for therapeutic goods is not a fee or charge for a service. Much of what TGA does is not for Industry but for the community, or Government. The fees and charges are set at a level to cover all of TGA's activities, not only those provided to Industry. This approach to cost recovery is not found in other countries.

RATIONALE FOR COST RECOVERY

This section addresses the questions posed in Section 3.2 of the Commission's Issues Paper.

Why do you think cost recovery has been (or should be) implemented for Commonwealth regulatory, administrative and information agencies?

- As noted in the Commission's Paper, cost recovery has been implemented for a variety of reasons. In the case of the TGA regime, the Council can only surmise that the reason was to help pay for the costs the Government incurred in regulating the Industry.

What are or should be the objectives of implementing cost recovery?

- Where there is a capturable commercial benefit costs should be recovered for the particular service provided.

What is your understanding of the rationale for their introduction? Has the rationale changed since their introduction?

- To help pay for the costs the Government incurred in regulating the Industry. In practice, the approach has changed to recovering the full cost of the agency.

Was account taken of the public benefits (if any) of the activities for which cost recovery was implemented?

- The Council has consistently argued that community service obligations form a significant part of the TGA's activities and should be paid for by Government. To the extent that the current regime is that of 100% cost recovery, clearly the public benefits of TGA's activities have not been taken into account.

Was revenue raising an important rationale in itself?

- Clearly, yes. It is the only rationale.

Do you think the arrangements have achieved their objectives? How successful have they been in recovering costs?

- The arrangements have recovered costs.

A failsafe business

The TGA cost recovery regime has by and large covered the agency's costs. This is hardly surprising given that the fees and charges are so arranged as to recover those costs, and that where there is a shortfall against forecast revenues, then the fees and charges in the subsequent year are refigured to claw back the deficit. TGA operates a monopoly on services which the consumer - Industry - is compelled to purchase in order to stay in business. Nice work if you can get it.

PUBLIC BENEFITS OF REGULATION, ADMINISTRATION AND INFORMATION ACTIVITIES

Economic effects

This section addresses the questions posed in Section 3.3 of the Commission's Issues Paper.

When is it appropriate to implement full or partial cost recovery? Under what circumstances should activities of regulatory, administrative and information agencies be funded wholly from the budget?

- The Council considers that from the viewpoint of transparency and accountability there is a strong argument for some significant level of Government contribution to the costs of an agency, in order to maintain financial discipline, management efficiency, and Parliamentary scrutiny on that agency.

- Without some Government involvement there is no interest on the part of central Government oversighting agencies in the management and efficiency of an agency. Why should there be? As efficiency gains do not contribute to the Budget, there is no incentive for outside agencies to focus on the activities of the agency. There are no budget savings to be garnered, only costs incurred in investigating. And opportunity costs incurred in diverting resources away from agencies where savings and efficiencies might contribute to the budget bottom line.

- As there are no Parliamentary appropriations there is little or no Parliamentary oversight of the agency or its operations.

- Ultimately these inefficiencies and costs feed into Industry costs and consumer prices. The community pays many fold the savings which Government might proclaim in its Budget.

What rules should apply to sharing costs where there are both private and public benefits and costs involved?

- Where a private, capturable benefit is obtained from a service provide by Government, it should be paid for. Where that service is a compulsory entry point for business ie. without it business cannot trade, then the service should be provided at cost. Where it is an optional service eg. market research it should be costed on a commercial basis.

- Where the good or service is provided for public benefit, the costs should be as low as possible commensurate with covering costs.

- Where the good or service is provided in competition with the private sector eg. market forecasts, data, publications, it should be costed on a commercial basis.

What impacts do fees and charges of regulatory, administrative and information agencies (including the ACCC) have on competition?

Fees and charges add to costs. Small enterprises may find the burden of fees and charges more burdensome than larger enterprises as the individual charge may represent a higher proportion of their running costs. It costs the same to list a CHP with a market of say $1 million as it does to list a product with a market of say $10,000. And it cost the same to maintain that product on the ARTG, or vary the product, or gain advertising clearance.

What are the specific public and private benefits and costs of the activities of regulatory, administrative and information agencies to which cost recovery is or might be applied?

- Public benefits include enforcement of regulation, prosecution of breaches, international liaison, involvement in bilateral, regional and international committees, providing policy advice to the Minister and Government, in-service training, legal advisings, Website management, publicity, agency management and budgeting, and good public administration.

- Private benefits include the ability to produce and sell products, and the ability to advertise and make claims about products.

- Public costs in the current regime are nil - the agency operates on full cost recovery.

- Private costs are the reciprocal of public benefits - Industry pays for all the public benefits under full cost recovery.

Can you give examples of how fees and charges have significantly distorted economic activity? How might these distortions be avoided?

- The cost of evaluating a new CHP substance is high - upwards of $10,000. There is no capturable commercial benefit to a company from having a new substance evaluated and approved for use as an ingredient as there are no patent protections for CHPs. Once a new substance is approved, all players can use the substance. Accordingly, very few companies are able or prepared to trail blaze.

- This situation reflects the paradigm of the TGA regime, which was established primarily to address the concerns of the pharmaceutical industry seeking speedy approvals of new, patented drugs.

