

Regulations Governing Reviewing Procedure of Drug Injury Review Committee of Ministry of Health and Welfare

(Amended Date:2014-10-23)

1. Promulgated by the Executive Yuan, the Department of Health Order Wei-Shu-Yao-Tzu No. 0920313489, on January 9th, 2003; The Regulations shall be effective on the day of the promulgation.

Promulgated by the Executive Yuan Order Yuan-Tai-Gui-Zi No. 1020141353, the related authorities and responsibilities previously belonged to the Department of Health in Paragraph 1, Article 2, shall be transferred under the charge of "Ministry of Health and Welfare" since July 23rd, 2013 on July 19th, 2013. (Title: Regulations Governing Reviewing Procedure of Drug Injury Review Committee of Department of Health)

2. Article 2 and the title amended and promulgated by the Ministry of Health and Welfare Order Bu-Shou-Shi-Zi No. 1031203330, on October 23rd, 2014

Article 1 These regulations are promulgated pursuant to the Paragraph 1 of Article 15 of Drug Injury Relief Act.

Article 2 Applicants of Drug Injury (hereinafter referred as "the applicants") shall submit an application to the commissioned authority (institution) or organization by the Ministry. The authority (institution) or organization shall investigate and write the review report and then send with evidence and data related to review to drug review committee of Ministry of Health and Welfare (hereinafter referred as "the Review Committee") The Review Committee shall make a determination within three months after receiving an application of drug injury relief; the three months period may be extended one month if necessary.

Article 3 Before the Review Committee reviewing an application of drug injury relief, it may send the applicant to two to four medical or pharmaceutical

related professionals, or commission to domestic or international medical centers or academic institutions for preliminary review if necessary.

The Review Committee starts reviewing an application by preliminary review by one to two medical or pharmaceutical related committee members, and then holds the Review Committee meeting. When reviewing a case, the opinion of preliminary review shall be considered, and may After the review result being ratified by the competent authority, the Review Committee shall send the review result to the applicant.

- Article 4 When the Review Committee believes documents from the applicant are incomplete and can be fulfilled or require an applicant to submit interpretation or evidence, the competent authority, other commissioned authority (institution) or organization may inform the applicant to fulfill the requirements within 15 days after receiving the notice. The application shall be rejected if the required documents did not submit before the expiration date or the documents are still not fulfilling the requirements.
- If there is a legitimate reason with submitting the required documents mentioned in the preceding paragraph, the applicant may apply for an extension for document submission before the expiration date, however, the extension period shall not be over 15 days and may be applied only once.

- Article 5 When the Review Committee considers it is necessary to reexamination or to interview the victim, it may assign a medical institution or a physician to re-exam, or assign a specific person to interview the victim. The victim shall not refuse, avoid or impede without a legitimate reason.

- Article 6 When the Review Committee considers it is necessary to access medical records or related data or to interview related medical institutions, it may request competent authority to assist.
- Article 7 In the case of an application the is reviewed and complied with the elements of drug injury relief, the amount of the payment shall be determinate according to Drug Injury Relief Payment Standard
- Article 8 These regulations shall be effective as the date of promulgation.