

SUBMISSIONS RECEIVED

THE COMMITTEE RECEIVED 31 PUBLIC SUBMISSIONS AND
92 CONFIDENTIAL SUBMISSIONS

NAME	POSITION	ORGANISATION
Dr Andrew Wilson	Chief Health Officer	NSW Health Department
Ms Annie Madden	NUAA Co-Ordinator	NSW Users & AIDS Association Inc.
Mr Martyn Goddard	Program Consultant	Clinical Trials and Treatments Advisory Committee
Dr Anna McNulty	Chair, NSW Chapter	Australasian College of Sexual Health Physicians
Dr Katherine Brown	Convenor, Medical Directors of Sexual Health Clinics	Australasian College of Sexual Health Physicians
Dr William Rawlinson	Medical Virologist, SEALS	Virology Division Department of Microbiology Princes of Wales Hospital
A/Prof Susan Kippax	Director	National Centre in HIV Social Research
Mr Laurence Fong	Associate Director, Pharmacoeconomics & Government Relations	Schering-Plough Pty Ltd
Dr Richard West	Chairman, Advisory Committee on Infection Control	Royal Australasian College of Surgeons
Dr Dominic Dwyer	Medical Virologist	Institute of Clinical Pathology and Medical Research
Mr Matthew Martin	HIV Community Support Worker	Macquarie Area Sexual Health
Ms Suzy Wilds	Clinical Nurse Consultant (HIV/STD/BBV)	Macquarie Area Sexual Health
Ms Jan Cregan	<i>for</i> The Community Working Group	Prisons and Blood Borne Communicable Diseases
Dr Susanne Benjamin	Medical Officer, Hepatitis Lookback Unit	NSW Red Cross Blood Bank
Ms Fiona Clark	Product Manager	Roche Pharmaceuticals
Ms Pamela Heikkinen	Business Unit Manager	Roche Diagnostics
Mr Stuart Loveday	Executive Officer	Hepatitis C Council of NSW
Mr Chris Puplick	Chairman	Australian National Council on AIDS and Related Diseases (ANCARD)
Ms Judy James	Executive Officer	Australian Acupuncture Association
Mr Leo Keliher	Commissioner	Department of Corrective Services
Mr Bryan Suter		Hepatitis Australia Pacific

NAME	POSITION	ORGANISATION
Dr John Smart		Family Medical Centre
Ms Pam Shipway	Director/Co-ordinator	TRAIDS Unit
Prof Geoffrey Farrell	Storr Professor of Hepatic Medicine	Storr Liver Unit Department of Medicine Westmead Hospital
Dr Alex Wodak	Director, Drug and Alcohol Services	St Vincent's Hospital Sydney Limited
Professor W Reed	Chairman	NHMRC Working Party on Hepatitis C
A/Prof G McCaughan	Physician in Charge, Transplant Hepatology	The A. W. Morrow Gastroenterology and Liver Centre
Ms J Pritchard-Jones	Area Hepatitis C Nurse Consultant	The A. W. Morrow Gastroenterology and Liver Centre
Dr Nick Crofts	Head, Epidemiology	The Macfarlane Burnet Centre for Medical Research
Ms Jenny Melrose	Residential Support Worker	Foley House Incorporated
Mr Bill Robertson	Manager	Foley House Incorporated
Ms Jenny Melrose	<i>for</i> The Residential Support Workers	Foley House Incorporated
Professor John Kaldor	Deputy Director and Professor of Epidemiology	National Centre in HIV Epidemiology and Clinical Research
Ms Elizabeth Percival	Executive Director	Royal College of Nursing
Ms Anne Looby	Clinical Nurse Specialist	St. George Hospital

WITNESSES AT HEARINGS

THE COMMITTEE HEARD EVIDENCE FROM 68 WITNESSES
IN ADDITION TO TWO IN CAMERA WITNESSES

THURSDAY, 2 OCTOBER 1997

Dr Alex Wodak Director
Alcohol and Drug Service
St Vincents Hospital

Ms Janice Pritchard-Jones Coordinator
Hepatitis C Services
Central Sydney Area Health Service