- This paucity of new substances - freely available in most other countries - has restricted the growth of the CHP Industry in Australia.

- The situation could be avoided by altering the regulatory paradigm to reflect the reality that CHPs are not pharmaceutical drugs, are low risk, and freely available elsewhere. A simpler approach which considers overseas usage and availability is needed.

- A number of companies have relocated overseas in order to avoid costs of listing and restrictions on advertising, marketing directly back into Australia through the Internet and mail (imports for personal use are permitted outside the TGA regime).

Do they discourage/encourage uptake of the services concerned? Is this appropriate?

- The TGA regime is a disincentive to new entrants. In addition to the fees and charges, the complexity of the system requires use of professional consultants to guide a new entrant through the system.

Should fees and charges be set so as to reflect private and public benefits? Are they?

- There will always be public benefits to be reflected in cost recovery arrangements. One is the need for Government involvement in its agencies to maintain discipline and efficiency in administration. Another may be policy advice and support to Government. There will be specific issues for each agency, such as enforcement or international cooperation.

With respect to regulatory activities, is it possible to establish the proportion of costs that should be paid by those regulated (those creating the risks giving rise to the need for regulation), beneficiaries (those who benefit directly from the existence of regulation) and the wider community?

- The Council has put the view to Government that the current regulatory regime is inappropriate for CHPs. They are low or no-risk products that require much lighter regulation. The low risks of CHPs hardly gave rise to the current regime; rather the current regime, when established in 1989, drew in CHPs. Government and Industry were developing a new regulatory approach; with the benefit of hindsight the regime has proved onerous.

- In an appropriate regime cost recovery should be set at a rate benchmarked against best practice for the service provided. Industry is keen to maintain a Register, Good Manufacturing Practice benchmarking, and an Advertising Code appropriate to CHPs.

- The beneficiaries of the regime include consumers, who are assured of safe products, and the general community which benefits from the enhanced health of consumers of CHPs (which are not subsidised and indeed attract a 10% GST).

Are you aware of cost recovery being wrongly applied to a particular activity? Are there other cases where it should be applied but is not?

- As noted above, many activities of TGA are community service or public benefit obligations. Cost recovery has been applied to those activities through the full cost recovery regime.

Can beneficiaries of activities be easily identified? What are the implications if they cannot be easily identified?

- Yes, all products must be listed on the ARTG by the Sponsor, who may be a manufacturer, importer, exporter or distributor of the product. Their name is on the label, or they hold a license to manufacture product for others.

Monopoly pricing

Government monopoly

The Council applauds the discussion in this section of the Commission's Paper, and share its concerns about the economic efficiency effects of cost recovery for government services in monopolistic environments.

How does the monopoly provision of regulatory, administrative and information activities affect fees and the operation of agencies?

Accountability and performance standards

- Even though Industry is directed to pay for many activities it does not have any interest or involvement in, TGA is not accountable to Industry for its budget, expenditure, program activities or performance standards.

- For proper accountability there should be a direct correlation between the corporate plan, costings and deliverables, with measurable performance indicators specified for each sector appropriate to cost recovery.

Lack of discipline

- Full cost recovery imposes few disciplines on an organisation. As the agency does not receive Parliamentary appropriations there is no imperative for scrutiny by Government or Parliament.

- Shortfalls in revenue one year are made up with increases in fees the next year. CPI increases are added on. There are no Productivity Dividends required by the Government.

What are the effects on clients of such monopolistic behaviour?

- Despite good personal relations between Industry and officials, the cost recovery regime promotes frustration and cynicism, rather than understanding and appreciation, towards the system and the agency. The regime restricts market growth both domestic and export. Notwithstanding a range of consultative arrangements - which are difficult and costly for an Industry characterised by small enterprises to manage - ultimately the agency reports to its Master, the Government, not to Industry. And its Master has directed that TGA recover the full costs of its activities.

What measures are or could be used by agencies to overcome the problems of monopoly pricing (for example, benchmarking)?

- The Council suggests contestability and outsourcing where feasible, in an effort to reduce costs and set benchmarks. In addition, consistent with NCP principles, the question should be asked regularly whether regulation is necessary and whether there is scope for industry co-regulation or self-regulation.

Is cost padding a problem? How might the fees of regulatory, administrative and information activities be adjusted to promote administrative efficiency, for example, incentive regulation such as adjusting prices by 'inflation less a margin for productivity improvement' (CPI minus X)?

- As noted above, full cost recovery is inimicable to good governance. The Council considers that from the viewpoint of transparency and accountability there is a strong argument for some significant level of Government contribution to the costs of an agency, in order to maintain financial discipline, management efficiency, and Parliamentary scrutiny on that agency.

- An efficiency dividend would be a good start. Why should a cost-recovering agency be exempted from a discipline applied routinely to other Government agencies when there are no other disciplines, no benchmarks, no guidelines, no competition, no regulations as to how it conducts its business, no marketplace?

