The Minutes of the Proceedings of the 3rd Meeting (in the fiscal year from 2009 to 2010) of "The Advisory Council about the Studies on the Development and the Evaluation of Novel Safety Test Methods Considering International Trends (commonly called: the Advisory Council of JaCVAM)"

Date: November 19th, 2010 (Friday); 14:00 to 16:30
Place: The 21st Meeting Room, the Ministry of Health, Labour and Welfare (MHLW)
Attendants: Tsunehiko Iwai, Hiroshi Ono, Fumio Sagami, Masatoshi Narita, Takatoshi Kuhara, Ken Uwagawa (substitution), Yukiko Kanazawa (substitution)
Chairperson: Yasuo Ohno
Secretary Office: Hajime Kojima
Observers: Masaki Shibatsuji, Toshinari Mitsuoka, Shinichi Mikuni, Hiroshi Itagaki, Takeme Yoshida, Hiroaki Mamiya, Akiyoshi Nishikawa, Junichi Akagi

(The persons above are listed in no particular order and their titles are omitted.)

Discussion topics

1. Confirmation of the minutes of the previous proceedings
Following the opening address of Dr. Ohno as the chairperson, the discussion of the topics started.
Confirming the draft minutes of the 2nd proceedings shown in the reference 1, the organization Dr. Sagami of the Advisory Council belongs to was modified to "Japan Pharmaceutical Manufacturers Association (Nihon Seiyaku Kogyo Koyokai)" from "Japan Pharmaceutical Manufacturers Society (Nihon Seiyaku Kogyo Kai)". The unclear meaning of the part of 4-4) "the lack of awareness of the issues in ICCR as regulation authorities" was pointed out, and this part was deleted.

3. The activity of JaCVAM and its plans for future

Dr. Kojoma of the secretary office explained the activity of JaCVAM and its future plans (the reference 3), the progress of the validation and the evaluation of test methods (the reference 4), the situation of utility of JaCVAM web site (the reference 7), and international harmonization (the reference 8) using corresponding references, respectively. Compared with the period of the foundation of JaCVAM, the requirements for international cooperation are increased, and a lot of persons attended the international conferences.

In the section of questions and answers, Dr. Kuhara of the Advisory Council inquired about the relation with International Cooperation on Alternative Test Methods (ICATM). Dr. Kojima explained that JaCVAM would promote the cooperation with ICATM. Dr. Iwai of the Advisory Council questioned about the present situation of ICATM that seems to separate from International Cooperation on Cosmetics Regulations (ICCR), and required the active cooperation with ICCR. He also provided his opinion that, even the test methods included in OECD test guidelines (TG), it is unclear how to utilize them on the submission of quasi-drugs in Japan. To this, Dr. Mitsuoka answered that OECD TG is basically acceptable, and they would like to prepare the guidance for quasi-drugs.

Dr. Kojima then explained recent activity of JaCVAM and its future plans using the reference 9. In these 5 years, The reports of 6 proposals of novel test methods were made, and the principle for future would be mainly international cooperation with ICATM. Dr Uwagawa of the substituted member of the Advisory Council inquired about the relation between OECD TG working group and JaCVAM. To this, Dr. Nishikawa answered that the Biological and Safety Research Center of NIHS deals with OECD TG.

3. Problems of the activity of JaCVAM

Dr. Kojima explained the evaluation and the problems of JaCVAM using the references 10 and 11. He introduced that 1) JaCVAM is one of core organizations of ICATM internationally, 2) JaCVAM is invited to various

conferences held in Europe and US, 3) the validations under the leadership of JaCVAM are highly rated because of their quality of the data and speed, 4) when KoCVAM was founded, JaCVAM was regarded as its model, and so on. On the other hand, he reported as the problems of JaCVAM that 1) the advices from the Advisory Council and the Steering Committee are not realized, 2) the budgets from other Ministries and the industry are not available, 3) because of the limitation of the budget, the expenses necessary for international association are not enough, 4) as it has not been decided how to use the proposals from JaCVAM in the administrative office, the motivation of the members of the Advisory Council and the Committees seems decreasing, and so on.

In the section of questions and answers, the members provided the following opinions and the proposals.

(1) The problem of the impossibility of the realization of the advices

Dr. Nishikawa showed as the conclusion of the Steering Committee that it is necessary to organize a working group concerning the structure of JaCVAM.

(2) and (3) The problem of the budgets and the expenses

Dr. Iwai proposed the supply of the budget to JaCVAM from Japan Cosmetic Industry Association (JCIA). To this proposal, Dr. Ohno and Dr. Mitsuoka explained that, although individual researchers are able to obtain competitive budgets from the industry, there is no method to obtain the expenses from the industry and similar organizations as a national institute. However, they would like to examine the method to receive the supportive budget using related societies (e.g., Japanese Society for Alternative to Animal Experiments) as the window for it. Dr. Ono questioned about travel expenses, and Dr. Kojima answered that Research Grants from the MHLW are able to use travel expenses, but the plans of official trips should be made at the beginning of the fiscal year. As a result, the attendance at international conferences or the invitation of experts in foreign countries for validations and the evaluations by the third party held in Japan are difficult.

(4) The problem that it has not been decided how to use the proposals from JaCVAM in the administrative office

There was no answer to this problem. Dr. Mitsuoka provided his opinion

that at least the preparation of the guidance clearly showing the limit of the alternative methods (the applicable area) in quasi-drugs is necessary.

(5) Other problems

Dr. Itagaki pointed out that the number of cooperators for JaCVAM is small at present and a large burden is imposed on the same limited part of people. He provided the opinion that, to reward the cooperators for their effort, the some system to increase the motivation is necessary. Dr. Yoshida reported that the cooperation is now applied to the board of directors in the Japanese Society of Toxicology. Dr. Kojima hoped that the validation under the leadership of Japanese Society for Alternative to Animal Experiments is reopened. Dr. Ohno insisted that JaCVAM is the only organization that has the ability of the validation and the evaluation of the alternative methods constantly, and questioned about the relationship with Ministry of Economy, Trade and Industry; METI). To this question, Dr. Sanekuni answered that METI has examined how to support JaCVAM.

4. Others

Dr. Kuhara distributed "The Guide Book of the Committee of Animal Experiments" (the reference 12) to applicants. The term of office of the members of the Advisory Committee is two years, and the term of the present members finished at this meeting. Dr. Kojima reported that the request for the next members was planning to be done later.

The list of the distributed references

1) The Minutes of the Proceedings of the 2nd Meeting (in the fiscal year from 2009 to 2010) of "The Advisory Council about the Studies on the Development and the Evaluation of Ultramodern Safety Test Methods Considering International Trends" (in Japanese)
2) The list of the members of JaCVAM 2010 (in Japanese)
3) The major activity of JaCVAM 2009 – 2010 (including future plans) and the events related to the alternative methods (in Japanese)
4) The progress of the development of the test methods that JaCVAM participated in (in Japanese)

5) The draft of the modified regulation of JaCVAM (in Japanese)
6) The utility of JaCVAM web site (in Japanese)
7) The review of JaCVAM (in Japanese)
8) JaCVAM and international harmonization (in Japanese)
9) JaCVAM update for ICATM coordinating meeting (in Japanese)
10) The evaluation of JaCVAM and the subjects to be solved (in Japanese)
11) The problems of the activity of JaCVAM (in Japanese)
12) "The Guidebook of the Committee of Animal Experiments, (2)&(3)" Laboratory animal and environment, No. 35, Vol. 18(1), pp.1-32; No. 36. Vol. 18(2), pp. 152-186 (2010) (in Japanese)