FRIDAY, 3 OCTOBER 1997

Dr Andrew Wilson Chief Health Officer
NSW Health

Mr David Fowler Manager, HIV/AIDS/Hepatitis
AIDS and Infectious Diseases Unit
NSW Health

Ms Helen Taylor Policy Analyst, Hepatitis
AIDS and Infectious Diseases Unit
NSW Health

Mr Stuart Loveday Executive Officer
Hepatitis C Council of NSW

Mr Paul Harvey Senior Project Officer
Hepatitis C Council of NSW

Dr John Kaldor Deputy Director
National Centre for HIV Epidemiology and
Clinical Research
University of New South Wales

Ms Margaret MacDonald Senior Research Assistant
National Centre for HIV Epidemiology and
Clinical Research
University of New South Wales

MONDAY, 10 OCTOBER 1997

Ms Pam Shipway Director/Coordinator
Transfusion Related AID and Infectious Diseases Unit

Dr Susanne Benjamin	Head Hepatitis Lookback Unit NSW Red Cross Blood Bank
Ms Pamela Heikkinen	Business Unit Manager Roche Pharmaceuticals
Mr Pascal Mittermaier	Marketing Manager Roche Pharmaceuticals
Ms Fiona Clark	Product Manager for PCR Roche Pharmaceuticals
Dr Dominic Dwyer	Medical Virologist Department of Virology Institute of Clinical Pathology and Medical Research Centre for Infectious Diseases and Microbiology Laboratories Westmead Hospital

MONDAY, 27 OCTOBER 1997

A/Prof William Rawlinson	Senior Medical Virologist South Eastern Area Lab Service Associate Professor School of Pathology, University of NSW Virology Division, Department of Microbiology Prince of Wales Hospital
Ms Rowena Kir	Director of Regulatory Affairs and Pharmacoeconomics Schering-Plough Pty Ltd
Dr Michael Rallings	Regional Medical Director Schering-Plough Pty Ld
Mr Laurence Fong	Associate Director Pharmacoeconomics and Government Relations Schering-Plough Pty Ltd
Ms Fadia Matouk	Commercial Division Director, Sales Marketing Schering-Plough Pty Ltd
Prof Robert Batey	Director Gastroenterology Department John Hunter Hospital

THURSDAY, 6 NOVEMBER 1997

Dr Anna McNulty	Chair NSW Chapter of the Australasian College of Sexual Health Physicians
Dr Neil Bodsworth	Australasian College of Sexual Health Physicians
Dr Ingrid van Beek	Director Kirkteon Road Centre
Mr Steven Hall	Coordinator National Hepatitis C Education Program Royal Australian College of General Practitioners
Mr Bill Robertson	Manager Foley House
Ms Jenny Melrose	Acting Supervisor Foley House

FRIDAY, 7 NOVEMBER 1997

Ms Annie Madden	Co-ordinator NSW Users and AIDS Association
Mr Tony Rance	Positive Users Development Worker NSW Users and AIDS Association
Ms Fiona Poeder	Tribes Manager NSW Users and AIDS Association
Mr Ron Bennison	Policy Worker NSW Users and AIDS Association
Mr Michael Gersak	NUAA Management Committee NSW Users and AIDS Association
Mr Miles Rooke	Advocacy Worker NSW Users and AIDS Association
Shah Habib	Student
Mr Ron Hill	Financial Co-ordinator NSW Users and AIDS Association

Ms Joanne Lancaster	NSW Users and AIDS Association
Mr Gary Gahan	NSW Users and AIDS Association
Mr Ben Fairleigh	NSW Users and AIDS Association
Ms Carol Charles	NSW Users and AIDS Association
Mr Darren Riley	NSW Users and AIDS Association
Mr Sam Hookey	NSW Users and AIDS Association
Ms Sarah Lord	NSW Users and AIDS Association
Mr John Carey	NSW Users and AIDS Association
Mr Chris Puplick	Chairman Australian National Council on AIDS and Related Diseases

