



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 August 2011
EMA/584252/2011
Administration

Rules governing the in-service training at the EMA

THE EXECUTIVE DIRECTOR

HAVING REGARD to Council Regulation (ECC) No 726/04 establishing the European Agency for the Evaluation of Medicinal Products,

HAVING REGARD to the budget of the EMA and in particular budget item 153,

WHEREAS it is necessary to draw up rules to govern in-service training organised by the EMA,

HAS ADOPTED the following rules.

Article 1 - General

These rules govern the official traineeships scheme of EMA. This scheme is addressed mainly to young university graduates, without excluding those who – in the framework of lifelong learning – have recently obtained a university diploma and are at the beginning of a new professional career.

The aims of the official in-service training with EMA are:

- To provide young or recent university graduates with a unique and first hand experience of the workings of EMA. To provide an understanding of the objectives and the goals of EMA's coordination role in the evaluation and supervision of medicinal products throughout the European Union.
- To enable such trainees to acquire practical experience and knowledge of the day-to-day work of the Agency's units and sectors. To provide the opportunity to work in a multi-cultural, multi-linguistic and multi-ethnic environment, contributing to the development of mutual understanding, trust and tolerance. To promote European integration within the spirit of new governance and through active participation to create awareness of true European citizenship.
- To provide the opportunity to young university graduates to put into practice knowledge acquired during their studies, and in particular in their specific areas of competence. To introduce these graduates to the professional world and the constraints, duties and opportunities therein.



EMA, through its official traineeships scheme:

- Benefits from the input of enthusiastic graduates, who can give a fresh point of view and up-to-date academic knowledge, which will enhance the everyday work of the EMA;
- Creates a pool of people with first-hand experience of and trained in European procedures, who will be better prepared to collaborate and co-operate with the EMA in the future;
- Creates long-term “goodwill ambassadors” for European ideas and values both within the European Union and outside.

Article 2 – Eligibility

Trainees are accepted from nationals of the Member States of the European Union and of candidate countries benefiting from a pre-accession strategy. However, a limited number of nationals of non-Member States are also accepted according to available resources.

Candidates must have completed the first cycle of a higher education course (university education) and obtained a full degree or its equivalent by the closing date for applications. For minimum national qualifications required by the legislation in the country where the diploma was obtained, see Annex I.

In order for the trainee to fully profit from the traineeship and to be able to follow meetings and perform adequately:

- Candidates from Member States must have very good knowledge of at least two Community languages, of which one should be the main working language of the EMA (English).
- Candidates from non-Member States must have very good knowledge of the main working language of the EMA (English).

Applicants are selected on the basis of qualifications; an appropriate geographical distribution will be maintained.

Article 3 - Status

1. Admission to in-service training does not confer on trainees the status of other servants of the Communities nor does it entail any right or priority with regard to an appointment in the services of the EMA. Trainees can apply during their in-service training to EMA open recruitment procedures advertised in the Official Journal of the European Union in case they fulfil the advertised minimum criteria. In no way can in-service training lead to a temporary agent contract without the successful outcome of an open recruitment procedure.
2. Under exceptional circumstances a contract agent contract for a maximum length of one year with a maximum extension of one further year may be granted to a person who has been awarded in-service training following completion of his or her traineeship at the EMA. These exceptional circumstances may include maternity, paternity leave replacement, family leave or parental leave replacement, unpaid leave or long term serious sickness of an EMA temporary agent and in particular, replacement of EMA scientific staff. All requests to Administration for such replacements must be duly substantiated and justified by the Head of Unit concerned. In accordance to Article 25 of the Staff Regulations decisions on appointment are advertised within the EMA in the usual way.

