



UEMO

UNION EUROPÉENNE DES MÉDECINS OMNIPRATICIENS/MÉDECINS DE FAMILLE

EUROPEAN UNION OF GENERAL PRACTITIONERS/FAMILY PHYSICIANS

UEMO BULLETIN N°5 – 2016

Dear UEMO Members,

The buzzword this past month seems to have been “antimicrobial resistance (AMR)”. It has been discussed both at the World Health Annual Assembly and at the European Union institutions, which have created a new EU Health Award to recognise the work of NGOs in fighting AMR. UEMO has also participated in a meeting on AMR, organised by the European Commission.

The EU Tobacco Products Directive (TPD) reached an important milestone on 20th May, the date by which EU Member States should have implemented all the new measures contained in the Directive. The TPD is a hugely important issue for the healthcare industry, as reflected in the two articles in this edition dealing with (1) the changes introduced by the Directive and (2) the industry appeal at the CJEU and its final judgment.

Also interestingly for UEMO members, the European Commission proposals for updating the EU Audiovisual Rules, which also include measures to change advertising of food items high in fats, salt and sugar, were officially presented in May.

I am looking forward to some interesting discussion on these and many other topics at the UEMO General Assembly in Porto next month. I hope to see you there.

Yours sincerely,

Aldo Lupo

EU NEWS

- ❖ European Commission Proposes Updates to EU Audiovisual Rules
- ❖ EU Tobacco Products Directive Becomes Applicable
- ❖ CJEU: EU Tobacco Products Directive is Legally Valid
- ❖ EMA Annual Report 2015 Published
- ❖ eHealth Week 2016 in Amsterdam This June
- ❖ New EU Health Award to Recognise Efforts in the Fight Against Antimicrobial Resistance

UEMO NEWS

- ❖ UEMO Attends European Commission Organised Meeting on Antimicrobial Resistance
- ❖ UEMO Participated in the E Health Stakeholder Group
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OTHER NEWS

- ❖ 69th World Health Assembly: Outcomes and Discussion Points
- ❖ WHO Warns of Zika Transmissions in Europe, but Does Not See Threat in Rio



EU NEWS

EUROPEAN COMMISSION PROPOSES UPDATED TO EU AUDIOVISUAL RULES

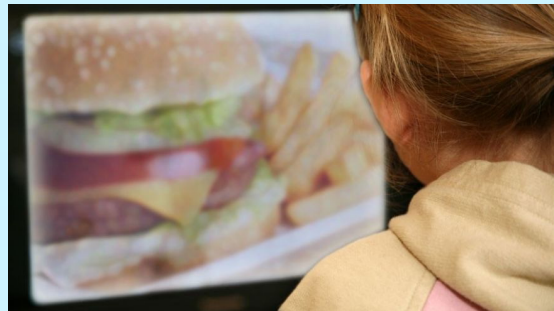
28TH MAY 2016

At the end of May, the European Commission presented its proposal for an updated Audiovisual Media Services Directive. The proposal comes after an extensive public consultation with stakeholders, held from July to September 2015.

The overarching aim of the revised EU Audiovisual Media Services Directive (AVMSD) is to create a fairer environment for all players, promote European films and culture, protect children and tackle hate speech better. The revised AVMSD will also strengthen the promotion of European cultural diversity, ensure the independence of audiovisual regulators and give more flexibility to broadcasters over advertising. The Directive forms part of the EU Digital Single Market strategy and reflects a new approach towards online platforms.

Within the scope of the Directive, among other issues, is the protection of minors from inappropriate advertising. The Directive in particular targets the advertising of foods and beverages containing nutrients and substances with a nutritional or physiological

effect, excessive intakes of which in the overall diet are not recommended, including foods high in fat, trans-fatty acids, salt or sodium and sugars. The Directive advises Member States to develop self- and co-regulatory codes of conduct regarding the advertising of such products to ensure that their nutritional characteristics are not promoted in a positive light. The codes should be created with an aim to reduce the exposure of minors to advertising of the products mentioned above. The start of the legislative procedure now starts.



