

■ ZUR SACHE

Brexit: The role of the EMA vis-à-vis the Member States' Combined Team for Handling Human Pharmaceuticals

European Medicines Agency: From Business as it used to be to New Horizons

Professor Dr Rolf Baß, retired Director at the German Federal Institute for Drugs and Medical Devices, Berlin, Germany

References

[1] EMA 2017: United Kingdom's withdrawal from the European Union („Brexit“) (6.9.2017). Available at: <http://www.ema.europa.eu/ema/> -- following the menu: “About us” > UK's withdrawal from EU” (last accessed at 24 January 2018).

[2] EMA 2017: European Medicines Agency Brexit Preparedness Business Continuity Plan. EMA/196585/2017 – 13 October 2017. Available at [1] > PDF link within the text (last accessed at 24 January 2018).

[3] EMA 2017: Regulatory guidance for pharmaceutical companies to prepare for UK's withdrawal from EU. Available at [1] -- following the menu on the right side (last accessed at 24 January 2018).

[4] EMA 2017: Questions and answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure -- Rev. 01, published on 1 December 2017. PDF available at [3] -- following the menu on the right side (last accessed at 24 January 2018).

[5] Ian Schofield: Don't Expect Business As Usual From EMA During Transition, Says BIA Head. Scrip 22 November 2017. Available at: <https://scrip.pharmaintelligence.informa.com/SC099933/Dont-Expect-Business-As-Usual-From-EMA-During-Transition-Says-BIA-Head> (last accessed at 24 January 2018).

[6] European Commission / EMA: Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use (no date given). Available at: <http://www.ema.europa.eu/ema/> -- following the menu “About us” > UK's withdrawal from EU > Guidance for companies > (PDF)” (last accessed at 24 January 2018).

[7] EU-UK: Joint Report from the Negotiators of the European Union and the United Kingdom Government on progress during phase 1 of negotiations under Article 50 TEU on the United Kingdom's orderly withdrawal from the European Union. 8 December 2017 -- TF50 (2017) 19 – Commission to EU 27. Available at: https://ec.europa.eu/commission/sites/beta-political/files/joint_report.pdf (last accessed at 24 January 2018).

[8] UK House of Commons – Library – Briefing Paper -- Number 8148, 20 November 2017:

Brexit and medicines regulation. Available at: <http://www.parliament.uk/commons-library> -- following the menu: "Brexit: research and analysis [right side menu] > Health and social care > Brexit and medicines regulation" – full report PDF at the end of the text (last accessed at 24 January 2018).

[9] Report by President Donald Tusk to the European Parliament – "The EU door remains open to the UK". 16 January 2018. Available at <http://www.consilium.europa.eu/en/> -- following the menu: "Press > Press releases > 16 January 2018" and also "Press > Council streaming > 16 January 2018" (last accessed at 25 January 2018).

END