EXHIBIT 11

WHO COLLABORATING CENTRE
FOR INTERNATIONAL
DRUG MONITORING

CAVEAT DOCUMENT

Accompanying statement to data released from the
WHO Collaborating Centre

The WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden receives summary clinical reports about individual suspected adverse reactions to pharmaceutical products from National Centres in countries participating in a Collaborative Programme. Only limited details about each suspected adverse reaction are received at the Centre. It is important that the limitations and qualifications which apply to the information and its use are understood.

The term "pharmaceutical product" is used instead of "drug" to emphasize that products marketed under one generic or trade name may vary in their content of active or other ingredients, both in time or from place to place.

The reports submitted to the Collaborating Centre in many instances describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. In most instances it cannot be proven that a pharmaceutical product or ingredient is the cause of an event.

The reports, which are submitted to National Centres, come from both regulatory and voluntary sources. Some national Centres accept reports only from medical practitioners; other National Centres accept reports from a wider spectrum of health professionals. Some National Centres include reports from pharmaceutical companies in the information submitted to the Collaborating Centre; other National Centres do not.

The volume of reports for a particular pharmaceutical product may be influenced by the extent of use of the product, publicity, nature of reactions and other factors which vary over time, from product to product and country to country. Moreover, no information is provided on the number of patients exposed to the product.

Thus the sources of reports accepted by National Centres vary, as do the proportions.

A number of National Centres which contribute information to the Collaborating Centre make an assessment of the likelihood that a pharmaceutical product caused the suspected reaction. Other National Centres do not document such assessments on individual reports in the WHO data base.

Processing time varies from country to country. Reporting figures obtained from the Collaborating Centre may therefore differ from those obtained directly from National Centres.

For the above reasons interpretations of adverse reaction data, and particularly those based on comparisons between pharmaceutical products, may be misleading. The information tabulated in the accompanying printouts is not homogeneous with respect to the sources of the information or the likelihood that the pharmaceutical product caused the suspected adverse reaction. Some describe such information as "raw data". Any use of this information must take into account at least the above.

Some National Centres which have authorized release of their information strongly recommend that anyone who intends to use it should contact them for interpretation.

Any publication, in whole or in part, of the obtained information must have published with it a statement:

(i) of the source of the information,

(ii) that the information is not homogeneous at least with respect to origin or likelihood that the pharmaceutical product caused the adverse reaction,

(iii) that the information does not represent the opinion of the World Health Organization.

Omission of these 3 statements may exclude the responsible person or organization from further information from the

Total per reaction

System Organ : Application site disorders

INJECTION SITE REACTION 1

ROUTE: Intravenous

AUS 1

System Organ : Body as a whole - general disorders

ALLERGIC REACTION 1

ROUTE: Intravenous

GFR 1

ANAPHYLACTIC SHOCK 11

ROUTE: Intravenous

GDR 1
GFR 10

ANAPHYLACTOID REACTION 2

ROUTE: Intravenous

AUS 1
POL 1

BACK PAIN 1

ROUTE: Intravenous

CZE 1

CHEST PAIN 1

ROUTE: Intravenous

AUS 1

FATIGUE 1

ROUTE: Intravenous

YUG 1

FEVER 2

ROUTE: Intravenous

CZE 1
NET 1

PALLOR 3

ROUTE: Intravenous

CZE 1
GFR 2

SYNCOPE 5

ROUTE: Intravenous

NET 1
ROM 1
SCH 1
SVK 1

Total per reaction

System Organ : Body as a whole - general disorders

SYNCOPE 5

ROUTE: Intravenous

YUG 1

System Organ : Cardiovascular disorders, general

CIRCULATORY FAILURE 15

ROUTE: Intravenous

CAN 1
GFR 13
NET 1

CYANOSIS 1

ROUTE: Intravenous

YUG 1

HYPERTENSION 1

ROUTE: Intravenous

AUS 1

HYPOTENSION 6

ROUTE: Intravenous

AUS 2
NET 1
ROM 1
YUG 2

System Organ : Centr & periph nervous system disorders

COMA 2

ROUTE: Intravenous

GFR 2

CONVULSIONS 1

ROUTE: Intravenous

ITA 1

DIZZINESS 1

ROUTE: Intravenous

AUS 1

DYSTONIA 1

ROUTE: Intravenous

GFR 1

FAECAL INCONTINENCE 2

ROUTE: Intravenous

GFR 2

Total per reaction

System Organ : Centr & periph nervous system disorders

HYPERTONIA 1

ROUTE: Intravenous

GFR 1

PARAESTHESIA 1

ROUTE: Intravenous

AUS 1

TREMOR 1

ROUTE: Intravenous

CZE 1

VERTIGO 1

ROUTE: Intravenous

GFR 1

System Organ : Gastro-intestinal system disorders

ABDOMINAL PAIN 3

ROUTE: Intravenous

GFR 2
ITA 1

DIARRHOEA 1

ROUTE: Intravenous

SVK 1

NAUSEA 4

ROUTE: Intravenous

GFR 2
ITA 1
YUG 1

VOMITING 6

ROUTE: Intravenous

GFR 3
NET 1
SVK 1
YUG 1

System Organ : Heart rate and rhythm disorders

CARDIAC ARREST 2

ROUTE: Intravenous

GFR 2

Total per reaction

System Organ : Heart rate and rhythm disorders

TACHYCARDIA 1

ROUTE: Intravenous

AUS 1

System Organ : Liver and biliary system disorders

HEPATIC ENZYMES INCREASED 1

ROUTE: Intravenous

SWE 1

System Organ : Musculo-skeletal system disorders

ARTHRALGIA 1

ROUTE: Intravenous

AUS 1

System Organ : Psychiatric disorders

AGITATION 2

ROUTE: Intravenous

AUS 1
GFR 1

ANXIETY 1

ROUTE: Intravenous

GFR 1

SOMNOLENCE 1

ROUTE: Intravenous

GFR 1

System Organ : Respiratory system disorders

APNOEA 2

ROUTE: Intravenous

GFR 2

DYSPNOEA 9

ROUTE: Intravenous

AUS 2
CZE 1
GFR 3
ROM 1
YUG 2

LARYNX OEDEMA 1

ROUTE: Intravenous

SVK 1

Total per reaction

System Organ : **Skin and appendages disorders**

ANGIOEDEMA 4

ROUTE: Intravenous

GFR 3
SVK 1

PRURITUS 3

ROUTE: Intravenous

AUS 3

RASH 1

ROUTE: Intravenous

AUS 1

RASH ERYTHEMATOUS 1

ROUTE: Intravenous

ROM 1

RASH MACULO-PAPULAR 1

ROUTE: Intravenous

AUS 1

SWEATING INCREASED 1

ROUTE: Intravenous

GFR 1

System Organ : **Special senses other, disorders**

TASTE PERVERSION 2

ROUTE: Intravenous

YUG 2

System Organ : **Urinary system disorders**

FACE OEDEMA 1

ROUTE: Intravenous

SVK 1

System Organ : **Vascular (extracardiac) disorders**

PHLEBITIS 1

ROUTE: Intravenous

AUS 1

Total per reaction

System Organ : Vision disorders

MYDRIASIS 1

ROUTE: Intravenous

ROM 1

System Organ : White cell and res disorders

EOSINOPHILIA 1

ROUTE: Intravenous

AUS 1

Total number of reactions: 114