Impacts on agencies

Integrity

The Council applauds the discussion in this section of the Commission's Paper, and share its concerns about the integrity of public finance where agencies could retain fees and charges without central clearance or review processes. The Council agrees that such agencies would have an incentive to devise new and possibly inappropriate ways of raising revenue. There may be benefit from more explicit links between revenue raised and services provided, for example imposing

higher fees to provide resources to fast track approvals, but given the lack of proprietorial rights for CHPs, fast tracking arrangements are of limited benefit to the Industry and certainly do not provide an offset for the disadvantages of the current arrangements.

Should agencies be able to retain control of some or all of the fees and charges they collect? Under what circumstances?

- There may be a case for applying some of the fees collected to improvement in the services offered. This could include the promotion and development of the industry the agency serves eg. research.

- An alternative view is that such funds should be returned to Industry as an efficiency bonus, in the form of a dividend or in future reductions in fees.

What would be the incentive effects from doing this or not doing this? What are the benefits and costs of such an approach?

- There would be incentive to industry in paying fees if it knew some of those fees represented in effect an industry levy to be applied to research useful to industry.

- There would be incentive to the agency in improving its relations with its clients, improving its efficiency and giving it flexibility to undertake new tasks of use to the community.

What are the implications for public accountability of agencies retaining revenue?

- The agency should be prepared to be a partner with its clients in managing the retained revenues.

How are or might these be addressed?

- Establish a joint management group to oversight use of the retained funds, reporting jointly to the Minister.

Does cost recovery lead to excessive regulation or inefficiently administered regulation? Give examples.

- Full cost recovery removes external pressures on budget performance (particularly when public interest considerations, including satisfying the letter of the Regulations, are judged to be paramount) and questions of whether the activity is useful or effective expenditure are less likely to arise.

- In its submission to the Commonwealth's Review of Administrative Arrangements for Public Health and Safety Regulation, the Council noted instances of excessive regulation. Two case

studies involved the use of selenium and *Scutellaria incana* and *lateriflora* in therapeutic goods. These are attached to this Submission.

For cost recovery arrangements with which you are familiar, what are the costs to agencies of operating those arrangements

- Given that the agency with which the Council is familiar, the TGA, operates on a full cost recovery basis which is neither transparent nor accountable, it is not possible for Industry to identify the costs to the agency of operating the regime. The agency aligns fees to cover its costs.

The Commission is aware of examples where levies are formally earmarked to particular agencies through special appropriations from the budget. How does the direct linking of revenues raised influence agencies' overall budgets?

- The Council has no direct experience of this situation and accordingly is unable to comment.

What examples are there of less formal linking of fees and revenues?

- The Council has no direct experience of this situation and accordingly is unable to comment.

Impacts on businesses

Different folks different strokes

The Council applauds the discussion in this section of the Commission's Paper, and share its concerns about the way cost recovery arrangements may impact differently on businesses according to the size or nature of those businesses, and the way in which fees and charges are structured. The CHP Industry is characterized by small and medium enterprises; in fact, only a small number of players would be defined as medium, few as large. As noted earlier the Council's experience is that the imposition of flat fees has a greater impact on small businesses than on larger businesses. Compliance costs are also an issue, particularly for small businesses.

Are the characteristics of client businesses important in setting fees and charges?

- Government must be careful before differentiating between enterprises in fees and charges. There are significant equity issues involved. Should one section of industry be subsidising its competitors in the other section? Where is the cutoff point between sectors? Is there a disincentive to grow beyond one sector the other? The larger businesses already pay tax commensurate with their activities, and in the CHP Industry, pay more fees and charges as they seek approval for more products each year.

- Should Government be concerned to encourage a sector of industry for policy reasons, this might best be addressed through more general policy mechanisms which do not differentiate within and between businesses in the regulated industry.

Is it appropriate to vary fees according to some measures of firm size or throughput? How? Why?

- The Council believes that for the CHP Industry variation according to firm size would create more complexities and inequities than such a policy might seek to address.

What are the impacts of the cost recovery arrangements on businesses generally, and small businesses in particular?

- The general impact is that of increasing costs. For small businesses the administrative and compliance costs are relatively higher. There is an argument for simplifying and reducing any regime of fees and charges to reduce that regulatory burden.

Do the arrangements have different impacts on small businesses and large businesses?

- Small businesses have fewer people to manage regulatory arrangements. They have fewer product sales to amortise the costs.

- Larger business pay larger fees.

How much does it cost businesses to comply with the cost recovery arrangements (for example, through additional book keeping costs)?

- It has been estimated that fees and charges themselves can amount to the equivalent of 15% of after tax profit for a medium sized company. As to the costs to the enterprise of complying with cost recovery, the system normally presents a single bill to the company (usually once a year) for all activities during the period, which would be processed in accordance with normal company practice.

- ***What effects does the structure of the cost recovery arrangements have on efficiency and competition (for example, levies based on sales compared with flat fees)?***

- The Council has no direct experience of this situation and accordingly is unable to comment.

How can cost recovery arrangements be designed to minimise unwanted effects on businesses?

- Government should accept responsibility for Community Service. These activities have nothing to do with Industry and should not be paid for by Industry. They are in no way a service provided for a fee or charge.

- For proper accountability there should be a direct correlation between the corporate plan, costings and deliverables, with measurable performance indicators specified for each sector appropriate to cost recovery.

- Full cost recovery imposes few disciplines on an organisation. As the agency does not receive Parliamentary appropriations there is no imperative for scrutiny by Government or Parliament.

