

Hepatitis B Foundation



The European profile of Hepatitis Delta and bulevirtide

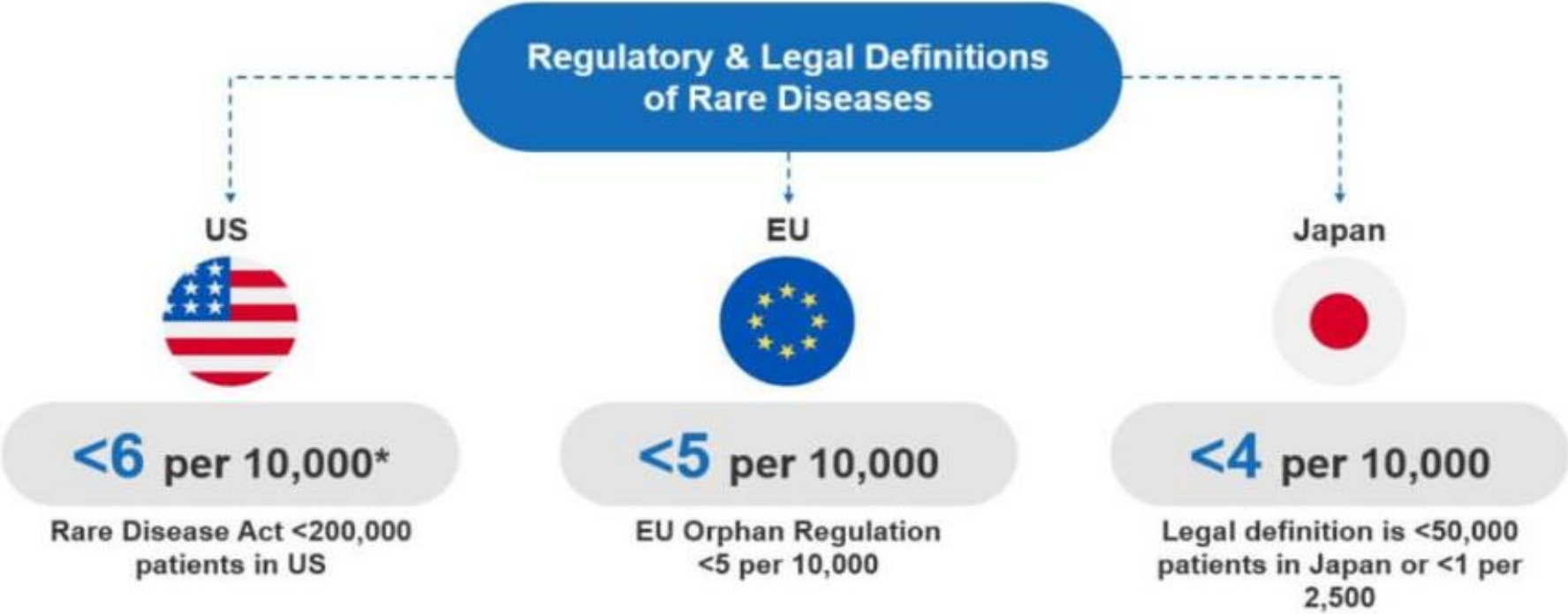
Webinar 8th June 2023

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- ELPA (European liver patients Scientific Committee coordinator)



Definition of Rare/Orphan Disease Hepatitis Delta is an “orphan” disease and Bulevirtide is an “orphan” treatment. It was approved by the EMA on July 2020, for the treatment of chronic HDV infection, based on data from phase 2 clinical trials and considering the lack of therapeutic options



*200,000 patients per US 2019 population size of 329 million equals 6 per 10,000

Barriers, challenges and gaps. Hep Delta in Spain

- The situation of patients diagnosed with hepatitis Delta is special, it is a rare disease, poorly known and underdiagnosed, does not have an alternative treatment.
- Current situation of the patient who knows that the drug bulevirtide was approved by the EMA 2 years ago, is of sadness and anxiety. Patients do not have time, they are being made to live uncertainty and anguish about their situation waiting for reimbursement to be approved.
- Present status: It is a situation of inequality and uncertainty, Public Health benefits would be great and it is not just a matter of an individual concern
- Criteria should be that it is a serious disease, there is no alternative, and moreover they can not wait because it can lead to irreversible sequelae.

Hepatitis Delta in Spain. Epidemiology.

Some data of the Spanish Registry

The Registry of patients with hepatitis Delta, created in 2022 by the Spanish Association for the Study of the Liver (AEEH), includes 213 patients with active follow-up, and informs about epidemiological, clinical and virological variables during evolution. Average age 52 years, 54% male, 57% born in Spain and 21% in Eastern Europe. Mean follow-up of 6 years.

Estimated general prevalence of HBV in Spain 0,22-0,50 %, about 90.000 people. Estimated co-infected with HDV are 5% , 4000-5000 people.

Considering patients included in the Registry, 45% already had cirrhosis at the time of being diagnosed and 19% had portal hypertension. During the follow-up 11% and 15% developed cirrhosis and portal hypertension, which is a high percentage considering the short follow-up.

Hepatitis Delta in Spain. Conference on the situation of inequity related to approval of new orphan drugs

On the 1st June of 2023, was presented in Barcelona the conference: **“How to prevent patients from waiting two years for new orphan drugs (organized by farmaindustria.es)”**

- There is an urgent need to improve disponibility of orphan treatments in Spain.
- The law is different in each European country and the average time for approval in Spain is more than 700 days

Patients do not have time when a new and effective medication has already been authorized in Europe and can not be administered in their country.

All the speakers, patients, academics, managers, politicians, agreed that the situation has to be improved urgently.

Patients and families are living the situation with anxiety and uncertainty

Why bulevirtide should be approved?

Based on:

- It is not only a question that hepatitis Delta is a serious illness
- Without therapeutic options
- Patients can not wait because the quality of life and survival without treatment will be worse and the disease progresses with serious sequels and complications that are potentially irreversible
- Patients suffer a situation of inequity

How to overcome unmet needs of Hepatitis Delta in Spain

Our demands representing the voice of the liver patients. What could be done to increase visualization and empower patients

- More campaigns updating information to professionals and health care teams and managers
- Accurate information about prevalence of HCV, HBV and also HDV in each country should be published
- Take into account that hepatitis Delta is a “rare” disease. Therefore it has specific features, few numbers and study methods. It is clinically heterogeneous, narrative of patients is essential.
- Advocate more for accelerate approval of new and advanced effective innovative therapies. The law has to be changed in favor of patients who suffer

ASSCAT published Hep D patient’s testimonials. <https://asscat-hepatitis.org/wp-content/uploads/asscatinforma-24.pdf>

“ Hepatitis Delta. La perspectiva de los pacientes. Opinión del experto clínico y del experto de laboratorio”

ASSCAT sent an informative note to associates, diagnosed with HBV, to make them aware that it is necessary to ensure whether or not they have hep Delta, so that their doctor in case he does not know it, can carry out an analysis.

How to overcome unmet needs of Hepatitis Delta in Spain

- First: increase information/screening/hep D diagnosis/assess liver function/control and treatment
- Time needed to get access for advanced and innovative medicines should be shortened
- It is crucial recognize the need of equity and transparency in the access to new medications in “orphan” diseases with the participation of patients in all the process
- Is not only a matter of costs but the health value associated at individual level and also at poblational level that should be reminded
- It is a complex issue but should be solved avoiding long term decisions and uncertainty