



DE-DESIGNATION OF YELLOW FEVER VACCINATION CENTRES



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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 vaccine 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 in order 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 the UK, the Department of Health (DH) is the national health administrative system tasked with the designation responsibility.
- 1.5 In accordance with its powers the DH has delegated the responsibility for designation of YFVCs to the Health Protection Agency who has, in turn, given NaTHNaC the responsibility, under the Health Protection Agency Act 2004 and Regulation 7 (a) of The Health Protection Agency Regulations 2005, to oversee the designation and administration of yellow fever vaccination centres in England, and by the Welsh Assembly under Welsh Health Circular, 2005, 064 to designate and administer YFVCs in Wales, and from October 2007 to Northern Ireland by Direction of the Department of Health, Social Services and Public Safety, Belfast.
- 1.6 As a consequence, NaTHNaC 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 NaTHNaC continually monitors YFVCs' compliance with the standards through, amongst other things, an ongoing YFVC Assessment and Audit programme.
- 1.8 As well as designating YFVCs, NaTHNaC also has the power to de-designate those YFVCs who fail to maintain the standards required for designation.
- 1.9 Such de-designation will take place in accordance with the 'De-designation processes' contained herein.

¹ World Health Organization. International Health Regulations (2005). Geneva: World Health Organization, 2005:1-60.

2. De-designating a YFVC

- 2.1** NaTHNaC will de-designate an existing YFVC if at any time, whether through the ongoing Assessment and Audit programme or otherwise, it comes to NaTHNaC's attention that a YFVC is in breach of, or otherwise failing to maintain, the standards of practice required in accordance with the parts 2 to 10 of the "Designation of Yellow fever Vaccination Centres – Information Pack" and thereafter fails to remedy such breach(es) in the time period(s) specified by NaTHNaC.
- 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 (ICVP) 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 payment of a registration fee in accordance with paragraph 3.3 of the Information Pack.
- 2.2.4** The requirement to be familiar with the Summary of Product Characteristics (SmPC) of the live attenuated Yellow fever vaccine in accordance with part 4 of the Information Pack.
- 2.2.5** The requirements for record keeping laid down in Part 5 of the Information Pack.
- 2.2.6** The requirements with regard to storage of the yellow fever vaccine as laid out in Part 6 of the Information Pack.
- 2.2.7** The requirements for disposal of the yellow fever vaccine in accordance with part 7 of the Information Pack.
- 2.2.8** 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.
- 2.2.9** 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.
- 2.2.10** The standards outlined in the Code of Practice found in Appendix 1 to the Information Pack.

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 and payment of a registration fee will be dealt with separately to breaches of the standards contained in the Assessment and Audit documentation.

3.2 Breaches of the standards for designation save for those breaches relating to the failure to attend mandatory training or pay a re-registration fee

Should it come to NaTHNaC's attention, either through the Assessment and Audit programme or otherwise, that a designated YFVC is in breach in any of the standards contained in the Assessment and Audit documentation then the following de-designation process will be followed -

3.2.1 Should the breach become apparent either as part of the Assessment and Audit programme or in circumstances outside of such programme then the designated YFVC will receive notification as to which standards have been breached together with the time period in which such standards need to be remedied and notification that the YFVC has been categorised as "under review" (*Assessment and Audit Report, Appendices 1 & 2*).

3.2.2 Should a serious breach become apparent either as part Assessment and Audit programme or in circumstances outside of such programme then a designated YFVC will receive notification as to which standards considered important by NaTHNaC have been breached together with the time period in which such standards need to be remedied and notification that the YFVC has been suspended from administering yellow fever vaccinations (*Assessment Audit Report, Appendices 3 & 4*).

3.2.3 Should the breaches specified in paragraph 3.2.1 and the serious breaches specified in paragraph 3.2.2 above not have been remedied in the requisite time period then NaTHNaC will withdraw the designated status of the YFVC such that they will no longer be able to administer yellow fever vaccinations (*Appendices 9 & 10*).