Find out more:

- ❖ Proposal for an Updated Audiovisual Media Services Directive: <http://bit.ly/1sYPAUz>
- ❖ European Commission press release: <http://bit.ly/1WS7GE7>



EU TOBACCO PRODUCTS DIRECTIVE BECOMES APPLICABLE

22ND MAY 2016

As of 20th May, the EU Tobacco Products Directive (TPD) becomes applicable in EU Member States. The Directive was adopted and entered into force on 19th May 2014. The main objective of the Directive is to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of protection for European citizens. The Directive is seen as a historic step and has been lobbied against extensively by the tobacco industry, which believes that the measures introduced in the new legislation are excessive and disproportionate.



A key change for the tobacco industry will be the new requirements on the labelling and marking of tobacco product packets. 65% of the front and the back of cigarette and roll-your-own tobacco packs will have to be covered with graphic health warnings which will include EU-approved photos, text and cessation messages. The warnings are grouped in three sets, which

will have to be rotated annually to ensure that they retain their impact for as long as possible. Tobacco products packs will now also have to include a message stating that “tobacco smoke contains over 70 substances known to cause cancer”.

The shape of the packs is also regulated under the new Directive. Slim packs and other irregularly shaped packs will be prohibited and all packs will be required to have a cuboid shape. Each pack will have to contain at least 20 cigarettes, as packs containing fewer cigarettes are favoured by people on a tight budget.

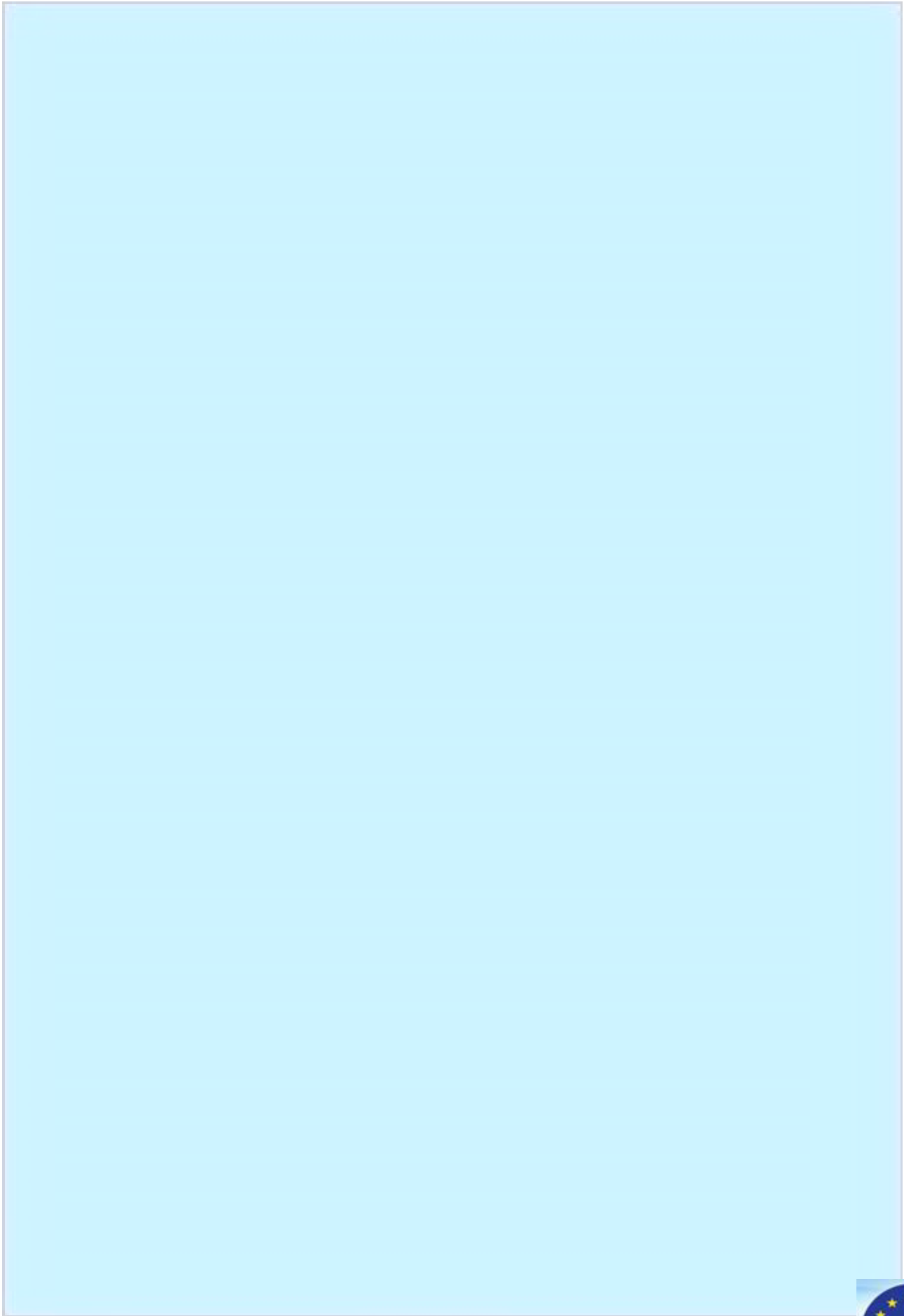
Under the TPD, a ban on menthol and other flavoured cigarettes and roll-your-own tobacco products will come into effect in 2020. According to the European Commission, these products mask the taste and smell of tobacco and make smoking more appealing.