- Activities should be contested by the private sector to benchmark performance.

- Guidelines should be developed to ensure an equitable, efficient, accountable and transparent system that appropriately balances Government obligations to the community, and Industry obligations to pay for services provided.

Are some parts of Industry having undue influence on the policy process to the detriment of others (for example, are large firms dominating the way in which regulatory, administrative and information activities are delivered and priced to the disadvantage of small firms)?

- The CHP Industry has differentiated itself from the pharmaceutical industry, and through the Council has participated in consultative arrangements on the cost recovery regime. The Council is by and large satisfied that the resulting arrangements are as equitable as could be achieved in the imposed circumstances of full cost recovery.

Impacts on consumers

Pass the parcel

The Council agrees with the Commission that to the extent that businesses can pass on costs, consumers may also indirectly bear some of the fees paid by businesses for regulatory, administrative and information activities.

What are the private benefits of the goods and services to which these fees relate?

- The major private benefit of the goods and services provided by the TGA is the availability of high quality low risk CHPs which consumers seek to enhance and maintain their health and wellbeing. To the extent that in most other countries these products are freely available with far less regulation, it is difficult to see the benefit of the regulatory regime, and in particular the costs which are passed on from fees and charges imposed and the restriction on access to new products imposed by regulation and the costs of evaluation discussed earlier.

Where consumers are direct users should they be charged full, partial or no costs?

- The Council has no direct experience of this situation and accordingly is unable to comment.

And if so, how should they be charged?

- The Council has no direct experience of this situation and accordingly is unable to comment.

Should a distinction be made between fees charged for services requested (for example, publications) and fees that are mandated (for example, passport fees)?

- Yes. As noted earlier, where a private, capturable benefit is obtained from a service provide by Government, it should be paid for. Where that service is a compulsory entry point for business ie. without it business cannot trade, then the service should be provided at cost. Where it is an optional service eg. market research it should be costed on a commercial basis.

- Where the good or service is provided for public benefit, is should be funded by Government.

- Where the good or service is provided in competition with the private sector eg. market forecasts, data, publications, it should be costed on a commercial basis.

- Where it is requested, it should be costed on a commercial basis.

Should government agencies charge different fees for the same service depending on whether the fees are paid by consumers, businesses or other government agencies? Should prices vary for different types of consumers (for example, pensioner discounts)?

- For reasons of simplicity, predictability and equity, discounts should only be offered as part of a wider social policy eg. senior citizens cardholders.

To what extent are cost recovery arrangements borne by consumers indirectly, that is, how much of the fees paid by businesses are passed on to consumers? How much is absorbed through lower margins?

- The Council is unable to offer any firm view, except to suggest that inevitably some or most of the regulatory costs imposed by Government, of which full cost recovery is only a part, would be passed on to consumers and some absorbed in lower margins, hence lower profits, and ultimately lower taxes.

COSTING ISSUES

This section addresses the questions posed in Section 3.4 of the Commission's Issues Paper.

The Council notes the Commission's approach that costing of an activity can involve three distinct steps: defining the activity to be costed; measuring the direct and indirect costs of providing that service; and apportioning costs where appropriate. It also notes there are different approaches to measuring the costs of a service, each of which must include the direct cost of providing the service, but that methods differ depending on whether indirect costs (such as overheads) and capital costs are included in the cost base.

Under what circumstances should capital costs be recovered?

- Parliament decides regulation should be imposed in the public interest, and requires that these regulations be implemented in the public interest. Capital costs, such as buildings and equipment arise from this imposition by Parliament. Accordingly, capital costs, incurred to carry out Parliament's directions, should be regarded as a public interest or community service obligation. Prisoners are not charged for their accommodation; the regulated industry should not be charged for the community service obligations component of the regulator's activities.

  For example, TGA currently is funded through fees and charges on approvals and listings of new products on the ARTG. If industry did not seek any new listings, industry should not be charged to maintain the regulatory apparatus, which would be providing no services to industry. Yet the Parliament would expect there to be a structure in place to monitor and advise on therapeutic goods.

  The Council strongly opposes full cost recovery and has no comment on the remainder of the questions posed in this Section.

PUBLIC ADMINISTRATION ISSUES

This section addresses the questions posed in Section 3.5 of the Commission's Issues Paper.

The principles are there - use them

The Council applauds the discussion in this section of the Commission's Paper, and notes that there are well-established, broad principles of public policy design and administration which are relevant to cost recovery. These include, but are not limited to, issues of appropriateness, effectiveness, efficiency, accountability, transparency, impartiality, certainty/predictability, accessibility and equity. The issue appears to be that, well-developed though they may be, these principles are not necessarily practiced.

How do the cost recovery arrangements with which you are familiar measure up to these sorts of public policy criteria?

- The TGA arrangements measure up poorly. They lack transparency and consistency, are unpredictable, and as argued previously, are inappropriate.

What issues and principles should be addressed in government guidelines for the design and administration of cost recovery? How should they apply?

- There are well-established, broad principles of public policy design and administration which are relevant to cost recovery. These include, but are not limited to, issues of appropriateness, effectiveness, efficiency, accountability, transparency, impartiality, certainty/predictability,

accessibility and equity. As noted above, the issue appears to be that, well-developed though they may be, these principles are not necessarily practiced.