Article 4 - Organisation

1. Before each in-service training period the Executive Director determines the number of trainees, to be attached to each unit, on the basis of the funds available.
2. Trainees are placed under the responsibility of an adviser. Each adviser may be responsible for only one trainee per training period. The adviser must guide and closely follow the trainee during his/her traineeship, acting as his/her mentor. The adviser must notify immediately the Head of Section/Sector concerned and Human Resources of any significant incidents occurring during the traineeship (in particular professional incompetence, absences, sicknesses, accidents, bad behaviour, or interruption of the traineeship), which come to his/her attention, or of which the trainee has informed him/her.
3. Trainees are allowed to attend meetings on subjects of interest to their work (unless these meetings are restricted or confidential), receive documentation and participate in the work of the section/sector to which they are attached at a level corresponding to their educational and working background. Subject to the approval of their adviser and providing it does not conflict with the accomplishment of the tasks assigned to them, they are entitled to attend meetings in a section/sector other than the one to which they are attached, unless these meetings are restricted or confidential, with the aim to get an understanding of the objectives and goals of the EMA.

Article 5 - Duration of in-service training

1. Training periods last at least three and at most nine months. There is one annual intake with a start date of 1 October each year. There is no possibility to delay or defer the start date of the traineeship.
2. Training periods are initially offered for a period of six months with the option reserved to the Agency to extend the traineeship for a further three months. Trainees will be notified one month in advance if they are to receive an extension to their traineeship of three months. The maximum total training period is nine months.
3. The training period for one trainee in Human Resources may exceptionally be extended for up to a maximum period of thirteen months to assist with the organisation of the EMA in-service training.
4. In-service training periods may not be repeated or extended beyond the maximum length laid down in these rules.

Article 6 - Admission

1. Applications should be made in accordance with the procedures established by the EMA. All necessary instructions are published on the EMA Website.
2. If an application is unsuccessful a candidate may re-apply for a subsequent training period. It is, however, necessary to submit a fresh application. The EMA does not keep applicants' files from one in-take to another.

Article 7 - Selection procedure

1. The EMA makes its selection of trainees on the basis of the applications received. Candidates who are offered a traineeship will be required to provide documented evidence of the qualification referred to in Article 2 prior to starting the traineeship.
2. Successful candidates will typically have a background relating to the activities of the EMA, i.e. pharmacy, medicine, chemistry, life sciences and health care. Qualified candidates with an interest in any support function (for example information technologies, legal affairs, internal audit, internal and external communication, Human Resources, budget, accounts, infrastructure services, document management, project management and meeting management) are welcomed too. Any candidate who meets the minimum eligibility criteria may apply.
3. Shortlisted candidates currently in employment within the pharmaceutical industry or other commercially motivated healthcare sectors including consultancy and/or legal services will be required to produce documentary evidence that they have resigned and ended all contractual associations with their employer before being allowed to take up duties at EMA.
4. Priority is given to a limited number of candidates coming from national regulatory authorities from Member States and from the European scientific expert network.
5. Candidates can be contacted over the phone by the different units and sectors of the EMA to check availability and to discuss reciprocal expectations prior to the final selection decision.
6. The Executive Director makes the final selection of applicants on the basis of the proposals submitted by the units concerned.
7. Successful applicants are informed by letter, in duplicate, of the dates of the training period. A copy of these rules is enclosed with the letter.
8. Recruited trainees are responsible for making sure that they obtain the correct visa, where applicable, to enter the United Kingdom. EMA is able provide only a limited support when sponsoring a visitor as British immigration authorities require sometimes very lengthy documentation.

Article 8- Rights and duties of trainees

1. Trainees shall be required to comply with the instructions given by their advisers, by their Head of Unit or Head of Section/Sector to which they are assigned and with the instructions issued by Human Resources. They must also comply with the rules governing the in-service training programme and the internal rules governing the functioning of the EMA, in particular the rules concerning security and confidentiality.
2. Trainees must take part in all activities organised for them, respecting the timetables and programs laid down.
3. During their in-service training, trainees must consult their advisers, Head of Section/Sector, Head of Unit or, if unavailable, Administration on any action they propose to take on their own initiative relating to the EMA's activities.
4. In line with the EMA Code of Conduct, Trainees must exercise the greatest discretion regarding facts and information that come to their knowledge during the course of their training. They must not, in any manner whatsoever, disclose to any unauthorised person any document or information

not already made public. EMA reserves its legal right to terminate the traineeship and to pursue any person who does not respect this obligation. Trainees will continue to be bound by this obligation after the end of their training.

