

Brussels, 14 January 2015
Case No: 76688
Event No: 734118

EFTA SURVEILLANCE
AUTHORITY

Minutes of College meeting 1 - 14 January 2015

Members present: Oda Helen Sletnes, Helga Jónsdóttir and Frank Büchel

Officials present: Bernhard Zaglmayer, Gjermund Mathisen, Brit Helle, Xavier Lewis, Jonas Pålshammar, Gabrielle Somers, Ruta Janeckaite, Andreas Kjeldsberg Pihl and Nina Hoppe

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1. Agenda

Event [734111](#)

The College approved the Agenda

2. Decisions taken by delegation procedure

[734107](#)

The College took note of the decisions taken by delegation

3. **Case 69202: Failure by Iceland to transpose Article 8 of Directive 91/533/EEC on an employer's obligation to inform employees of the conditions applicable to the contract or employment relationship**

Event [699088](#)

The College adopted a decision to close a case concerning Iceland's failure to transpose Article 8 of the Act referred to at point 25 of Annex XVIII to the EEA Agreement (*Council Directive 91/533/EEC of 14 October 1991 on an employer's obligation to inform employees of the conditions applicable to the contract or employment relationship*), as adapted to the EEA Agreement by Protocol 1 thereto, as **Decision No. 1/15/COL**

4. **Case 66381: Failure by Iceland to correctly implement Directive 2004/39/EC (MiFID)**

Event [730725](#)

The College adopted a decision to close an own-initiative case concerning Iceland's failure to adopt the necessary measures to fully implement the Act referred to at point 31ba of Chapter III of Annex IX to the Agreement on the European Economic Area (*Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments amending Council Directives 85/611/EEC and 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC*), as adapted to the EEA Agreement by Protocol 1 thereto into its national law, as **Decision No. 2/15/COL**

5. **Case 75927: Non-implementation by Liechtenstein of Directive 2013/10/EU (Aerosol dispensers - labelling provisions)**

Event [731992](#)

The College adopted a decision to close a case on Liechtenstein's failure to take the measures necessary to implement the Act referred to at point 1 of Chapter VIII of Annex II of the Agreement on the European Economic Area (*Commission Directive 2013/10/EU of 19 March 2013 amending Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures*), as adapted to that Agreement by Protocol 1 thereto, into its national law and/or its failure to notify the Authority forthwith of these measures, as **Decision No. 3/15/COL**

6. **Case 75930: Non-implementation by Liechtenstein of Directive 2011/88/EU (Provisions for engines placed on the market under the flexibility scheme)**

Event [731995](#)

The College adopted a decision to close a case on Liechtenstein's failure to take the measures necessary to implement the Act referred to as a new indent at point 1a of Chapter XXIV of Annex II of the Agreement on the European Economic Area (*Directive 2011/88/EU of the European Parliament and of the Council of 16 November 2011 amending Directive 97/68/EC as regards the provisions for engines placed on the market under the flexibility scheme*), as adapted to that Agreement by Protocol 1 thereto, into its national law and/or its failure to notify the Authority forthwith of these measures, as **Decision No. 4/15/COL**

7. **Case 76499: Non-implementation by Iceland of Directive 2012/46 (Measures against the emission of gaseous and particulate pollutants from internal combustion engines)**

Event [731357](#)

The College adopted a decision to issue a letter of formal notice to Iceland in accordance with Article 31(1) of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice for that State's failure to take the measures necessary to implement the Act referred to as a new indent at point 1a of Chapter XXIV of Annex II to the Agreement on the European Economic Area (*Commission Directive 2012/46/EU of 6 December 2012 amending Directive 97/68/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery*), as adapted to that Agreement by Protocol 1 thereto, into its national law and/or its failure to notify the Authority forthwith of these measures, as **Decision No. 5/15/COL**

8. **Case 76500: Non-implementation by Norway of Directive 2012/46 (Measures against the emission of gaseous and particulate pollutants from internal combustion engines)**

Event [731354](#)

The College adopted a decision to issue a letter of formal notice to Norway in accordance with Article 31(1) of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice for that State's failure to take the measures necessary to implement the Act referred to as a new indent at point 1a of Chapter XXIV of Annex II to the Agreement on the European Economic Area (*Commission Directive 2012/46/EU of 6 December 2012 amending Directive 97/68/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery*), as adapted to that Agreement by Protocol 1 thereto, into its national law and/or its failure to notify the Authority forthwith of these measures, as **Decision No. 6/15/COL**