- One issue to consider is that of accountability to government. As argued above, the Government must have some significant involvement in any agency funding arrangements in order to apply discipline, and to ensure that whatever guidelines are in place are actually followed fully and consistently.

Cost recovery design

The principles are there - use them or lose them

It is pleasing to note that the Office of Regulation Review has set out some principles for good regulatory design processes and, through Regulatory Impact Statements, has scrutinised some (but by no means all) proposals for new regulatory charges. Similarly, public finance principles and processes, such as those of the Department of Finance and Administration, the Auditor General, and Cabinet and parliamentary committees, can help to guide the design of cost recovery arrangements at a broad level.

If these mechanisms were effective the Commission would not need to undertake this Inquiry.

What is the best way to introduce and design new cost recovery arrangements?

- Use the existing central agency expertise in a coordinated way to design cost recovery regimes in accordance with consistent, public guidelines.

What scrutiny should be given to new cost recovery proposals? By whom?

- A central agency should have responsibility for monitoring cost recovery arrangements. That agency should act as an Ombudsman for those paying fees and charges. It should report periodically to the Parliamentary Public Accounts or other appropriate Committee through its Minister.

With regard to the cost recovery arrangements with which you are familiar, what scrutiny was given to the proposals to introduce cost recovery charges? Was a Regulatory Impact Statement undertaken?

- The Council is unaware of what scrutiny was given to the cost recovery arrangements within Government. The Council is not aware that any Regulatory Impact Statement was prepared.

- The Council is not aware whether TGA has prepared any Regulatory Impact Statements for its regulations. It is noted that other Commonwealth agencies publish such Statements as a matter of course in the development of regulations.

Who should be consulted prior to the introduction and design of cost recovery arrangements? How should their interests and concerns be taken into account?

- All stakeholders, together with the central agency responsible for oversighting the activities of the regulatory agency.

With regard to cost recovery arrangements with which you are familiar, who was consulted prior to their introduction? How was their advice or comments taken into account?

- The Government imposed cost recovery without consultation. The level of fees and charges for various activities was negotiated with Industry representatives, with full cost recovery being a given.

Cost recovery implementation

We have the principles - but not the guidelines?

The subtleties might be lost on Industry, but it appears that currently there are principles for good regulatory design processes - but no guidelines for the implementation and administration of government cost recovery arrangements. There were some documents produced by the Department of Finance and Administration (and its predecessors) that addressed these issues but these apparently are no longer in publication. Some agencies have developed their own sets of principles and procedures for implementing and administering cost recovery arrangements.

Principles must be confirmed and guidelines established to ensure consistency, transparency and accountability in cost recovery arrangements.

What principles and guidelines are currently used in implementing and administering cost recovery arrangements for regulatory, administrative and information activities? How do they apply? How could they be improved?

- The Council is only familiar with TGA arrangements. The principles and guidelines informing these arrangements are not clear, beyond recovering the full cost of running the agency through negotiation with Industry on apportioning the fees and charges to various activities.

- Acceptance of public benefit of community service obligations by Government, and efforts to reduce costs through contestability of some activities and innovation in management and systems.

- Ultimately, a new regulatory paradigm for the CHP Industry is required to reduce inappropriate regulation form the Industry.

With regard to the cost recovery arrangements with which you are familiar, has the same agency both developed and implemented cost recovery policy? If so, have any conflicts of interest arisen? What should be done about any such conflicts?

- As far as the Council is aware, the same agency has developed and implemented cost recovery policy. It is not clear whether any conflict of interest may have arisen, given that the Government directed the agency to impose full cost recovery.

Accountability

Accountability and transparency - Part 1 - industry Interest

The Council fully endorses the Commission's comments that accountability and transparency are important issues where the public interest is substantially involved — the greater the potential impact on the public, the more important is the need for public accountability. The Council fully agrees that information on the extent, rationale and administration of cost recovery should be readily available.

In relation to the agency with which you are familiar, how accountable and transparent are they? Is it easy to get information about them?

- Much room for improvement in provision of meaningful information, and accountability to stakeholders for activities undertaken.

Is the information provided consistent and predictable? Is it sufficient to enable businesses to make informed decisions about the costs associated with regulatory, administrative or information activities?

- Once fees and charges are set, and assuming there are no sudden, unpredictable and major changes, then Industry can factor fees and charges into its business operations. At least until there is a sudden, unpredictable and major change brought about by revenue shortfalls, cost overruns, unforeseen events etc.

How could the accountability and transparency of cost recovery arrangements be improved?

- Improved flow of information on business performance, and greater stakeholder input into annual operating plans.

Public Interest

Accountability and transparency - Part 2 -The Public Interest

The Council notes that one reason for introducing cost recovery may be to enhance accountability. Clearly where the costs fall on a clearly identifiable group, that group will have an interest in minimising costs. But the Commission notes that allowing such a group to have too much say in the operation of the agency could have broader implications for accountability to the wider community.

The Council fully agrees. That is a powerful public benefit argument for Government always maintaining a significant financial interest in an agency, in order to ensure that an agency is not perceived as being under the influence of the Industry it seeks to regulate.

