This case was considered by a Fitness to Practise Panel which applied the General Medical Council's Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988

Date of Fitness to Practise Panel Hearing:	23 May – 14 August 2007 10 - 21 December 2007 3-13 January 2008 25 February – 30 March 2008
Name of respondent doctor:	SHARMA, Tonmoy
Registered qualifications:	MB BS 1987 Dibrugarh;
Registered address:	United States
Reference number:	3632509
Type of Case:	New case of conduct
Panel:	Mr A Popat CBE, Chairman (Lay) Ms L Boait (Lay) Ms J Julien (Lay) Dr S Pande (Medical) Dr M Sheldon (Medical)
Legal Assessor:	Mr Robin Hay
Secretary to the Panel:	Mrs Nilla Varsani JP

Representation:

Miss Joanna Glynn QC, instructed by Field Fisher Waterhouse, represented the General Medical Council.

Dr Sharma was present and was not represented.

Charge:

That, being registered under the Medical Act 1983

1. You held the positions of Clinical Lecturer and then Clinical Senior Lecturer at the Institute of Psychiatry ["IOP"], King's College, University of London from May 1995 until August 2001;

Admitted and Found Proved

PhD thesis

2. a. On 30 July 1999 you were offered the Chair in Psychiatry at the Department of Psychiatry and Behavioural Sciences at the University College, London University, subject to conditions which included the successful completion of your PhD,
Found Proved

b. You told the Appointments Board that you would submit your PhD thesis by the end of September 1999. The thesis had to be submitted to Professor G, one of your supervisors,
Found Proved

c. In August 2000 you told Professor M (Professor of Psychiatry at the IOP) that you had given Professor G some of the chapters of your thesis,
Found Proved

d. On 10 May 2001 you stated again to Professor M that you had given Professor G some of the chapters of your thesis,
Found Proved

e. On 4 June 2001 your informed Professor M by email that you had sent draft chapters of your thesis by email to Professor G,
Found Proved

f. Each of the statements set out in 2.c. to e. above was untrue in that you never submitted any chapter of your thesis to Professor G at any time,
Found Proved

g. Your conduct in this respect was

i. dishonest,
Found Proved

ii. unprofessional;
Found Proved

3. a. You described yourself as “Tonmoy Sharma MD PhD” on websites, including that of a company in which you had a controlling interest, ~~your company’s website, www.psychmed.org.uk,~~
Found Proved (as amended)

b. Not having obtained a PhD at any time, your misrepresentations were

i. dishonest,
Found Proved

ii. unprofessional;

Found Proved

"Professor Sharma"

4. a. In 2002 you were invited by a colleague to present several lectures as a "visiting professor" at Pittsburgh University in the United States of America; this was not a formal appointment,
Admitted and Found Proved

b. From January 2002 you referred to yourself as "Professor Tonmoy Sharma" in professional correspondence between yourself and persons working in the field of medicine in England, including the Chairman of an Ethics Committee, apparently on the basis of the said invitation,
Found Proved

c. You knew or ought to have known that the use by you of the title "professor" in such circumstances was

i. misleading,
Found Not Proved

ii. not accepted practice amongst academics in the United Kingdom;
Found Not Proved

Misrepresentations about ethics approval

5. a. As a principal investigator ["PI"] undertaking research studies it was your responsibility to obtain, by the submission of accurate and truthful information, relevant ethics committee approval for such studies before they could commence,
Admitted and Found Proved

b. you were responsible for the submission of incorrect and potentially misleading information to a number of ethics committees, in that the committees were informed by way of the study protocols that ethics committee approval for the study in question had already been obtained from the Bethlem and Maudsley Ethical Committee (Research), Institute of Psychiatry, as follows

i. an application dated 4 April 2000 to the Dartford and Gravesham Local Research Ethics Committee ["LREC"] ("D&G 23/00") for approval for a study entitled "*Clinical Efficacy and side effects of Ziprasidone in Recent Onset Psychosis: a cognition and functional magnetic resonance (fMRI) Study*", with the study Protocol containing at section 6 an assertion that the ~~study has ethical permission from the Bethlem and Maudsley Ethical Committee~~ applicants have ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol",
Found Proved (as amended)

ii. an application made in April 2000 to the Maidstone LREC ("23/00M") for approval for the study named in 5.b.i. above, with the study Protocol containing at section 6 an assertion that the ~~study has ethical permission from the Bethlem and Maudsley Ethical Committee~~ applicants have ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol",
Found Proved (as amended)

iii. an application made on or about 23 June 2000 to the Dartford and Gravesham LREC ("D&G 30/00") for approval for a study entitled "*A Naturalistic multimeasure study of clinical and cognitive efficacy of Amisulpride, Quetiapine, Risperidone and Olanzapine in Schizophrenia*", with the study Protocol containing at section 6 an assertion that the ~~study has ethical permission from the Bethlem and Maudsley Ethical Committee~~ applicants have ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol";
Found Proved (as amended)

6. a. On or about 4 May 2000 you submitted as "principal applicant" an application to the Alzheimer's Society for a grant towards a study entitled "*Effects of Rivastigmine in Patients with Mild Memory Impairments and Alzheimer's Disease: A Functional Magnetic Resonance Imaging Investigation*",
Found Proved

b. The application form contained the statement that ethical permission had been obtained for the study from the Ethics Committee (Research) of the Institute of Psychiatry and Maudsley Hospital,
Found Proved

c. This statement was untrue in that no such ethical permission had been obtained;
Found Proved

COGS EC approval

7. a. You conducted as PI a study entitled "A *Naturalistic Study of Clinical Cognitive Efficacy of Amisulpride in Schizophrenia: Comparison with Olzanapine"* (also known as the "COGS" study) without ethics committee approval,
Found Proved

b. You misled the funders of the said COGS study, namely Sanofi-Synthelab ["Sanofi"], by asserting incorrectly that ethics committee approval had been obtained for the study, as follows:

i. you sent an email to Dr S of Sanofi on 2 November 1999 in which you stated "Here is revised protocol…We are keen to start and have ethics permission…",

Found Not Proved

ii. the Protocol referred to in 7.b.i. above contained, at section 6, an assertion that the study has ethical permission from the Bethlem Maudsley Ethical Committee,
Found Not Proved

iii. you sent a study report to Sanofi dated 3 October 2000 in which you stated "Ethical approval to conduct this study was sought and granted by the South London and Maudsley NHS Trust",
Found Proved

iv. you told representatives of Sanofi at a meeting on 13 December 2000 that the study had ethics committee approval from West Kent, and produced a letter dated 4 September 2000 in relation to D&G 30/00 in support of this assertion,
Found Proved

v. In a letter dated 6 June 2001 to Dr R of Sanofi you stated that the "study was being carried out under the ethics permission from West Kent under the title of '*The effects of typical and atypical antipsychotics on cognition in West Kent*'" and subsequently from the Dartford and Gravesham LREC;
Found Proved

8. Your actions at 5. – 7. above

a. Were misleading,
Found Proved in relation 5, 6, 7a, 7b(iii), 7b(iv) and 7b(v)

b. Were untruthful,
Found Proved in relation 5, 6, 7a, 7b(iii), 7b(iv) and 7b(v)

c. Fell significantly short of the standards to be expected of a medical practitioner undertaking medical research on human subjects;
Found Proved in relation 5, 6, 7a, 7b(iii), 7b(iv) and 7b(v)

First Episode studies

9. a. You were a PI for a multi-centre international study sponsored by the Janssen Research Foundation ["Janssen"] entitled "*Double–blind evaluation of risperidone vs haloperidol on the long term morbidity of early psychotic patients*", also known as "RIS-INT-35" or "the Janssen First Episode Study",
Admitted and Found Proved

b. No document submitted by you or on your behalf to an ethics committee for approval of the said study refers to functional magnetic resonance imaging,

structural magnetic resonance imaging ["Structural MRI"] or magnetic resonance spectroscopy ["spectroscopy"], in particular

i. the study protocol,
Found Proved

ii. the Patient Information Letter / Informed Consent Form,
Found Proved

iii. any amendments or addenda to the study protocol,
Found Proved

c. As a consequence the study had no ethics committee approval for any of these procedures to be carried out on patients entered into the study,
Found Proved

d. Between 4 February 1997 and 15 May 1997 you caused five patients who had been recruited into the said study to undergo scanning, including structural MRI and spectroscopy, without EC approval,
Found Proved

e. Your conduct in respect of 9.d. was

i. unprofessional,
Found Proved

ii. unethical,
Found Proved

iii. not in the best interests of the study patients;
Found Proved

10. a. Contemporaneously with the study referred to in 9.a. above you were PI in a study funded by Eli Lilly and Company Limited ["Lilly"] entitled *"Acute and Long term efficacy of Olanzapine in First Episode Psychotic Disorders: a randomised Double-Blind Comparison with Haloperidol"*, also known as "FID-MC-HGDH", or "the Lilly First Episode Study",
Admitted and Found Proved

b. The battery of tests provided for in the Lilly First Episode Study Protocol was more extensive that those provided for in the Janssen First Episode Study Protocol,
Found Proved

c. To your knowledge

i. the Janssen First Episode patients were exposed to a similar level of testing to that of the Lilly First Episode patients, beyond what was provided for

in the Janssen protocol, including scanning,
Found Proved

ii. case report forms ["CRFs"] were created and completed for tests carried out on Janssen and Lilly First Episode patients, in addition to those CRFs provided specifically for the Janssen and Lilly First Episode studies,
Found Proved

d. You took steps to ensure that the Janssen Research Foundation and Eli Lilly did not become aware of each other's First Episode study, including instructing your staff to remove any documentation relating to one company's study when representatives of the other company attended the research site at the IOP,
Found Proved

e. As a result of 10.c.i. and ii. above you were able to pool data from both studies and to increase the numbers for subsequent publication,
Found Proved

f. Your conduct in this respect was

i. dishonest,
Found Proved

ii. unprofessional,
Found Proved

iii. not in the best interests of the study patients;
Found Proved

11. a. You permitted pre-pulse inhibition tests to be carried out on the patients enrolled in the Janssen and Lilly First Episode studies in heads 10. and 11. above,
Found Not Proved

b. There was no ethics committee approval for such tests on these patients,
Found Proved

c. As a result no appropriate consent was or could have been obtained from the patients,
Found Proved

d. your conduct in 11.a. – c. above

i. was unethical,
Found Not Proved

ii. fell significantly short of the standards to be expected of a medical

practitioner undertaking medical research on human subjects;
Found Not Proved

12. a. You undertook, or caused to be undertaken, MRI and MRS scanning of healthy volunteers ("controls") as part of the Janssen and the Lilly First Episode studies during the period October 1997 to 2000 without ethics committee approval,
Found Proved

b. Your conduct in 12.a. above

i. was unethical,
Found Proved

ii. fell significantly short of the standards to be expected of a medical practitioner undertaking medical research on human subjects;
Found Proved

