



STATUTORY INSTRUMENTS.

S.I. No. 531 of 2019



INFECTIOUS DISEASES (PREVENTATIVE MEASURES) (HIV PrEP)
REGULATIONS 2019

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I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by sections 5 and 31 (as amended by section 34 of the Health Act 1953 (No. 26 of 1953)) of the Health Act 1947 (No. 28 of 1947), hereby make the following regulations:-

1. These Regulations may be cited as the Infectious Diseases (Preventative Measures) (HIV PrEP) Regulations 2019.

2. These Regulations shall come into operation on 1 November 2019.

3. In these Regulations—

“Directive” means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001¹, as amended from time to time;

“HIV” means human immunodeficiency virus, a virus that has been specified as an infectious disease under Regulation 6 of the Infectious Diseases Regulations 1981 (S.I. No. 390 of 1981);

“HIV PrEP” means a pre-exposure prophylaxis medicinal product which—

- (a) has received a marketing authorisation in accordance with Article 6 of the Directive,
- (b) involves the use of antiretroviral medicinal products to prevent persons who have not been infected with HIV from being infected with HIV, and
- (c) is being provided to suitable candidates by the HSE for the purposes of Regulation 4 of these Regulations;

“HSE” means the Health Services Executive;

¹ OJ No. L 311, 28.11.2001, p. 67.

“medical services relating to HIV PrEP” means all medical services that are to be provided by the HSE to suitable candidates in relation to their usage of HIV PrEP, whether—

- (a) through its own hospitals, clinics or other facilities and by its own staff, or
- (b) through facilities and persons contracted by it for such purposes;

including the supply of HIV PrEP, subsequent monitoring to ensure correct usage, and the provision of advice and information on risk reduction;

“medicinal product” has the meaning assigned to it by Article 1 of the Directive;

“registered medical practitioner” has the meaning assigned to it by section 2 of the Medical Practitioners Act 2007 (No. 25 of 2007), as amended from time to time;

“suitable candidates” means persons who meet such criteria as may be specified in relevant clinical guidance published by the HSE relating to the appropriate persons to whom medical services relating to HIV PrEP should be provided by the HSE and who are in receipt of a prescription for HIV PrEP provided to them by a registered medical practitioner.

4. The HSE shall provide medical services relating to HIV PrEP to suitable candidates, the costs of which shall be borne by the HSE.

5. The HSE shall publish information relating to—

- (a) the provision of, and
- (b) the criteria that persons are required to meet in order to be deemed suitable candidates for receiving,

medical services relating to HIV PrEP for the purposes of Regulation 4 on its website and shall also make this information available at any hospitals, clinics or facilities providing such services.



GIVEN under my Official Seal,
25 October, 2019.

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Regulation and does not purport to be a legal interpretation)

The purpose of these Regulations is to provide for the roll-out, by the HSE, of a comprehensive programme of HIV PrEP for persons at substantial risk of sexual acquisition of HIV.

The Regulations also provide for related services to be provided without charge to those accessing the programme (i.e. the costs will be borne by the HSE).

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