Last but not least, the TPD, for the first time ever, also includes new rules for electronic cigarettes, especially as regards their safety, quality and volume/concentration. Mandatory health warnings will have to be put on e-cigarette packaging, advising consumers that e-cigarettes contain nicotine and should not be used by non-smokers.

Find out more:

- ❖ Revision of the Tobacco Products Directive (EC webpage):
<http://bit.ly/iiv9LxP>
- ❖ European Commission press release:
<http://bit.ly/1Tj9a9b>





CJEU: EU TOBACCO PRODUCTS DIRECTIVE IS LEGALLY VALID

5TH MAY 2016

Poland, supported by Romania and the UK, has recently brought a case against the EU Tobacco Products Directive before the Court of Justice of the EU (CJEU). The countries, in particular, objected against the banning of menthol cigarettes, as well as several provisions of the Directive and inquired as to whether or not they are valid.

The CJEU has now issued its judgment and clearly states that the new Directive is valid and that the EU has not surpassed its legitimacy in introducing the new measures.

The EU Tobacco Products Directive focuses on three key areas – (1) the prohibition of menthol cigarettes, (2) introducing new standards for the labelling and packaging of tobacco products, and (3) introducing special rules for electronic cigarettes.

According to the CJEU, menthol cigarettes are more attractive to consumers due to their pleasant flavour. Reducing the appeal of these products could contribute to reducing the prevalence of tobacco use and improve the protection of human health, especially for young people. Furthermore, the CJEU holds that prohibiting menthol cigarettes will facilitate the smooth functioning of the internal market for tobacco and related products.

The CJEU views the new standards for the labelling and packaging of tobacco products as adequate in order to ensure the protection of consumers against the risks associated with tobacco use. The CJEU clearly states that the EU legislature does not go beyond the limits of what is appropriate and necessary in this regard.

Last but not least, with respect to the separate legal regime and rules for e-cigarettes, the CJEU identifies that e-cigarettes display different objective characteristics than tobacco products. Therefore, subjecting them to a different legal regime does not impede fair competition and equal treatment.



Find out more:

- ❖ CJEU press release:
<http://bit.ly/1W8qpuR>



EMA ANNUAL REPORT 2015 PUBLISHED

19TH MAY 2016

The European Medicines Agency (EMA) has published its annual report for 2015, which commemorates the 20th anniversary of the Agency and highlights the accomplishments achieved throughout the past year.