The Council notes mention of a 1991 the Finance and Administration manual titled *Guidelines for Costing of Government Activitie*s, and a 1996 manual titled *Guide to Commercialisatio*n, in which it gave some indications of how to implement cost recovery in organisations which recover costs from levies or industry taxes. The Council hopes these and other documents, in particular the Commission's own Report and recommendations, will inform cost recovery arrangements in the future.

To whom should cost recovery arrangements be directly accountable?

- The Minister, through an oversighting group involving all stakeholders and the central agency responsible for oversighting the activities of the regulatory agency.

How should the public interest be protected?

- A central agency should have responsibility for monitoring cost recovery arrangements. That agency should act as an Ombudsman for those paying fees and charges. It should report periodically to the Parliamentary Public Accounts or other appropriate Committee through its Minister.

What if any restrictions should be placed on membership of the boards of the agencies concerned? Why?

- Arrangements for appointments to Government Boards are well developed and involve openness and transparency, including conflict of interest provisions, and should apply equally to cost recovery agencies.

Review

Accountability and transparency - Part 3 - Regular Review

The Council applauds the Commissions support for regular review and evaluation of cost recovery arrangements to ensure that they remain appropriate, effective and efficient. A regular review process would involve consultation with users, businesses, consumers and community groups, and Government oversighting agencies, aimed at affirming effective cost recovery arrangements.

In relation to the cost recovery arrangements with which you are familiar: What processes currently exist for review or evaluation? How regularly are the arrangements reviewed? Against what criteria? Who is consulted in this process?

- There is a TGA Industry Consultative Committee. It meets periodically, largely to adjust fees and charges - share the pain - against Government imperatives of full cost recovery.

How can existing review and evaluation processes for cost recovery arrangements be improved? What criteria should be used? Who should be consulted?

- More transparency in the operation of cost recovery arrangements, and greater participation by stakeholders in developing the arrangements, would go some way to improving review and evaluation processes.

Access and equity

Access and equity rely on consultation

The Council agrees that access and equity principles are important for all government agencies. Information about government services, regulations and processes must be easily accessible to all potential users. Various regulatory, administrative or information cost recovery arrangements will have different implications for public access and equity.

No-one likes to pay fees, charges and taxes. We would all prefer a free good or service. The Council considers that ownership is a key goal for any cost recovery arrangements. The key principle to encourage ownership is equity. To avoid cross-subsidisation by stakeholders of other stakeholders requires careful and transparent consultation between the agency and all stakeholders to determine appropriate levels of fees and charges.

What are the access and equity implications of cost recovery arrangements?

- The key implication is the need for arrangements to be based on full and transparent consultation to ensure that any issues relating to scaling of fees or flat fees, cross-subsidisation across industry sectors etc, are known to, understood and accepted by stakeholders.

What access and equity considerations should be taken into account when introducing, designing and administering cost recovery arrangements?

- There will need to be a balance of benefits and obligations across the range of stakeholders. The key is to ensure that all stakeholders understand and accept the arrangements. This is achieved through consultation and establishment of review an evaluation mechanisms which encourage stakeholder ownership of the arrangements.

In relation to the cost recovery arrangements with which you are familiar:
How are access and equity affected by cost recovery? Are they enhanced or impeded?

- The imposition by Government of full cost recovery, on a 'take it, you have no choice' basis, ensured that Industry would never develop any sense of ownership of the arrangements. Access and equity have been goals sought by Industry, which has been on the back foot since the arrangements were imposed. The process has been a model of bad public policy valiantly implemented by an agency at Government direction.

When do government agencies charge different prices to different users of the same service? On what basis (for example, means testing, size of firm, public or private sector, residency status)? And with what effects?

- The Council's experience has been that of cooperating with other Industry sectors to differentiate aspects of TGA services relevant to the various sectors. Accordingly different prices are charged for different services.

In relation to the cost recovery arrangements with which you are familiar, are there different benefits or costs for large and small businesses? For urban and regional consumers? For other groups within the community? With what effects?

- The benefits and costs are similar for small and larger businesses, although smaller businesses may face larger compliance burdens and the costs are relatively larger in terms of unit sales, while larger businesses face larger absolute costs spread over greater unit sales.

- The cost recovery arrangements may present a significant barrier to entry for small businesses (but as noted earlier, the regulatory regime is a larger barrier than the fees and charges per se).

LEGAL AND CONSTITUTIONAL ISSUES

This section addresses the questions posed in Section 3.6 of the Commission's Issues Paper.

The Law and cost recovery

The Council notes that the way in which the legal authority for a fee is established can have important implications for how fees are set, including international implications. The Council notes that on one view many fees and charges imposed by TGA may arguably be taxes imposed without Parliamentary approval.

On the other hand, there is the attraction to stakeholders of flexibility in arrangements allowed by administratively set fees - they can go down as well as up in response to developments.

The main point is to have consistent, transparent and accountable arrangements.

How have legal and constitutional constraints influenced cost recovery arrangements?

- The Council has little direct experience. It is aware of the view that the current full cost recovery arrangements with TGA could be challenged in the courts as representing a tax imposed without the consent of Parliament.