FRIDAY, 28 NOVEMBER 1997

Dr Nick Crofts	Head Epidemiology and Social Research Unit Macfarlane Burnett Centre for Medical Research
Professor Geoff Farrell	Director Storr Liver Unit Department of Medicine, University of Sydney Westmead Hospital
Dr Richard West	Chair Advisory Committee on Infectious Control Royal Australian College of Surgeons
Mr Doug Mellors	HCV+

THURSDAY, 26 FEBRUARY 1998

Dr Julian Gold	Director Albion Street Centre Senior Staff Specialist Prince of Wales Hospital
Ms Jennifer Ross	Executive Director Haemophilia Foundation of Australia

Mr David Richardson President
Haemophilia Foundation of NSW

Rev Harold Smart HCV+

Mr Peter Garling, SC Barrister

Mr Graham Stone Manager, HepCare
NSW Health

MONDAY, 16 MARCH 1998

Ms Kathy Sport Filmmaker

MONDAY 23 MARCH 1998

Mr Tony Butler Project Officer
NSW Health

Ms Amanda Christianssen TB Coordinator
NSW Health
Former Clinical Nurse Consultant
Corrections Health Service

Mr Gino Vumbaca Manager
HIV and Health Promotions Unit
Department of Corrective Services

Professor Geoff McCaughan Acting Director
AW Morrow Gastroenterology and Liver Centre
Royal Prince Alfred Hospital

Ms Susan Harper Acting Clinical Nurse Consultant
Corrections Health Service

Ms Sandra Parsons Clinical Nurse Specialist
Corrections Health Service

Ms Jan Cregan Representative of the Community Working Group on
Prisons and Blood Borne Communicable Diseases

Mr George Selvanera Representative of the Community Working Group on
Prisons and Blood Borne Communicable Diseases

MONDAY, 30 MARCH 1998

Mr Tim Sladden Epidemiologist
Northern Rivers Institute of Health and Research
Northern Rivers Health Service

Ms Audrey Lamb HCV+

Ms Helen Kerr-Roubicek Manger
Student Counselling and Welfare
Department of Education and Training

A/Prof Andrew Lloyd Department of Infectious Diseases
Royal Prince Henry Hospital
Inflammation Research Unit
School of Pathology, University of NSW

Mr Stuart Loveday Executive Officer
Hepatitis C Council of NSW

**GOVERNMENT RESPONSE
TO NSW HEPATITIS C
TASKFORCE REPORT**

IMPLEMENTATION OF HEPATITIS C TASKFORCE REPORT RECOMMENDATIONS

Progress on each recommendation of the NSW Taskforce Report was provided by NSW Health in a document tabled on 3 October 1997.

1.1 State-wide HCV education plan for health care and social welfare workers.

In 1995, an Infection Control Education strategy was implemented to support implementation of the revised Infection Control Policy 95/13 and enhance the infection control infrastructure.

Earlier in 1997, a copy of the booklet "Hepatitis C what you need to know" was mailed to all NSW registered medical practitioners, dentists and a long list of other relevant health care workers and institutions. The impact of this initiative will be evaluated.

Since the advent of the Third National AIDS Strategy, HIV/AIDS Coordinators across NSW have become increasingly involved in HCV education and prevention initiatives. NSW Health has recently undertaken a mapping exercise to document the HCV education initiatives being undertaken Statewide.

The demonstration projects being undertaken in 8 Area Health Services across NSW each involve health care worker education regarding HCV. The lessons learned from these projects will help to guide the detail of future policy.