The overall aim of EMA is to foster scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health. Scientific advice continues to be a central pillar of EMA's activities and has helped stimulate innovation, as shown by the annually increasing number of requests for EMA's opinion.

A total of 93 medicines for human use were recommended for marketing authorisation by EMA last year. In contrast, 14 medicines for veterinary use were granted the EMA recommendation for marketing authorisation. The EMA recommendations are sent to the European Commission, which then has the final say on the marketing of new medicines.

A positive trend has been noted on the amount of patients taking the opportunity to report on side effects of new medicines. All such reports are recorded in the EU adverse drug reaction collection and management system EudraVigilance, managed by EMA. Last year more than 1.2 million new reports were recorded. Over 48,000 reports

originated from patients in the European Economic Area, representing a 30% rise compared to the year 2014.

Throughout the past year, EMA has been busy with launching several new projects. One of the most noteworthy is the new PRIME (PRiority MEDicines) scheme, which aims to support the development of medicines that address unmet medical needs. EMA has also started initiatives targeting antimicrobial resistance and other public health threats, as well as a range of new activities to further strengthen the safety monitoring of medicines. Work has also been carried out to advance the development of the clinical trial portal and database, which is a key contribution to the 2015 EU Clinical Trials Regulation.



EMA has also been active at international level, contributing to the global response to the outbreak of the Ebola virus by helping with rapid identification and acceleration of the development of treatments and vaccines.

Find out more:

- ❖ EMA press release:
<http://bit.ly/1V7BScE>
- ❖ EMA Annual Report 2015:
<http://bit.ly/1W3WnI6>



EHEALTH WEEK 2016 IN AMSTERDAM THIS JUNE

17TH MAY 2016

eHealth Week this year will take place as part of the Dutch Presidency of the Council of the European Union and will be organised by the Dutch Ministry of Health, the European Commission, and HIMSS Europe, from 8th to 10th June 2016 in Amsterdam, the Netherlands. Events throughout the Week will focus on three main themes: (1) empowering people, (2) trust and standards, (3) social innovation and transition.



The eHealth Week will feature a series of presentations, workshops, sessions and panel discussions, all designed to facilitate discussions on the latest developments in eHealth in Europe. The ultimate goal of the week will be to bring the public and private sectors together to discuss how they can complement each other's efforts and learn from each other.

EU Commissioner for Health and Food Safety Vytenis Andriukaitis has already confirmed his participation at the eHealth Week 2016. It is expected that several other prominent international and

national organisations and public administration bodies will also attend the event.

Find out more:

- ❖ eHealth Week 2016 website:
<http://www.ehealthweek.org/>



NEW EU HEALTH AWARD TO RECOGNISE EFFORTS IN THE FIGHT AGAINST ANTIMICROBIAL RESISTANCE

26TH MAY 2016

In order to foster the fight against antimicrobial resistance (AMR), the EU has created a new EU Health Award, which will be presented to non-governmental organisations (NGOs) that have excelled in their efforts towards reducing the threat of AMR to human health. AMR is currently one of the key priorities of the EU, on par with the fight against climate change.

International, European, national and regional NGOs are all eligible for the award and are urged to submit their applications to the European Commission by 31st July 2016. Applications highlighting efforts in the following areas are particularly welcome: (1) prevention of infection, (2) appropriate use of antimicrobials, (3) surveillance, (4) tackling AMR from a specific disease perspective such as, for example, tuberculosis or HIV/AIDS, and (5) other initiatives that can reduce the threat to human health from AMR.



The winners of this EU Health Award will receive a cash prize of up to €20 000. All shortlisted candidates will be invited to an Award Ceremony attended by the Commissioner for Health and Food Safety, Vytenis Andriukaitis.