9. **Case 76498: Non-implementation by Liechtenstein of Directive 2012/46 (Measures against the emission of gaseous and particulate pollutants from internal combustion engines)**

Event [731350](#)

The College adopted a decision to issue a letter of formal notice to Liechtenstein in accordance with Article 31(1) of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice for that State's failure to take the measures necessary to implement the Act referred to as a new indent at point 1a of Chapter XXIV of Annex II to the Agreement on the European Economic Area (*Commission Directive 2012/46/EU of 6 December 2012 amending Directive 97/68/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal*

combustion engines to be installed in non-road mobile machinery), as adapted to that Agreement by Protocol 1 thereto, into its national law and/or its failure to notify the Authority forthwith of these measures, as **Decision No. 7/15/COL**

10. Case 74421: Failure by Norway to comply with Regulation (EC) 1907/2006 (REACH)

Event [726591](#)

The College adopted a Decision to issue a letter of formal notice to Norway in accordance with Article 31(1) of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice for that State's breach of its obligations:

- arising from the Act referred to at point 12zc of Chapter XV of Annex II to the EEA Agreement (*Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended*, in particular Article 128 thereof, as adapted to the EEA Agreement by Protocol 1 thereto, by maintaining in force section 2 paragraph 32 of the Norwegian Product Regulation which bans the manufacture, import, export and sale of consumer products containing 0.001% or more by weight of perfluorooctanoic acid and
- arising from the Act referred to at point 1 of Chapter XIX of Annex II *Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, as amended*, in particular Article 8(1) third subparagraph thereof, as adapted to the EEA Agreement by Protocol 1 thereto, by failing to notify the Authority of the change to the concentration limit of perfluorooctanoic acid as set out in section 2 paragraph 32 of the Norwegian Product Regulation from the draft regulation originally notified within the context of the DTR procedure in 2010,

as **Decision No. 8/15/COL**

11. Cases 75779 and 75870: Non-incorporation by Iceland of Regulations (EU) No 1235/2010 (Pharmacovigilance of medicinal products for human use and establishing a European Medicines Agency) and (EC) No 1027/2012 (Pharmacovigilance)

Event [731070](#)

The College adopted a decision to deliver a reasoned opinion to Iceland in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning the failure by Iceland to make the Acts referred to at point 15zb of Chapter XIII of Annex II to the Agreement on the European Economic Area:

- *Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and Regulation (EC) No 1394/2007 on advanced therapy medicinal products*
- *Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance)*

As such part of its internal legal order, as **Decision No. 9/15/COL**

12. Case 75780: Non-implementation by Iceland of Directive 2010/84/EU (Community code relating to medicinal products for human use)

Event [731064](#)

The College adopted a decision to deliver a reasoned opinion to Iceland in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning the failure by Iceland to adopt the measures necessary to implement the Act referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area (*Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use*) or, in any event, its failure to notify the Authority forthwith of the measures it has adopted to implement the Act, as **Decision No. 10/15/COL**

13. Cases 75781 and 75828: Non-implementation by Iceland of Directives 2011/62/EU (Community code relating to medicinal products for human use) and 2012/26/EU (Pharmacovigilance)

Event [731134](#)

The College adopted a Decision to deliver a reasoned opinion to Iceland in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning the failure by Iceland to adopt the measures necessary to implement the Acts referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area:

- *Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products*
- *Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance)*

or, in any event, its failure to notify the Authority forthwith of the measures it has adopted to implement the Acts, as **Decision No. 11/15/COL**

14. Decision taken by written procedure

None

15. Other Business

None

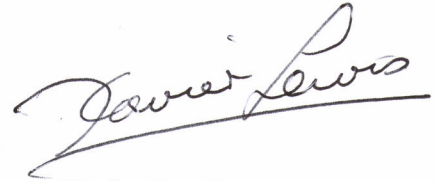
16. Minutes of the College Meeting no. 1, held on 14 January 2015

Event [734118](#)

The College approved the Minutes of the College Meeting held on 14 January 2015



Oda Helen Sletnes
President



Xavier Lewis
Director