- As noted by the Commission, international obligations may also influence the design of cost recovery arrangements. These may include the Closer Economic Relations trade agreement between Australia and New Zealand, the non-discrimination commitments made under Australia's membership of the World Trade Organisation (WTO), and other agreements covering the mutual recognition of standards.

- It is conceivable that an overseas interest might consider whether the arrangements breach WTO obligations in relation to Technical Barriers to Trade and Sanitary and Phyto-Sanitary Agreements, but such concerns would relate to the overall regulatory regime for CHPs rather than cost recovery arrangements per se.

- Fees being charged which do not relate to a direct service being provided may be unconstitutional as they are in fact taxes which are not supported by taxing legislation.

Are there any international obligations influencing the design of cost recovery arrangements? How?

- The Council is not aware of any, apart from the possible implications of the WTO referred to above.

Some cost recovery arrangements are implemented through Commonwealth/State agreements or through jointly established bodies.
What constitutional problems are there in implementing cost recovery for such bodies? How have these been addressed?

- The Council has no view on this matter.

TECHNOLOGY ISSUES

This section addresses the questions posed in Section 3.7 of the Commission's Issues Paper.

What implications, if any, do changes in the nature of regulated activities as a result of new and emerging technologies have for the way in which cost recovery is implemented?

- Costs should come down, certainly in relation to services dealing with information. The regulation of CHPs is about information. Information on the product, the ARTG is a database, advertising is media etc.

- Much of the information currently required is not needed. Many processes can be self-certifying.

How should cost recovery apply to the regulation of new and emerging technologies (such as gene technology)?

- Any specific Government policies in relation to an industry sector should be developed in the context of industry policy, consistent with cost recovery arrangements that are consistent, equitable, transparent and accountable.

Are there any particular effects of cost recovery arrangements on innovation by users? Do they impede the uptake of new technology?

- To the extent that they impose a cost, both monetary and compliance, they represent an impediment. However, arrangements are not likely to be a threshold issue where they are consistent, equitable, transparent and accountable.

Changing technologies - a changing paradigm?

The Council endorses the Commission's comments that changing technology also can affect the way the regulatory, administrative and information agencies themselves are organised and interface with the public. And so it should. Industry survives by adapting to the future, so should regulators.

Many of the services currently provided can be carried out over the Internet. Many already are. There is a need to rethink the regulators role in the light of new information technology, including forming links with new stakeholders

What are the implications of the Internet for cost recovery of regulatory, administrative and information services?

- The issues facing Government in terms of cost recovery for services provided over the Internet are those faced by Industry which provides information over the Internet (as distinct from providing goods in response to orders for goods placed over the Internet). Council Members are involved in e-commerce and although E-commerce remains in its infancy the protocols of e-commerce are regularising. Agencies will be in the same position as Industry.

What information services could be supplied free of charge on the Internet and what information services should attract a fee?

- As noted earlier, where a private, capturable benefit is obtained from a service provide by Government, it should be paid for. Where that service is a compulsory entry point for business ie. without it business cannot trade, then the service should be provided at cost. Where it is an optional service eg. market research it should be costed on a commercial basis.

- Where the good or service is provided for public benefit it should be borne by Government.

- Where the good or service is provided in competition with the private sector eg. market forecasts, data, publications, it should be costed on a commercial basis.

Are there technology developments other than electronic and Internet technology that will change the way agencies deliver services? How might these affect cost recovery arrangements?

- The Council has no specific suggestions.

For cost recovery arrangements with which you are familiar:
What types of online services (for example, online applications) are cost recovery arrangements being applied to?

- Online applications for listing, or variation to listings, on the ARTG are in train.

How is the Internet changing the way regulatory, administrative and information activities are being organised, delivered, costed and priced?

- The Council is not conscious of orchestrated change. Rather, Internet seems to be viewed as a different sort of fax, mail or floppy disc.

- Free publications are posted on the TGA Website and can be downloaded (not relevant to cost recovery).

What difficulties are arising in charging for online regulatory, administrative and information activities?

- See above; not yet applicable.

SPECIFIC ISSUES RELATING TO TPA FEES

The Council has no specific comment on TPA fees beyond noting that all Government fees and charges should be subject to the same uniform guidelines based on appropriate acknowledgement of community service obligations, transparency and accountability.

Attachment

SECTION 3.3 - PUBLIC BENEFITS OF REGULATION, ADMINISTRATION AND INFORMATION ACTIVITIES

Does cost recovery lead to excessive regulation or inefficiently administered regulation? Give examples.

Case study - Selenium

Selenium for human therapeutic use has been a prescription only substance because of its listing in Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

In February 1993 ANZFA developed a Proposal P92, which included permission for inclusion of Selenium in Sports Foods. After five years of consideration by ANZFA, the Australia New Zealand Food Standards Council adopted the proposed Standard R10, which included selenium in supplementary sports foods at levels of 26µg organic and 52µg inorganic selenium per daily dose. The Standard came into force on 13 March 1998.

