HONG KONG DOCTORS UNION
香港西醫工會

Our ref: HKDU/139/2010

6 July 2010

Professor Virginia Wong
Chairman
HKU / HA HKW Institutional Review Board
Room 901, Administration Block
Queen Mary Hospital
102 Pokfulam Road
Hong Kong

Dear Professor Virginia Wong, Chairperson, IRB,

Re: Guidance from Hong Kong Department of Health on Safety and Quality Standards of Avastin

On behalf of the Drug Safety Consortium, comprising of member associations of Hong Kong Doctor's Union, The Practising Pharmacist Association of Hong Kong, Alliance of Patient's Mutual Help Organizations, and Retina Hong Kong, we would like to draw your kind attention to the reply letters from the Hong Kong Department of Health, dated 14 June 2010 and 2 July 2010, in regard to the definition of optimal standards of safety and quality of Avastin products to be used on patients in Hong Kong.

The Department of Health has advised of the need that "only drugs meeting the optimal safety and quality standards are administered on the patient" [1] and has advised that the exact definition of "optimal safety and quality standards" of any form of Avastin products to be administered to patients, are to "comply with the critieria as stated with the approved (product) specifications registered with the Pharmacy and Poisons Board." [2] The Department of Health draws to our attention of the need to ensure that any form of Avastin products to be administered to the patient should comply with the approved safety and quality standards including the following:

1. Avastin should be stored between 2 to 8 degrees Celsius
2. Avastin should be used immediately after the sterile parenteral vial is opened (and discard any unused portion after opening)
3. Avastin should be used according to the method of administration recommended by the manufacturer

Therefore, any form of Avastin products which may be stored, handled, repackaged, and administered in a different manner which deviates from the above approved drug product specifications does not provide for the Department of Health's guidance for health care professionals to ensure that only drugs of optimal standards of safety and quality are to be administered to the patient.

With the clear guidance from the Hong Kong Department of Health on the use of Avastin products, it is ethical and appropriate for the IRB to oversee that the clinical trial design being proposed ensures that only those Avastin products which meet the above critieria should be used to treat patients during the course of the proposed "Avastin in HA" clinical trials. Otherwise, patients would not be ensured that only drug products of optimal standards of safety and quality are being administered to them as advised by the HK Department of Health.

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Furthermore, we would like to again seek your advice on the appeals procedure for the decision of the IRB should we object to the IRB's decision made in relation to the approval of the proposed "Avastin in HA "clinical trial.

Thank you for your kind attention to this important matter regarding patient safety and we look forward to your kind reply.

Yours faithfully,

Dr. Yeung Chiu-Fat
President
Hong Kong Doctors Union

Ms. Iris Chang
President
The Practising Pharmacists Association of Hong Kong

Mr. K. P. Tsang
Chairman
Retina Hong Kong cum Alliance for Patients Mutual Help Organizations

cc: Members of the Legislative Council Panel on Health Services
Ms. Connie Lau, Chief Executive, Consumer Council
Dr. Chow Yat Ngok, York, Secretary for Food and Health, Food and Health Bureau
The Society of Hospital Pharmacists of Hong Kong
The Pharmaceutical Society of Hong Kong
The Practising Pharmacists Association of Hong Kong
Hong Kong Doctors Union
Hong Kong Medical Association

references:

1. Reply Letter from Department of Health Dated 14 June 2010
2. Reply Letter from Department of Health Dated 2 July 2010

香港特別行政區政府
衞生署藥劑事務部
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THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION
PHARMACEUTICAL SERVICE
DEPARTMENT OF HEALTH
PUBLIC HEALTH LABORATORY CENTRE, 3RD FLOOR,
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FAX OUT

本署檔號 OUR REF.: DH PS 7-35/1
電 話 TEL.: (852) 2319 8500
圖文傳真 FAX NO.: (852) 2834 5117

14 June 2010

Mr Tsang Kin Ping
President
Retina Hong Kong
101, G/F, Lai Huen House, Lai Kok Estate
Cheung Sha Wan
Kowloon.

Dear Mr Tsang,

Clinical trial of drugs, and off-label use of Avastin for the treatment of age-related macular degeneration (AMD)

Thank you for your two letters dated 10.5.2010 and 2.6.2010 respectively on the above subject.

I wish to inform you that in Hong Kong, clinical trials are regulated under the Pharmacy and Poisons Regulations. The purpose is to ensure adequate protection of the welfare of the trial subjects, the robustness of the trial protocol and the reliability of the results of the trial. As regards the clinical trial of "Avastin" for use in the treatment of AMD by the Hospital Authority, I have been informed by the Hospital Authority (HA) that HA is currently going through the proper procedures to obtain approval before beginning the trial.

As regards the off-label use of "Avastin" by private ophthalmologists for the treatment of AMD, I have written to the Hong Kong College of Ophthalmologists drawing their attention to the need to ensure that only drugs meeting the optimum safety and quality standards are administered to the patient.

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I thank you again for bringing the above matters to my attention.

Yours sincerely,

(A W K Chan)
for Director of Health

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FAX OUT

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2 July 2010

Mr Tsang Kin-ping
President
Retina Hong Kong
101 G/F, Lai Huen House
Lai Kok Estate
Cheung Sha Wan
Kowloon
Hong Kong

Dear Mr Tsang,

Definition of Drugs of Optimal Safety and Quality Standards

Thank you for your letter dated 18 June 2010 on the above subject.

All pharmaceutical products, including Avastin, must satisfy the requirements on safety, efficacy and quality before registration with the Pharmacy and Poisons Board (PPB) can be approved. As you are aware, Avastin is a registered pharmaceutical product and the optimal safety and quality standards should comply with the criteria as stated in the approved specifications registered with the PPB.

Avastin is a sterile parenteral product with no preservative. It should be stored between 2 - 8 °C. It should be used immediately after the vial is opened.

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To reiterate, it is always a good practice for medical professional to adhere to the method of administration as recommended by the manufacturer on any pharmaceutical product, in particular a sterile product like Avastin.

Thank you for your concern on the matter.

Yours sincerely,

(Linda Woo)
Chief Pharmacist

c.c. Members of the Legislative Council Panel on Health Services
Secretary for Food and Health
Consumer Council
Hong Kong Doctors Union
The Practising Pharmacists Association of Hong Kong
The Pharmaceutical Society of Hong Kong
The Society of Hospital Pharmacists of Hong Kong
Hong Kong Medical Association

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