13. a. In 1997 you threatened to cease treating patient RL, who was enrolled in the Janssen First Episode study, if she withdrew from the study,

In light of the Panel's determination in relation to the Rule 27(1)(e)(i) submission the Panel did not consider this head of charge

b. Your conduct in 13.a. above was a gross breach of relevant ethical standards;

In light of the Panel's determination in relation to the Rule 27(1)(e)(i) submission the Panel did not consider this head of charge

Novartis INDDEX study

14. By a Letter of Agreement dated 29 April 1999 and signed by you on or about 7 June 1999 you were appointed Main Investigator for a Study on behalf of Novartis Pharmaceuticals UK Limited ("Novartis") bearing the Novartis Study code CENA713 IA07 and known as "A Prospective, Randomised, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Effect of Exelon on the Time to Clinical Diagnosis of Alzheimer's Disease in Subjects with Mild Cognitive Impairment" ("The INDDEX Study");
Admitted and Found Proved

15. a. You as PI ~~included, or were responsible for~~ intentionally acted so as to facilitate the inclusion of the Novartis INDDEX Study patients' data and the Novartis Cognitive Battery Case Report Form in an apparently additional and wholly separate trial or study initiated by you ~~and described by you as IOP-TS-30~~,
Found Proved (as amended)

b. Your actions at 15.a. above were

i. undertaken without the consent of Novartis,
Found Proved in relation to both the patients' data and the case report forms

ii. an unauthorised use of Novartis' intellectual property,
Found Proved in relation to the patients' data

iii. undertaken without the respective Novartis' patients' informed consent;
Found Proved in relation to the patients' data. This head cannot apply to the case report forms

c. You thereby acted in manner that

i. was dishonest,
Found Proved

ii. was unethical,
Found Proved

iii. was unprofessional;
Found Proved

~~16. a. You told SB of Novartis during the course of a "For Cause" Audit conducted by her between 9 -11 May 2001 into the Inddex study that study IOP-TS-30 was an Alzheimer's Society sponsored study,~~

~~b. To your knowledge the Alzheimer's Society had not at that stage made a decision whether to sponsor IOP-TS-30, and in fact never did sponsor the study,~~

~~c. Your actions at 16.a. above were~~

~~i. misleading,~~

~~ii. untruthful;~~

17. a. You knowingly generated the misunderstanding on the part of Novartis that the INNDEX study was to be conducted ~~at or~~ in connection with or otherwise affiliated to the IOP and thereafter was being so conducted,
Found Not Proved (as amended)

b. The study in fact

i. was being carried at Abbeydale Court, Walthamstow,
a private hospital unconnected to the IOP,
Found Proved

ii. was not being conducted at, in connection with or affiliated to the IOP in any official capacity, save for MRI scanning carried out at the Maudsley Hospital,
Found Proved

iii. was carried out without the knowledge of the appropriate personnel within the IOP,
Found Proved

iv. involved the use of IOP headed paper and IOP headed documentation without the appropriate knowledge or appropriate permission of the IOP,
Found Proved

v. was conducted without the appropriate Ethics Committee permission from the IOP/ Bethlem & Maudsley LREC,
Found Proved

c. Your conduct in 17.a. and 17.b.i. – v. above

i. was misleading towards Novartis,
Found Not Proved

ii. was dishonest towards Novartis,
Found Not Proved

iii. risked misleading patients,
Found Proved in relation to 17b (i)-(v) only

iv. risked compromising the legal status of staff employed by IOP,
Found Not Proved

d. During the course of the Audit you told SB

i. that Abbeydale Court was connected to the IOP,
Found Proved

ii. that you had discussed Ethics Committee approval with the IOP and that no IOP related Ethics Committee approval was required as no IOP patients were involved in the study,
Found Proved

e. Your statements at 17.d. above were

i. misleading,
Found Proved

ii. untruthful;
Found Proved

18. a. As PI for the INDDEX study you had overall responsibility for and supervision of the said study,
Admitted and Found Proved

b. During the course of the conduct of the study

i. there was an absence of appropriate source documentation as to patients' histories and eligibility to participate in the study,
Found Proved

ii. there was a lack of appropriate communication to patients' general practitioners,
Found Not Proved

iii. some of the patient records were incomplete or inadequate,
Found Proved

c. Your conduct in 18.a. and b. above fell significantly short of the standards to be expected of a medical practitioner managing and conducting medical research on human subjects;
Found Proved

Inddex Advertisement

19. a. On or about 28 October 1999 you applied to the Redbridge and Waltham Forest LREC for permission to recruit patients to the Inddex study by using a newspaper advertisement,
Admitted and Found Proved

b. The LREC provided to you a reasoned refusal of this application dated 16 November 1999,
Admitted and Found Proved

c. You were responsible for an "article" appearing in a local newspaper dated 9 December 1999, seeking to recruit patients into the study and providing contact details for prospective participants,
Found Proved

d. The article amounted to an advertisement, albeit in a different format, and was thus in contravention of the instructions provided to you by the LREC dated 16 November 1999,
Found Proved

e. Your conduct in this respect was

i. unprofessional,
Found Proved

ii. unethical,
Found Proved

ii. not in the best interests of the study or its patient recruits;
Found Proved

COGS – Sanofi study

IOP/Psychmed

20. a. From or about July 1999 onwards you communicated regularly with Dr S of Sanofi concerning the proposal, inception and consequent commencement and funding of the COGS study, (bearing the full title set out in 7.a. above),
Admitted and Found Proved

b. The COGS study draft but unsigned and unamended Clinical Trials Agreement ("the draft Agreement") defined certain terms including

i. you as "the Investigator", being of "Section of Cognitive Psychopharmacology, Institute of Psychiatry, Denmark Hill, London",
Found Proved

ii. "Clinical Trial", meaning "the investigation to be conducted by the Investigator at The Institute of Psychiatry, Denmark Hill, London", and,
Found Proved

iii. "Investigation Site", meaning "premises occupied by the Institute of Psychiatry, Denmark Hill, London",
Found Proved

c. The COGS study

i. was being carried out by Psychmed Limited ["Psychmed"], a private commercial company unconnected to the IOP but in which you had a significant interest,
Found Proved

ii. was not being conducted at, in connection with, under the auspices of or affiliated to the IOP in any official capacity,
Found Proved

iii. was being carried out without the prior knowledge or permission of the

appropriate personnel within the IOP such that you were in breach of your conditions of service with the IOP,
Found Proved

d. At no time prior to your contact with Dr B of Sanofi in late November 2000 did you inform in terms either Dr S or any other appropriate personnel from Sanofi that the COGS Study was in fact being conducted by Psychmed,
Found Proved

e. Your conduct in 20.a. to d. above

i. was misleading towards Sanofi,
Found Proved

ii. was dishonest towards Sanofi,
Found Proved

iii. was misleading towards the IOP,
Found Proved

iv. risked misleading patients;
Found Proved

COGS subset

21. a. By a letter dated 5 August 2004 from your solicitors RadcliffesLeBrasseur to the General Medical Council it was stated on your behalf that

i. the COGS Study "fell firmly within the remit" of an earlier Ethics Committee "broadly defined" approval granted for a Study entitled "*A Comparison of the Effects of Conventional and Novel Anti-psychotic Drugs on Cognitive Function Regional Cerebral Blood Flow and Basal Ganglia Volume"* by West Kent in 1996 under their reference 57/96, and
Admitted and Found Proved

ii. thereafter a number of further ethics committee approvals were obtained for more specifically designed studies "in which individual novel anti-psychotic medications were defined, so as to include Amisulpride, Quetiapine and Risperidone,"
Admitted and Found Proved

b. During the course of your regular communication with Dr S concerning the inception, planning and thereafter commencement of the COGS Study you at no time informed Dr S that the COGS Study was envisaged as being or was in fact linked in any way to any other Study,
Found Proved

c. Dr S agreed on behalf of Sanofi to make installment payments in relation to the COGS Study on the basis that the COGS Study was a stand alone Study,
Found Proved

d. As a consequence of 21.a., b. and c. above you thereby acted in a manner that was

i. dishonest,
Found Proved

ii. misleading;
Found Proved

Lilly "Switch"

22. a. On 28 September 1999 you signed a Letter of Agreement with Lilly in relation to your investigator initiated study entitled "*A Comparison of the effects of conventional antipsychotics, olanzapine and risperidone on basal ganglia size and regional cerebral blood flow using structural and functional magnetic resonance imaging in schizophrenia and related psychosis",* also known as IOP-TS-41. This document required you, among other things, to

i. "conduct the Study in accordance with the study protocol",
Admitted and Found Proved

ii. "furnish Lilly with a brief summary of the status of the Study on a quarterly basis",
Admitted and Found Proved

iii. "notify Lilly immediately of any changes in your status as the investigator",
Admitted and Found Proved

b. The study was not conducted in accordance with the protocol in that:

i. the number of scans per patient was different,
Found Not Proved

ii. the report referred to 6 weeks treatment on conventional antipsychotics before the study start; this was not specified in the protocol,
Found Not Proved

iii. the assessments undertaken on the patients were different,
Found Proved

c. In the interim report to Lilly of 8 December 2001 you said you had recruited

"20 normal control subjects matched to patient population". Such recruitment was not provided for by any protocol or amendment thereto for the study,
Found Proved

d. On 27 September 2002 you told SA of Lilly that normal controls were not part of the original study but that you had numerous normal control protocols and related ethics approvals for various paradigms; if you decided to leave the normal controls in the study, then the relevant paperwork regarding ethics approval would follow;
Found Proved

23. Your conduct in respect of 22.b. – d. above

In light of the Panel's finding in relation Head 22b this head has been considered in relation to 22c and d only

i. was inappropriate,
Found Proved

ii. was unethical,
Found Proved

iii. fell significantly short of the standards to be expected of a medical practitioner managing and conducting medical research on human subjects;
Found Proved

