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I. Status of the Medical Devices Regulation

Following the adoption by the Council of the partial general approach on the Medical Devices and In Vitro Diagnostic Medical Devices Regulations in June, the Working Party (WP) on Pharmaceuticals and Medical Devices has started the work 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 technical inconsistencies.

In order to meet the ambitious timeline presented by the Luxemburgish Minister, Mrs Lydia Mutsch, on the occasion of the exchange of views that took place on 16 July 2015 at the European Parliament's (EP) Environment, Public Health and Food Safety Committee (ENVI), the WP has dedicated five meetings during the month of July to these dossiers. The envisaged timetable for finishing the dossier is as follows:

- Recitals: work started on the 6th of July and continued on the 22nd of July.
- Technical Inconsistencies: discussed on the 23rd of July and from 8th of September onward.
- Consolidated text: by the end of September for both MDR and In Vitro Diagnostics.
- Compromise text: to be submitted to the Council on the 5th of October for adoption.
- Trialogue meetings: 3 meetings at the beginning of October, November and December to discuss the political issues and technical meetings in between

During the exchange of views with Ms. Mutsch, Dr. Liese shared the Parliament's concern, which does not agree with the Council on the issue of scrutiny included in the Regulation, particularly with the fact that the Council had decided to only have scrutiny for a small group of products. Dr. Liese explained that the EP would like to have scrutiny for a much larger group of products, which could be inspected when there are reasonable grounds to do so. In response to this, Ms. Mutsch explained that divergent views in the Council have led to the current

compromise and that she hopes to be able to find a compromise with the EP on this issue as well.

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II. UK: MHRA review on draft guidance on the re-manufacturing of single-use devices

On 20 July 2015, the Medicines and Healthcare products Regulatory Agency (MHRA) launched for public consultation a *Draft Guidance document on the re-manufacturing of Single Use Devices (SUDs)*, aiming at medical devices industry, healthcare establishments and healthcare professionals.

Key points include:

- While in the UK reprocessing of SUDs is discouraged by the MHRA, single-use devices may be re-manufactured prior to being placed on the market, for a limited number of times, as long as the re-manufacturing company demonstrates to the notified body (Class I Medical Devices are therefore excluded) that the re-manufactured SUD clearly meets all appropriate criteria foreseen in the European legislation on medical devices and place a CE-mark on its product.
- The re-manufacturer accepts all liabilities and obligations for the re-manufactured SUD. In this regard, the Guidance refers, by way of example, to the obligations of the re-manufacturer on technical documents, decontamination, cleaning, sterilization and bioburden, labelling and risk management and post-market surveillance.
- Healthcare organisations re-manufacturing SUDs must have a contract with a specific re-manufacturer, to which the SUDs must be returned.
- A re-manufactured single-use device should only be used on an individual patient during a single procedure.

Deadline for comments is on 1 September 2015. The final guidance will be produced by the end of 2015 and may be reviewed in the future in order to be in line with the Medical Devices Regulation, when adopted.

For more information:

https://www.gov.uk/government/news/re-manufacture-of-single-use-devices-survey-on-draft-guidance

III. €1.7B budget for research in 2016

On 28 July the European Commission adopted the annual work programme for the European Research Council (ERC).

The ERC's mission is to encourage the highest quality research in Europe through competitive funding and to support investigator-driven frontier research across all fields, on the basis of scientific excellence.

The work programme recently adopted sets out the ground rules on €1.67 billion of grants. It provides information on the eligibility criteria, deadlines and the process to follow to submit the proposals or the deadlines, amongst other things.

The grants are divided into three categories: starting, consolidator and Advanced Grants

Starting grants are designed to support excellent Principal Investigators at the career stage at which they are starting their own independent research team or programme. Starting Grants may be awarded up to a maximum of EUR 1 500 000 for a period of 5 years18.

ERC Consolidator Grants are designed to support excellent Principal Investigators at the career stage at which they may still be consolidating their own independent research team or programme. They may be awarded up to a maximum of EUR 2 000 000 for a period of 5 years.

Advanced Grants are designed to support excellent principal Investigators at the career stage at which they are already established research leaders with a recognised track record of research achievements. Applicant Principal Investigators must demonstrate the ground-breaking nature, ambition and feasibility of their scientific proposal.

Advanced Grants may be awarded up to a maximum of EUR 2 500 000 for a period of 5 years.

For more information:

http://erc.europa.eu/sites/default/files/document/file/ERC_Work_Programme_2016.pdf

IV. DG Research priority list

On 24 July, the Commissioner for Research, Carlos Moedas, presented a poster with a to-do list summing up the top priorities of his five-year term, which had been sent the day before to the civil servants working in his research directorate.

Importantly, Moedas' priorities list includes new ideas, such as the creation of the European Innovation Council (EIC), a programme which would to support innovations in any field, including healthcare.

Taking the form of a one-stop innovation house, it will created by streamlining, re-branding and re-packing some of the Horizon 2020 innovation calls. In order to achieve this, all the innovation support in Horizon 2020 will be reviewed prior to the Horizon 2020 mid-term review in 2017. However, the Commissioner does not intend to review any budget lines.

The priorities list also makes reference for the first time to the creation of an Ombudsman to police scientific misconduct, but no more information has been provided in this regard.

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V. Relevant Parliamentary Questions

Relevant Parliamentary Questions (PQs) raised or answered during the month of July focused on eHealth and mHealth.

A question tabled by Mr. Pablo Iglesias MEP(GUE/NGL, Spain) on the **roll-out of mHealth in Europe** on 10 June 2015 noted that mHealth solutions hold great potential for individuals to engage more with their own health however the distinction between solutions is unclear. He asked if the Commission will introduce specific legislation calling for transparency about who is behind the apps and provide clarity over the rules pertaining to quality, protection of privacy, liability and redress.

A question also tabled by Pablo Iglesias MEP on **e/mHealth and prospective guidelines** on 10 June 2015 highlighted that, in order for the EU to exploit the e/mHealth revolution effectively and create a new prevention culture, it is crucial that investments are coupled with health system changes that allow actors to use these developments effectively including training and integration of these new tools. He asked if the Commission will seek to develop concrete and evidence-based user guidelines such as those being drafted for nurses and social workers by the ENS4Care project partners.

A question tabled by Ivan Jakovcic (ALDE, Croatia) on **eHealth** on 21 April 2015 noted the opportunities of using internet technology in the healthcare sector, but that it will only acquire its full meaning when there is a single European system for the exchange of knowledge and experience by using the advantages of the internet. He asked how the Commission intends to propose a networking and the creation of a single European medical system for efficient exchange of knowledge and experience among physicians (at least in emergencies and complicated cases).

The answer given by Mr Andriukaitis, Commissioner of Health and Food Safety, on 17 June 2015 noted the Commission's support to Member States through the eHealth network which adopted patient summary guidelines to provide continuity of care and patient safety and guidelines on ePrescriptions. Further actions on deploying eHealth solutions are planned under the 2015 work plan of the Health Programme such as the set-up of an IT platform to connect European Reference Networks. Furthermore, on the 6 May 2015, the Commission launched the new Digital Single Mark strategy which includes the area of eHealth. The Horizon 2020 Work Programme 2014-2015 supports regulatory and legal process development to address possible barriers to procurement of innovative solutions in healthcare.