1.2 NSW Health support the establishment of a National HCV Advisory Committee.

The Department supports a National advisory process by providing input to the National Health and Medical Research Council (NHMRC) HCV Committee. The adoption of hepatitis C into the Australian National Council on AIDS and Related Diseases (ANCARD) workplan where hepatitis C has overlap with prevention of HIV/AIDS is a welcomed recent development.

1.3 Funding for an appropriate statewide response to HCV be considered by the Senior Executive Council of NSW Health.

Funding was reviewed and a budget allocated for implementation of the Hepatitis C Taskforce Recommendations. This is currently \$515,000 p. a.

2.1 HCV surveillance be improved to identify incidence more effectively and to report on risk factors associated with infection. This will be achieved by a 12 month pilot study, commencing in 1995, elements of which include, on a five percent sample of notifications: active follow up of seropositive tests to enable optimal ascertainment of incident cases; and collection of information on risk factors associated with both incident and prevalent cases as they are notified.

Throughout 1995, five percent of new HCV notifications were followed up to ascertain incident cases and collect risk factor information where possible. The Commonwealth Department of Human Services and Health collated data submitted from all states. To date this data is of limited usefulness because of a high proportion of missing risk factor data. Public Health Units have indicated that there are significant difficulties in following up HCV notifications. Recurrent enhancement funds were allocated to public health units to improve surveillance from 1996/7.

2.3 NSW Health draft revised Public Health Act Regulations to allow for risk factor surveys in HCV positive individuals.

The Department's Legal Branch has advised AIDS/Infectious Diseases Branch that this cannot be achieved by revising regulations; the Public Health Act itself would need to be revised.

2.4 NSW Health contribute to, and facilitate monitoring of, HCV research in serially tested populations coordinated by the National Centre in HIV Epidemiology and Clinical Research.

The NHMRC is the main agency with responsibility for research funding. Commonwealth funding of these types of studies is already under way as part of the Australian HIV Surveillance Strategy.

3.1 Low cost and effective mechanisms to raise and maintain high levels of hepatitis awareness be developed including:

- **school based education campaigns providing objective information about disease risks of drug injecting and other shared exposures, and appropriate measures for harm minimisation;**
- **education campaigns specifically targeting persons infected with HCV;**
- **education campaigns specifically targeting Injecting Drug Users (IDUs);**
- **appropriate telephone advice and counselling services should be developed to disseminate information about hepatitis C. The development and coordination of these programs should be coordinated by the AIDS/Infectious Disease Branch.**

The Department currently directs more than \$1.0M p.a. of National Drug Strategy funding towards ensuring that classroom teachers are adequately prepared to undertake this work.

The Hepatitis C Council of NSW is funded by NSW Health specifically to provide information and support including a telephone information service for people affected by HCV.

The NSW Users and AIDS Association (NUAA) and the Needle and Syringe Program also undertake some work in this area.

The Needle And Syringe Programs, NUAA and other providers of education programs targeting injecting drug users already include HCV in their information and education initiatives.

The Department currently directs National Drug Strategy funding to CEIDA to provide the Infectious Disease Project for Drug and Alcohol and allied workers.

3.2 AIDS/Infectious Disease Branch facilitate improved access to sterile injecting equipment by:

- **increasing the throughput of the needle and syringe exchange program in NSW to reach the target of nine million per year by the year 2000;**
- **identifying "blackspots" in the availability of sterile injection equipment and develop strategies to rectify the situation;**
- **establishment of a pilot, and time-limited, needle/syringe program (NEEDLE AND SYRINGE PROGRAMS) in a suitable Correctional facility.**

A recent review of the NSW needle and syringe Program considered these issues in detail and mechanisms of enhancing the availability of sterile equipment for IDU have been recommended.

The Taskforce recommendation concerning prisons is not within the power of NSW Health to implement without full cooperation from the other sectors involved, together with bipartisan political support.

3.3 Public Health Division review treatments for drug users (especially methadone maintenance programs) with a view to increasing the following characteristics: effectiveness; capacity; range of treatment; attractiveness; retention; access to methadone programs in correctional facilities; participation of young drug users and consumer input.