Find out more:

- ❖ European Commission press release: <http://bit.ly/1XUCdjB>



UEMO NEWS

UEMO ATTENDS EUROPEAN COMMISSION ORGANISED MEETING ON ANTIMICROBIAL RESISTANCE

26TH MAY 2016

In May, UEMO was invited to participate in a one-day meeting on antimicrobial resistance at the European Commission premises in Luxembourg. The meeting, held on 25th May 2016, focused on the preparation of EU guidelines on prudent use of antimicrobials in human health.

UEMO was glad and honoured to be invited to the meeting, particularly given that general practitioners are at the forefront in preventing and fighting antimicrobial resistance.

UEMO Secretary General Dr Giuseppe Enrico Rivolta was present at the meeting to represent the interests of UEMO members. The meeting was attended by several other stakeholders and representatives of EU Member States.

UEMO ATTENDS THE FIRST EHEALTH STAKEHOLDER MEETING

18TH MAY 2016

UEMO was appointed permanent member to the eHealth Stakeholdergroup this spring. VP Kjartan Olafsson represents UEMO with VP Calin Bumbulut as his alternate.

"The eHealth Stakeholder Group is one of the informal EC expert groups to provide inputs on the eHealth policy and advises the Commission.

The meeting took place in Brussels 18th of May 09.30 - 17.30. It was chaired by Paul Timmers Director for Digital Society, Trust and Security, DG CONNECT.

Themes for information and discussion:

- eHealth Action Plan
- mHealth policy actions
- Implementation of eHealth Digital service Infrastructure under Connecting Europe Facility (CEF)
- eHealth Network meetings



- Feedback from the Joint Action supporting the eHealth Network

- Information about projects going on

UEMO was very welcome and EU officials are eager to know GPs views on eHealth in future. In a tour de table UEMO presented some general views and underlined that the organisation is going actively into a policymaking phase on eHealth. The UEMO will be invited to present its policy document in a later meeting.

UEMO MEETS DG GROWTH TO DISCUSS PROFESSIONAL QUALIFICATIONS DIRECTIVE

3rd May 2016

UEMO meets DG Growth for the professional qualifications directive (full report as UEMO document).

The most important part of the meeting focused on the implementation of the Directive 2013/055 on the recognition of professional qualifications (alert mechanism and language skills).

The national strategy of the UEMO for implementing family medicine as a speciality was also discussed.

FINAL EVENT OF THE JOINT ACTION ON HEALTH WORKFORCE PLANNING AND FORECASTING

10TH MAY 2016

UEMO is a partner in the Joint Action on Health Workforce Planning and Forecasting (JA-HWF), which was launched in April 2013. The Joint Action culminated at the beginning of May with a Final Event in Mons, Belgium.



The event was opened by European Commissioner for Health and Food Safety Vytenis Andriukaitis and featured presentations on the achievements of the Joint Action. In particular, the Handbook of Good Practices and Methodologies, as well as a study on European health workforce and a data analysis of the current health workforce, as developed by the JA-HWF, were introduced during the event.

The audience included national ministries, stakeholders and several international organisations.



In going a step further than the already achieved results, the JA-HWF final event also aimed to provide a platform for Member States to discuss next steps in the field of health workforce planning and forecasting to find possible solutions for the shortage of healthcare workers in Europe.

Find out more:

❖ JA-HWF website:

<http://healthworkforce.eu/>

OTHER NEWS

69TH WORLD HEALTH ASSEMBLY: OUTCOMES AND DISCUSSION POINTS

29TH MAY 2016

From 23rd to 28th May, over 3,500 delegates from the World Health Organisation's (WHO) 194 Member States met in Geneva, Switzerland, for the annual World Health Assembly.

Discussions and speeches at the Assembly celebrated the recent progress made in global public health, particularly in combatting HIV, tuberculosis, malaria and polio, as well as in improving maternal and child health, and drew attention to the recent outbreaks of Ebola, MERS coronavirus, Zika and urban yellow fever. According to the WHO, these emerging and re-emerging infectious diseases represent a challenge

that the world is not yet fully prepared to cope with.

