Part I of II

EPVC Newsletter

August 2014 Volume 5, Issue 8

Egyptian Pharmaceutical Vigilance Center (EPVC)

Pharmacovigilance Department

Inside this issue:

Sovaldi® (Sofosbuvir) tablet - Approval for Treatment of Chronic Hepatitis C (CHC) in Egypt

On 10/07/2014, Technical Committee Approved Sovaldi® (Sofosbuvir) for treatment of Chronic Hepatitis C (CHC) infection; based on Egyptian Pharmacovigilance Center (EPVC) assessment.

Gilead Sciences Inc. commit to perform post-marketing observational study (registry) in "*Specialized Centers for hepatic viruses Treatment*" in Egypt to demonstrate (the patient demographics, Polymerase Chain Reaction (PCR) results as efficiency indicator & safety reports indicate adverse drug reactions (ADRs))

Sofosbuvir is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. Its efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection.[1]

Recommendation for HealthCare Professionals (HCPs):

1. The recommended dose of Sofosbuvir is one 400 mg tablet, taken orally, once daily with or without food.[1]
2. Sofosbuvir should be used in combination with ribavirin or in combination with pegylated interferon and ribavirin for the treatment of CHC in adults.[1]
3. Recommended regimen for patients with genotype 1 or 4 CHC is "Sofosbuvir + peg interferon Alfa + ribavirin" for 12 weeks.[1]
4. Recommended regimen for patients with genotype 2 CHC is "Sofosbuvir + ribavirin" for 12 weeks.[1]

5. Recommended regimen for patients with genotype 3 CHC is "Sofosbuvir + ribavirin" for 24 weeks.[1]

6. Sofosbuvir in combination with ribavirin for 24 weeks can be considered as a therapeutic option for CHC patients with genotype 1 infection who are ineligible to receive an interferon-based regimen.[1]

7. Recommended regimen for "patients with Hepatocellular Carcinoma Awaiting Liver Transplantation" is Sofosbuvir in combination with ribavirin is recommended for up to 48 weeks or until the time of liver transplantation, whichever occurs first, to prevent post-transplant HCV reinfection.[1]

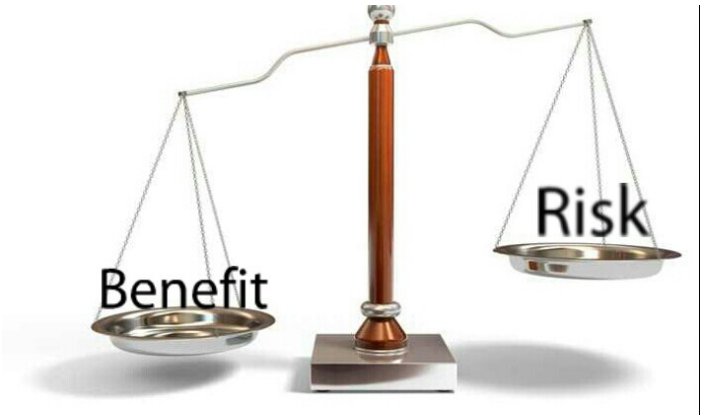
References

[1] FDA - Approval of Sovaldi® (Click Here)

Domperidone - Pharmacovigilance Committee recommends new restrictions and label update

Pharmacovigilance Committee (PVC) recommended on 17/07/2014 regarding Domperidone Containing products based on "*Egyptian Pharmacovigilance Center (EPVC) assessment of documents submitted by Marketing Authorization Holders (MAHs) of products containing Domperidone*"; in addition to "*Pharmacovigilance Risk Assessment Committee (PRAC) recommendations on 07/03/2014*" the following:

1. **Cancelation** of **oral solid dosage forms** contain Domperidone in Concentration **higher than 10mg**
2. **Cancelation** of registered **suppositories** contain Domperidone in Concentration **10mg & 60mg**
3. **Product information** of **Suppository** formulations contain Domperidone in Concentration **30mg** should be **amended** to **restrict usage** to **adults and adolescents** weighing 35 kg or more; In addition amend outer package to eliminate usage in Children
4. **Measuring devices** should be **included** with



liquid formulations containing Domperidone to allow accurate dosing by bodyweight

5. **Label** of Products containing **Domperidone** should be **reviewed** by Pharmacological Committee to take into consideration the following:
   - **Dosage** for **adults** and adolescents weighing 35 kg or more: **10 mg up to three times daily by mouth**. These patients may also be given the medicine as suppositories of 30 mg twice daily.
   - **Dosage** For **children** and adolescents weighing less than 35 kg: **0.25 mg / kg bodyweight by mouth** up to three times

daily.

