EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Annex VI Service Level Agreement for Medical Service Provider

The term 'medical service provider' referred to in this document is the contractor with which the Agencies i.e. EMA, EBA and CEPOL have signed a contract for the provision of medical services to its staff members - EMA/2012/18/HR

1. Legal Basis

The Staff Regulations of the European Union set out the rules for pre-employment medicals, annual medicals, occupational health review, invalidity, sick and special leave and other related matters. Implementing rules on sick leave and special leave are in place. The pre determined tests for pre-employment and annual medicals must be followed. Policy guidance will be sought as needed by the agencies from the medical service of the European Commission.

2. Pre-employment Medicals

2.1. The medical service shall note that the prospective staff member may have to travel from abroad to attend the pre-employment and therefore these appointments must be maintained and unchanged by the medical service save for reasons of force majeure. In addition, appointments between 11AM and 4PM are preferred as this timing facilitates travel and reduces costs for the Agencies.

2.2. The attached certificate should be used as the fitness certificate – *to be added once contract has been awarded.*

2.3. Medical certificates for pre-employments examinations must arrive at the Agencies' addresses accordingly within a maximum of two weeks from the date of the appointment. These certificates must be sent via e-mail first (scanned signed original) and then via post (the original). If further examination/tests are required (or for any other reason) and this timeframe cannot be met the medical provider must inform the Agencies' HR immediately;

2.4. The medical service shall follow the list of tests specified in the Technical Specifications for the pre-employment medical and charge the Agencies only for this service. Should additional tests be desirable and/or requested these must be at the prospected staff member's expense and not invoiced to the Agencies.

2.5. Pre-employment full medical reports must not be sent in any format to the Agencies' HR unless otherwise requested and consent given by the respective prospected staff member.

3. Annual medicals

3.1. The medical service shall follow the list of tests/examinations included in the Technical Specifications and charge the Agencies only for those listed. Should additional tests (any test/examination outside the list of tests) be desirable/requested/suggested by the doctor or staff member these must be at the staff members expense and not invoiced to the Agencies.

3.2. The medical report to staff member is sent to this person within one week of the appointment electronically or/and via post.

3.3. Annual medical reports must not be sent in any format to the Agencies' HR unless otherwise requested and consent given by the respective staff member.

4. Occupational health review (OHR)

4.1. The medical service shall carry out the OHR by the deadline specified by the Agencies. The medical service must make every effort to pro-actively contact the staff member in order to do the review by the deadline and to the necessary follow ups pro-actively.

4.2. Where exceptionally the deadline cannot be met the Agencies' HR/contact point must be informed immediately.

4.3. Where no deadline was specified by the Agencies an OHR appointment shall be given within one week of the staff member or personnel department contacting the medical service.

4.4. The medical service shall pro-actively communicate to the Agencies every six months the name of the doctor undertaking OHRs. The doctor performing OHR must not carry out pre-employments or annual medicals for any of the staff members of the Agencies.

4.5. The OHR report must include a summary information (oral) to the Agencies (to the given contact point/HR) is done within three days of the appointment and the report is issued within one week of the appointment. The report must be sent in an electronically format (only) to the Agencies, paper report is not required for this service.

4.6. This report must not be filed together with the Annual Medical or pre-employments reports of the respective staff member but separately. If tests/further examinations are required and this timeframe cannot be met the medical provider must inform the Agencies' HR contact point on the same day of the appointment or as soon as this information is available.

4.7. The medical service will act proactively to remind, if necessary repeatedly, the staff member to complete any relevant tests and/or attend/book appointments so deadlines set by the Agencies can be met without delays.

4.8. Medical report must also be sent to the staff member either electronically and/or via post as preferred/requested by the staff member.

5. Personal details

The medical service shall make every effort to ensure that staff member's names are correctly spelled on all letters/reports/invoices as well as gender and date of birth. Reports shall be filed in the file correspondent to that staff member's correct name/surname; this will have data protection consequences if not well managed.

6. Delivery of medical reports

6.1. All reports and/or certificates sent electronically to staff member and/or Agencies' contact points/HR must be password protected to be set and communicated by the medical provider directly to the staff member and the Agencies' contact point accordingly.

6.2. Staff members or prospected staff members must be given the choice to receive the medical reports electronically and/or via post at their chosen and communicated addresses.