3.2.4 Should the breaches specified in paragraph 3.2.1 and the serious breaches specified in paragraph 3.2.2 above be remedied by the YFVC within the requisite time period then the "under review" categorisation will be removed and/or the suspension lifted and the YFVC will be entitled to administer yellow fever vaccinations as normal (*Appendices 7 & 8*).

3.3 Failure to attend mandatory training or to pay a re-registration fee

Should a designated YFVC fail to abide by the training requirements laid down in the standards for designation or fail to submit a re-registration fee in accordance with those standards then the following de-designation process will be followed -

3.3.1 The designated YFVC will be notified that they are in breach of the relevant standard for designation i.e. the standard relating to training and/or the standard relating to payment of the re-registration fee, and the YFVC will be given 14 days in which to remedy the breach (*Appendices 11 & 12*).

3.3.2 Should action be taken to remedy the breach in the 14 day time period specified then the YFVC will be entitled to continue to administer yellow fever vaccinations as normal (*Appendix 15*).

3.3.3 Should there be a failure to remedy the breach within the 14 day time period specified then NaTHNaC will withdraw the designated status of the YFVC such that they will no longer be able to administer the yellow fever vaccinations (*Appendices 13 & 14*).

4. Further breaches of the standards for designation whilst “under review” or suspended

4.1 Should a YFVC commit further breaches of the standards for designation whilst under review or suspended then NaTHNaC shall withdraw the YFVC’s designated status notwithstanding when such further breaches are rectified (*Appendices 5 & 6*).

5. Repeated breaches of the standards for designation

5.1 Should a YFVC commit repeated breaches of the standards for designation whether such standards are considered to be serious or otherwise then NaTHNaC has a discretion to withdraw the YFVC’s designated status notwithstanding the fact that such breaches may be repeatedly rectified.

6. Applications for designation following de-designation

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

6.2 Any de-designated YFVC reapplying for designated status will be subject to a review by NaTHNaC as part of the reapplication process to ensure compliance with the standards.

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

7. Disputes and Appeals against de-designation

7.1 Should a YFVC that has been de-designated feel that they have complied with and met all of the conditions and standards of designation, as laid down by NaTHNaC, to include the requirements for training and the payment of a registration fee, then notwithstanding having been de-designated the de-designated YFVC has the right to appeal against NaTHNaC's decision to de-designate in accordance with this paragraph 7.

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

Service Manager
The Yellow Fever Vaccination Centre Programme
The National Travel Health Centre and Network (NaTHNaC)
5th floor west, 250 Euston Road
London, NW1 2PG

7.3 In the event of a YFVC concluding that the complaint made by the YFVC has not been dealt with appropriately by NaTHNaC then the YFVC has the right to appeal or take their complaint to the Chair of the NaTHNaC steering group, which such appeal or complaint should be addressed to:

The Director
The National Travel Health Centre and Network (NaTHNaC)
5th floor west, 250 Euston Road
London, NW1 2PG

7.4 Arbitration

In the event that a YFVC feels that their complaint or appeal against NaTHNaC has not been dealt with appropriately by the Chair of the NaTHNaC steering group then the YFVC may appeal to:

The Chief Executive
Health Protection Agency
7th Floor, Holborn Gate
330 High Holborn
London WC1V 7PP

Whose decision in all matters will be final.

Appendix 1

Dear

Notice of intention to review your status as a designated YFVC

As you are aware and in accordance with the “Designation of Yellow Fever Vaccination Centres – Information Pack”, to maintain your status as a designated YFVC there are certain standards that you are obliged to uphold.

It has come to our attention following completion and submission of the Assessment and Audit that your YFVC is in breach of the standards of designation outlined in the enclosed Assessment and Audit report.

As a consequence of this breach and in accordance with paragraph 3.2.1 of the document “De-designation of Yellow Fever Vaccination Centres” we are writing to tell you that NaTHNaC has been obliged to categorise you as “under review”.