Further examples of inappropriate assertions / conduct re ethics approvals

24. a. At a meeting on 6 April 2001 at the IOP you told LC of the IOP that there are two types of study, one of which is an "Investigator ~~Initiated~~ Initiative Study" that can be performed without specific ethics committee approval,
Found Not Proved (as amended)

b. This assertion was

i. misleading,
Found Not Proved

ii. untrue;
Found Not Proved

25. a. On or about 21 August 1996 you, as PI, submitted to the Redbridge and Waltham Forest Ethics Committee an application form for ethics committee approval for a study entitled "*A study of cognitive effects and basal ganglia changes of conventional and atypical antipsychotics in schizophrenic patients*" (which involved treatment with clozapine and risperidone) along with a draft protocol with the same study title,
Admitted and Found Proved

b. The Redbridge and Waltham Forest Ethics Committee approved the study on 12 December 1996 under their reference LREC (R&WF) 51,
Admitted and Found Proved

c. On 13 January 1997 you signed an agreement with Janssen (as sponsor) to undertake as PI a study entitled "*Cognitive Efficacy and changes in basal ganglia volume in schizophrenia – effects of Risperidone and conventional antipsychotics",* also known as RIS-GBR-25,
Admitted and Found Proved

d. You thereafter provided to Janssen copies of letters from various ethics committees on the basis that they indicated approval for Janssen's study RIS-GBR-25, including the letter from Redbridge and Waltham Forest Ethics Committee under reference LREC (R&WF) 51,
Found Proved

e. These letters purportedly approved studies with various different study titles, such that in January 1997 Janssen sought, and were later provided with, a specific declaration from you that the various Ethics Committee approvals "appertained to" their study RIS-GBR-25,
Found Proved

f. You were obliged to obtain ethics committee approval for the RIS-GBR-25 study, by submitting applications in the name of that study protocol along with that study protocol to the various ethics committees,
Found Not Proved

g. In having failed to obtain ethics committee approvals as described in 25.f. above, you

i. acted in an inappropriate manner as regards the study sponsor,
Found Not Proved

ii. acted unethically,
Found Not Proved

iii. acted in a manner that fell significantly short of the standards to be expected of a medical practitioner managing and conducting medical research on human subjects;
Found Not Proved

Patient Recruitment

26. a. During 2003 in order to recruit patient participants into studies being conducted by you some patients were contacted variously

i. in an unsolicited fashion by telephone, in writing or in person,
Found Proved

ii. without prior contact with the medical practitioner, psychiatric nurse or care coordinator responsible for that patient's care,
Found Proved

iii. in terms that offered and made financial inducements to participate in a study beyond reimbursement of travel expenses,
Found Not Proved

iv. without providing adequate information to the prospective participant,
Found Proved

~~v. without, having recruited a patient to participate in a study, thereafter informing the medical practitioner, psychiatric nurse or care coordinator responsible for that patient's care of the patient's involvement in a study and whether that involvement involved taking medication~~,

~~b. Some patients so recruited at 26.a. above were offered or were prescribed study medication~~,

c. In about February 2003 you were contacted by CB, Team Manager at Kingswood Community Health Centre ("Kingswood") and told that Kingswood would not co-operate in your study and that you would have to go through the proper channels (meaning via Dr Sa, Medical Director of West Kent NHS and Social Care Trust) before any patients would participate in a further study conducted by you,
Found Not Proved

d. Regardless of that instruction at 26.c. above you nonetheless continued to try to recruit patients into your studies without first informing the appropriate Kingswood medical staff,
Found Not Proved

~~e. You retained patient data gained from the conduct of earlier studies beyond the conclusion of those studies,~~

f. You were responsible for the actions at 26.a~~., b.,~~ and d. ~~and e.~~ above either personally or as PI or as the person otherwise in charge of those studies or prospective studies,
Found Proved (as amended)

g. By your conduct and responsibility at 26.a, ~~, b. and~~ d. and f. above you acted in a manner that
(as amended)
In light of the Panel's finding in relation to Head 26a(iii) and d this head of charge was only considered in relation to Head 26(i), (ii) and (iv).

i. was unprofessional,
Found Proved

ii. risked compromising patient care,
Found Proved

iii. risked compromising patient welfare,
Found Proved

iv. was outside the terms of relevant Ethics Committee approval,
Found Not Proved

v. was unethical;
Found Proved

And that in relation to the facts alleged you have been guilty of serious professional misconduct.
Guilty of Serious Professional Misconduct

Determination on the facts:

Dr Sharma:

The Panel has given detailed consideration to all the oral and documentary evidence adduced in the course of this hearing and has taken into account the submissions made by both Miss Glynn and by you.

The Panel has well in mind that the burden of proof rests on the General Medical Council and that you do not have to prove anything. The standard of proof required is that before an allegation can be found proved the Panel must be satisfied so that it is sure that it has been proved.

The Panel has kept in mind throughout its deliberations that you are unrepresented and that you have been undertaking your own defence in this long and complex hearing, which has been spread over many months. The Panel has made allowance, where it thinks appropriate, for the difficulties faced by you in conducting your own defence and has borne in mind that you needed and were given, additional time during the course of the hearing to prepare your defence as the evidence unfolded. In particular the Panel has noted that a feature of this case is that at intervals during the hearing you have produced a number of documents. It has taken into account what you have said about the difficulties you have had in obtaining these documents.

You have in the course of written submissions to the Panel, although not repeated orally, made a number of serious allegations against the GMC and Counsel appearing on its behalf. These include that the Panel has been misled, that the evidence has been suppressed or distorted and that the GMC did not call witnesses who may have assisted

your case. However, the Panel is satisfied that the GMC and its legal team have conducted this case with exceptional fairness and it was open to you to put your case in cross examination of witnesses and to call any witnesses you chose, to advance your case. The essence of this part of your submission would appear to be that the GMC have misunderstood and misinterpreted the evidence in this case.

The Panel has noted that the allegations concern events which took place several years ago. It is aware that the longer the time that has elapsed since an alleged incident the more difficult it may be for you to answer it. When deciding whether the Panel is sure that a fact has been made out it has kept in mind whether the time lag has put you at a disadvantage in putting your case or could otherwise prejudice your defence.

In this case because you are unrepresented the Panel has given reasons for its findings in some detail.

The Panel has considered each head and sub-head of charge separately. It has made the following findings on the facts:

Head 1 has been admitted and found proved.

PhD thesis

Head 2a has been found proved.
Professor N confirmed that you were interviewed by an appointments board and that on 30 July 1999 you were offered the Chair in Psychiatry, at University College, London University, subject to conditions which included the successful completion of your PhD. You did not dispute this.

Head 2b has been found proved.
Professor N's evidence was that in the course of your interview you said that you would submit your PhD thesis by the end of September 1999. Professor G was your registered supervisor; your thesis should have been submitted to him. This was also not disputed by you.

Head 2c has been found proved.
Head 2d has been found proved.
Head 2e has been found proved.
You did not dispute Professor M's evidence that you informed him in August 2000, on 10 May 2001 and on 4 June 2001 that you had given Professor G some of the chapters of your thesis.

Head 2f has been found proved.
Professor G's evidence was that no chapters of your thesis were submitted to him at any time. Although Professor G holds an unfavourable opinion of your organisational abilities the Panel found him to be a reliable witness.

In your defence you referred the Panel to the e-mail from your secretary AB, addressed to you, dated 27 July 2000. This e-mail was not shown to Professor M or Professor G at the

time. Indeed the first occasion on which it was produced to them was in the course of this hearing and then at a late stage. It was necessary to recall them to give further evidence in this regard. The Panel finds it extraordinary that such a document would not have been produced by you for them to comment soon after its receipt. As a consequence the Panel has serious doubts about the authenticity of this document and can place little probative value on it. In addition you did not reply to LW's e-mail to you, dated 3 July 2000 which specifically enquired as to the progress of your PhD thesis. Furthermore, although at the outset you contended that some chapters of your thesis were sent to Professor G by e-mail, as the evidence unfolded you changed your ground to the effect that it had in fact been sent by post. Professor G's evidence was that he did not receive any chapters either by e-mail or by post.

In the light of the evidence the Panel is satisfied that you never submitted any chapters of your thesis to Professor G at anytime.

Head 2g(i) has been found proved.
Head 2g(ii) has been found proved.

Head 3a as amended to read 'You described yourself as "Tonmoy Sharma MD PhD" on websites, including that of a company in which you had a controlling interest' has been found proved.

Head 3b(i) has been found proved.
Head 3b(ii) has been found proved.
It is not disputed that you described yourself as "Tonmoy Sharma MD PhD" on websites, including that of a company in which you had a controlling interest.

In your defence to 3b(i) and (ii), you have submitted that you have a Doctorate of Science which is equivalent to a PhD. The evidence before the Panel is that you have a DSc from Canterbury University, a foreign based institution with an office in India. You contended that a DSc is at least equivalent to a PhD and that the degrees are in effect interchangeable. However in evidence you agreed that Canterbury is not a prestigious university and that the doctorate was obtained without the academic rigour necessary for the award of a PhD by a reputable university. The Panel is satisfied that you have not obtained a PhD within the usually accepted definition. In representing that you had a PhD you acted both dishonestly and unprofessionally. In determining this the Panel has taken into account that at the relevant time you were experienced in supervising PhD students and were well aware of the rigours involved in obtaining a PhD at a reputable academic institution.

Professor Sharma
Head 4a has been admitted and found proved.

Head 4b has been found proved.

Head 4c(i) has been found **not** proved.
Head 4c(ii) has been found **not** proved.

There is no dispute that in 2002 you were invited by Professor K to present lectures as a 'visiting professor' at Pittsburgh University in the United States of America. On the basis of this invitation, from January 2002 you referred to yourself as "Professor Tonmoy Sharma" in professional correspondence with people working in the medical field, including the Chairman of an Ethics Committee.

At the outset of this hearing you accepted that this was not a formal appointment. Your evidence has been that although you now realise that this was not a formal appointment you were not aware of this at the time. You were also not aware at that time that there was a formal process for obtaining a professorship.

The Panel was not satisfied so that it could be sure that you knew or ought to have known that the use by you of the title 'professor' in such circumstances was misleading and not accepted practice amongst academics in the United Kingdom. In this context you said in your evidence that when you did become aware that this was not a formal appointment you ceased to use the title.

Misrepresentations about ethics approval

Head 5a has been admitted and found proved.

Head 5b(i) as amended to read 'an application dated 4 April 2000 to the Dartford and Gravesham Local Research Ethics Committee ("D&G 23/00") for approval for a study entitled "*Clinical Efficacy and side effects of Ziprasidone in Recent Onset Psychosis: a cognition and functional magnetic resonance (fMRI) Study*", with the study Protocol containing at section 6 an assertion that the applicants have ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol",' has been found proved.

