

11 February 2013

David Olszowka
Falsified Medicine Consultation
MHRA
Area 5-M, 5th Floor
151 Buckingham Palace Road
London SW1W 9SZ

Dear Mr Olszowka

**European Directive 2011/62/EU of the European Parliament and of the Council
("the Falsified Medicines Directive")**

Thank you for the opportunity to comment on the Falsified Medicines Directive. The British HIV Association welcomes the implementation of this new legislation, and recognises that existing safeguards have not prevented the infiltration of counterfeit HIV medications into the UK supply chain in recent years. It is also the case that people living with HIV may take nutritional supplements or complementary remedies and may self-prescribe with medicines (such as hormones, steroids, phosphodiesterase inhibitors) sourced through the internet. The Association requests that the following be considered:

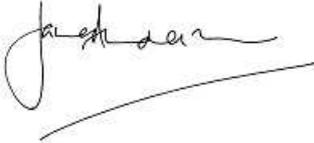
- 1 Cost models used in appraising different options for implementation of this Directive do not always distinguish between harms which resolve, and those which do not. Although this is not a problem specific to HIV therapy, counterfeit HIV medicines can place our patients at great risk, not least because any resistance which arises is permanently archived. The Association believes that the potential loss of health suffered by the patient, and the consequent lifelong costs of alternative drug regimens should be factored into these considerations.
- 2 HIV services are configured to deliver healthcare within Networks, and many of these operate in a model where a central provider 'hub' supports smaller units, often across traditional Trust boundaries. In specific scenarios (e.g. Sexual Assault Referral Centres), supply of HIV drugs in a timely manner is important. We are unclear whether the obligations placed upon brokers may restrict this practice, and we would value guidance on this, and whether new institutional arrangements need to be enacted in order to comply with the law.
- 3 While this legislation deals with falsified medicines which either do not contain, or contain the wrong amount of active ingredient, we are uncertain whether the converse would also be included, namely the inclusion of (small) amounts of antiviral drugs in 'herbal' or 'traditional' medicines. People with HIV infection may turn to

traditional or complementary therapies instead of anti-retroviral agents, and acquire resistance.

In summary BHIVA supports this legislation, which we believe to be in the best interests of people living with HIV.

With kind regards

Yours sincerely

A handwritten signature in black ink, appearing to read 'Jane Anderson', with a long horizontal flourish extending to the right.

Professor Jane Anderson
Chair
British HIV Association (BHIVA)