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BIOLOGICAL AGENTS AND TOXINS ACT (CHAPTER 24A)

BIOLOGICAL AGENTS AND TOXINS ACT (AMENDMENT OF FIRST AND FIFTH SCHEDULES) ORDER 2011

In exercise of the powers conferred by section 62 of the Biological Agents and Toxins Act, the Minister for Health hereby makes the following Order:

Citation and commencement

1. This Order may be cited as the Biological Agents and Toxins Act (Amendment of First and Fifth Schedules) Order 2011 and shall come into operation on 1st October 2011.

Amendment of First Schedule

- **2.** The First Schedule to the Biological Agents and Toxins Act is amended by deleting paragraph (a) of item 8 in Part I under the heading "VIRUSES" and substituting the following paragraph:
 - "(a) Human immunodeficiency virus (HIV) Types 1 and 2, except for any advanced generation HIV lentiviral vector, which means
 - (i) any third or higher generation HIV vector; or
 - (ii) any HIV vector with all of the following features:
 - (A) comprises a minimum of 4 plasmids in total which includes all types of plasmid (e.g. packaging, structural, accessory, etc.);
 - (B) HIV genes are split to a minimum of 2 packaging plasmids;
 - (C) the env gene encoding for the HIV envelope is replaced;
 - (D) the *vif*, *vpr*, *vpu* and *nef* genes are either absent or altered to be non-functional;

- (E) the *rev* and *tat* genes are absent, non-functional or expressed from a separate construct; and
- (F) the *Gag* and *Pol* genes are split over at least 2 plasmids or there is deletion in the 3'LTR or both.".

Amendment of Fifth Schedule

3. The Fifth Schedule to the Biological Agents and Toxins Act is amended by deleting the full-stop at the end of item 7, and by inserting immediately thereafter the following item:

"8. HT-2 toxin.".

Made this 19th day of September 2011.

YONG YING-I Permanent Secretary, Ministry of Health, Singapore.

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