Head 5b(ii) as amended to read 'an application made in April 2000 to the Maidstone Local Research Ethics Committee ("23/00M") for approval for the study named in 5.b.i. above, with the study Protocol containing at section 6 an assertion that the applicants have ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol",' has been found proved.

Heads 5b(i) and (ii) refer to the assertion that the applicants have ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol". The assertion was made to two different Local Research Ethic Committee's. You do not dispute that you were the principal investigator and that you were therefore responsible for the accuracy and contents of the application.

You have submitted that the assertion in the protocols meant no more, than that the 'component' (sic) parts of the protocol had been approved by the Bethlem and Maudsley Ethical Committee.

Professor S in Part 2 of his report at Section 3 states that the assertions made to Dartford and Gravesham Research Ethics Committee and the Maidstone Research Ethics Committee could be expected to be interpreted as meaning the whole study as described

in the Protocol had already been approved by Bethlem & Maudsley Ethics Committee.

The Panel concurs with Professor S's opinion. You were the Principal Investigator and you had a duty not to mislead the ethics committee. The Panel found that your use of the word 'studies' and your failure to elaborate or explain the relevance of the statement is extremely significant.

Head 5b(iii) as amended to read 'an application made on or about 23 June 2000 to the Dartford and Gravesham Local Research Ethics Committee ("D&G 30/00") for approval for a study entitled "*A Naturalistic multimeasure study of clinical and cognitive efficacy of Amisulpride, Quetiapine, Risperidone and Olanzapine in Schizophrenia*", with the study Protocol containing at section 6 an assertion that the applicants have ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol",' has been found proved.

The application in Head 5b(iii) had a different study title but similar principles apply. You were the Principal Investigator for this application to Dartford and Gravesham Ethics Committee for approval of the Switch Study. The Study Protocol had not been approved by the Bethlem & Maudsley Ethics Committee at that time. The only Bethlem & Maudsley ethics approvals which could have been relevant based on the drugs involved were 234/95 and 142/96. The Panel has determined that these are different studies as they both have different methodologies and fall short of the basic principles behind obtaining ethics approval. The Panel again concurs with Professor S that, 'it is even difficult to see how cutting and pasting from the disparate Bethlem & Maudsley approvals could make a similar 'jigsaw'' (Addendum 2 paragraph 6.5). The Panel is therefore satisfied that there was no valid approval by the Bethlem & Maudsley Ethics Committee for this study. It finds that your assertion was misleading, that you were untruthful and that your conduct falls short of the standards expected of a medical practitioner undertaking medical research on human subjects.

In the light of the above findings Head 8a, 8b and 8c have been found proved in relation to Head 5 in its entirety.

Head 6a has been found proved.
Head 6b has been found proved.
Head 6c has been found proved.
The evidence is that the Bethlem and Maudsley ethics approval 069/99 was not appropriate to the proposed Alzheimer's Society study. Among other matters it did not provide for the use of any drugs.

Furthermore the Bethlem and Maudsley ethics approval 131/00, which would have been appropriate, was not granted until January 2001, whereas the application and assertion to the Alzheimer's Society had been made on 4 May 2000.

You have contended that the assertion was made in the erroneous belief that there was an appropriate ethics committee approval. You point to the 131/00 application as having been made when you realised this. You did not raise this contention until late in the hearing;

significantly this was after the evidence of Professor S had made it clear that 069/99 was not appropriate.

The Panel rejects your explanation and is satisfied that your assertion to the Alzheimer's Society that there was ethics committee approval for the study was not made in error and that you made it knowing it to be untrue.

Head 8a has been found proved in relation to Head 6 in its entirety.
Head 8b has been found proved in relation to Head 6 in its entirety.
Head 8c has been found proved in relation to Head 6 in its entirety.

COGS EC approval

Head 7a has been found proved.

Head 7b(i) has been found **not** proved.
Head 7b(ii) has been found **not** proved.
It is accepted that as this is an investigator initiated study, a protocol specific to the COGS study and its two drugs would not need to be submitted to the ethics committee. You have submitted that this assertion referred to Bethlem & Maudsley 142/96. The letter from MC to you dated 18 October 1999 confirms that you were notified that the addition of Amisulpride to Bethlem & Maudsley study 142/96 had been approved by the Chairman of the ethics committee.

Head 7b(iii) has been found proved.
You sent a study report dated 3 October 2000 to Dr B of Sanofi. The report stated that ethical approval had been sought from and granted by the South London & Maudsley NHS Trust for the research to be conducted. You have again relied upon Bethlem & Maudsley 142/96. The assertion in the report was not correct as none of the patients came from the South London & Maudsley catchment area. The report is in your name and it is clear that you were responsible for its contents as the evidence is, that it was modified by you and returned to TH in its amended form on 6 October 2000.

Head 7b(iv) has been found proved.
You informed Dr B and Dr Bo that the COGS study was covered by ethics approval 30/00 Dartford and Gravesham and in support, provided the letter dated 4 September 2000. The Panel is satisfied that at least 6 patients were recruited in the study by 17 July 2000 and that some 10 or 11 patients had already been 'ascertained' before ethical approval was granted on 23 August 2000.

Head 7b(v) has been found proved.
The assertion in your letter to Dr R dated 6 June 2001 was incorrect. The Panel is therefore satisfied that by making this assertion you misled Sanofi.

In the light of the evidence the Panel is satisfied that the funders had a right to know that ethics approval had been granted for the studies that they were funding. Sanofi had a duty to check that the appropriate ethics permissions had been granted. At the relevant time you

had been undertaking research for a significant period; you were an experienced researcher. It was therefore not only misleading but untruthful to state that there was ethics approval when it was clear that this was not the case.

Head 8a has been found proved in relation to Heads 7a, 7b(iii), 7b(iv) and 7b(v) only.
Head 8b has been found proved in relation to Heads 7a, 7b(iii), 7b(iv) and 7b(v) only.
Head 8c has been found proved in relation to Heads 7a, 7b(iii), 7b(iv) and 7b(v) only.

First Episode studies

Ethical approval is required for any specific patient study. An ethics committee has a duty to ensure that a study is ethically sound. It must be satisfied that the study is scientifically valid and that patients are adequately protected. This latter requirement includes ensuring that patients are not over exposed to testing. This is described by Professor S as the 'no jigsaw/total burden principle'. The ethics committee must be made aware of the total burden of patient exposure to testing, not only at the time of the original application but also at any subsequent application, to extend the scope of the study, however made.

Head 9a has been admitted and found proved.
Head 9b(i) has been found proved.
Head 9b(ii) has been found proved.
Head 9b(iii) has been found proved.

Head 9c has been found proved.
At the outset of the hearing you accepted that Janssen First Episode Studies protocol did not provide for patients to be scanned. However you contended, in reliance on 142/96 that there was generic approval for the scanning of patients with schizophrenia. The Panel is satisfied from the documentary evidence before it that 142/96 as amended, was approval for a switch study only. This did not include the Janssen First Episode Study. In reaching this conclusion the Panel has further accepted the evidence of MC that there would be an audit trail whenever there was approval for an amendment to a granting of ethics approval. There is therefore no documentation to indicate any such amendment approving scanning for Janssen First Episode patients.

The Panel also considered the letter from Dr Ro ('Ro letter' at DB-55), who was then your Registrar, dated 7 January 1997, which you produced for the first time at a late stage in the course of the hearing, on 11 January 2008. You relied on this letter to show that permission had been sought, and by implication subsequently granted, to amend 142/96 to permit scanning on First Episode Study patients. This letter is not supported by any other documentation. The Panel therefore has serious doubts about the authenticity of this document. In particular there is no reference to it or to its contents in the Bethlem and Maudsley minutes. Moreover, Dr Ro has no recollection of having written it. The Panel places little probative value upon it.

Head 9d has been found proved.
The Panel accepts TH's evidence that her schedule indicates that 5 patients were recruited between 4 February 1997 and 15 May 1997.

In undertaking this study without ethical approval your conduct was unprofessional, unethical and not in best interests of the study patients. Therefore Heads 9e(i), (ii) and (iii) have been found proved.

Head 10a has been admitted and found proved.

Head 10b has been found proved.

Head 10c(i) has been found proved.
Head 10c(ii) has been found proved.
The evidence of Dr Do was clear and cogent. It was to the effect that additional tests, beyond those specified in the protocol were conducted on Janssen First Episode Patients. Also, that further Case Report Forms were completed for Janssen and Lilly patients additional to those provided for in the protocols relevant to each group of patients. The evidence of DM and TH confirmed that the additional testing was undertaken pursuant to your instructions.

Head 10d has been found proved.
You have not disputed this head of charge but your case has been that you were doing no more than taking necessary steps to preserve the confidentiality of the Janssen and Lilly studies by ensuring that neither sponsor was aware of the others study. The Panel whilst acknowledging the importance of confidentiality, has heard in evidence and accepted, that sponsors are usually informed that competing studies are being undertaken, although of course the specific details of a study should remain confidential. This is clearly the evidence of Professor W, GH, Professor S, Dr Do and DM.

Head 10e has been found proved.
The Panel is satisfied that in acting as you did in 10d above, your intention was to conceal from each sponsor the fact that you were using the identical group of patients for their studies. Your intention was to publish based on the pooled data without disclosing to the sponsor the nature of its source.

In December 2007 you produced to the Panel DB-26 page 3 and DB-24 to support that in December 1998 and February 1999 Lilly were aware of the Janssen First Episode Study. This has no bearing on the position during 1997 and earlier in 1998 in the evidence provided by those working on the two studies.

It is clear from the evidence that you knew that you were asking your staff to conduct activities which were outside that which had ethics committee approval. You did not have ethics committee approval to conduct the additional tests. As a consequence the Janssen patients were subjected to tests beyond those approved. Furthermore, these were sponsored studies and the intellectual property was owned by the pharmaceutical companies. The Panel is satisfied that your conduct towards them was dishonest. It was also unprofessional and not in the best interests of the study patients.

In view of the above findings Heads 10f(i), (ii) and (iii) have been found proved.

Head of Charge 11
The Panel has heard that Professor Ku conducted pre-pulse inhibition tests on Janssen and Lilly First Episode patients. There was no ethical approval for such testing on these specific patients and consequently no appropriate informed consent could be obtained. However the Panel is not satisfied that you permitted these tests to be conducted. It therefore finds,
Head of charge 11a has been found **not** proved.
Head of charge 11b has been found proved.
Head of charge 11c has been found proved.
Head of charge 11d has been found **not** proved.