In accordance with such a categorisation you have 14 days in which to remedy the breach(es) specified above and confirm that you are compliant with the standards of designation as laid down in the “Code of Practice Appendix 1 – Designation of Yellow Fever Vaccination Centres – Information Pack”.

Please note that any failure to remedy the breach within 14 days or any further breaches of the standards of designation whilst categorised as “under review” will result in your removal from the register of designated YFVCs (in accordance with paragraph 3.2.3. and paragraph 4 of the document – De-designation of Yellow fever Vaccination Centres).

Yours sincerely

Appendix 2

Dear

Notice of intention to review your status as a designated YFVC

As you are aware and in accordance with the “Designation of Yellow Fever Vaccination Centres – Information Pack”, to maintain your status as a designated YFVC there are certain standards that you are obliged to uphold.

It has come to our attention that your clinic is in breach of the following standard/s of designation as outlined below –

[Details of breached standards to be added here]

As a consequence of this breach and in accordance with paragraph 3.2.1 of the document “De-designation of Yellow Fever Vaccination Centres” we are writing to tell you that NaTHNaC has been obliged to categorise you as “under review”.

In accordance with such a categorisation you have 14 days in which to remedy the breach and confirm that you are compliant with the standards of designation as laid down in the “Code of Practice Appendix 1 – Designation of Yellow Fever Vaccination Centres – Information Pack”.

Please note that any failure to remedy the breach within 14 days or any further breaches of the standards of designation whilst categorised as “under review” will result in your removal from the register of designated YFVCs (in accordance with paragraph 3.2.3. and paragraph 4 of the document – De-designation of Yellow Fever Vaccination Centres).

Yours sincerely

Appendix 3

Dear

Notice of intention to suspend your YFVC from administering any further yellow fever vaccinations

As you are aware and in accordance with the “Designation of Yellow Fever Vaccination Centres – Information Pack”, to maintain your status as a designated YFVC there are certain standards that you are obliged to uphold.

It has come to our attention following completion and submission of the Assessment and Audit that your YFVC is in breach of the standards of designation outlined in the enclosed Assessment and Audit report.

It is NaTHNaC’s view that breach of the above standard/s is so serious as to make it unsafe for your clinic to continue to administer yellow fever vaccinations whilst the breach is further investigated. As a consequence of this breach and in accordance with paragraph 3.2.2 of the document “De-designation of Yellow Fever Vaccination Centres” we are writing to tell you that NaTHNaC has been obliged to suspend your clinic from administering any further yellow fever vaccinations. As a result of this suspension you are required to cease administering yellow fever vaccinations immediately. You have also been temporarily removed from the YFVC locator on the NaTHNaC website. Should you continue to administer the vaccinations then NaTHNaC will have no choice but to report such administration to the relevant professional bodies and remove your centre from the register of designated YFVCs.

In accordance with such a suspension you have 28 days in which to remedy the breach and confirm that you are compliant with the standards for designation as laid down in the “Code of Practice Appendix 1 – Designation of Yellow Fever Vaccination Centres – Information Pack”.

Please note that any failure to remedy the breach within 28 days or any further breaches of the standards of designation whilst under suspension will result in your removal from the register of designated YFVCs (in accordance with paragraph 3.2.3 and paragraph 4 of the document – De-designation of Yellow Fever Vaccination Centres).

Yours sincerely

Appendix 4

Dear

Notice of intention to suspend your YFVC from administering any further yellow fever vaccinations

As you are aware and in accordance with the “Designation of Yellow Fever Vaccination centres – Information Pack”, to maintain your status as a designated YFVC there are certain standards that you are obliged to uphold.

