投稿 ▶原著

カルタヘナ法（第一種使用等）に関わる医薬品業界の過去と現在

日本製薬工業協会 医薬品評価委員会 基礎研究部会 革新的医薬品・医療技術課題対応チーム*1

（受付：令和4年4月25日，受理：令和4年7月20日）

Past and Current Status of Cartagena Act “Type 1 Use” by the Pharmaceutical Industry

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Summary

Approval of Type 1 Use Regulation based on the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act) is required prior to the initiation of clinical trials for drugs/vaccines containing Living Modified Organisms (LMO), in Japan. The Cartagena Act became effective in 2004, and therefore we considered that it is time to evaluate the experience of the pharmaceutical industry with the approval processes for “Type 1 Use”. We conducted a questionnaire survey covering the duration from document preparation to approval, uncertain points in document preparation, and difficulties encountered during the approval processes among Japan Pharmaceutical Manufacturers Association (JPMA) member companies. Forty-one companies responded, and seven companies had experience of Type 1 Use application. The results of the survey suggested that companies involved in the development of drugs and vaccines including LMO had struggled to join in global clinical trials at an early stage after the introduction of the Cartagena Act in Japan. However, the survey revealed that the time from initiation of communication with the Pharmaceuticals and Medical Devices Agency (PMDA) to approval has been shortened following the establishment of a PMDA consultation procedure for issues related to the Cartagena Act because of more accurate prediction of the work period until approval. Very recently, application and approval procedures of Type 1 Use Regulations have been greatly improved as a result of discussions among pharmaceutical industry groups, PMDA, MHLW and academia. Various reference documents for preparation of Cartagena application have also recently become available. Thus, it is expected that many of the issues identified in the survey will soon be resolved. Further cooperation among stakeholders in the future is expected to accelerate the efficient development of products including LMOs.

Key words

Cartagena Act, LMO, Gene Therapy, Type 1 Use, Biological Diversity Risk Assessment Report