The NSW Methadone Program was reviewed by the Department's Drug and Alcohol Directorate in 1995. Research related to the issues raised in the recommendation occurs in nationally funded drug and alcohol research programs.

3.4 NSW Health support the development of community development organisations to deal with the spread of HCV.

The Department currently funds two community development organisations whose work covers this area. These are the Hepatitis C Council of NSW and the NSW Users and AIDS Association (NUAA). Both of these organisations receive recurrent funding.

3.5 The following recommendations be referred to an appropriate inter-Departmental committee for consideration: (At time of writing, it was presumed that a NSW Intersectoral Advisory Committee for Health would be formed; this has not yet been formally established)

The current emphasis on law enforcement measures which restrict drug supplies and increase the likelihood of drug use by injection should be reviewed with the aim of facilitating the transition from injecting to non-parenteral drug use;

Paraphernalia should be included in exemptions for legislation which covers needle and syringe exchange programs (s19 and s20 of the Self Administration (Drugs Misuse and Trafficking Act 1985);

The size of prison populations should be reduced by making drug policy more flexible and improving non-custodial sentencing options for IDUs;

The recommendations have implications for other government sectors and have not been supported in the past. This has been due in part to lack of community support for such recommendations and the political complexities of the issues.

These issues overlap with those addressed in a document released in September 1995 entitled "Prisons and Blood Borne Communicable Diseases, the Community Policy" which was a joint initiative of the AIDS Council of NSW (ACON), the Hepatitis C Council of NSW, NSW Users and AIDS Association (NUAA) and four other community based organisations.

These recommendations are in the area of responsibility of the Attorney General and the Minister for Police.

Similar recommendations were made in the "Puplick Report - The Courage of our Convictions HIV/AIDS: The National Strategy and the Laws of NSW" Report to the Minister for Health 1993.

Responding to the recommendations in the Puplick Report, the (then) Attorney General advised that "the principle of non-custodial sentences for minor offences is already 'enshrined' in NSW criminal law in that section AB of the Justices Act 1902 provides that in a summary proceedings, a Justice or Justices shall not sentence a person to full time imprisonment unless satisfied, having considered all possible alternatives, that no other course is appropriate".

3.5 cont.: HCV infected individuals should be protected against discrimination.

Legislatively some provision already exists to protect people from discrimination. Part 4A of the Anti-Discrimination Act 1977 deals with discrimination on the grounds of disability. Under the Act "disability" includes the presence in a person's body of organisms causing or capable of causing disease or illness. Thus, the provisions of Part 4A would apply in relation to persons infected with HCV. The Act prohibits unlawful discrimination in the workplace, education and training, provision of goods and services, accommodation and in registered clubs. There is an exception in the Act where the discrimination is reasonably necessary to protect public health.

3.6 The Centre for Research and Development within NSW Health adopt the following as research priorities for NSW:

- **reducing the size of the drug injecting population;**
- **improving the effectiveness of treatment for persons using potentially injectable illicit drugs;**
- **development of non-reusable injection equipment;**
- **behavioural and ethnographic research into young injectors and particularly into initiation of injecting and sharing of body fluids;**
- **effectiveness of bleach and other agents used for decontamination of injecting equipment.**

These are the ongoing concerns of the National Drug and Alcohol Research Centre (NDARC). The Commonwealth is the appropriate funding agency for the work of National Centres. NSW Health works closely and cooperatively with this and other relevant research agencies.

3.7 That AIDS/Infectious Diseases Branch revise The Skin Penetration Guidelines and the Public Health Act 1991-Regulation and develop an effective implementation strategy. Such a strategy should include prisons.

The AIDS/Infectious Diseases Branch commenced a review of the Regulation and associated Skin Penetration Guidelines. This review is continuing as part of the work of the Environmental Health unit. Environmental Health Officers have a role in ensuring compliance of these guidelines.