It has come to our attention that your clinic is in breach of the following standards of designation as outlined below –

[Details of breached standards to be added here]

It is NaTHNaC’s view that breach of the above standard/s is so serious as to make it unsafe for your clinic to continue to administer yellow fever vaccinations whilst the breach is further investigated. As a consequence of this breach and in accordance with paragraph 3.2.2 of the document “De-designation of Yellow Fever Vaccination Centres” we are writing to tell you that NaTHNaC has been obliged to suspend your clinic from administering any further yellow fever vaccinations. As a result of this suspension you are required to cease administering yellow fever vaccinations immediately. You have also been temporarily removed from the YFVC locator on the NaTHNaC website. Should you continue to administer the vaccinations then NaTHNaC will have no choice but to report such administration to the relevant professional bodies and remove your centre from the register of designated YFVCs.

In accordance with such a suspension you have 28 days in which to remedy the breach and confirm that you are compliant with the standards for designation as laid down in the “Code of Practice Appendix 1 – Designation of Yellow Fever Vaccination Centres – Information Pack”.

Please note that any failure to remedy the breach within 28 days or any further breaches of the standards of designation whilst under suspension will result in your removal from the register of designated YFVCs (in accordance with paragraph 3.2.3 and paragraph 4 of the document – De-designation of Yellow Fever Vaccination Centres).

Yours sincerely

Appendix 5

Dear

Notice of intention to De-designate your YFVC from administering any further yellow fever vaccinations

Further to your categorisation as a clinic “under review” it has come to NaTHNaC’s attention that your YFVC has committed further breaches of the standards for designation as set out below –

[Details of breached standards to be added here]

In accordance with paragraphs 3.2.3 and 4 of the document “De-designation of a Yellow Fever Vaccination Centres” NaTHNaC has therefore had no choice but to withdraw your status as a designated YFVC.

In accordance with such a withdrawal you are required to cease administering yellow fever vaccinations immediately.

Please note that NaTHNaC has notified your local Primary Care Trust and/or your Health Board that you have failed to meet our requirements as a registered YFVC and that you have been removed from the register. NaTHNaC has also notified the vaccine manufacturers that you have been removed from the register and that you are no longer therefore entitled to purchase yellow fever vaccine in the absence of a validated designated YFVC registration number. Please note that any continued use of yellow fever vaccine at your YFVC will be in breach of the IHR and English law and NaTHNaC will be obliged to report such practice accordingly. Please dispose of any yellow fever vaccinations held at the YFVC in accordance with part 7 of the “Designation of Yellow Fever Vaccination Centres – Information Pack”.

Should you wish to regain designated status in the future please make a further application and NaTHNaC will review this in accordance with the policies and procedures applicable at the time.

Yours sincerely

Appendix 6

Dear

Notice of intention to De-designate your YFVC from administering any further yellow fever vaccinations

Further to the recent suspension of your YFVC from administering yellow fever vaccinations it has come to NaTHNaC's attention that your clinic has committed further breaches of the standards for designation as set out below –

[Details of breached standards to be added here]

In accordance with paragraphs 3.2.3 and 4 of the document “De-designation of a Yellow Fever Vaccination Centres” NaTHNaC has therefore had no choice but to withdraw your status as a designated YFVC.

In accordance with such a withdrawal you are required to cease administering yellow fever vaccinations immediately.

Please note that NaTHNaC has notified your local Primary Care Trust and/or your Health Board that you have failed to meet our requirements as a registered designated YFVC and that you have been removed from the register. NaTHNaC has also notified the vaccine manufacturers that you have been removed from the register and that you are no longer therefore entitled to purchase yellow fever vaccine in the absence of a validated designated YFVC registration number. Please note that any continued use of yellow fever vaccine at your YFVC will be in breach of the IHR and English law and NaTHNaC will be obliged to report such practice accordingly. Please dispose of any yellow fever vaccines held at the clinic in accordance with part 7 of the “Designation of Yellow Fever Vaccination Centres – Information Pack”.

Should you wish to regain designated status in the future please make a further application and NaTHNaC will review this in accordance with the policies and procedures applicable at the time.

Yours sincerely

Appendix 7

Dear

Lifting of “Under Review” categorisation

Further to your categorisation as a clinic “under review” and further to NaTHNaC’s receipt of satisfactory confirmation that your clinic is now in compliance with the standards of designation, NaTHNaC is pleased to inform you that your YFVC is no longer categorised as “under review” and can continue to administer yellow fever vaccinations as normal.

