



DE-DESIGNATION OF YELLOW FEVER VACCINATION CENTRES

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INDEX

	Page
1. Introduction	3
2. De-designating a YFVC	4
3. The de-designation process	5 - 6
4. Repeated breaches of the standards for designation	7
5. Applications for designation following de-designation	7
6. Disputes and appeals against de-designation	7 - 8
Appendices (letters for the process of de-designation)	9 - 20

1. Introduction

1.1 The International Health Regulations (IHRs) on Yellow Fever vaccinations assist in preventing the international spread of Yellow Fever.

1.2 Under the IHRs, Yellow Fever can only be administered at Yellow Fever Vaccination Centres (YFVCs) that are designated by a State Party's national health administrative system (as defined by the IHR).

1.3 In order to gain designated status, YFVCs need to both achieve and thereafter maintain certain standards to allow them to administer the Yellow Fever vaccine. It is the remit of each State Party's national health administrative system to regulate the practices and procedures of the YFVCs in order to ensure "the quality and safety of the procedures and materials employed."¹

1.4 In Scotland, the Scottish Government is the national health administrative system tasked with the designation responsibility.

1.5 In accordance with its powers the Scottish Government has delegated the responsibility for designation and administration of YFVCs to Health Protection Scotland (HPS). The legislative authority for HPS to do this on behalf of the Scottish Government falls under section 10 of the National Health Service (Scotland) Act 1978 and specifically the National Health Service (Functions of the Common Services Agency) (Scotland) Amendment (N0.2) Order 2006 SS1/206/603.²

1.6 As a consequence, HPS has produced the information pack "Designation of Yellow Fever Vaccination Centres" that provides, amongst other things, details of the standards that have to be met in order for centres to become, and thereafter maintain their status as designated YFVCs.

1.7 HPS continually monitors YFVC's compliance with the standards through, amongst other things, an ongoing YFVC review programme.

1.8 As well as designating YFVCs, HPS also has the power to de-designate those YFVCs who fail to maintain the required standards.

1.9 Such de-designation will take place in accordance with the de-designation processes contained herein.

¹ Revision of International Health Regulations. WHA 58.3. Fifty-eighth World Health Assembly. 23 May 2005. Annex 6 and 7. Also see Chapter 1 Arrival and Departure. Available at <http://www.who.int/csr/ihr/en/>

² National Health Service Amendment Order
http://www.oqps.gov.uk/legislation/ssi/ssi2006/ssi_20060603_en_1

2. De-designating a YFVC

2.1 HPS will de-designate an existing YFVC if at any time, whether through the ongoing inspection process or otherwise, it comes to their attention that a YFVC is in breach of, or otherwise failing to maintain, the standards of practice required in accordance with the parts 2 – 11 of the “Designation of YFVCs – Information pack”.

2.2 For the avoidance of doubt each YFVC is required to maintain the following standards in order to remain as a designated centre:–

2.2.1 The requirement to issue an International Certificate of Vaccination or Prophylaxis in accordance with paragraphs 2.2 – 2.4 of the Information pack.

2.2.2 The “Conditions of Designation” laid down in paragraph 3.1 of the information pack.

2.2.3 The requirement to be familiar with the Summary of Product Characteristics of the live attenuated vaccine in accordance with paragraph 4 of the information pack.

2.2.4 The requirements for record keeping laid down in Part 5 of the information pack.

2.2.5 The requirements with regard to storage of the yellow fever vaccine as laid out in Part 6 of the information pack.

2.2.6 The requirements for disposal of the yellow fever vaccine in accordance with Part 7 of the information pack.

2.2.7 The requirements for dealing with the yellow fever vaccine should the cold chain be interrupted as laid down in Part 8 of the information pack.

2.2.8 The requirement that all healthcare professionals with responsibility for immunisation should be familiar with techniques for the management of anaphylaxis as laid down in Part 9 of the information pack.

2.2.9 The standards outlined in the Conditions of Registration found at Appendix 1a to the information pack.

2.2.10 Any designated YFVC who fails to maintain the standards laid out in the information pack and part 2.2 herein will become subject to the de-designation process described in part 3 herein.

3. The de-designation process

3.1 For the purposes of the de-designation process breaches of the standards with regard to the attendance at training will be dealt with separately to breaches of the other standards contained in the information pack.

3.2 Breaches of the standards for designation in parts 2 – 11 of the Information pack other save for those breaches relating to the failure to attend mandatory training

3.2.1 Should it come to the attention of HPS, either through the ongoing review process or otherwise, that a designated YFVC is in breach or otherwise failing to maintain any of the standards dealt with by this paragraph 3.2, then the following de-designation process will be followed:

3.2.1.1 Should the breach become apparent as part of the ongoing review process, then the designated YFVC involved will receive notification from HPS of whatever standard/s has been breached together with notification that the YFVC has been categorised as “under review” and will be subject to a further, more detailed, record and/or YFVC review (Appendix 1).