Such “slow motion” disasters as climate change, antimicrobial resistance and the rise of chronic non-communicable diseases, were also highlighted during the Assembly. The WHO and Member States were urged to take action before these disasters reach a point of no return, after which the harm done will be irreversible.

Delegates at the Assembly agreed that universal health coverage is key to achieving the health-related Sustainable Development Goals (SDGs). A consensus was also reached on the need to transform health systems to better respond to modern day challenges. Health care systems need to become more patient-centred, instead of focusing on diseases. People should be empowered to take charge of their own health rather than simply being recipients of health care services. Unless the necessary changes are made, health systems will become increasingly fragmented, inefficient and unsustainable.



Several new resolutions were passed at the WHO Assembly, including the first hepatitis strategy, which includes the



first-ever global targets for viral hepatitis and a commitment to achieve a 30% reduction in new cases by 2020. Additional commitments were made with regards to obesity, nutrition, tobacco control, HIV and sexually transmitted diseases, access to medicines, and integrated health services.

Find out more:

- ❖ WHO press release (1):
<http://bit.ly/1syvmjw>
- ❖ WHO press release (2):
<http://bit.ly/1X4so5h>

WHO WARNS OF ZIKA TRANSMISSIONS IN EUROPE, BUT DOES NOT SEE THREAT IN RIO OLYMPICS

30TH MAY 2016

Since the outbreak of the Zika virus in Latin America, the World Health Organisation (WHO) has been issuing periodical reports on the status of the outbreak. The most recent report for the WHO European Region assesses the possibility of the outbreak reaching Europe. Although on average the risk remains low, the WHO warns that it is still a possibility and action should be taken to prevent the spread of the Zika virus in Europe.



The risk of the Zika virus spreading is higher in countries that have a higher concentration of Aedes mosquitoes, including the island of Madeira, as well as the Black Sea coastal areas of Georgia and the Russian Federation. Countries in the Mediterranean region remain at a moderate risk for local Zika virus transmission. The WHO recommends that these countries and regions strengthen and/or maintain their vector control activities, improve their entomological surveillance and work on reduction strategies. All countries are advised to make sure they have sufficient laboratory capacity to test for Zika virus or have protocols in place to ship samples abroad for testing.

At the same time, the WHO has also weighed in on the debate about whether this summer's Olympic Games in Rio de Janeiro should be moved or cancelled due to the spread of the Zika virus. The WHO maintains that cancelling or changing the location of the Olympics will not significantly alter the international spread of the Zika virus. Instead, the best way to reduce the risk of disease is to follow public health advice, whereby pregnant women are advised not to travel to areas that have been affected by the Zika virus



outbreak and persons having been in areas affected by the Zika outbreak should refrain from sexual activity for at least four weeks after their visit.

Find out more:

- ❖ WHO press release:
<http://bit.ly/1Ny85br>
- ❖ WHO report on the Zika Virus (May 2016):
<http://bit.ly/23X5Pw8>
- ❖ WHO press release regarding the Olympics and the Zika virus: <http://bit.ly/1sisV4S>

SUCCESSFUL TRIALS FOR NEW EBOLA VACCINE

7TH MAY 2016

A break-through has been achieved in finding a cure for the Ebola virus. Researchers at the University Medical Centre in Hamburg-Eppendorf in Hamburg, Germany, have been working, with support from the World Health Organisation, to develop a medicine to counter the virus and help manage any future outbreaks.

In a trial of the newly developed drug, 158 healthy adults from Germany, Switzerland, Gabon and Kenya were administered increasing doses of the potential vaccine in order to test the safety, tolerability and immune response in humans. Scientists discovered that even after giving a single dose, the human immune system was stimulated and started developing antibodies to combat the Ebola surface protein, which is part of

the new vaccine. Overall, no serious side-effects or adverse reactions were observed.



Scientists are optimistic about the possibilities of the new medicine, which will now undergo further testing in order to determine the optimal dose and its effects on children.

Find out more:

- ❖ News article from Pan-European Networks:
<http://bit.ly/1qXrmb7>

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