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Food and Drug Administration Rockville MD 20857 Dennis Brydges Executive Officer Food and Agriculture Organization 1001 22nd Street, NW Washington, D.C. 20437 Dear Mr. Brydges: On behalf of the Food and Drug Administration, I am pleased to recognize your invitation to Mr. Sidney H. Rogers, director of the Investigation Division to review the Food and Agriculture Organization's National Export Certification Program and its application to export practices. Travel will take place in Rome, Italy from 10-27 July 2002. According to your letter of 12 May 2002, we understand that your organization will reimburse the costs of air fares, accommodation, meals and various expenses. Once Mr. Rogers has returned and submitted his claim, you will be notified to our Accounting Accounts Debtors Branch about the amount to be reimbursed. The tests must be carried out by the Food and Drug Administration. Added to your reference are some general details about guidelines for FDA employees who speak or participate outside seminars and conferences. Sincerely, Malcolm Frazier, Director, Office of Resource Management EnclosureFMD 13 Distribution: Regional Food and Drug Directors and District Directors of FDA Staff Offices Issued by: ORA/ORO/Division of Field Investigations (HFC-130) Publication Date: November 2002 This section: What is Hepatitis D? Hepatitis D is a viral infection that causes inflammation and damage to the liver. Inflammation is a swelling that occurs when body tissues are injured or infected. Inflammation can damage organs. Viruses invade normal cells in the body. Many viruses cause infections that can spread from person to person. Hepatitis D virus is unusual because it can only infect you if you also have hepatitis B virus infection. In this way, hepatitis D is a double infection. You can protect yourself from hepatitis D by protecting yourself from hepatitis B by getting the hepatitis B vaccine. Hepatitis D spreads in the same way as hepatitis B is spread by contact with the blood of an infected person or other body fluids. Hepatitis D virus can cause acute or chronic infections, or both. Acute hepatitis D Acute hepatitis D is a temporary infection. The symptoms of acute hepatitis D are the same as any type of hepatitis symptoms and are often more severe.¹⁹ Sometimes your body is able to fight off infection and the virus disappears. Chronic hepatitis D Chronic hepatitis D is a long-term infection. Chronic hepatitis D occurs when your body is unable to fight off the virus and the virus does not go away. In people with chronic hepatitis B and hepatitis D, complications occur more frequently and quickly than people who have chronic hepatitis B alone.²⁰ How do hepatitis D and hepatitis B infections occur together? Hepatitis D and hepatitis B infections can occur in the same and direct way as coins or superinfection. People can only become infected with hepatitis D if they also have hepatitis B. you are receiving both hepatitis D and hepatitis B infections at the same time. Coinfections are usually caused by acute, or short-term, hepatitis D and B infections. Coinfections can cause severe acute hepatitis. In most cases, people are able to recover from and fight acute hepatitis D and hepatitis B infections and viruses. However, in less than 5 percent of people with coinfection, both infections become chronic and do not go away.²¹ Superinfection Superinfection occurs if you already have chronic hepatitis B and then become infected with hepatitis D. When you get a superinfection, you may have severe acute hepatitis symptoms.¹⁹ Up to 90 percent of people with superinfection are unable to fight off hepatitis D virus, and develop chronic hepatitis D.²⁰ As a result, these people will have both chronic hepatitis D and chronic hepatitis B. How often is hepatitis D? Hepatitis D is not common in the United States. Hepatitis D is more common in other parts of the world, including Eastern and Southern Europe; Mediterranean and Middle East; parts of Asia, including Mongolia; Central Africa; and the Amazon River Basin in South America.²² ²³ What is most likely to be hepatitis D? Hepatitis D infection occurs only in people with hepatitis B. People are more likely to have hepatitis D in addition to hepatitis B if they are What are the complications of acute hepatitis D? In rare cases acute hepatitis D can lead to acute liver failure, a condition in which the liver suddenly fails. Although acute hepatic failure is uncommon, hepatitis D and B infections are more likely to cause acute liver failure than hepatitis B infection alone.²⁴ What are the complications of chronic hepatitis D? Chronic hepatitis D can cause cirrhosis, liver failure and liver cancer. People with chronic hepatitis B and D are more likely to develop these complications than people with chronic hepatitis B alone.²⁰ Early diagnosis and treatment of chronic hepatitis B and D may reduce your chances of developing serious health problems. Cirrhosis Cirrhosis is a condition in which the liver slowly breaks down and is unable to function normally. Scar tissue replaces healthy liver tissue, partially blocking blood flow through the liver. In the first stage of cirrhosis, the liver continues to work. As cirrhosis worsens, the liver begins to fail. Liver failure Also called end stage liver disease, liver failure progresses over months or years. With end-stage liver disease, the liver can no longer perform important functions or replace damaged cells. Liver cancer Taking chronic hepatitis B and chronic hepatitis D increases your chances of developing liver cancer. Your doctor may recommend blood tests and ultrasound or other types of imaging tests to check for liver cancer. Finding cancer at an early stage improves the possibility of curing cancer. What are the symptoms of hepatitis D? Most people with acute hepatitis D have