- **Domperidone-containing medicines** should continue to be **used** in for the management of the symptoms of **nausea and vomiting**. Domperidone should no longer be authorized to treat other conditions such as bloating or heartburn
- The medicine should **not** normally be **used** for **longer than one week**
- The medicine must **not** be **given** to patients with moderate or severe impairment of liver function, or in those who have existing abnormalities of electrical activity in the heart or heart rhythm, or who are at increased risk of such effects.
- The medicine should **not** be **used** with other medicines that have similar effects on the heart or reduce the breakdown of domperidone in the body (thus increasing the risk of side effects).

6. **MAHs** of products containing Domperidone are **obligated** to:
   - **Submit** the relevant changes to **variation** committee
   - **Submit** the amended Product information (taking into consideration the aforementioned changes) to **Pharmacological** committee
   - **Distribute** Direct HealthCare Professional Communication (**DHPC**) letter including the new restrictions on Product Usage

Lidocaine - Pharmacovigilance Committee recommends new restriction and label update Concerning Usage for teething pain treatment in Children

Pharmacovigilance Committee (PVC) recommended on 17/07/2014 regarding (**Oral Viscous solution containing Lidocaine in Concentration 2%**) based on "*Egyptian Pharmacovigilance Center (EPVC) assessment*"; in addition to "*FDA recommendations on 26/06/2014*" the following:

1. Oral Viscous solution containing Lidocaine in Concentration 2% or higher; should not be used to treat infants and children with teething pain.

2. Addition of this warnings to label information of Oral Viscous solution containing Lidocaine in Concentration 2%

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NORCB Newsletter

June 2014 Volume 5, Issue 6

National Organization for Research & Control of Biologicals

Post Marketing Surveillance and Adverse Event Following immunization Department

Inside this issue:

GAVI Alliance addresses MSF concerns on infant Hepatitis B vaccine

Medecins Sans Frontieres recently expressed concern about the slow implementation of the World Health Organization's recommendation that a dose of hepatitis B vaccine be delivered immediately after birth.

Since 2000, the GAVI Alliance has supported infant hepatitis B vaccinations in nearly all GAVI-supported countries. Hepatitis B causes around 260,000 deaths each year in GAVI-eligible countries, according to the World Health Organization.

GAVI recently evaluated the value of providing financial support to countries that give birth doses of the hepatitis B vaccine. Fifteen vaccines were evaluated on their value and feasibility of support. The GAVI board chose not to offer financial support to countries looking to introduce birth doses of the vaccine, however, after analysis and extensive consultation.

The evaluation showed significant challenges other than the price of the vaccine for the implementation of the practice. The cost per dose of the birth dose of the vaccine was equivalent to the minimum amount of co-financing contributed to GAVI-supported vaccines by GAVI-eligible countries. Many of the births in GAVI-eligible countries also occur outside health care facilities, which would make it difficult to administer the vaccine in the 24 hour window after birth.

GAVI is focusing its limited resources on vaccines with higher impact and is open to working collectively toward encouraging greater use of the vaccine.

Reference:

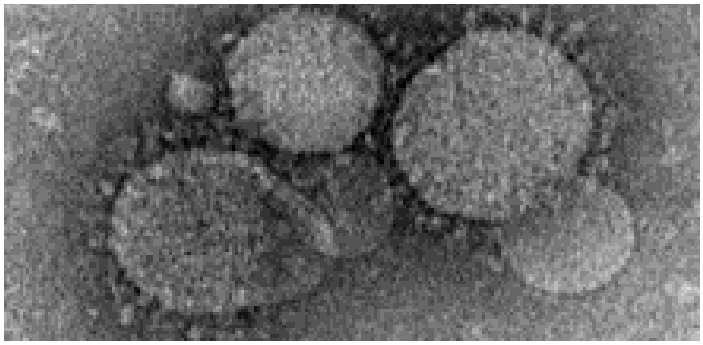
Vaccine News Daily : ***(Click here)***

CDC confirms U.S. MERS-CoV patients did not spread virus to high-risk contacts

The Centers for Disease Control and Prevention confirmed on Tuesday that neither of the two Middle East respiratory syndrome coronavirus (MERS-CoV) patient in the U.S. spread the disease to their household members or healthcare workers.

The CDC collected specimens from those who had come into contact with the two MERS-CoV patients, one in Florida and the other in Indiana, who were confirmed to have the virus in May. The results of the rRT-PCR tests on those specimens came back negative for both current and previous MERS-CoV infection.

"The negative results among the contacts that CDC considered at highest risk for MERS-CoV infection are reassuring," David Swerdlow, who is leading CDC's MERS-CoV response, said. "Today, the risk of MERS-CoV infection in the United States remains low, but it is important that we remain vigilant and quickly identify and respond to any additional importations."