7. Special leave for reasons of illness

7.1. Staff members may be granted special leave for a variety of circumstances. For serious illness of children up to two working days of special leave per child may be granted by the Agencies with a maximum of six working days in total per child per calendar year. For very serious illness of a child up to five working days of special leave per calendar year may be granted by the Agencies with a maximum of 15 working days per child per calendar year. For both types of special leave the Agencies may ask the medical service for a medical recommendation on the basis of a medical certificate that may be in a variety or EU languages regarding the illness of the child.

7.2. The Agencies may also ask the medical service for a medical recommendation on applications (medical certificates) for special leave due to illness of other family members.

7.3. For all these requirements the medical service shall provide the medical recommendation to the Head of HR of the Agencies within one week of transmission of a case and its supporting documents as applicable and/or the appointment with the staff member concerned.

7.4. Where there is an appointment with the staff member the medical service shall invoice the Agencies directly.

8. Sick leave overseas

8.1. Staff members may be granted permission by the Agencies to spend sick leave overseas on the basis of therapeutic advantage. The medical service will be asked to provide a medical assessment and recommendation on a given case. This assessment must be sent to the Agencies in a report format within one week of the appointment.

9. Travel clinic

This service is only applicable when staff members are requested by the Agencies to go on official business trips. The medical service shall give advice on e.g. vaccinations and any other medical matters related to the case.

10. Seasonal flu vaccination

The Agencies offer its staff members the seasonal flu vaccine every winter. The medical service shall provide this service at the Agencies premises or otherwise requested. The Agencies will provide support to the organisation of the programme, if this takes place at the Agencies' premises. The medical service must be fully responsible for the management of the clinical waste of the programme.

11. Invalidity

11.1. For any invalidity cases the medical service may be nominated to act on behalf of the Agencies. Where so nominated the medical service shall be responsible for all aspects of the invalidity review in line with the Staff Regulations. The medical service shall use the templates (forms and letters) provided by the Agencies. The medical service shall keep the personnel department informed at all times of the status of a particular invalidity case on going.

11.2. The medical provider will also represent the Agencies for any invalidity cases on the Invalidity Committee under the EU Staff Regulations and manage the work of the Invalidity Committee.

11.3. The Invalidity Committee consists of:

a) a doctor of the medical service provider (the successful tenderer), which would normally be a doctor specialised in occupational health issues, e.g. an occupational physician;

b) a doctor representing the staff member (normally family GP or other, chosen by staff member);

c) and a third doctor, agreed by above parties a) and b).

d) This therefore involves liaison between different doctors who may be in different locations in UK or abroad.

e) Meetings of the invalidity committee {doctors a), b) and c)} can take place as well by telephone, videoconference, but there can be significant logistical arrangements as all doctors have limited availability. Timely follow-up and pro-active management of the committee is a requirement. The successful tenderer/medical service provider must be the driver and organiser of the committee meeting(s) and respect the deadlines set by the Agencies.

f) The committee has legal powers under EU staff legislation and as in all legal matters good record keeping and proper administration is a major service requirement.

The normal turnaround time for an invalidity case is between three and six months.

11.4. The Agencies provide the documents and templates that the committee will use well in advance of the deadlines. An invalidity case procedure manual is also made available. The medical service shall arrange for interpretation and/or translation of documents whenever needed. It shall take into account the language of medical documents, the linguistic preferences of the staff member concerned and of the other doctors comprising the invalidity committee. The costs of the service of a given case must be notified to the

Agencies in writing within two weeks in advance of the appointment. The Agencies will bear the costs involved.

12. Psychological services

12.1. In case that the medical service subcontracts the psychological services, the medical service must maintain appropriate liaison with this subcontractor. Any medical or serious problem that could put the staff member in a dangerous position or at risk this must be addressed immediately by the provider of the service. The Agencies' HR must be informed within one day of such a change in the case.

12.2. Where there is an appointment with the staff member the medical service shall invoice the Agencies directly. The terms of this service level agreement apply to any sub-contracted medical service performing psychological services.

13. Antivirals

13.1. The medical service is responsible for the purchase and storing the Agencies' stock. However, this stock is the property of the Agencies. The Agencies shall bear the costs of the purchase and storage.

13.2. The medical service is responsible for suitable security of this stock and to ensure enhanced security in the event of a pandemic threat.

13.3. The medical service shall make it available within two days of the notification by the Agencies together with suitably qualified staff for prescription purposes. The Agencies will bear the costs for the appointments for any staff member to prescribe the medicine and should be invoiced directly.

