



Health and Social Care Act 2012

2012 CHAPTER 7

PART 2

FURTHER PROVISION ABOUT PUBLIC HEALTH

57 Functions in relation to biological substances

- (1) The appropriate authority must—
 - (a) devise standards for the purity and potency of biological substances,
 - (b) prepare, approve, hold and distribute standard preparations of biological substances,
 - (c) design appropriate procedures for testing biological substances,
 - (d) provide or arrange for the provision of laboratory facilities for testing biological substances,
 - (e) carry out tests on biological substances,
 - (f) examine records kept in connection with the manufacture and quality control of biological substances,
 - (g) report on the results of tests or examinations conducted in pursuance of paragraph (e) or (f), and
 - (h) carry out or arrange for the carrying out of such research, or provide or arrange for the provision of such information or training, as it considers appropriate in connection with the functions mentioned in paragraphs (a) to (g).
- (2) The appropriate authority may do anything which it considers is appropriate for facilitating, or incidental or conducive to, the exercise of any of its functions under this section.
- (3) Subsections (4) and (5) apply to any person that exercises functions similar to those of the appropriate authority under this section (whether or not in relation to the United Kingdom).
- (4) The appropriate authority must co-operate with the person in the exercise of those functions.

Changes to legislation: *Health and Social Care Act 2012, Section 57 is up to date with all changes known to be in force on or before 20 April 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

- (5) The person must co-operate with the appropriate authority in the exercise of the authority's functions under this section.
- (6) The appropriate authority may make charges (whether or not on a commercial basis) in respect of anything done by it under this section.
- (7) Any function conferred on the appropriate authority by this section may be performed by either the Secretary of State or the Department of Health, Social Services and Public Safety in Northern Ireland acting alone or both of them acting jointly (and references in this section to the appropriate authority are to be construed accordingly).
- (8) In this section “biological substance” means a substance whose purity or potency cannot, in the opinion of the Secretary of State, be adequately tested by chemical means.

Commencement Information

II S. 57 in force at 1.4.2013 by S.I. 2013/160, art. 2(2) (with arts. 7-9)

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Changes and effects yet to be applied to :

- specified provision(s) amendment to earlier commencing SI 2012/1831 art. 10 by [S.I. 2012/2657 art. 15](#)

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- Pt. 9 Ch. 1B inserted by [2022 c. 31 s. 96](#)
- s. 102(4)(ba) inserted by S.I. 2019/93, Sch. 1 para. 13(3) (as substituted) by [S.I. 2019/1245 reg. 28](#) (This amendment not applied to legislation.gov.uk. The affecting statutory instrument has no legal effect. It was made under a procedure which meant that it ceased to have effect 28 days after signing unless it was debated and approved in Parliament within that time. It was not debated and approved within 28 days, so it has expired with no effect.)
- s. 105(3A)(3B) inserted by [2013 c. 24 Sch. 14 para. 21](#)
- s. 106(3A)(3B) inserted by [2013 c. 24 Sch. 14 para. 22](#)
- s. 250(2)-(2B) substituted for s. 250(2) by [2022 c. 31 s. 95\(2\)\(a\)](#)
- s. 250(6)-(6D) substituted for s. 250(6) by [2022 c. 31 s. 95\(2\)\(d\)](#)
- s. 251251ZA substituted for s. 251 by [2022 c. 31 s. 95\(3\)](#)
- s. 251C(6A) inserted by [2022 c. 31 s. 95\(4\)\(a\)](#)
- s. 259(1)(aa)(b) substituted for s. 259(1)(b) by [2022 c. 31 s. 98\(b\)](#)
- s. 259(1)(aa) words substituted by [S.I. 2023/98 Sch. para. 17\(11\)\(a\)\(iii\)](#) (This amendment comes in force at the same time as 2022 c. 31, s. 98 comes into force)
- s. 259(10A)(10B) inserted by [2022 c. 31 s. 98\(h\)](#)
- s. 304(5)(ja) inserted by [2022 c. 31 s. 95\(5\)](#)