Head 12a has been found proved.
Head 12b(i) has been found proved.
Head 12b(ii) has been found proved.
The Panel is satisfied by the evidence of TH, that as shown in her schedule, healthy controls were recruited specifically into this study and that they were scanned as Janssen First Episode Patient controls. Moreover Dr H's evidence, which the Panel accepts, was that as a healthy control he underwent scanning.

In the light of the Panel's earlier determination in relation to the Rule 27(1)(e)(i) submission the Panel has **not** considered Head 13.

Novartis INDDEX study

Head 14 has been admitted and found proved.

Head 15a has been amended to read, 'You as PI intentionally acted so as to facilitate the inclusion of the Novartis INDDEX Study patients' data and the Novartis Cognitive Battery Case Report Form in an apparently additional and wholly separate trial or study initiated by you and described by you as IOP-TS-30.' This head of charge has been found proved, save for the phrase 'and described by you as IOP-TS-30'.

The evidence indicates that it was intended that the Inddex data should be used as part of a larger 'overall' study. Dr So's unchallenged evidence was that the aim was to recruit 30 patients for Inddex and that the additional files were to be used in conjunction with the Novartis Inddex files in a separate study after the Inddex study was unblinded. He further said that IOP-TS-30 was a study of healthy controls and that in the course of the study they used the same scales as were used in the Inddex study. Dr So's e-mail dated 3 July 2002 sets out a list of those scanned for Inddex and TS-30. In effect it indicates that although the controls were specific to the Inddex study, the data and that of the Inddex patients were to be amalgamated into one overall study.

The Panel found the evidence of SB, JS and Professor W to be supportive of that of Dr So and to be a clear indication of what was intended.

Head 15b(i) has been found proved in relation to both the patients' data and the case

report forms.
Head 15b(ii) has been found proved in relation to the patients' data only.
Head 15b(iii) has been found proved in relation to the patients' data only.
The Panel is satisfied by the evidence that the intellectual property in the patients' data, but not the case report forms which are available in the public domain, belonged to Novartis. Novartis had not given its consent for you to use this data and your use of it was unauthorised.

The Panel is satisfied that your actions were dishonest and as a consequence were unethical and unprofessional. Therefore
Head 15c(i) has been found proved.
Head 15c(ii) has been found proved.
Head 15c(iii) has been found proved.

Head 16 has been withdrawn.

Head 17a as amended to read, 'You knowingly generated the misunderstanding on the part of Novartis that the INDDEX study was to be conducted in connection with or otherwise affiliated to the IOP and thereafter was being so conducted,' has been found **not** proved.

The minutes of a meeting held on 11 April 2001 attended by SB and SV record, 'that Novartis had known that Psychmed was a separate entity from the IOP and were happy to contract with it on that basis'. This is supported by a letter from SB dated 19 April 2001 addressed to you at Abbeydale Court. Furthermore, there is clear evidence that the CRO and Ingenix were aware that the study was being conducted at Abbeydale Court.

Head 17b(i) has been found proved.
Head 17b(ii) has been found proved.
Head 17b(iii) has been found proved.
Head 17b(iv) has been found proved.
The evidence of Professor M and LC, secretary to the IOP and the minutes of the meeting on 11 April 2001 was that Psychmed and the IOP were two independent organisations with no formal connection. In her evidence, LC indicated that there was no record of the Inddex study on the books of the IOP. Furthermore she had no knowledge of the Inddex Study until April 2001. The Panel is satisfied by the evidence of LC's that IOP headed paper should not have been used in correspondence other than for IOP purposes.

Head 17b(v) has been found proved.
It was accepted by you that the Inddex study did not have ethics committee approval from the IOP/Bethlem and Maudsley Local Research Ethics Committee.

Head 17c(i) has been found **not** proved.
Head 17c(ii) has been found **not** proved.
Head 17c(iii) has been found proved in relation to 17b (i)-(v) only.
Despite not having the appropriate ethics approval your use of the IOP letter headed paper for the patient information sheets and consent forms could lead patients to believe that this

was an IOP study.

Head 17c(iv) has been found **not** proved.
The e-mail from SV dated 31 August 2000 (DB-26 page 11), was to the effect that there were Novartis' indemnities in place for the Inddex study at Abbeydale Court and the members of the research team. The Panel is therefore not satisfied that your conduct risked compromising the legal status of the staff employed by the IOP who were working at Abbeydale Court.

Head 17d(i) has been found proved.
Head 17d(ii) has been found proved.

Head 17e(i) has been found proved.
Head 17e(ii) has been found proved.
You have not disputed that you told SB that Abbeydale Court was 'connected' to the IOP. You agreed that you discussed with her the issue of IOP approval and informed her that as no patients from the IOP were involved and that Local Research Ethics Committee approval was not required. The Panel has found that there is no evidence in the IOP records that there was such a discussion. Furthermore, the Panel is satisfied that ethics approval by the IOP was required. Your assertion was therefore misleading and untrue.

Head 18a has been admitted and found proved.

Head 18b(i) has been found proved.
The patients' record should have contained a checklist of the exclusion criteria and a letter from or a note of a telephone conversation with the general practitioner to the effect that he had considered and approved the checklist. There were no patient histories from any external sources to support the patients eligibility for the trial. The suitability of the patients for the trial could therefore only be assessed by the information given by the patient and his carer. The Panel is satisfied that the general practitioner input was essential. A patient, particularly a vulnerable patient or his carer would be unable to provide sufficient and reliable information for an accurate decision to be made about his suitability for the study.

Head 18b(ii) has been found **not** proved.
There are before the Panel copies of letters sent to general practitioners. The Panel was therefore not satisfied that there was a lack of appropriate communication.

Head 18b(iii) has been found proved.

In his evidence VM referred to his monitoring report 7 (C5A Tab 2 page 79, where he recorded that in relation to three patients there was no previous medical history or GP notes. Furthermore the Novartis final For Cause Audit Report (C5A Tab 7 page 113) recorded that for all patients no patient histories from external sources (GP's) were available to support eligibility for the trial.

In the light of the above findings Head 18c has been found proved.

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Inddex Advertisement

Head 19a has been admitted and found proved.

Head 19b has been admitted and found proved.

Head 19c has been found proved.

Head 19d has been found proved.

Head 19e(i) has been found proved.
Head 19e(ii) has been found proved.
Head 19e(iii) has been found proved.
As the Principal Investigator of the study responsibility for the 'article' lies with you. The article contains a specific quote attributed to you. Although in your evidence you said that you were unable to remember whether or not you spoke to the journalist, the Panel is satisfied that you would not have allowed a member of your team to conduct such an interview with a reporter. You were experienced in giving interviews and given that you were specifically instructed by an ethics committee not to advertise you should have been more careful in what you said.

The Panel is satisfied that the 'article' amounted to an advertisement which contravened the instructions from the Local Research Ethics Committee on 16 November 1999. The article may have led to a patient contacting you directly to participate in a study without a general practitioner being aware of such contact. This could not be in the best interests of such a patient.

COGS – Sanofi study
IOP/Psychmed

Head 20a has been admitted and found proved.

Head 20b(i) has been found proved.
Head 20b(ii) has been found proved.
Head 20b(iii) has been found proved.

Head 20c(i) has been found proved.
Head 20c(ii) has been found proved.
Head 20c(iii) has been found proved.
Your salary was being paid through and was controlled by the IOP. The actual source of your salary is irrelevant. You would not have been subject to the IOP disciplinary procedures unless you were an IOP employee. The Panel is satisfied that you were an employee at the IOP and that the terms and conditions of service applied. In accordance with your contract of employment you had an obligation to inform appropriate personnel within the IOP about the COGS study. This you did not do.

Head 20d has been found proved.

The Panel found Dr S to be a honest and credible witness. It is clear from his evidence that his understanding was that on behalf of Sanofi he was contracting with the IOP, where the trial was to be conducted. There was nothing in the correspondence between you and Dr S to indicate that in reality the contract was with your research company Pyschmed rather than with the IOP.

The Panel accepts Dr S's evidence in regard to your letter to him dated 17 July 2000 on Pyschmed headed paper (C3A Tab 6 page 118), that he assumed Pyschmed to be a payment conduit to the IOP. The e-mails that appear at DB-26 pages 18-21, between you and AB were not copied to Dr S and he was therefore unaware of their contents.

Head 20e(i) has been found proved.
Head 20e(ii) has been found proved.
Head 20e(iii) has been found proved.
Head 20e(iv) has been found proved.
By failing to inform Sanofi through Dr S or otherwise, that the study was being conducted by Pyschmed you misled Sanofi into believing that it was funding a study at the IOP. You further misled the IOP by failing to disclose the fact that you were conducting the study on behalf of Pyschmed. Moreover your use of patient information sheets relevant to the study which referred to it as being conducted at the IOP could have led patients to believe that this was an IOP study.

COGS subset
Head 21a(i)has been admitted and found proved.
Head 21a(ii) has been admitted and found proved.

Head 21b has been found proved.
Head 21c has been found proved.
The Panel is satisfied that Dr S was not aware at the time that COGS was to be anything other than a stand alone study comparing the efficacy of their drug Amilsulpride with their competitor drug Olanzapine. It was on the basis that the COGS was a stand alone study that Sanofi made instalment payments.

The Panel is satisfied that if as you agree, COGS was being conducted by you as part of a wider study, you had a duty to make this clear to Sanofi. In the light of these findings head 21d(i) and (ii) have been found proved.

Lilly "Switch"
Head 22a(i) has been admitted and found proved.
Head 22a(ii) has been admitted and found proved.
Head 22a(iii) has been admitted and found proved.

Head 22b(i) has been found **not** proved.
The Panel is not satisfied that the number of scans per patient was different. The evidence indicates that three scans were conducted; this accords with the provision in the protocol.

Head 22b(ii) has been found **not** proved.

There were three patient groups which were switched from conventional antipsychotics. Although this is not specifically stated in the protocol, it was implicit for there to be any useful comparison.

Head 22b(iii) has been found proved.
The evidence indicates that the assessments which were being undertaken were different. However, the tests being performed were scientifically more valid and although the change should have been discussed with Lilly the Panel has found that this is not a significant failing on your part as it would have resulted in a more comprehensive study.

Head 22c has been found proved.
Head 22d has been found proved.
The interim report of 8 December 2001 and SA's oral evidence supports these heads of charge. Your letter dated 2 October 2002 to SA indicates that healthy volunteers who were not historical controls were entered into this specific study. Professor S's evidence was that you should not have implemented a change to the protocol without obtaining the appropriate ethical approval. The Panel accepts that whilst the change may have been for scientifically valid reasons ethical approval should have been obtained.