5. In line with the 'Implementing rules concerning the handling of declared interests of employees of the European Medicines Agency', Trainees at the EMA are not permitted to hold on starting the traineeship or seek to acquire during their traineeship at the Agency direct financial interests in a pharmaceutical company or own a current patent for a medicinal product. All such direct interests must be disposed of prior to the start of the traineeship. Trainees will be required to make a public declaration of interests upon starting their traineeship.
6. Upon leaving, during the time period equivalent to the length of the traineeship, Trainees are requested to inform EMA of any occupational activity, paid or unpaid, they engage in. Within 45 working days from the date of the Trainee's request for engaging in an occupational activity, the Agency will communicate any objection or concerns to the Trainee regarding his/her request. No reaction from the Agency after 45 working days implies tacit agreement to the occupational activity stated in the request.
7. Trainees must not have any professional connections with third parties, who might be incompatible with their traineeship (i.e. must not work for lobbyists, legal attachés, etc.), and they are not permitted to exercise any other gainful employment during the period of the traineeship, which may adversely affect the work assigned during the traineeship. If a conflict of interest should arise during their assignment, trainees should immediately report this to their adviser, to their Head of Unit or Head of Section/Sector and to Human Resources in writing.
8. Trainees must respect the same rules for contacts with the Press as other EMA staff and follow the instructions provided. EMA reserves the right to terminate the traineeship and to pursue any person who does not respect this obligation.
9. Trainees must not, either alone or with others, publish or cause to be published any matter dealing with the work of the EMA without the written permission of the relevant services. Human Resources will provide specific instructions on how to obtain such permission and should receive a copy of those permissions together with a copy of any publication or article published. Such permission is subject to the conditions in force for all EMA staff. All rights, for any articles or other work done for the Agency, are the property of the Agency.
10. At the end of their in-service training, trainees must submit to their advisers a report on their activities during the training period. The advisers will then forward this report to Human Resources together with their own reports on the trainees. In the light of these reports, the trainees receive, at the end of their in-service training, a certificate specifying the length of the in-service training and the unit to which they were attached.
11. Trainees must carefully record their activities and their daily working hours in ActiTrak from the first day up to the final day of service. ActiTrak is the basis for EMA's activity-based costing approach.

Article 9 - Absences

1. Trainees should keep the same hours of work and have the same EMA holidays, if they fall during their traineeship, as EMA staff. Trainees are entitled to 2 days leave per month. This entitlement is acquired pro rata to the months worked. Days of leave not taken are not paid in lieu. Days for trips and visits organised either by Human Resources, days taken for participation to any competition,

exam or university work, etc. are to be deducted from this entitlement. Trainees are not permitted to take flexileave. Human Resources and the Head of Unit or the Head of Section/Sectors concerned oversee that the above rules are respected. Leave requests should respect the needs of the Service. Absences must first be approved by the Head of Unit or Head of Section/Sector concerned. A copy of the approved requests must be sent to Human Resources.

2. In case of sickness, trainees must notify the secretary of the Head of Sector immediately, and if absent for longer than three calendar days, must produce a medical certificate, indicating the probable length of absence, which must be forwarded to Human Resources. A trainee who is absent because of illness may be subject to medical checks in the interest of the service.
3. When trainees are absent without justification or without notifying their adviser and the Head of Unit or Head of Sector concerned, Human Resources may decide to immediately terminate the traineeship without further notice. Any overpayment of the grant is to be reimbursed to EMA. The trainee will also not be entitled to receive the travel allowance.

Article 10 – Maternity leave

1. A trainee who is pregnant shall be granted maximum maternity leave of twelve weeks, during which period she shall receive the grant as set out in Article 11 of these rules. The leave shall start not earlier than six weeks before the expected date of confinement as shown in a medical certificate, which must be provided to Human Resources, and end not earlier than six weeks after the actual date of childbirth.
2. For health and safety reasons, a trainee who is pregnant must inform Human Resources at the latest fifteen weeks before the expected date of confinement.
3. Maternity leave cannot go beyond the duration of the traineeship contract.

