Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人　医薬品医療機器総合機構

Special Approval for Emergency on Remdesivir for COVID-19

8th May, 2020

The MHLW granted the Special Approval for Emergency for treatment of COVID-19 on 7th May, 2020 with approval conditions to allow the access to the potential treatment of this disease.

What is Special Approval for Emergency?

Under article 14-3 of the Pharmaceuticals and Medical Devices Act, a certain medical product may be approved when 1) an emergency situation requires an unapproved medical product to be used to prevent damage to the public health caused by the spread of diseases, 2) such emergency situation cannot be managed appropriately by any means other than the use of the unapproved product, and 3) such product is legally available in a country with a regulatory system for medical products that is equivalent to Japan. Once designated by the Cabinet Order, the application for such a product meeting these criteria is submitted, and it will be urgently proceeded to discussion by the Pharmaceutical Affairs and Food Sanitation Council. When the Council recommends approval of the product, the Minister of Health, Labour and Welfare may grant the products the Special Approval for Emergency. While such approval is processed much faster than regular approval, the Minister can request the marketing authorization holder to implement appropriate safety monitoring and other measures as necessary. The Minister can withdraw the approval in a case where the conditions above no longer persists or withdrawal is necessary to prevent damage to the public health.

Special Approval for Emergency of Remdesivir

Following the Emergency Use Authorization of remdesivir by the U.S. FDA on 1st May, the MHLW regarded this product to satisfy the above conditions after the designation of the Cabinet Order on 2nd May. Accordingly, on the basis of the application submitted from Gilead Sciences on 4th May, the PMDA prepared the report for the available information, approval conditions, labeling of remdesivir etc., then its result was further discussed by the Pharmaceutical Affairs and Food Sanitation Council of the MHLW on 7th May. The report issued by the PMDA will be published on PMDA's website once available. As a result, remdesivir was recommended for the Special Approval for Emergency as the treatment of patients with COVID-19. The Special Approval for Emergency was granted with several conditions such as:

- written informed consent prior to administration
- risk management plan to be implemented
- submit the results of additional clinical trials at earliest convenience, at latest within 9 month.
- surveillance/registry of all patients conducted during the designated period.

The clinical trials of local and multiregional for remdesivir are still ongoing and need to be completed. Throughout this Special Approval for Emergency, the PMDA and the MHLW will continue to evaluate its efficacy and safety and disseminate its information, while taking necessary actions immediately.

Close communication among regulators is essential to develop drugs and plan safety managements smoothly.

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