In the light of the Panel's finding in relation Head 22b this head has been considered in relation to 22c and d only. Accordingly
Head 23(i) has been found proved.
Head 23(ii) has been found proved.
Head 23(iii) has been found proved.

Further examples of inappropriate assertions/conduct in relation to ethics approvals

Head 24a as amended to read, 'At a meeting on 6 April 2001 at the IOP you told LC of the IOP that there are two types of study, one of which is an "Investigator Initiative Study" that can be performed without specific ethics committee approval,' has been found **not** proved.

Head 24b(i) has been found **not** proved.
Head 24b(ii) has been found **not** proved.
The Panel agrees with Miss Glynn's concession that there is insufficient evidence for the Panel to find this head of charge proved.

Head 25a has been admitted and found proved.

Head 25b has been admitted and found proved.

Head 25c has been admitted and found proved.

Head 25d has been found proved.

Head 25e has been found proved.

In the course of her final submissions Miss Glynn applied under Rule 24(4) to amend Head

of Charge 25 f and g. She has conceded that as Janssen switch was a hybrid of a sponsored and investigator initiated study, there is no requirement for the application to be in the same name as the protocol or even for a protocol to be submitted. She therefore submits that the head of charge should be amended to reflect the basis of conduct on which this allegation is based. This she says is the misleading nature of the 'declaration' in Exhibit 4B/4. Miss Glynn has contended that you have always been aware of the thrust of the GMC's case under this head of charge and that there would be no unfairness or injustice to you if the charge were to be amended.

You have opposed the application. You have submitted that it is made late in the day; that it was apparent as long ago as July 2007, in the course of Professor S's evidence, that the evidence did not support the charge. Moreover had the charge been amended in early course you could have cross examined GH to deal with it. As a consequence you have been deprived of the opportunity to put your defence to this aspect of the charge.

Rule 24(4) enables the Panel, where at any stage it appears that a charge should be amended, to make such amendments that appear necessary or desirable provided that the Panel is satisfied that no injustice would be caused.

The Panel has considered the nature of the proposed amendment. The Panel has determined that the application to amend could and should have been made earlier, certainly before the close of evidence. If the proposed amendment were allowed you would have been deprived of an opportunity in the course of cross examination to deal with the charge as amended. The Panel cannot be satisfied that no injustice would be caused to you as a consequence. The Panel has therefore rejected Miss Glynn's application to amend this head of charge.

Head 25f has been found **not** proved.

Head 25g(i) has been found **not** proved.
Head 25g(ii) has been found **not** proved.
Head 25g(iii) has been found **not** proved.

Patient Recruitment

Head 26a(i) has been found proved.
Head 26a(ii) has been found proved.
There is clear evidence from patients RN and PB, Dr Ke, Dr He, and Dr Ar that patients were approached in an unsolicited fashion in that there was no prior contact with the medical professional responsible for the patient's care. In particular Patient PB first participated in the Janssen switch study in May 1997, she was then approached by a member of your team some years later in May 2003 and asked to participate in a different study. Her details were obtained from a database created when she first participated in the Janssen Switch study.

Head 26a(iii) has been found **not** proved.
Application forms for Local Research Ethics Committee approval require details of

payments to patients. The evidence before the Panel in relation to studies M57/96 and 142/96, (Local Research Ethics Committee applications in C2C, Tab 14 - page 28 and Tab16 – page 3) refer to payments of £10 in one case and £15 in the other. By implication these sums represent no more than compensation for the time taken to participate in the study. The Panel is therefore not satisfied that the use of the term 'remuneration' amounts to a financial inducement to patients to participate in a study.

Head 26a(iv) has been found proved.
Having taken into account the particular vulnerability of the prospective participants the Panel is satisfied that you did not provide adequate information to them. Patient PB believed that she was a participant in the study and given her vulnerability she should have been provided with more than just a leaflet. As a researcher you have a duty to ensure that a patient or participant has sufficient opportunity to consider all of the information that has been provided and that they are able to come to a reasoned decision.

Head 26a(v) has been withdrawn.

Head 26b has been withdrawn.

Head 26c has been found **not** proved.

Head 26d has been found **not** proved.
Although there is evidence that the letter was sent to you by CB the Panel is not satisfied that there is evidence to show that you received it. Furthermore in the absence of a reply from you it is likely that there could have been a follow up from CB. There is no evidence of this.

Head 26e has been withdrawn.

Head 26f as amended to read, 'You were responsible for the actions at 26a and d above either personally or as PI or as the person otherwise in charge of those studies or prospective studies,' has been found proved.

The stem of Head 26(g) was amended to read, 'By your conduct and responsibility at 26a, d and f above you acted in a manner that ' and then are the five sub heads.

In the light of the Panel's finding in relation to Head 26a(iii) and d this head of charge was considered only in relation to Head 26a(i), (ii) and (iv).

Head 26g(i) has been found proved.
Head 26g(ii) has been found proved.
Head 26g(iii) has been found proved.
Head 26g(iv) has been found **not** proved.
Head 26g(v) has been found proved in the context that you did not comply with ethical guidelines for research.

Throughout this determination save for head of charge 26g(v), the Panel, where it has

found proved that your conduct was unethical, it has done so in the context of its finding that you acted without ethics committee approval.

Having reached its findings on the facts, the Panel then considered whether the facts found proved either individually or cumulatively would be insufficient to support a finding of serious professional misconduct. The findings of the panel indicate serious failings of personal integrity and honesty, of good clinical research practice, in regard to the potential welfare of patients and participants in ethical research and of appropriate standards of commercial behaviour, which risk bringing the reputation of medical profession into disrepute and thereby undermining the public and commercial confidence in research. The Panel has therefore found that the facts proved against you would not be insufficient to support a finding of serious professional misconduct.

The Panel will now invite Miss Glynn to adduce evidence, if she wishes to do so, as to the circumstances leading up to the facts which have been found proved, the extent to which those facts indicate serious professional misconduct on your part and as to your character and previous history. After that, the Panel will invite you to address them on those matters and also to adduce evidence in mitigation, if you wish to do so. When making submissions on sanction both Miss Glynn and you are reminded that reference to the Indicative Sanctions Guidance should be made.

The Panel will then proceed to consider whether you have been guilty of serious professional misconduct in respect of those facts that have been found proved against you, and, if so, they will go on to consider whether or not they should make any direction regarding your registration.

Determination on Serious Professional Misconduct and Sanction:

Dr Sharma:

The Panel has considered this case in accordance with the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988.

The Panel has heard that between May 1995 and August 2001 you held the positions of Clinical Lecturer and later Clinical Senior Lecturer at the Institute of Psychiatry, King's College, University of London.

On 30 July 1999 you were offered the Chair in Psychiatry at the Department of Psychiatry and Behavioural Sciences at the University College, London University, subject to conditions which included the successful completion of your PhD. You told the Appointments Board that you would submit your PhD thesis by the end of September 1999. The thesis was to be submitted to Professor G, your PhD supervisor. In August 2000 you told Professor M (Professor of Psychiatry at the Institute of Psychiatry) that you had given Professor G some of the chapters of your thesis. On 10 May 2001 you stated again to Professor M that you had given Professor G some of the chapters of your thesis. On 4 June 2001 you informed Professor M by email that you had sent draft chapters of your thesis by

email to Professor G. The Panel has found that the statements made to Professor M were untrue in that at no time did you submit any chapters of your thesis to Professor G. The Panel has therefore found that you lied to Professor M, on three occasions. The public expects doctors to conduct themselves honestly and with integrity in all aspects of their professional activities. The Panel has found your conduct in lying to Professor M to be dishonest and unprofessional.

You described yourself as 'Tonmoy Sharma MD PhD' on websites, including that of a company in which you had a controlling interest. You had not been awarded a PhD. You were a supervisor of PhD students and were well aware of the academic rigour necessary to achieve the award of such a degree. The Panel has found your conduct in wrongly representing that you had such a respected qualification to be dishonest and unprofessional.

As a principal investigator undertaking research studies it was your responsibility to obtain relevant ethics committee approval before a study could commence. It is essential that the application for ethics committee approval, including the protocol and any subsequent amendments should be accurate and comprehensive. You were responsible for the submission of incorrect and potentially misleading protocols in applications to a number of ethics committees:-

a. an application dated 4 April 2000 was submitted to the Dartford and Gravesham Local Research Ethics Committee ["LREC"] ("D&G 23/00") for approval for a study entitled "*Clinical Efficacy and side effects of Ziprasidone in Recent Onset Psychosis: a cognition and functional magnetic resonance (fMRI) Study*". The study Protocol included at section 6 an assertion that the applicants had ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol";

b. In April 2000 an application was submitted to the Maidstone LREC ("23/00M") for approval for the study named in 'a' above. There was an assertion at section 6 of the study Protocol that the applicants had ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol";

c. On or about 23 June 2000 an application was submitted to Dartford and Gravesham LREC ("D&G 30/00") for approval for a study entitled "*A Naturalistic multimeasure study of clinical and cognitive efficacy of Amisulpride, Quetiapine, Risperidone and Olanzapine in Schizophrenia*". At section 6 of the Protocol there was an assertion that the applicants had ethical permission from the Bethlem and Maudsley Ethical Committee "to carry out the studies mentioned in this protocol".

Professor S's evidence as an expert was that the assertions in these applications were misleading. In each case they could be expected to be interpreted as meaning that the entire study described in the Protocol had already been approved by Bethlem & Maudsley Ethics Committee. In each case this assertion was untrue. It found that use of the word 'studies' and your failure to elaborate or explain the relevance of the assertions to be misleading and untruthful. You were the principal investigator and you had a duty not to

mislead the ethics committee. Your conduct falls significantly short of the standards to be expected of a medical practitioner undertaking medical research on human subjects.

On or about 4 May 2000 you submitted as "principal applicant" an application to the Alzheimer's Society for a grant towards a study entitled "*Effects of Rivastigmine in Patients with Mild Memory Impairments and Alzheimer's Disease: A Functional Magnetic Resonance Imaging Investigation*". The application form contained an assertion that ethical permission had been obtained for the study from the Ethics Committee (Research) of the Institute of Psychiatry and Maudsley Hospital. In fact no such ethical permission had been obtained. The Panel found your assertion to be misleading and untruthful and that your conduct falls significantly short of the standards to be expected of a medical practitioner undertaking medical research on human subjects.