4.1 It is recommended that funding be made available to provide validation testing for all positive screening tests in public patients and appropriate prognostic and antiviral tests. Tenders should be called for the establishment of two major reference sites in NSW. Selection should be based on the expertise and experience of the laboratories, the ability to interpret tests and to develop new tests. Reference laboratories should also be allowed to charge referring private laboratories for the costs of validation testing.

Medicare currently funds the initial antibody testing for HCV, while the more specialised supplementary testing is funded either by the patient or from hospital budgets. Part of the Hepatitis C Taskforce Implementation funding has to date been allocated to Area Health Services for this purpose.

4.2 The reference laboratories be linked with the National HIV Reference Laboratory and state reference laboratories.

Laboratories authorised to undertake HCV supplemental testing provide data to the National Serological Reference Laboratory for national collation.

4.3 A validation algorithm be developed and applied by the Commonwealth to all laboratories testing for HCV. Validation testing for initial positive tests should be rebateable under Medicare.

A validation algorithm provided to the Commonwealth has been approved by the NHMRC and is now in use by authorised laboratories.

4.4 AIDS/Infectious Diseases Branch establish a panel of review to annually review the HCV testing program.

The Department recently convened a working party to make recommendations concerning quality assurance for HCV testing in NSW. These recommendations were presented to the Commonwealth Department of Health and Family Services for consideration as part of the process of updating Commonwealth guidelines.

4.5 Research and development with regard to HCV testing be considered a priority and is an important component of a coordinated plan for HCV.

Clinical research funding is usually provided by the Commonwealth or by relevant industry funding sources.

5.1 Some enhancement of HCV consultant services is required in most health Areas/Districts. A comprehensive needs assessment and services planning project should be undertaken as a matter of urgency, and minimum service levels set based on a health outcomes approach. In the meantime the guidelines in the text of this Report should be used as the

basis for developing a comprehensive HCV clinical capability in NSW. The recommended minimum level of service provision is: one nurse consultant/educator per Area Health Service or per group of Districts (previous Regions); 1.5 hepatologists (full time hepatitis C) per 600,000 population; 0.5 resident medical officer (full time hepatitis C) per 600,000 population; adequate liver biopsy day stay beds and adequate ultrasound facilities.

Consultation with the relevant Departmental Branch suggested that further data are required to justify the stated resource recommendations. Perceptions of needs for clinical services will be re-examined in the light of the evaluation of the current Hepatitis C demonstration projects and a service development exercise is being considered for commencement in 1998.

5.2 *Statewide access to interferon under s100 be facilitated by authorising practitioners in each Area/District.*

This was made a priority in NSW and there are now 22 authorised Interferon prescribing centres Statewide and two more applications in progress.

5.3 *Non s100 listing patients be accepted for interferon treatment on compassionate grounds in carefully selected cases. This should require the approval of more than one hepatologist including an independent opinion from someone outside the treatment centre making the recommendation.*

NSW supports the urgent implementation of the current NHMRC recommendations for the broadening of the criteria for interferon treatment, and has made this view known to the Commonwealth.

5.4 *All services providing interferon or other treatments be required to provide data to the National Hepatitis C Treatment Database based at the John Hunter Hospital. The database should be extended to include data from liver transplant units.*

This is in place as a condition of approval to prescribe interferon as a s100 funded drug.

5.5 *The Australian Gastroenterology Institute be contracted under the Health Outcomes program to develop clinical best practice guidelines for HCV management and liver biopsy.*

The NHMRC convened a working party (which includes NSW clinicians) to develop clinical best practice guidelines. These were released in August 1997 and are now

guiding service provision developments as part of the current hepatitis C demonstration projects.