3.2.1.2 Should HPS become aware that a designated YFVC is in breach or otherwise failing to maintain one of the standards for designation in circumstances outside of the ongoing review process, then the designated YFVC involved will receive notification from HPS of whatever standard/s has been breached together with notification that the YFVC has been categorised as “under review” such that it will be subject to a detailed record and/or YFVC review (Appendix 2).

3.2.1.3 In circumstances where, in the judgement of HPS, the breach/es committed by a YFVC in paragraphs 3.2.1.1 and 3.2.1.2 are so serious as to put the YFVC’s ability to administer Yellow Fever vaccinations safely in doubt, HPS has an unfettered discretion to suspend the YFVC involved from administering any further vaccinations whilst the breaches are investigated (Appendix 3).

3.2.1.4 Should it come to the attention of HPS that further breaches of the standards for designation have been committed by any designated YFVC categorised as “under review”, then that YFVC will be suspended from being able to administer any further vaccines whilst the suspected breaches are investigated by HPS (Appendix 4).

3.2.1.5 Should it become apparent following the detailed review that the designated YFVC in question is complying with the standards for designation, then the “under review” categorisation will be lifted and the YFVC able to continue to administer yellow fever vaccinations as normal (Appendix 5).

3.2.1.6 Should HPS judge, during the review process, that the breaches committed by the designated YFVC render it unsafe for them to continue to administer yellow fever vaccines, then HPS has an unfettered discretion to suspend the YFVC involved from administering any further vaccines whilst the breaches are remedied and the standards met in accordance with paragraph 3.2.1.7 – 3.2.1.10 herein (Appendix 6).

3.2.1.7 Following the detailed review/further review, should the breaches be proven to be being committed by the designated YFVC categorised as “under review”, then a remedial time limited action plan will be agreed between HPS and the YFVC in order that the breaches be remedied (Appendix 7).

3.2.1.8 Following expiration of the time limit allowed in accordance with paragraph 3.2.1.7 herein, the designated YFVC categorised as “under review” will be subject to a further record and/or YFVC review (Appendix 7).

3.2.1.9 Should it become apparent during the further review that the breaches have not been remedied in accordance with the action plan then HPS will withdraw the designated status of the YFVC such that they will no longer be entitled to administer yellow fever vaccinations (Appendix 8).

3.2.1.10 Should the breaches have been remedied then the “under review” categorisation will be removed and/or the suspension lifted and the YFVC will be entitled to continue to administer yellow fever vaccinations as normal (Appendix 5).

3.3 Failure to attend mandatory training

3.3.1 Should a designated YFVC fail to abide by the training requirements laid down in the standards for designation, then the following de-designation process will be followed:-

3.3.1.1 The designated YFVC will be notified that they are in breach of the relevant standard for designation, i.e. the standard relating to training. The YFVC will be given a specified period in which to remedy the breach. Should action be taken to remedy the breach in the time period specified, then the designated centre will be entitled to continue to administer yellow fever vaccinations as normal (Appendix 9).

3.3.1.2 Should there be a failure to remedy the breach within the specified time period then the designated YFVC will be given notice that they have a further period to remedy the breach during which they will be suspended from being able to administer further yellow fever vaccinations. Should action be taken to remedy the breach in the further time period specified then the designated centre will be entitled to continue to administer yellow fever vaccinations as normal (Appendix 10).

3.3.1.3 Should there be a failure to remedy the breach within the further time period, then HPS will withdraw the designated status of the offending YFVC such that they will no longer be able to administer yellow fever vaccinations (Appendix 11).

4. Repeated breaches of the standards for designation

4.1 Should a centre commit repeated breaches of the standards for designation then HPS has discretion to withdraw their designated status notwithstanding the fact that such breaches may repeatedly be rectified

5. Applications for designation following de-designation

5.1 Centres that are de-designated will be entitled to apply to become designated centres again should they feel able to comply with the standards for designation in the future.

5.2 Any de-designated centres reapplying for designated status will be subject to a review by HPS as part of the application process to ensure compliance with the standards.

5.3 HPS has an unfettered discretion as to whether or not it is prepared to allow a formerly de-designated centre to become a designated centre again in the future.

6. Disputes and appeals against de-designation

6.1 Should a designated YFVC feel that they have complied with and met all the conditions of designation, as laid down by HPS, paragraph 3.1 of the information pack. The designated YFVC has the right to dispute and appeal against the decision of HPS to de-designate the YFVC.

6.2 In the event of a dispute or appeal against being de-designated the YFVC must in the first instance address their complaint to:

Yellow Fever Vaccination Centre Co-ordinator
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

6.3 In the event of a complaint made by a designated YFVC not being dealt with fairly by HPS, in the opinion of the designated YFVC then the centre has the right to appeal or to take their complaint to the Director, and should be addressed to:

The Director
Travel and International Health Section
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

6.4 Arbitration

In the event that the designated YFVC feels their complaint or appeal against HPS has not been dealt with fairly, then the designated YFVC may appeal to the Chief Executive of National Services Scotland, and should be addressed to:

The Chief Executive
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Whose decision in all matters will be final.