As principal investigator you conducted a study entitled "A *Naturalistic Study of Clinical Cognitive Efficacy of Amisulpride in Schizophrenia: Comparison with Olzanapine"* (the "COGS" study). The study was funded by Sanofi-Synthelab (Sanofi). You represented to Sanofi that there was ethics committee approval for the study. You had sent to Sanofi a study report dated 3 October 2000 in which you stated "Ethical approval to conduct this study was sought and granted by the South London and Maudsley NHS Trust"; at a meeting on 13 December 2000, you told representatives of Sanofi that there was ethics committee approval from West Kent, for the study; you produced a letter dated 4 September 2000 in relation to D&G 30/00 in support of this assertion. In a letter to Dr R, a senior Sanofi executive, dated 6 June 2001, you stated that there was ethical approval from West Kent for the study under the title '*The effects of typical and atypical antipsychotics on cognition in West Kent*'" and subsequently from the Dartford and Gravesham Local Research Ethics Committee. In fact there was no ethics committee approval for the study. The Panel has found your representations to Sanofi to be misleading and untruthful and that your conduct falls significantly short of the standards to be expected of a medical practitioner undertaking medical research on human subjects.

From July 1999 you communicated regularly with Dr S of Sanofi concerning the proposal, inception and consequent commencement and funding of the COGS study.

In the draft COGS study, 'Clinical Trials Agreement' certain terms were defined:

- you as "the Investigator", of "Section of Cognitive Psychopharmacology, Institute of Psychiatry, Denmark Hill, London",

- "Clinical Trial", as "the investigation to be conducted by the Investigator at The Institute of Psychiatry, Denmark Hill, London", and,

- "Investigation Site", as "premises occupied by the Institute of Psychiatry, Denmark Hill, London",

The COGS study was being conducted by Psychmed Limited ["Psychmed"], a private commercial company in which you had a significant interest. This company was unconnected to the IOP. The study was not being conducted by, under the auspices of, or

otherwise connected with the Institute of Psychiatry. At no time prior to your contact with Dr B of Sanofi in late November 2000 did you inform Dr S or any other appropriate personnel from Sanofi that the COGS Study was in fact being conducted by Psychmed. In breach of your conditions of service with the Institute of Psychiatry you were conducting the study without the prior knowledge or permission of the appropriate personnel within the Institute of Psychiatry. The Panel finds your conduct to be misleading and dishonest towards Sanofi, misleading towards the Institute of Psychiatry and that it risked misleading patients.

At no time in the course of your dealings with Dr S did you inform him that you intended the COGS study to be linked in any way to a larger study being undertaken by you. He was misled into believing that COGS was a stand alone Study. It was in that belief that he agreed, and caused to be made by Sanofi, instalment payments to Psychmed. The Panel finds your conduct in this regard to be dishonest and misleading.

You were a principal investigator for a multi-centre international study sponsored by the Janssen Research Foundation ["Janssen"] entitled "*Double–blind evaluation of risperidone vs haloperidol on the long term morbidity of early psychotic patients*", also known as "RIS-INT-35" or "the Janssen First Episode Study". There was no reference to functional magnetic resonance imaging ["fMRI"], structural magnetic resonance imaging ["SMRI"] or magnetic resonance spectroscopy ["MRS"] in the study protocol, the Patient Information Letter / Informed Consent Form, any amendments or addenda to the study protocol or any other document submitted by you to an ethics committee. As a consequence there was no ethics committee approval nor could there be informed consent for any of these procedures to be undertaken on patients entered into the study. Despite this between 4 February 1997 and 15 May 1997 five vulnerable psychiatric patients who had been recruited into the study underwent scanning, including SMRI and MRS. The Panel finds your conduct to be unethical, not in the best interests of the study patients and unprofessional.

Contemporaneously with the study referred to above you were also principal investigator in a study funded by Eli Lilly and Company Limited ["Lilly"] entitled *"Acute and Long term efficacy of Olanzapine in First Episode Psychotic Disorders: a randomised Double-Blind Comparison with Haloperidol"*, also known as "FID-MC-HGDH", or "the Lilly First Episode Study". The battery of tests provided for in the Lilly First Episode Study Protocol was more extensive than those specified in the Janssen First Episode Study Protocol. You were aware that the Janssen First Episode patients were exposed to a level of testing similar to that for the Lilly First Episode patients, and that this was beyond what was provided for in the Janssen protocol. Furthermore, case report forms were created and completed for tests carried out on Janssen and Lilly First Episode patients, in addition to those case report forms provided specifically for the Janssen and Lilly First Episode studies. You took positive steps to ensure that Janssen and Eli Lilly were unaware of each other's First Episode study by instructing your staff to conceal documentation relating to one company's study from the other when representatives of the other company attended the research site at the Institute of Psychiatry. As a result of this you were able to increase patient numbers and to pool data from both studies for use in preparing papers for possible future publication. You did not have ethics committee approval to conduct the additional tests upon Janssen patients. Furthermore, these were sponsored studies and so the intellectual

property was owned by the pharmaceutical companies. The Panel finds this conduct to be dishonest towards the pharmaceutical companies, not in the best interests of the study patients and unprofessional.

As part of the Janssen and the Lilly First Episode studies, between October 1997 and 2000 you conducted MRI and MRS scanning of healthy volunteers. This was beyond the ethics committee approval. This is unethical and the Panel finds your conduct to fall significantly short of the standards to be expected of a medical practitioner undertaking medical research on human subjects.

By a Letter of Agreement dated 29 April 1999 and signed by you on or about 7 June 1999 you were appointed principal investigator for a Study on behalf of Novartis Pharmaceuticals UK Limited ("Novartis"). The study was entitled "A Prospective, Randomised, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Effect of Exelon on the Time to Clinical Diagnosis of Alzheimer's Disease in Subjects with Mild Cognitive Impairment" ("The INDDEX Study"). You used the Novartis INDDEX Study patients' data and the Novartis Cognitive Battery Case Report Form in an additional and wholly separate study conducted by you. You used the patients' data and the case report forms without the consent of Novartis. The patients' data was Novartis's intellectual property and its use was unauthorised. Moreover this was without the patients' informed consent. The Panel finds your conduct to have been dishonest, unethical and unprofessional.

The INDDEX study was being conducted at Abbeydale Court, Walthamstow, a private hospital where you were a medical director. This was unconnected to the Institute of Psychiatry. It was not being conducted at, under the auspices of, or otherwise in conjunction with the Institute of Psychiatry, save that MRI scanning was undertaken at the Maudsley Hospital. Although the study was unconnected with the Institute of Psychiatry there was unauthorised use of Institute of Psychiatry headed paper and other documentation. The Study was conducted without ethics approval from the Institute of Psychiatry / Bethlem & Maudsley Local Research Ethics Committee. The Panel has found that there was a risk that patients would be misled by your conduct into believing that the study in which they were participating was conducted by the Institute of Psychiatry, a very prestigious institution.

Further, during the course of the For Cause Audit you told SB of Novartis that Abbeydale Court was connected to the Institute of Psychiatry; that you had discussed ethics committee approval with the Institute of Psychiatry and that no Institute of Psychiatry related ethics committee approval was required as no Institute of Psychiatry patients were involved in the study. The Panel finds these statements to be misleading and untruthful.

As principal investigator you had overall responsibility for and supervision of the INDDEX study. The Panel has found that some of the patients' records for the study were incomplete or inadequate. There was an absence of appropriate source documentation to patients' histories and eligibility to participate in the study. The patients' records should at the very least have contained a checklist of the exclusion criteria and a letter from or a note of a telephone conversation with the general practitioner or other appropriate medical

professional to the effect that he had considered and approved the checklist and the patients' eligibility. There were no patient histories from any external sources to support the patients eligibility for the study. Suitability for the study could therefore only be assessed from the information obtained from the patient and/or his carer. The Panel has found that general practitioner or other appropriate medical professional's input was essential. A patient, particularly a vulnerable patient and/or his carer would be unable to provide sufficient and reliable information for an accurate decision to be made about his suitability for the study. The Panel finds your conduct falls significantly short of the standards to be expected of a medical practitioner managing and conducting medical research on human subjects.

On or about 28 October 1999 you applied to the Redbridge and Waltham Forest Local Research Ethics Committee for permission to recruit patients to the INDDEX study by using a newspaper advertisement. On 16 November 1999 the Local Research Ethics Committee sent a reasoned refusal of this application. As the principal investigator of the study you were responsible for an "article" appearing in a local newspaper dated 9 December 1999, seeking to recruit patients into the study and providing contact details for prospective participants. The article amounted to an advertisement, and therefore contravened the Local Research Ethics Committee's decision. You were experienced in giving interviews and dealing with the press and in the light of the Local Research Ethics Committee decision you should have taken more care in what you said. The article could have led to direct patient contact without the general practitioner being aware of such contact. The Panel has found your conduct unethical, unprofessional and not to be in the best interests of the study or its patient recruits.

On 28 September 1999 you signed a Letter of Agreement with Lilly in relation to your investigator initiated study titled "*A Comparison of the effects of conventional antipsychotics, olanzapine and risperidone on basal ganglia size and regional cerebral blood flow using structural and functional magnetic resonance imaging in schizophrenia and related psychosis",* also known as IOP-TS-41. This document required you to conduct the Study in accordance with the study protocol, to furnish Lilly with a brief summary of the status of the Study on a quarterly basis and to notify Lilly immediately of any changes in your status as the investigator.

The study was not conducted in accordance with the protocol as assessments undertaken on the patients differed from those specified. Furthermore, you recruited 20 normal controls. Such recruitment was not provided for by the protocol nor was there an appropriate amendment to the ethics approval. On 27 September 2002 you informed SA of Lilly that normal controls were not part of the original study but that you had numerous normal control protocols and related ethics approvals for various paradigms; if you decided to leave the normal controls in the study, then the relevant paperwork regarding ethics approval would follow. Professor S's evidence is that you should not have implemented any such changes to the protocol without obtaining the appropriate ethical approval. The Panel therefore finds your conduct to be inappropriate, unethical and to fall significantly short of the standards to be expected of a medical practitioner managing and conducting medical research on human subjects.

In 2003, some patients who had participated in earlier studies were approached as potential participants in further studies. Patients were approached by you or on your behalf in an unsolicited fashion. This was by telephone or in writing without prior contact with the medical professional responsible for their care. Furthermore the information furnished to patients was inadequate.

The Panel finds that it is wholly inappropriate for particularly vulnerable patients to be approached in such a manner. The fact that a patient has participated in an earlier study does not entitle a researcher to approach him again without first contacting his medical professional. In this context the Panel has well in mind the guidance issued by the Royal College of Psychiatrists in June 2000.