14. Correspondence

All correspondence and envelopes sent to the Agencies by the medical provider must be marked private & confidential.

15. Languages

The medical service may be required to provide medically competent interpretation of consultation and/or translation of reports in any of the EU languages. The costs of the service of a given case must be notified to the Agencies in writing two weeks in advance of the appointment. The Agencies will bear the costs involved.

16. Files

16.1. The medical service is responsible for filing staff members' documents in the right file (particular attention shall be given for similar and/or same names/surnames). The staff member's file shall be made available to that staff member upon request in accordance with Art. 26A of the Staff Regulations within two weeks of the request.

16.2. The medical service shall ensure the integrity and completeness of the medical file and supply the staff member with copies from the file if so requested. The Agencies will bear the cost of any photocopying charges.

16.3. The Agencies will audit the medical files periodically subject to the staff member's consent to ensure the reports filled under the staff member's name and that all the relevant reports are on the file. The medical details are not audited.

16.4. The Agencies' HR may request copies of non-medical documents of any staff member from the files.

17. Retention policy

The medical service must consult the Agencies' HR before destroying any document. The Agencies' HR may also contact the medical service from time to time to request destruction of certain documents in line with its archiving policy as per bellow:

Name	Where is it filed	Retention period
Medical files - Staff resigned	Filed with the Agencies' Medical Provider	Destroy after 1 year following resignation or transfer to other EU body if applicable
Medical files - Staff retired	Filed with the Agencies' Medical Provider	Destroy after 1 year following retirement
Medical files - Staff active	Filed with the Agencies' Medical Provider	Retain during period of service – destroy 30 year old medical reports

18. Data transfer

The Agencies may request the medical service to transfer the medical file of a given staff member to another EU institution or another medical service provider. The staff member's consent form should be recorded on the template attached.

19. Confidentiality

19.1. The medical service shall respect medical confidentiality at all times.

19.2. The Agencies will transmit any medical documentation from a staff member in a sealed envelope and these shall be filed with the medical report of the respective staff member.

20. Cancellation of appointments

When a staff member or prospective staff member calls to re-arrange an appointment of any service the medical service must make absolutely clear whether or not a cancellation charge applies. This cancellation charge must be paid by the person and not invoiced to the Agencies unless otherwise agreed with the Agencies beforehand. The person must be informed clearly on the spot of this charge and their payment details requested.

21. Booking of appointments

21.1. Appointments must be given by the medical provider within two weeks from the day the medical service is contacted by the Agencies' staff member or prospected staff member.

22. Purchase Orders (PO)

All services requested by the Agencies must be accompanied by a PO which is a reference number that then goes on the respective invoices. This PO is given to the medical service at the time of booking. The medical service should not allocate an appointment to staff member or prospected staff members that does not provide a PO at the time of booking.

23. Invoices

23.1. The medical provider must invoice each of the three Agencies separately and in accordance with the service provided to each Agency.

23.2. Invoices must not include a mixture of services i.e. each invoice must include one service only.

23.3. For services where the fee charged to the Agencies may include several aspects e.g. for invalidity cases, the invoices must show a break down in detail of all charges and not present it in one figure.

23.4. The subcontractor, if applicable, must not invoice the Agencies directly, the fees of the subcontractor's services must be invoiced via the medical provider invoicing system.

23.5. The main body of the invoice should include the information as per below:

Appointment Date	Details	VAT rate	VAT amount	NET amount
00/00/00	Name of staff member + DOB + name of service provide e.g. PRE-EMPLOYMENTS + PO number	0.00	0.00	0.00

Followed by a shadow statement omitting the staff member's name as per below:

Appointment Date	Details	VAT rate	VAT amount	NET amount
00/00/00	DOB + Name of service provide + PO number	0.00	0.00	0.00

24. Relationship with the three Agencies under the contract

The medical provider must treat each Agency as individual identities with regards to invoicing or any other issues that may occur. Issues must be handled directly with the respective Agency with discretion and in a professional manner.

25. Contract management

The Agencies and the medical service will mutually provide contract manager details with a description of duties and decision making levels.

26. Changes to this SLA

The Agencies reserve the right to revise the terms of this SLA in line with its requirement and to notify the medical service of changes one month in advance and so far as is possible to agree mutually to the changes.

27. Should this SLA not be respected

Where the standards and deadlines of this service level agreement are not met the Agencies shall deduct 10% of the price of the service from the relevant invoice or any other way agreed with the medical service.