Changes to legislation: *The Human Medicines Regulations 2012, Section 126 is up to date with all changes known to be in force on or before 19 August 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*

STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 7

Traditional herbal registrations

[F1 Interpretation and application of Part]

Addition of vitamins or minerals

126. The addition to a traditional herbal medicinal product of a vitamin or mineral does not prevent a traditional herbal registration from being granted for the product if—

(a) there is well-documented evidence of the safety of the vitamin or mineral; and

(b) the action of the vitamin or mineral is ancillary to the action of the product's active herbal ingredients in connection with the use authorised by the traditional herbal registration.

Changes to legislation:
The Human Medicines Regulations 2012, Section 126 is up to date with all changes known to be in force on or before 19 August 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.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 11 para. 1(1)(d)-(f) inserted by S.I. 2019/775 reg. 63(2)(a)(ii) (This amendment not applied to legislation.gov.uk. Reg. 63(2)(a)(ii) substituted immediately before IP completion day by S.I. 2019/1385, reg. 1, Sch. 1 para. 7(2))
- Sch. 24 para. 18B inserted by S.I. 2024/832 reg. 142(e)
- Sch. 24 Pt. 1 para. 23 words omitted by S.I. 2024/832 reg. 142(f)
- Sch. 33A para. 57A inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(4) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(3) substituted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(2) words inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33B inserted by S.I. 2024/832 reg. 146
- reg. 3(12)(d)(ia) omitted by S.I. 2024/832 reg. 4(a)
- reg. 4(4)(d)(ia) omitted by S.I. 2024/832 reg. 5
- reg. 43(7)(b)(ii)(bb) words omitted by S.I. 2024/832 reg. 18(b)
- reg. 49(1ZA)-(1ZD) inserted by S.I. 2024/832 reg. 26(a)
- reg. 49(3ZA) inserted by S.I. 2024/832 reg. 26(d)
- reg. 51(9) words inserted by S.I. 2019/775, reg. 56 (as amended) by S.I. 2019/1385 Sch. 1 para. 5 (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 52(1)(a)(i)(ii) and words substituted by S.I. 2019/775 reg. 57(2) (This amendment not applied to legislation.gov.uk. Reg. 57 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 42)
- reg. 53(2)-(2C) substituted for reg. 53(2) by S.I. 2019/775 reg. 58(3) (This amendment not applied to legislation.gov.uk. Reg. 58 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 43)
- reg. 53(2)(a) substituted by S.I. 2019/775, reg. 58(3) (as amended) by S.I. 2019/1385 Sch. 1 para. 6(2) (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 55(1)(b)(iii)(bb) substituted by S.I. 2024/832 reg. 43(a)(ii)
- reg. 60A(10A) inserted by S.I. 2024/832 reg. 49(e)
- reg. 68(11H)-(A12) inserted by S.I. 2024/832 reg. 56(b)
- reg. 173(e) inserted by S.I. 2017/1322 Sch. 4 para. 2(2)(b) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(i).)
- reg. 240(2A) words inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(c) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 240(6A) inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(g) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)

- reg. 257(9) inserted by S.I. 2024/832 reg. 110(c)
- reg. 257AA257AB inserted by S.I. 2024/832 reg. 111
- reg. 327(1)(c)(va) omitted by S.I. 2024/832 reg. 128(a)
- reg. 346(2)(c)(iia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iiia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iva) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xviia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xxviiij) omitted by S.I. 2024/832 reg. 132(b)
- reg. 347B inserted by S.I. 2024/832 reg. 133