In June 1998 the then NFAA lodged an extensive submission to the Complementary Medicines Evaluation Committee (CMEC) for use of selenium as a listable ingredient in CHPs. The Committee considered the matter on 7 August. Selenium was said to be "the most complex evaluation yet prepared by the Complementary Medicines Section." The Committee recommended that:

- The National Drugs and Poisons Scheduling Committee (NDPSC) be requested to remove selenium in doses less than 100µg per daily dose from the SUSDP; and

- if NDPSC approved the change, there be a maximum dosage unit of 50 µg, appropriate warnings and advice on labels, and an education program be developed for trace mineral supplements.

These recommendations are conservative and well within the 400µg maximum daily intake recommended by WHO and supported by ANZFA. CMEC 8 in September 1998 further discussed selenium and considered further evidence from ANZFA and a draft submission to NDPSC and reaffirmed the decisions made at CMEC 7.

The Council made representation to the NDPSC prior to that Committee's consideration of the CMEC recommendation requesting that the NDPSC consider allowing a daily dose of 200 µg which is half of that recommended by the WHO as a maximum.

At its November Meeting, the NDPSC decided that it would deschedule selenium products with a maximum daily dose of 26 µg. This was just half the level already permitted in sports foods.

Following further representations from industry NDPSC at its March 1999 meeting further decided that levels could be permitted in therapeutic goods equivalent to those in sports foods. There was a further six months wait for this to take effect on the 18th September 1999. The net effect of the NDPSC deliberations was to delay the introduction of selenium supplements by over twelve months and to limit permitted levels to those already permitted in sports foods.

ANZFA had spent five years approving selenium. Why did it need to be considered by another group? And why should a committee comprising State pharmaceutical regulatory experts with no complementary healthcare expertise over-rule the decision of the expert complementary medicine committee?

It is difficult to see what value was added by this drawn out and unsatisfactory process. It is easier to assess the opportunity costs. Two Members of the Council have advised that the delays resulted in opportunity losses in the order of many millions of dollars.

Compliance costs also include cost to industry of any investigation and recall action. The Council fully supports appropriate and timely recall action in the case of public health and safety concerns, or where there is deliberate fraud and deception. Recalls for minor or technical breaches of requirements can impose an onerous regulatory burden on industry. At times they can be for little or no benefit to the community, and in fact possible detriment to the community.

Storm in a Skullcap – a case study

Industry had been using a plant called 'Skullcap (*Scutellaria lateriflora*) for decades in Australia, NZ, USA, Europe and Asia with no known reports of adverse events.

In early 1997 TGA Laboratories tested a number of products and found they did not contain *S. lateriflora* as entered on the ARTG. In June 1997 TGA advised several Sponsors that their product probably contained *Scutellaria incana*, not *lateriflora*. TGA had developed new analytical techniques which were able accurately and reliably to distinguish between the two species. These methods were not available to industry or other Governments.

It appeared that *S. incana* had been widely used as *S. lateriflora,* because internationally accepted identification methods had not picked the difference. Industry had sourced and supplied *S. lateriflora* for more than 30 years from the same US and European suppliers.

Recall action was implemented, largely on the basis that *S. incana* had not been approved for use in therapeutic goods, and also was misleading consumers, who were getting *S. incana* not *S. lateriflora*.

Consumers were not complaining. The products did what they were supposed to (mild sedative / calming effect). As there were no adverse reports of products containing *S. lateriflora* (or inadvertently, *S. incana*) there were no safety issues involved. There was no suggestion of deliberate substitution.

By October, the then NFAA was suggesting that all Sponsors be contacted, ARTG details be changed where *S. incana* was in actual use, and in future all raw material be authenticated on import against an established standard for *S. incana*. TGA proposed that all products incorrectly claiming to contain *S. lateriflora* be withdrawn, not because of public safety concerns but because the product was incorrectly labelled- although it was labelled in accordance with worlds best practice.

On 21 November TGA directed that product containing *S. lateriflora* be recalled to wholesale level. The product could be overstickered with the new name by a licensed manufacturer.

During December and January, the NFAA contacted 66 Sponsors with Skullcap products included in the ARTG. Recall action was directed to commence in early February. By October 1998 recall action had been completed (see Chronology at Attachment 6). In March 1999 CHC advised TGA that there were 67 products containing Skullcap on the market; and 19 were currently being supplied. There were three products containing *S. incana* on the market, but none of these were currently being supplied. Most Sponsors had deleted Skullcap from their product ranges as it was too difficult and costly to identify, given that the analytical methodology developed by TGA was not readily available to overseas suppliers. In April 1999 – two years after the issue first arose – the Council concluded that the matter had resolved itself, but to the detriment of industry and the consumer.

One supplier of material estimated that the cost to his business alone was $50,000 in time and resources dedicated to complying with TGA demands. Many other Sponsors and suppliers incurred similar costs, as did this Council and TGA. And the community has lost a valuable herb as most Sponsors stopped using it because world wide there are no safety data and no adverse reports on *Scutellaria incana*, as worlds best practice has identified and recorded this herb as *lateriflora* until the TGA proved otherwise. All reports in international literature refer to *lateriflora* and there are no data on *incana* available to substantiate claims.

TGA opened communication with Industry in an attempt to resolve this issue. However the highly prescriptive regulatory 'black letter law' framework provided little scope for discretion. Once the anomalies had been discovered, action had to be taken. The CHC believes that there has to be a better way.