Yours sincerely

Appendix 8

Dear

Lifting of “Suspension”

Further to the recent suspension of your clinic from administering yellow fever vaccinations and further to NaTHNaC’s receipt of satisfactory confirmation that your clinic is now in compliance with the standards of designation, NaTHNaC is pleased to inform you that the suspension has been lifted and your YFVC can continue to administer yellow fever vaccinations as normal.

Yours sincerely

Appendix 9

Dear

Notice of withdrawal of YFVC designated status

Further to your clinic being classified as “under review” due to breaches of the standards for designation, NaTHNaC note that your clinic has failed to rectify such breaches in the time period specified in the Assessment and Audit Report. In accordance with paragraph 3.2.3 and 4 of the document “De-designation of Yellow Fever Vaccination Centres” NaTHNaC therefore has no choice but to withdraw your status as a designated YFVC.

In accordance with such a withdrawal you are required to cease administering yellow fever vaccinations immediately.

Please note that NaTHNaC has notified your local Primary Care Trust and/or your Health Board that you have failed to meet our requirements as a registered designated YFVC and that you have been removed from the register. NaTHNaC has also notified the vaccine manufacturers that you have been removed from the register and that you are no longer therefore entitled to purchase yellow fever vaccine in the absence of a validated designated YFVC registration number. Please note that any continued use of yellow fever vaccine at your YFVC will be in breach of the IHR and English law and NaTHNaC will be obliged to report such practice accordingly. Please dispose of any yellow fever vaccines held at the clinic in accordance with part 7 of the “Designation of Yellow Fever Vaccination Centres – Information Pack”.

Should you wish to regain designated status in the future please make a further application and NaTHNaC will review this in accordance with the policies and procedures applicable at the time.

Yours sincerely

Appendix 10

Dear

Notice of withdrawal of YFVC designated status

Further to your clinic having been suspended due to breaches of the standards for designation, NaTHNaC would note that your clinic has failed to rectify such breaches in the time period specified in the Assessment and Audit Report.

In accordance with paragraphs 3.2.3 and 4 of the document “De-designation of a Yellow Fever Vaccination Centres” NaTHNaC has therefore had no choice but to withdraw your status as a designated YFVC.

In accordance with such a withdrawal you are required to cease administering yellow fever vaccinations immediately.

Please note that NaTHNaC has notified your local Primary Care Trust and/or your Health Board that you have failed to meet our requirements as a registered designated YFVC and that you have been removed from the register. NaTHNaC has also notified the vaccine manufacturers that you have been removed from the register and that you are no longer therefore entitled to purchase yellow fever vaccine in the absence of a validated designated YFVC registration number. Please note that any continued use of yellow fever vaccine at your YFVC will be in breach of the IHR and English law and NaTHNaC will be obliged to report such practice accordingly. Please dispose of any yellow fever vaccines held at the clinic in accordance with part 7 of the “Designation of Yellow Fever Vaccination Centres – Information Pack”.

Should you wish to regain designated status in the future please make a further application and NaTHNaC will review this in accordance with the policies and procedures applicable at the time.

Yours sincerely

Appendix 11

Dear

Notice of failure to comply with the training requirements

You will be aware that the standards for designation of yellow fever vaccination centres, in accordance with paragraph 3.1 of the document “Designation of Yellow Fever Vaccination Centres – Information Pack” require that a member of each YFVC attend a NaTHNaC sponsored yellow fever training session initially and then once every two years. It has come to our attention that no one from your centre has attended such a training event in the allotted time frame and thus your centre is in breach of the standards for designation.

NaTHNaC require that immediate action be taken to remedy this breach and we can advise you that your YFVC has 14 days in which to provide us with proposals as to how you intend to rectify this breach.