You were responsible for these actions either personally or as principal investigator or as the person otherwise in charge of those studies or prospective studies.

The agreement of a patient, who is under the care of another clinician, to take part in one study does not automatically give a researcher the right to approach directly the patient again for another study when the first one has finished. The system of recruitment to the second study should have been approved by the research ethics committee approving that study, just as it was for the first study. This is especially important in the case of vulnerable patients as their circumstances and treatment may have changed considerably. In the case of a patient with mental health problems communication with the medical professional responsible for his care is essential.

In addition, as a researcher you have a duty to ensure that a patient participant has sufficient opportunity to consider all relevant information in order that he may come to a reasoned and informed decision. The Panel finds that a direct approach to attempt to recruit patients for whom you had no clinical responsibility is unprofessional and risked compromising patient care and welfare. This conduct is unethical as you did not comply with the accepted standards of good practice for research upon human subjects especially in the case of vulnerable patients.

The Panel's findings indicate serious failings on your part in regard to personal integrity and honesty.

Doctors occupy a position in society of privilege and trust. They are expected to act with integrity and to uphold proper standards of conduct and behaviour. The 1995, 1998 and 2001 editions of Good Medical Practice relevant at the time require a doctor to be honest and trustworthy.

A researcher must be aware of and follow the principles of good clinical practice. One of the principal purposes of ethics committee practice and procedure is to ensure the safety and welfare of patient participants in research studies. It is essential that a researcher complies with the ethics committee procedure. He must be totally honest in the information that he submits to the ethics committee in an application for ethical approval. He must not provide, by inclusion or omission misleading information in his application.

Your actions disclose a serious disregard for established ethical procedures and practice. The Panel is seriously concerned at your lack of integrity in this regard. The Panel has well in mind paragraph 43 and 44 of Good Medical Practice (1995) which state respectively:

> *'If you are taking part in clinical trials of drugs or other research involving patients you must make sure that the research is not contrary to the patients' interests. Check that the research protocol has been approved by a properly constituted research ethics committee.'*
>
> *'You must keep to all aspects of the research protocol……'*

There are similar provisions in the 1998 and 2001 editions.

The Panel has found that your conduct could have given rise to risk to patients and further risks bringing the reputation of the medical profession into disrepute and thereby undermining public confidence in research.

Having considered the Panel's findings both individually and collectively it has found that your conduct has fallen well below the standard expected of a registered medical practitioner in a number of respects and such falling short is serious. It therefore finds you guilty of serious professional misconduct.

The Panel next considered what action, if any, to take in relation to your registration.

The Panel has borne in mind throughout its deliberations that any sanction imposed must be proportionate and appropriate, and that the purpose of sanctions is not to be punitive, but to protect patients and the public interest. The public interest includes not only the protection of patients, but also the maintenance of public confidence in the profession and the declaring and upholding of proper standards of conduct and behaviour. The public interest can also include a doctor's return to safe practice as a clinician, researcher or otherwise.

The Panel has given consideration to the submissions made by Miss Glynn, on behalf of the General Medical Council. She has submitted that the only appropriate sanction in this case is that of erasure. Although you have made no specific submissions about sanctions the Panel is aware that the question of what, if any, sanction to impose is a matter for the Panel, exercising its own independent judgment and that when considering sanctions the Panel should consider the least serious first and only if a lesser sanction would be insufficient should it move on to the more serious sanction.

The Panel has balanced the public interest against your own interests. It has taken into account the Indicative Sanctions Guidance published by the General Medical Council.

The Panel is in no doubt that it is necessary to take action against your registration and that the sanction imposed must mark strong disapproval of your behaviour. The Panel has well in mind the need to maintain public confidence in the profession and to declare and uphold proper standards of conduct and behaviour. Given the seriousness and gravity of your

misconduct the Panel has determined that to conclude this case without making any direction in respect of your registration, to issue a reprimand or to impose conditions would clearly be insufficient. Moreover, it would be difficult, if not impossible, to formulate conditions to address the issues of probity.

The Panel next considered whether a period of suspension would be appropriate. It has carefully balanced the public interest against your own interests. It has taken into account the aggravating features of this case and the mitigation that has been advanced by you.

The Panel is aware that you are a research psychiatrist of international repute; that you have published a substantial number of papers and that you have contributed significantly towards the advancement of medical science. This has been widely reflected in current clinical care. Furthermore a number of people depend for their employment upon your research activities. You do not currently live in the United Kingdom and are not at present involved directly in clinical medicine or in any personal research.

The Panel recognises that your misconduct occurred between the years 1997-2003. It has taken into account that there has been no repetition of misconduct since then. It has considered also the highly competitive circumstances in which you were working and the prevailing standards to which medical practitioners worked at the time of these events.

You have informed the Panel that you were appointed as a senior lecturer in 1996 and that your experience in research was an evolving process. You told the Panel that you were given no formal training or written guidance in ethics and that you simply emulated what was being done by your then senior, Professor M. The Panel has heard evidence that when you had doubts you took advice from MC, who was the administrator of the ethics committee and from Professor ML, the Chairman of the ethics committee. You have drawn the Panel's attention to the high volume of research work that you were undertaking at the time and you have specifically highlighted the positive balance of 'the number of things that I got right against those that I got wrong'.

There is no evidence before the Panel to demonstrate that your actions have caused direct harm to patients or their families nor have there been any previous findings made by the General Medical Council against you.

You have not provided the Panel with any testimonials. You have explained that this is because the people with whom you now work are abroad. You have however directed the Panel towards the evidence that it has heard from a number of witnesses during the course of this hearing. Professor M in his evidence described the dedication that you have towards your work and the academic excellence that you had achieved at quite a young age.

His reference, dated 20 May 1999, to University College London states that:

> '*Dr Sharma is a good communicator…….. he is in much demand as a speaker at conferences. Indeed he has already become well known internationally. Although Dr Sharma is relatively young to be applying for a Chair he has already accomplished a great deal.'*

Professor T, from Nicolaus Copernicus University in Poland, in his e-mail to Field Fisher Waterhouse, dated 2 July 2007 states that your role in the University is to advise them on the setting up of a centre for Cognitive Neuroscience. He has described you as one of the most accomplished scientists in your field and confirms that you are one of the most highly published and cited authors in the field of schizophrenia.

Professor K gave evidence about your abilities which he said were of a calibre sufficient to enable you to be appointed to a professorial Chair in the United States.

The Panel has heard that given your reputation in the academic field and in the pharmaceutical industry, almost everyone is aware of the General Medical Council proceedings but that despite this you have continued to be commissioned for research studies by a number of major pharmaceutical companies. You have informed the Panel of the important work that you have undertaken in respect of the Anti Stigma Campaign for Schizophrenia for the Royal College of Psychiatrists and that you have attended several courses on medical ethics which were not available at the material time.

Doctors occupy a position of privilege and trust in society and are expected at all times to act with integrity and to uphold proper standards of conduct. However, your conduct was in clear contravention of the General Medical Council Guidance and falls seriously short of the standards of conduct and probity expected to be upheld by a medical practitioner. Although it is not suggested that your dishonesty has been with the intention of achieving personal financial gain, lack of probity and integrity in relation to research misconduct is particularly serious. Such behaviour undermines the trust that both the public and the profession have in medicine as a science, regardless of whether this leads to direct harm to patients. It has the potential to have far reaching consequences.

The panel has been mindful of Lord Bingham's well known observation in the case of Bolton v The Law Society, adopted in the case of Dr Gupta, as noted in the Indicative Sanctions Guidance:-

> *"The reputation of the profession is more important than the fortunes of an individual member. Membership of a profession brings many benefits, but that is part of the price."*

The Panel also had in mind Lord Hoffman's judgment in Bijl v General Medical Council [2002] Lloyds Med Rep 60, in which he said:-

> *"The Committee was rightly concerned with public confidence in the profession and its procedures for dealing with doctors who lapse from professional standards. But this should not be carried to the extent of feeling it necessary to sacrifice the career of an otherwise competent and useful doctor who presents no danger to the public in order to satisfy a demand for blame and punishment……..."*

The Panel is concerned by the disregard that you have demonstrated towards your professional colleagues. You have demonstrated your persistent lack of insight into the

seriousness and consequences of your multiple failings during this relatively long period of time. You have during the course of this hearing continued to suggest that a number of people have acted in ignorance or behaved in an inappropriate, unfair or discriminatory way against you.

Whilst the Panel accepts that since 2003 there has been no repetition of such misconduct, in the light of your persistent lack of insight, it cannot be satisfied that such misconduct would not be repeated. In all the circumstances the Panel has concluded that your persistent and wide ranging dishonesty and untruthfulness, spanning a number of years, together with your lack of insight is so serious that it is fundamentally incompatible with your continuing to be a registered medical practitioner. In all the circumstances the Panel has therefore concluded that suspension would not be a sufficient sanction.

Accordingly the Panel has no alternative but to direct that your name be erased from the Medical Register. The Panel is satisfied that this is necessary in the public interest for the maintenance of confidence in the profession and in the interests of declaring and upholding proper standards of professional conduct and behaviour.

The effect of the foregoing direction is that, unless you exercise your right of appeal, your name will be erased from the register twenty-eight days from the date on which notice of this direction is deemed to have been served upon you.

Having reached a decision that your registration should be erased, the Panel is minded to consider, in accordance with Section 38 of the Medical Act 1983, whether to direct that your registration be suspended forthwith.

The Panel will invite submissions from Miss Glynn and you on this matter.

Determination on immediate sanction:

Dr Sharma:
Having determined that your name should be erased from the Medical Register, the Panel has considered in accordance with Section 38 of the Medical Act 1983 as amended, whether your registration should be suspended forthwith. The Panel is aware that it can direct that your registration be suspended immediately only if it is necessary for the protection of members of the public or if it is in your own best interests.

Miss Glynn has submitted on behalf of the General Medical Council that immediate suspension is necessary for the protection of members of the public.

You have submitted that suspension forthwith is not necessary as patients are not at any risk .

The matters identified in the determination, which necessitated the erasure of your name from the Medical Register, are of serious concern. The Panel has determined that your lack insight and that it cannot be satisfied that such misconduct would not be repeated.

The Panel has therefore determined that it is necessary for the protection of members of the public that your registration should be made subject to suspension with immediate effect.

This means that your registration will be suspended from today. The substantive direction for erasure, as already announced, will take effect twenty-eight days from today, unless you lodge an appeal in the interim. If you appeal, the immediate suspension will remain in force until the substantive direction takes effect.

That concludes this case.

Confirmed

30 March 2008 **Chairman**