

ECCA and EDMA Advance the EU Health Literacy Debate

As part of the 2011 European Cervical Cancer Week, EDMA, the European Diagnostic Manufacturers Association, and the ECCA, the European Cervical Cancer Association jointly organized the "Better Health Literacy for Better Health in Europe" dinner debate in presence of Vic Blaton, EFCC past president, and some EFCC representatives.

ECCA and EDMA made a timely contribution to the debate on Health Literacy at a lively dinner debate held in the Members Salon of the European Parliament on the evening of 25 January. Hosted by Irish MEP Marian Harkin, the event gathered numerous stakeholders from patient organizations, medical associations, the corporate world and the NGO community to debate how health literacy can be improved in the EU.

Mrs. Harkin opened the debate by highlighting the fact that poor health literacy in Europe is a significant barrier to both EU and national goals for improving the health of Europeans.

She also noted that poor health literacy has serious economic consequences for Europe, because it is associated with increased medical interventions that run up unnecessary costs for the European health-care systems.

Dr. Philip Davies of the European Cervical Cancer Association focused on the fact that health literacy is associated with increased participation in disease prevention programs such as cervical cancer screening. Unfortunately, low health literacy accompanies social deprivation so it is therefore mainly lower socioeconomic groups across Europe that fail to take advantage of these programs, and consequently bear an inequitable burden of disease.

Dr. Isabel de la Mata, principal public health advisor at DG SANCO of the European Commission, presented an overview of the efforts and the future steps the EU executive will make to foster health literacy and therefore have healthier citizens.

Dr. Jürgen Schulze, president of



Photo: Mariam Harkin, MEP; Dr. Silvia De San José Longueras, Dr. Isabel de la Mata, DG Sanco.

EDMA, noted that the IVD industry is very concerned about health literacy in Europe and very interested to make a positive contribution to the debate. Moreover, he pledged a closer collaboration between all the involved stakeholders to bypass common prejudices and ultimately to achieve the objectives of having sustainable public finances and better

empowered patients.

To this end, EDMA has delivered on a long-standing commitment by launching Lab Tests Online (www.labtestsonline.info): a global, multilingual, peer-reviewed, patient-centered information portal on laboratory testing organized by the American Association for Clinical Chemistry and coordinated by EDMA in Europe.

Mandatory Accreditation for Medical Laboratories in Romania

by Camelia Grigore, RSLM-EFCC representative

Romania first acknowledged the need to implement a quality management system according to international standards of medical laboratories in the late 1990s. Between 1998 and 2001, the Romanian Accreditation Body organized the first courses regarding the subject. The legislation regulating the standard of quality during that time was ISO/EN 17025. However, it was not adapted to the medical laboratory field. Moreover, the lecturers were engineers or chemists who did not use the proper medical language. The medical staff questioned the applicability of the rules with regard to the needs of a medical laboratory. Nevertheless, the Romanian Accreditation Body began the process of accreditation and an increasing number of laboratory professionals became interested in the field and received medical auditor licenses.

ISO/EN 15189, introduced in 2005, resolved the shortfalls of the previous legislation. It implemented standards adapted to the medical language and needs. More and more laboratories wanted to provide evidence of the quality of their work and began implementing the new standards.

In 2007, the Romanian Ministry of Health issued Order 1301/2007, providing, "Starting 1 January 2008, it is

compulsory for all medical laboratories in relation with the National Health Insurance House to implement a quality management system according to ISO/EN 15189." Medical laboratories were required to have at least 10 tests accredited.

It proved to be an efficient way of selecting laboratories that were competing for funds, as well as have laboratories resolve to fulfill the standards and improve their quality management system. The legislation was amended again in April 2009 when the National Health Insurance House announced, "Starting 1 January 2010, it is compulsory for all medical laboratories in relation with the National Health Insurance House to be accredited according to ISO/EN 15189 for 50% of the tests."

Were Romanian Medical Laboratories Prepared for Accreditation?

Romania did not have national guidelines regarding Good Laboratory Practices. Hospital laboratories used outdated equipment, there was no modern IT system in place, but the most pressing issue was the lack of funds to fulfill standard demands. On the other hand, laboratories operating in the private sector had access to new equipment and were able to engage

human resources and funds to fulfill EU standards. This led to an increase in competition between public and private laboratories for available funding, with private laboratories taking the lead in development. Because public hospitals did not have sufficient resources to

develop their capacities, a significant number of hospital labs were outsourced and private laboratories became dominant on the market.

Beginning with 2008, accreditation became a key objective for medical laboratories. In 2008, only around 2 laboratories received accreditation according to ISO/EN 17025 standards. During 2009 and 2010, an increasing number made efforts to fulfill the requirements, and in March

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