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# EAMBES newsletter
# June 2015

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## New Council Presidency

On 1 July 2015 Luxembourg is taking over the rotating Presidency of the Council of the EU, the European institution representing the executive governments of the EU Member states.

Their priorities will largely follow those of the Latvian's Presidency, in line with the 'Trio's priorities', set out before the Latvian, Luxembourg and Dutch presidencies. The formal priorities of the presidency include facilitating the creation of a strong regulatory framework providing European citizens with quick access to safe and high-quality medical devices, whilst promoting the innovation and competitiveness of the European market. The Luxembourg Presidency will oversee trialogues on the Medical Devices and In-Vitro Medical Devices Regulations. It will also focus on improved access to personalised medicine.

In order to conclude the development of the European Research Area (ERA), the Luxembourg Presidency will strive to improve the coordination and coherence of research policies at European and national level.

The upcoming Presidency will also give priority to digital technology with a view to implementing the digital single market. An approach based on the principle of 'digital by default' will be encouraged. The Presidency will promote initiatives in diverse fields including research and innovation (Big Data, Cloud Computing).

In order to overcome the existing legal and administrative obstacles that prevent the single market from deepening, the Luxembourg Presidency will encourage the use of the most effective regulatory and non-regulatory instruments, in particular harmonisation and mutual recognition, with a view to guaranteeing optimum legal

certainty, reducing regulatory fees for companies and offering consumers the widest possible choice.

For more information:

http://www.eu2015lu.eu/en/la-presidence/a-propos-presidence/programme-et-priorites/PROGR_POLITIQUE_EN.pdf

## New Group in the Parliament

On 16 June 2015, Ms. Marine Le Pen, on behalf of the French 'Front National' party, which until June was part of the Non-Aligned (NI) Group, announced that her party had gathered enough support from parties in the European Parliament to form a distinct political group. Under the name 'Europe of Nations and Freedoms(ENF)', this new group gathers anti-EU and anti-immigration focused MEPs.

By forming a group, the Front National will receive more speaking time and more staff as well as a higher likelihood of getting members on parliamentary committees.

The new group consists of MEPs from the Front National (France) and members from 6 other countries including PVV (Netherlands), Vlaams Belang (Belgium), UKIP (UK), Jobbik (Hungary), Lega Nord (Italy), KNP (Poland) and FPO (Austria) and will total at least 36 MEPs.

Although they are unlikely to take significant numbers from other groups, this represents a growing coordination of anti-EU sentiment and may grant this group the lead on a piece of legislation. However, given the reduced amount of legislation this year, the major groups will have significantly more points to use on important dossiers.

## DG SANTE Annual work plan for 2015

DG SANTE published on 2 June 2015 its annual work plan for 2015, which sets out the priorities and actions to be undertaken, including the allocation of resources, to implement the third Programme of the Union's action in the field of health (2014-2020).

Of particular interest are the actions related to medical devices and health technology assessment, which include:

- A more developed and coordinated Market surveillance of medical devices by Member States´ competent authorities.
- Maintenance and development of the European medical devices database (EUDAMED) and development of the future EUDAMED following the adoption of the new Regulations on medical devices. EUDAMED will allow the exchange of legal information related to the application of European Union Directives on medical devices between the Commission and the competent authorities in the EU Member States.

- Communication and publication actions to promote the understanding and correct implementation of the requirements and risks relating to medical devices following the adoption of the new Regulations.
- Technical and scientific opinions and advices allowing improved coordination and resource sharing between Member States and enhanced transparency regarding medical devices on the EU market.
- Support cooperation at scientific and technical level between Health Technology Assessment Bodies to ensure the sustainability of the joint work after EU funding under the Health Programme ends.

The future EUDAMED is due to be launched in the first semester of 2015, second semester in the case of the actions regarding the correct implementation of the new MDR and IVR, showing once again how keen the Commission is on seeing these regulations adopted as soon as possible.