Article 11 - Grants

1. Trainees will be awarded a monthly maintenance grant. The amount of the grant is decided by Human Resources and revised on a regular basis. The grant is dependent on budgetary constraints. The amount of the basic grant will be published on the website.
2. If the trainee terminates his/her contract early, he/she will be required to reimburse that part of the grant, which he/she may have received, relating to the period after the termination date.
3. Upon presentation of the proper justification, disabled trainees may receive a supplement to their grant equal to a maximum of 50% of the amount of the grant. Human Resources may consult the medical service of the EMA if necessary.

Article 12 - Travel expenses at the beginning and end of the in-service training

1. Trainees who receive a grant, whose place of recruitment at the beginning of the in-service training is not London are entitled to a compensation for the travel expenses incurred at the

beginning and end of the training as determined under this article. The trainee does not need to present proof of travelling.

2. The trainee must complete a minimum of three months of the training period to qualify for the travel allowance. Trainees whose place of recruitment is less than 150 km from the place of employment are not entitled to a travel allowance.
3. The postal address used in EMA's letter awarding the traineeship shall be considered to be the place of recruitment. No request for a change of address shall be granted once the decision to award a traineeship has been taken.
4. Travel expenses for the inward journey and for the outward journey are compensated in the form of a unique flat-rate payment based on the shortest distance by road between the place of recruitment and London as shown in the table below. For the purpose of the payments the distance within the meaning of these rules shall be determined by the shortest road distances as calculated by the Michelin route planner *ViaMichelin* (www.viamichelin.com)

Distance between place of recruitment and London (km)	Amount in Euro of the unique flat rate payment
0 – 150	0
> 150	76.44
> 300	135.89
> 500	220.84
> 800	356.73
> 1300	560.58
> 2000	671.01

5. Travel expenses of non-EU member country trainees are reimbursed on the basis of the rules above. However, unless specific provision is made to the contrary, where the place of recruitment is outside the European territory of a Member State travel expenses shall be reimbursed only from the point in the European territory of a Member State, which is nearest to the place of recruitment.

Article 13- Individual missions

1. In exceptional cases only, the Executive Director may, on a request from the Head of Unit concerned stating the grounds, grant authorization for a trainee to be sent on mission.
2. This authorization entitles trainees to reimbursement of mission expenses in accordance with the Staff Regulations of the European Communities and these expenses are charged to budget item 153.

Article 14- Tax arrangements

Maintenance grants awarded to trainees are not subject to the special tax regulations applying to officials and other servants of the European Communities. Trainees are solely responsible for the payment of any taxes due on the maintenance grant they receive from the EMA by virtue of the laws in force in the State concerned.

Article 15 – Sickness Insurance and accident insurance

1. Sickness insurance is compulsory. Unless otherwise communicated in writing, trainees will automatically be affiliated to the sickness insurance policy that the EMA holds with an insurance company. Trainees will be insured against sickness under the conditions laid down in those rules. The contribution of the trainees is one third of the premium, which is deducted from their monthly grant. In the event that the trainee decides to opt out of the sickness insurance policy offered by the EMA, he/she will need to communicate this in writing to the Head of Human Resources. Trainees who opt out of the sickness insurance policy will be responsible for registering with the UK National Health Service (NHS) or make other private arrangements.
2. During the in-service training a trainee is also personally insured against the risk of accidents on the same terms as persons at the EMA who are not covered by the Staff Regulations.

