EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 April 2016
EMA/133629/2016
Executive Director

# Decision of the Executive Director

on the rules governing the traineeship programme at the EMA

THE EXECUTIVE DIRECTOR

HAVING REGARD to Regulation (EC) No 726/04

WHEREAS it is necessary to draw up rules to govern traineeship programme organised by the EMA,

HAS DECIDED

## 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 traineeship programme 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 Divisions and Departments. 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2016. Reproduction is authorised provided the source is acknowledged.

EMA, through its official traineeship programme:

- 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 have to be nationals of the Member States of the European Union or of Norway, Iceland and Liechtenstein. Candidates must have completed the first cycle of a higher university education course and obtained a full degree or its equivalent by the receipt of the contract (i.e. end of July for 1 October intake and end of February for 1 April intake). 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 must have very good knowledge of at least two EU languages, of which one should be 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 the traineeship programme does not confer on trainees the status of other servants of the European Union nor does it entail any right or priority with regard to an appointment in the services of the EMA. Trainees can apply during their traineeship 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 the traineeship programme 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 a traineeship. 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, special projects in the interest of the Agency 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 Division concerned.

## Article 4 - Organisation

1. Before each traineeship programme period the Executive Director determines the number of trainees, to be attached to each Division, on the basis of the funds available.

2. Trainees are allocated to a Division. During the traineeship, trainees may be rotating within the Division; they may be involved in cross-Agency projects or be re-allocated to another position as agreed by management.

3. Trainees are placed under the responsibility of an adviser. 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 Division/Department 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.

4. 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 Division/Department 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 Division/Department other than the one to which they are attached, unless these meetings are restricted or confidential.

## Article 5 - Duration of the traineeship programme

1. Training periods last at least three and at most twelve months. There are two possible annual intakes with a start date of 1 October and 1 April each year. There is no possibility to delay or defer the start date of the traineeship. The number of trainees for each intake will be confirmed and can vary.

2. In addition, the Agency may decide on an additional trainee intake for special projects. The timing and duration of a special intake as well as the number of trainees and their allocation will be determined by the Agency as needed. The application and selection process is the same as for the intakes described under 5.1.

3. 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 six months. Trainees will be notified one month in advance if they are to receive an extension to their traineeship of six months. The maximum total training period is twelve months.

4. 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 traineeship programme.

5. Traineeship 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 traineeship programme. 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, facility 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. Shortlisted candidates who own shares in the pharmaceutical industry have to provide documentary evidence that they have sold the shares before taking up duties at EMA.
5. Candidates can be contacted over the phone by the different Divisions and Departments 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 traineeship period. A copy of these rules is enclosed with the letter.
8. The selection of trainees is confidential.

## 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 Division or Head of Department/Service to which they are assigned and with the instructions issued by Human Resources. They must also comply with the rules governing the traineeship 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 traineeship programme, trainees must consult their advisers, Head of Service/Department, Head of Division 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 traineeship. 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 traineeship.

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. Trainees must not have any professional connections with third parties, which 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 or non-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 Division or Head of Department/Service and to Human Resources in writing.

7. 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.

8. 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 (including thesis) 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.

9. At the end of their traineeship programme, 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 and may add elements to this report as appropriate. Trainees receive, at the end of their traineeship programme, a certificate specifying the length of the traineeship programme and the division to which they were attached.

10. Trainees must carefully record their activities and their daily working hours in SAP from the first day up to the final day of service. SAP is the basis for EMA's activity-based costing approach.

## Article 9 - Absences

1. Working time arrangements of the Agency apply to trainees. 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 in any competition, university work, etc. are to be deducted from this entitlement. Trainees are not permitted to take special leave, except for exam days (a maximum of 3 days per

traineeship) and a maximum of 3 days for serious family situations. Trainees should not take flexi leave or swap EMA holidays with working days.

Human Resources and the Head of Service/Department concerned oversee that the above rules are respected. Leave requests should respect the needs of the Service. Absences have first to be approved by the Head of Division or Head of Service/Department concerned.

2. In case of sickness, trainees must notify the secretary of the Head of Department 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 Division or Head of Department 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 traineeship programme

1. Trainees who receive a grant, whose place of recruitment at the beginning of the traineeship programme is not London are entitled to 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. The trainee is responsible for informing Human Resources immediately of any change of address.

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 traineeship contract 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. 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 Division 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 rules and conditions relating to the payment of mission expenses in force at the Agency[1] 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 Union. 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. The EMA does not provide private health insurance. Trainees are entitled to use the UK National Health Service (NHS). Therefore they are responsible for registering with their local General Practitioner (GP) to be able to use the NHS or make other private arrangements. The NHS service covers required health services for trainees during their stay in the UK while working for the Agency. Also all EU citizens should carry a European Health Insurance Card (EHIC) while abroad. EHIC entitles them to free or reduced-cost treatment in the EU.
2. During the traineeship programme a trainee is only 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 Division or Department 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 traineeship 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 Division or Head of Department 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. The traineeship programme shall end when the period for which it was awarded expires.

[1] *Articles 11 and 12 of Annex VII to the Staff Regulations and the provisions implementing these Articles shall apply mutatis mutandis*

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 Division or Head of Department 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 Division or Head of Department 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 April 2016 and supersede the rules dated 1 October 2015 (EMA/827799/2015).

(signature on file)

Guido Rasi

Executive Director

# Annex I

## *Examples of diplomas for which the level of education corresponds to that required for access to the traineeship*

| 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<br>In future: Bachelor (According to the Higher Education Act of 4 April 2003) |
| Bălgarija | Diplom za Visse Obrazowanie<br>(Диплома за Висше Образование)<br>Bakalavur (Бакалавър)<br>Magister (Магистър) |
| Ceská Republika | Diplom o ukončení<br>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) |
| Hrvatska/Croatie | Baccalaureus/Baccalaurea (Sveučilišni Prvostupnik/Prvostupnica) |
| Ireland/Eire | Bachelor's degree |
| Italia | Laurea –L (breve) |
| Κύπρος/Kibris | Πανεπιστημιακό διπλωμα |
| Latvija | Bakalaura diploms (<160 kredīti) |
| Lietuva | Bakalauras (<160 kreditas) |
| Luxembourg | Diplôme d'Ingénieur Technicien |
| Magyarország | Föiskolai Oklevél |
| Malta | Bachelor's degree |
| