EN
P-007508/2016
Answer given by Mr Andriukaitis
on behalf of the Commission
(4.11.2016)

1. The legislation[1] does not require the Commission to adopt the delegated act setting up the detailed rules for the safety features of medicinal products for human use within a specific legal deadline. Nevertheless, the Commission confirms that more time than initially expected was needed to adopt the provisions due to the impact assessment, the involvement of stakeholders and the complexity and technical nature of measures to be put in place.

2. The legislation[2] does not provide an obligation for the European Medicines Verification Organisation to share its contacts with the national medicines verification organisations.

3. Until the Treaties cease to apply to a Member State that has notified, in accordance with Article 50 of the Treaty on European Union (TEU)[3], the European Council of its intention to withdraw from the Union, that State remains a member of the Union with all rights and obligations of a Member State. In line with the Statement of 29 June 2016 of the Heads of State or Government of 27 Member States, as well as the Presidents of the European Council and the European Commission, there can be no negotiations of any kind before a notification under Article 50 TEU has taken place. At this stage, it is therefore not possible to give a more precise answer to the questions of the Honourable Member.

---

1 Article 54a of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; OJ L 311, 28.11.2001

2 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use; OJ L 32/1, 09.02.2016

3 http://eur-lex.europa.eu/summary/glossary/withdrawal_clause.html