Article 16 - Interruption and termination of training and sanctions

1. Under exceptional circumstances, at the written request of the trainee stating the relevant reasons and with proper justification, the Head of Human Resources may, after consultation with the Head of Unit or Head of Sector concerned, authorise an interruption of training for a given period. The grant is then suspended and the trainee is not entitled to reimbursement of any travel expenses incurred during that period. The trainee may return to complete the unfinished part of the training, but only up to the end of the same training period. No extension is possible.
2. If a trainee wishes to terminate his/her traineeship earlier than the date specified in the contract, a written request must be submitted by the trainee to Human Resources for approval. The request should state the relevant reasons and must be submitted at least three weeks in advance of the new termination date. The trainee must submit the request to Human Resources via his/her adviser and the Head of Unit or Head of Sector concerned. Trainees may only terminate their contract on the 1st and 16th of the month. Where appropriate, the equivalent part of the grant must be reimbursed to EMA.
3. In-service training shall end when the period for which it was awarded expires.
4. Trainees must exercise their duties and behave with integrity, courtesy and consideration. If the conduct of the trainee does not prove satisfactory, Human Resources, in response to a reasonable request by the adviser and approved, after hearing the trainee, by the Head of Unit or Head of Sector concerned, may at any moment decide to terminate the traineeship. Human Resources, following a justified request by the adviser and approved by the Head of Unit or Head of Sector concerned, reserves the right to terminate the traineeship if the level of the trainee's professional performance or knowledge of the working language is insufficient for the proper execution of his/her duties. Human Resources reserves the right to terminate the traineeship if at any moment it

becomes apparent that the trainee knowingly made wrongful declarations, or provided false statements or papers at the moment of application or during the traineeship period.

Article 17 –Data protection

EMA ensures that applicants' personal data are processed as required by Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (*Official Journal of the European Communities*, L 8 of 12 January 2001). A detailed data protection statement is available on the EMA website.

Article 18 - Final provisions

These rules take effect on 1 September 2011 and replace the rules of 1 June 2009.

(Signature on file)

Andreas Pott

Acting Executive Director

Annex I

Examples of diplomas for which the level of education corresponds to that required for access to the traineeship¹

Country	University level education – at least 3 years in length
Belgium FR	Actuellement : Licence ou équivalent - A l'avenir: Bachelor
Belgium NL	At present: Licentiaat, Meester, industrieel ingenieur, Gegradueerde
Bългария	In future: Bachelor (According to the Higher Education Act of 4 April 2003) Diplom za Visse Obrazovanie (Диплома за Висше Образование) Bakalavur (Бакалавър) Magister (Магистър)
Ceská Republika	Magister (Магистър) Diplom o ukončení Bakalářského studia
Danmark	Bachelorgrad
Deutschland	Fachhochschulabschluss (6-7 Semester)
Eesti	Bakalaureusekraad (<160 ainepunkti)
España	Diplomado/Ingeniero Técnico
France	Licence
Greece/Ελλάδα	Δίπλωμα Α.Ε.Ι. (πανεπιστημίου, πολυτεχνείου, Τ.Ε.Ι. υποχρεωτικής τετραετούς φοίτησης)
Ireland/Eire	Bachelor's degree
Italia	Laurea –L (breve)
Κύπρος/Kibris	Πανεπιστημιακό δίπλωμα
Latvija	Bakalaura diploms (<160 kredīti)
Lietuva	Bakalauras (<160 kreditas)
Luxembourg	Diplôme d'Ingénieur Technicien
Magyarország	Főiskolai Oklevél
Malta	Bachelor's degree
Nederland	Bachelor
Österreich	Fachhochschuldiplom (6-7 Semester)
Polska	Licencjat – Inżynier
Portugal	Bacharelato
România	Diplomă de Licența
Slovenija	Diploma o Pridobljeni Visoki Strokovni Izobrazbi
Slovenská Republika	Diplom o ukončení Bakalářského štúdia
Suomi/Finland	Kandidaatti / Kandidat examen Ammattikorkeakoulututkinto/Yrkeshögskoleexamen (min. 120 opintoviikkoa /studieveckor)
Sverige	Kandidatexamen (Akademisk examen omfattande minst 120 poäng, varav 60 poäng av fördjupade studier i ett ämne)
United Kingdom	Bachelor's degree / Diploma of Higher Education (DipHE)

¹ Situation as of 1 January 2007