symptoms that may include tired nausea and vomiting nausea and vomiting nausea pain over the liver, upper abdomen darkening the color of urine whitening the color of the stool yellowish tint on the whites of the eyes and skin, called jaundice Unlike, most people with chronic hepatitis D have few symptoms until complications develop, which could be several years after they were infected. Some of the symptoms of cirrhosis include weakness and feeling tired of weight loss swelling of the abdominal swelling of the ankles, called edema itching skin jaundice What causes hepatitis D? Hepatitis D virus causes hepatitis D. Hepatitis D virus spreads through contact with the blood of an infected person or other body fluids. Contact can occur by sharing drug needles or other drug materials with an infected person having unprotected sex with an infected person becoming an accidental stick with a needle that was used on an infected person Hepatitis D virus rarely spreads from mother to child at birth. You can't get hepatitis D out of it coughed about or sneezing on by an infected person drinking water or eating food hugging an infected person by shaking hands or holding hands with an infected person exchanging spoons, forks, and other eating supplies sitting next to an infected person As doctors diagnose hepatitis D? Doctors diagnose hepatitis D based on your medical history, physical exam and blood tests. If you have hepatitis D, your doctor may carry out tests to check your liver. Medical history Your doctor will ask about your symptoms and about the factors that may make you more likely to get hepatitis D. Physical exam During a physical exam, your doctor will examine signs of liver damage, such as changes in skin color swelling in your shins, legs, or ankle tenderness or swelling of the abdomen What tests do doctors use to diagnose hepatitis D? Doctors use blood tests to diagnose hepatitis D. Your doctor may order tests to check for liver damage, find out how much liver damage you have, or rule out other causes of liver disease. Blood tests Your doctor may order one or more blood tests to diagnose hepatitis D. A healthcare professional will take a blood sample from you and send the sample to the lab. Your doctor may order one or more blood tests to diagnose hepatitis D. Your doctor may recommend tests to see if you have liver damage or how much liver damage you have, or to rule out other causes of liver disease. These tests may include blood tests, elamy, a special ultrasound that measures the stiffness of your liver, liver biopsy, in which the doctor uses a needle to take a small piece of tissue from the liver. The pathologist will examine the tissue under the microscope to look for signs of damage or disease. Doctors usually use liver biopsy only if other tests do not provide enough information about liver damage or disease. Talk to your doctor about what are the most suitable for you. How do doctors treat hepatitis D? For the treatment of chronic hepatitis D, doctors can treat them with medicines called interferons such as peginterferon alfa-2a (Pegasys). Researchers are studying new treatments for hepatitis D. In addition, medicines may be needed to treat hepatitis B. These are usually medicines taken once daily by one day by one. How do doctors treat complications of hepatitis D? If chronic hepatitis D causes cirrhosis, you should see a doctor who specializes in liver disease. Doctors can treat health problems associated with cirrhosis with medications, surgery, and other medical procedures. If you have cirrhosis, you are more likely to develop liver cancer. Your doctor may order an ultrasound or other type of imaging test to check for liver cancer. If acute hepatitis D causes acute liver failure or chronic hepatitis D causes liver failure or liver cancer, you may need a liver transplant. How can I protect myself from hepatitis D infection? If you do not have hepatitis B, you can prevent hepatitis D infection by taking measures to prevent hepatitis B infection, such as getting a hepatitis B vaccine. If you are not sewn with hepatitis B, you cannot receive hepatitis D. If you already have hepatitis B, you can take steps to prevent hepatitis D infection by not sharing drug needles or other medicinal materials that wear gloves, if you have to touch another person's blood or open sores not sharing personal items such as toothbrushes, beards, or nail cutting How can I prevent the spread of hepatitis D to others? If you have hepatitis D, follow the steps above to avoid spreading the infection. Your sex partners should get a hepatitis B test and, if they are not infected, get the hepatitis B vaccine. Preventing hepatitis B will also prevent hepatitis D. You can protect others from infection with your doctor, dentist and other healthcare professionals that you have hepatitis D or blood production, sperm, organs or tissues. Is there a vaccine for hepatitis D? No vaccines against hepatitis D are currently available. Hepatitis B vaccine can prevent hepatitis D by preventing hepatitis B. Talk to your doctor about a healthy diet. You should also avoid alcohol as this can cause more liver damage. References [19] Farci P, Niro GA. 2012;32(3):228[u2012]236. [20] Ahn J, Gish RG. Hepatitis D virus: screening call. Gastroenterology and hepatology. 2014;10(10):647[u2012]666. [21] Roy PK. Hepatitis D. Medscape website. . Updated March 16, 2017. Available June 5, 2017. [22] Rizzetto M. Hepatitis D virus: introduction and epidemiology. Cold Spring Harbor prospects for medicine. 2015;5(7):a021576. [23] Hoonagle JH. Type D (delta) hepatitis. Journal of the American Medical Association. 1989;261(9):1321-1325. Pathogenesis, epidemiology, natural history and clinical manifestations of hepatitis D virus infection. UpToDate website. . Updated 20 July 2016. Available June 5, 2017. 2017.

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