For more information:

http%3a%2f%2fec.europa.eu%2fhealth%2fprogramme%2fdocs%2fwp2015_en.pdf

http%3a%2f%2fec.europa.eu%2fhealth%2fprogramme%2fdocs%2fwp2015_annex_en.pdf

## Council Partial General Approach on Medical Devices

On 19 June 2015, the Employment, Social Policy, Health and Consumer Affairs Council adopted a partial general approach –excluding the recitals- on the Medical Devices and In Vitro Diagnostic Medical Devices Regulations.

After three years of debate, this achievement represents an important milestone in the adoption of new legislation on medical devices. It needs to be remembered that the European Parliament adopted its position in October 2013 but negotiations could not continue between the institutions until the Council agreed on a general approach.

Under the mantra "*Let's not make the best the enemy of the good*", most delegations (with the exceptions of Germany and Poland) agreed to move to the next stage, despite not fully agreeing with the outcomes on some elements of the general approach.

The most controversial topics are still the premarket assessment of high risk devices, reprocessing, inclusion in the scope of the legislation of aesthetic products and the unique device identification system, which will constitute the main subjects of discussion in the trialogues ahead.

As a next step, the Council needs to finalise the outstanding technical work concerning the preamble of the two draft regulations (which give important clues for interpretation of the articles in the body of the regulations) and check technical inconsistencies with a

view to preparing a general approach for the two draft regulations. Trialogues are due to start in autumn.

## Communication on the European Citizens' Initiative "Stop Vivisection"

The European Commission adopted on 3 June 2015 a Communication on the European Citizens' Initiative "Stop Vivisection".

It explains that, whilst the Commission does share the conviction that animal testing should be phased out in Europe, it does not intend to submit a proposal to repeal Directive 2010/63/EU on the protection of animals used for scientific purposes and is not intending to propose the adoption of a new legislative framework. In a nutshell, the reasons given are the following:

- The complete replacement of animal testing is currently not possible while needing to ensure a high level of protection of human and animal health and the environment.
- The Directive is needed to ensure a high level of protection of the animals used in research.
- At the same time, Directive 2010/63/EU is the catalyst for the development and uptake of alternative approaches. The use of animals in research actually provides a mechanistic understanding of the biology of animals and humans, which enables the development of more ethical, cost-effective, predictive and faster alternative methods.

The Communication sets out a number of actions that the Commission will take towards the goal of phasing out animal testing. These include the development, validation and implementation of new alternative approaches.

The Commission reiterates its intention to continue to promote the development and implementation of alternative approaches for regulatory and research use. This will include close cooperation between the Commission, Member States and international organisations and be supported, as appropriate by EU programmes.

When talking about the alternatives, the report refers to “computational tools to analyse biological processes and to simulate the complex mechanisms involved in health and disease” as “technological advances have revolutionised biomedical research” and may contribute to reduce animal testing.

**Phasing out animal testing – Other foreseen actions**

**1. Accelerating progress in the Three Rs** (the requirement to Replace, Reduce and Refine the use of animals wherever possible) **through knowledge sharing:** The Commission will analyse technologies, information sources and networks from all

relevant sectors with potential impact, and will present by end 2016 an assessment of options to enhance knowledge sharing among all relevant parties.

**2. Enforcement of compliance with the Three Rs principle and alignment of relevant sector legislation:** The Commission will actively monitor compliance with the Directive, in particular the Three Rs principle, and with the relevant obligations in sector legislation to use available alternatives. The Commission will also actively monitor the correct enforcement by all Member States.

By end 2016, the Commission will examine regulatory requirements in the relevant sector legislation mandating animal testing to assess if the legislative text enables an efficient up-take of available alternative approaches and the Commission will ensure that future proposals for relevant sector legislation will reflect the rules on the protection of animals used for scientific purposes.

The Commission plans to review it in 2017 and will emphasize the availability of alternative approaches. In addition, the Directive requires an implementation report in 2019. These reports will be the first assessments of the extent to which the Directive is reaching its objectives.

**3. Engaging in a dialogue with the scientific community:** By end 2016 the Commission will organise a conference engaging the scientific community and relevant stakeholders in a debate on how to exploit the advances in science for the development of scientifically valid non-animal approaches and advance towards the goal of phasing out animal testing. On that occasion it will present a progress report on the actions taken.

For more information:

http://ec.europa.eu/citizens-initiative/public/initiatives/finalised/answered