Almost all of the people who traveled on airplanes or buses with the infected patients were contacted by the CDC, public health agencies or foreign ministries of health.

None of those who were tested showed evidence of MERS-CoV, although the CDC said that may change as the investigation continues.

Most cases of MERS-CoV are characterized by an acute respiratory illness with a cough, fever or shortness of breath.

Reference:

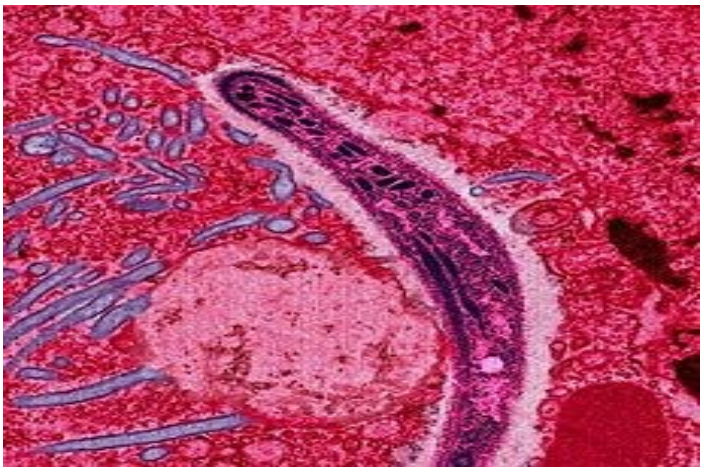
Vaccine News Daily : ***(Click here)***

Study of new malaria vaccine shows promise

Scientists from the National Institute of Allergy and Infectious Diseases (NIAID) announced on Monday improvements to an experimental vaccine designed to spur production of antibodies against the AMA1 malaria parasite protein.

The new candidate delivers AMA1 protein together with part of another parasite protein, RON2.

The AMA1-RON2 complex is used to attach ma-



laria parasites to red blood cells. The vaccine, when injected into mice, prompted an antibody response that protected the mice from lethal forms of the disease.

Additionally, antibodies produced in response to the AMA1-RON2 vaccine offered protection when administered to non-vaccinated mice as well.

The research suggests that the method could be used in testing on human malaria vaccines.

The original AMA1-targeting experimental vaccine was developed more than a decade ago by NIAID scientists. The vaccine displayed promise in non-human experiments and in early-stage clinical trials. When human trials were conducted in malaria-endemic countries, however, the results were disappointing.

The research was conducted by Louis Miller, M.D., and Prakash Srinivasan, Ph.D., of the Laboratory of Malaria and Vector Research at NIAID.

NIAID conducts and supports global research at the National Institute of Health. The institution looks to study the causes of infectious and immune-mediated diseases. It works to improve the prevention, diagnosis and treatment of these illnesses.

Reference

Vaccine News Daily : (Click here)

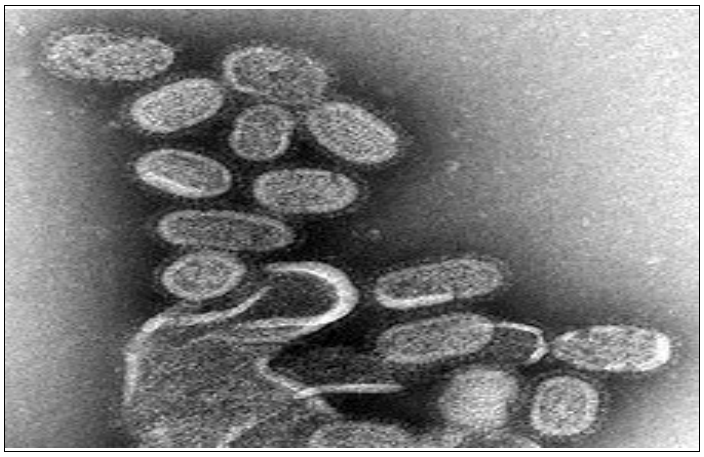
U.S. facility to produce cell-based influenza vaccine

The FDA approved on Wednesday the manufacture of a seasonal influenza vaccine using cell-based technology in a U.S. facility for the first time.

The facility is located in Holly Springs, N.C., and is owned by Novartis. It was built in 2009 through a partnership between Novartis and the Biomedical Advanced Research and Development Authority (BARDA).

The vaccine, manufactured by the facility, will prevent seasonal influenza and pandemic influenza viruses.

The project is sponsored by BARDA, which is part o the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR).



The project supports a multi-use approach to emergency preparedness through drugs, vaccines, diagnostics and devices.