5.6 *A short course in HCV management and counselling be established by AIDS/Infectious Diseases Branch for GPs, Medical Officers and consultant nursing staff. Completion of this course should provide accreditation for GPs wishing to participate in shared care.*

This concept is discussed regularly with GP representatives. To date there is no consensus on whether such a program is needed as there are several other initiatives which may achieve the same aims, including the NSW Hepatitis C demonstration projects and several Commonwealth funded projects being conducted by Divisions of General Practice in NSW. The need for such an accreditation program will become clearer following the evaluation of these projects.

5.7 *Appropriate coding systems for hepatitis be developed for the medical records system.*

The coding of hepatitis is currently under review by the National Coding Centre.

**INTERFERON CRITERIA
COMPARISONS**

PATIENT GROUPS ELIGIBLE FOR INTERFERON THERAPY.

A COMPARISON OF CURRENT SECTION 100 CRITERIA WITH NHMRC AND NIH RECOMMENDATIONS/PROPOSALS

	Section 100	NHMRC*	NIH
# 1, 2, 3, 12	Patients with chronic hepatitis C evident on liver biopsy (except in patients with inherited coagulation disorders) with repeatedly positive anti-HCV antibody test and an elevated ALT on 3 occasions over a period of 6 months qualify for treatment with Interferon alfa. If the ALT remains greater than the upper limit of the laboratory reference range after 12 weeks, treatment is to cease.	All HCV antibody patients with any elevation of ALT should qualify; but patients with normal ALT values should be monitored regularly by their clinician. Patients with minimal ALT elevation or with normal LFT's and positive HCV serology or HCV RNA testing should also qualify for treatment.	Chronic Hep. C patients with persistently elevated ALT, positive HCV RNA and livery biopsy should qualify for treatment. Patients with chronic hepatitis C at greatest risk for progression to cirrhosis should be treated. Liver biopsy is indicated when histological findings will assist decision making regarding patient management.
4.	Patients who do not have cirrhosis or other liver disease, qualify for treatment.	Patients with cirrhosis should be treated at a higher dosage regimen of 4.5 MIU daily for 6 months.	Patients with decompensated cirrhosis should not be treated but should have liver transplants.
5.	HIV positive patients are excluded from treatment.	HIV positive patients should qualify for treatment. The individual clinician will determine if interferon alfa is appropriate to offer patients with advanced HIV disease.	Patients with stable HIV infection with good clinical and functional status should qualify for treatment.
6.	Patients who are not pregnant, not lactating or are practicing adequate birth control should qualify for treatment.	Patients who are not pregnant, not lactating or are practicing adequate birth control should qualify for treatment.	-
7.	No history of significant psychiatric illness, no history of autoimmune liver disease.	No history of significant psychiatric illness, no history of autoimmune disease.	Contraindications which should be carefully considered are a history of major depressive illness, cypopenia, active alcohol or illicit drug use, hyperthyroidism, renal transplantation or autoimmune disease.
8.	Would be likely to attend regularly for treatment and follow-up.	-	-

Section 100		NHMRC	NIH
9, 10.	Patients who have not utilised illicit drugs within the previous 12 months or take no more than 7 standard alcoholic drinks/week, qualify for treatment.	Injecting drug users and patients on Methadone program should qualify for treatment. Due to the risk of side effects patients should be assessed individually by their managing physician to determine whether there is any evidence of psychological instability.	Treatment of patients who are drinking significant amounts of alcohol or who are actively using illicit drugs should be delayed until habits discontinued for at least 6 months.
11.	The course of treatment is limited to 3 million units subcutaneously three times weekly for up to 52 weeks.	-	-
13.	The course of treatment must be continuous and excludes retreatment of non responders or patients who relapse and thus patients eligible for the 12 months course will be new patients and current responding patients who have not completed 6 months treatment.	Patients who have relapsed following an initial response to a 6 month course of interferon should be treated again with interferon alfa for 12 months.	Non responders should not be treated with the same regimen of interferon but should be considered for combination therapy or enrolment in investigational protocols using different dosages or agents. Patients who have an ETR to a 6 month course of interferon alfa but then relapse, should receive 12 months treatment with interferon alfa or be considered for combination therapy with Interferon alfa plus Ribavirin or other regimens, preferably in a clinical trial.
14.	-	Patients with extraheptic manifestations of hepatitis C should be treated.	Extra hepatic manifestation, ie. mixed cryoglobulinaemia should qualify for treatment.
15.	-	-	Therapy should not be withheld on the basis of high RNA levels, genotype or mode of acquisition.
16.	-	-	Patients with acute Hep. C should be treated.
17.	Children under 18 years of age also qualify for treatment.	Children should be treated. The dose for children under 18 years of age should be 3 MIU/m ² three times per week (dose not to exceed 5 MIU/m ²).	Firm recommendations cannot be made on patients under 8 years or over 60 years of age because of incomplete data. These patients should be managed on an individual basis or in the context of clinical trials.