Should we not hear from your YFVC with appropriate proposals for rectification within this time period then we can advise that NaTHNaC will have no option but to de-designate your YFVC (in accordance with paragraph 3.3 of the document De-designation of a Yellow Fever Vaccination Centres).

Yours sincerely

Appendix 12

Dear

Notice of failure to pay renewal fee

You will be aware that the standards for designation of yellow fever vaccination centres in accordance with paragraph 3.1 of the document “Designation of Yellow Fever Vaccination Centres – Information Pack” require that each YFVC pay a renewal fee in order to maintain their designated status, It has come to our attention that your YFVC has failed to pay this fee and is thus in breach of the standards for designation.

NaTHNaC require that the renewal fee be paid within 14 days of your receipt of this letter. Should there be a failure to pay the fee within this 14 day period then we can advise that NaTHNaC will have no option but to de-designate your clinic (in accordance with paragraph 3.3 of the document De-designation of a Yellow Fever Vaccination Centres).

Yours sincerely

Appendix 13

Dear

De-designation due to failure to comply with training requirements

Further to the letter dated [*insert date*] your YFVC has failed to provide NaTHNaC with proposals as to how your YFVC is to rectify the failure to attend NaTHNaC sponsored yellow fever training programme in accordance with the standards for designation in the required time frames.

In accordance with paragraph 3.3.1.3 of the document “De-designation of Yellow Fever Vaccination Centres” NaTHNaC therefore has had no choice but to withdraw your status as a designated YFVC.

In accordance with such a withdrawal you are required to cease administering yellow fever vaccinations immediately.

Please note that NaTHNaC has notified your local Primary Care Trust and/or Health board that you have failed to meet our requirements as a registered clinic and that you have been removed from the register. NaTHNaC has also notified the vaccine manufacturers that you have been removed from the register and that you are no longer therefore entitled to purchase yellow fever vaccine in the absence of a validated designated YFVC registration number. Please note that any continued use of yellow fever vaccine at your clinic will be in breach of IHR and English Law and NaTHNaC will be obliged to report such practice accordingly.

Please dispose of any yellow fever vaccines held at the clinic in accordance with Part 7 of the “Designation of Yellow Fever Vaccination Centres – Information Pack”.

Should you wish to regain designated status in the future please make a further application and NaTHNaC will review this in accordance with the policies and procedures applicable at the time.

Yours sincerely

Appendix 14

Dear

De-designation due to failure to pay re-registration fee

Further to our letter dated [*insert date*] your YFVC has failed to pay the re-registration fee in accordance with the standards for designation in the required time frame.

In accordance with paragraph 3.3.1.3 of the document “De-designation of yellow fever vaccination centres” NaTHNaC has therefore had no choice but to withdraw your status as a designated YFVC.

In accordance with such a withdrawal you are required to cease administering yellow fever vaccinations immediately.

Please note that NaTHNaC has notified your local Primary Care Trust and/or Health board that you have failed to meet our requirements as a registered clinic and that you have been removed from the register. NaTHNaC has also notified the vaccine manufacturers that you have been removed from the register and that you are no longer therefore entitled to purchase yellow fever vaccine in the absence of a validated designated YFVC registration number. Please note that any continued use of Yellow fever vaccine at your clinic will be in breach of IHR and English Law and NaTHNaC will be obliged to report such practice accordingly.

Please dispose of any yellow fever vaccinations held at the clinic in accordance with Part 7 of the “Designation of Yellow fever Vaccination Centres – Information Pack”.

Should you wish to regain designated status in the future please make a further application and NaTHNaC will review this in accordance with the policies and procedures applicable at the time.

Yours sincerely

Appendix 15

Dear

Successful remediation of breach of standards for designation

Further to the letter dated [*insert date*] NaTHNaC is pleased to confirm that your YFVC has remedied the breach of the standards for designation specified in that letter and has successfully confirmed that it is in compliance with the standards for designation within the required time period.

NaTHNaC can therefore confirm that no further action will be taken and your YFVC is therefore entitled to continue to administering yellow fever vaccinations as normal.

Yours sincerely