The Holly Springs facility is prepared to produce up to 200 million doses of the pandemic influenza vaccine within six months of the declaration of a pandemic.

The facility opened in 2012 for the purpose of providing an FDA approved cell-based influenza vaccine in the case of an emergency. The vaccine, called Flucelvax, was the first cell-based influenza vaccine approved by the FDA for use in the United States. It was made by Novartis in Germany.

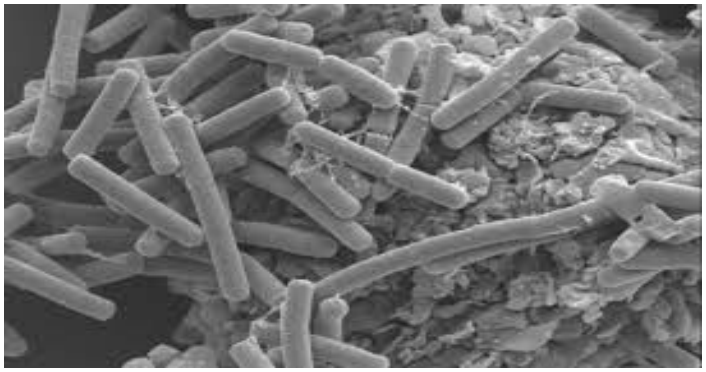
The U.S. facility will be able to increase seasonal vaccine production by at least 50 million doses.down from 10 last week, with the south-central region experiencing the most cases. Arkansas, Kansas, Oklahoma and Texas were at the top of CDC's influenza-like illness activity scale. While Alabama, Louisiana, Vermont and Virginia all dropped off the top rung over the past week, across the Atlantic in Europe flu activity is still on the rise. Incidence of influenza rose in 17 of the 29 countries that reported data, although only Greece suffered a high intensity of flu.

Reference

Vaccine News Daily : ***(Click here)***

Scientists identify new microbes linked to severe diarrhea

- Study findings published in Genome Biology indicate that researchers identified microorganisms that may trigger diarrheal disease and others that may protect against it, reported Science Daily.
- Professor O. Colin Stine of the University of Maryland said "we were able to identify interactions between microbiota that were not previously observed, and we think that some of those interactions may actually help prevent the onset of severe diarrhea."
- Investigators used high-throughput 16S rRNA genomic sequencing to examine both "good" and "bad" microbiota in samples taken from 992 children under the age of 5 in Bangladesh, Gambia, Kenya and Mali who were suffering from moderate-to-severe diarrhea.
- The researchers identified statistically significant disease associations with several organisms already implicated in diarrheal disease, such as members of the Escherichia/Shigella genus and Campylobacter jejuni.



- They also found that organisms not widely believed to cause the disease, including Streptococcus and Granulicatella, correlated with the condition in their study.
- Moreover, the study revealed that the Prevotella genus and Lactobacillus ruminis may play a protective role against diarrhea.

Reference:

First Word Pharma: (Click Here)

What is Pharmacovigilance

According to the WHO, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

What is the Egyptian Pharmaceutical Vigilance Center

With the increasing demand for patient's safety which is becoming more stringent, the regulatory authorities are facing an increased demand for patient welfare and safety. Thus, The Egyptian Pharmaceutical Vigilance Center (EPVC) is constructed within The Central Administration of Pharmaceutical Affairs (CAPA) Ministry of Health to be responsible for the collection and evaluation of information on pharmaceutical products marketed in Egypt with particular reference to adverse reactions. Furthermore, EPVC is taking all appropriate measures to:

1. Encourage physicians and other healthcare professionals to report the suspected adverse reactions to EPVC.
2. Necessitate the pharmaceutical companies to systematically collect information on risks related to their medical products and to transmit them to EPVC.
3. Provide information to end-users through adverse drug reaction news bulletins, drug alerts and seminars.

A call for reporting

Please remember that you can report suspected adverse reaction of medicines to EPVC, and adverse reaction following immunization to NORCB using the following communication information

Communications information

Central Administration of Pharmaceutical Affairs
Egyptian Pharmaceutical Vigilance Center
Pharmacovigilance Department

21 Abd El Aziz Al Soud Street. El-Manial, Cairo, Egypt, PO Box: 11451
Phone: +202 – 23684288,
Fax: +202 – 23610497
Email: pv.center@eda.mohealth.gov.eg

www.epvc.gov.eg

National Organization for Research & Control of Biologicals
Post Marketing Surveillance and Adverse Event Following immunization Department

51 Wezaret El Zeraa Street, Agouza, Giza P.O. Box: 354 Dokki
Phone: +202 – 37 480 478 ext. 118
Fax: +202 – 37480472
Email: pmsdep@yahoo.com