* NHMRC, 1997:35

Numbering maintained as per Section 100 criteria.

Source: Schering-Plough submission

**NSW HEPATITIS C
DEMONSTRATION PROJECTS:
AIMS AND OBJECTIVES**

I THE RURAL HEPATITIS C DEMONSTRATION PROJECT

This project aims to improve access to treatment and support for people with HCV in rural areas, and to improve the coordination of their care.

The project's objectives include:

- to map current services and resources;
- develop a model of coordinated care for rural areas;
- develop protocols and guidelines in consultation with other projects;
- identify general practitioners and other health care and support workers who can provide support, information, counselling and treatment for people with and affected by HCV;
- identify specialists interested in becoming interferon prescribers in those areas currently without prescribers, and general practitioners interested in placement with prescribers for further training;
- develop and implement general practitioner and health care worker education sessions in all aspects of HCV, in conjunction with Divisions of General Practice, the RACGP and other relevant agencies;
- establish education support networks to enable the ongoing education of health care workers; and
- identify consumers who can provide education for health care workers and involve them in all aspects of training.

II CENTRAL/SOUTH EASTERN SYDNEY HEPATITIS C DEMONSTRATION PROJECT

The objectives of this project are:

- set up monthly specialist HCV clinics at the Kirketon Road Centre (Kings Cross), Livingstone Road Sexual Health Centre (Marrickville), Newtown NSEP and Bayside Methadone Clinic (Kogarah);
- map current services and resources;
- develop and deliver education and training to general practitioners and other health care workers;
- develop, in consultation with other projects, management and referral protocols; and
- improve surveillance of HCV by improving notification, conducting exposure assessments on incident cases and conducting a survey of HCV related morbidity.

III THE WESTERN SYDNEY HEPATITIS C DEMONSTRATION PROJECT

The aim of this project is to develop a model of care for HCV positive methadone clients. The project will develop a counselling/psychosocial support model for HCV in conjunction with the Liver Clinic and the Department of Psychiatry at Westmead Hospital.

The objectives of the project are:

- map available HCV services in the Area and their level of support;
- document surveillance and notification procedures and referral patterns;
- conduct needs assessments of both people with HCV and service providers;
- train methadone prescribers and clinic staff, and other relevant service providers;
- develop a model for ongoing assessment and referral of methadone clients;
- produce resources for methadone providers and clients; and
- develop indicators and referral protocols for psychiatric/psychosocial support.

IV THE SOUTH WESTERN SYDNEY HEPATITIS C DEMONSTRATION PROJECT

The aim of this project is to address the specific issues of access, information, treatment and care for people from non-English speaking backgrounds.

The objectives of the project are:

- encourage community awareness of HCV through social marketing, community development and consultation;
- increase the skills of targeted general practitioners in diagnosis and management of HCV;
- develop a shared care model involving general practitioners and specialist services;
- develop resources for general practitioners, specialists and other health care workers caring for people of non-English speaking backgrounds; and
- improve HCV surveillance by improving notification of acute cases and the provision of demographic and risk factor information.