TRANSPOSITION NOTES

Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance

Directive 2012/26/EU amends Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Directive 2012/26/EU mainly makes changes to the pharmacovigilance provisions of Directive 2001/83/EC in order to strengthen public health protection. Pharmacovigilance is the monitoring of the safety of medicines. In this regard, Directive 2012/26/EU:

- Amends article 23a of Directive 2001/83/EC to ensure that reasons accompany a notification to the UK licensing authority to suspend temporarily or permanently the marketing of a medicinal product;

- Amends articles 31 and 34 of Directive 2001/83/EC to clarify the procedures for EU referrals;

- Amends article 107i of Directive 2001/83/EC to reduce the events that automatically trigger the urgent EU action procedure;

- Amends article 123(2) of Directive 2001/83/EC to require notification to the UK licensing authority of the withdrawal of a medicinal product from the market or non-renewal of an authorisation;

- Further amends article 123(2) of Directive 2001/83/EC to tighten up the requirement to provide reasons when notifying a temporary or permanent suspension of marketing of a medicinal product, a request to withdraw an authorisation or non-renewal of an authorisation under article 123(1);

- Adds article 123(2a) of Directive 2001/83/EC to ensure notifications to the UK licensing authority under articles 123(2) are made in relation to action in third countries in certain circumstances;

- Adds article 123(2b) of Directive 2001/83/EC to require notification to the European Medicines Agency (EMA) in certain circumstances; and requires the EMA to forward the notifications to Member States;

- Amends article 123(4) of Directive 2001/83/EC to ensure that the EMA include reasons in its published annual list of medicinal products whose authorisations have been refused, revoked or suspended or whose supply have been prohibited or have been withdrawn from the market.

Directive 2012/26/EU also provides for some miscellaneous clarifications and corrections in relation to Directive 2001/83/EC.

The new Directive is transposed by the Human Medicines (Amendment No. 2) Regulations 2013 which makes changes to the Human Medicines Regulations 2012.

Article of Directive 2012/26/EU	**Article of Directive 2001/83/EC affected**	**Objective**	**Implementation (references are to the Human Medicines Regulations 2012)**
1(1)	23a	Requires that notifications under article 23a are accompanied by reasons	73 and 113
1(2)	31	Amends and clarifies EU referral procedures	None required
1(3)	34(3)	Amends and clarifies EU referral procedures	None required
1(4)	37	Removes erroneous reference to article 36	None required
1(5)	63	Clarifies that labels and leaflets need not be in all official languages of Member States	None required. UK law is already clear on this point – see regulation 266
1(6)	85a	Corrects oversight in Directive 2001/83/EC in relation to falsified medicines	None required. This article has been transposed by regulation 44, as amended by SI 2013/1855
1(7)	107i(1)	Amends the urgent EU actions procedures	196
1(8)	107i(2)	Amends the urgent EU actions procedures	196
1(9)	107i(3)	Amends the urgent EU actions procedures	196
1(10)	107i(5)	Amends the urgent EU actions procedures	196
1(11)	107j(1)	Amends the urgent EU actions procedures	196
1(12)	123	Amends notification requirements	73 and 142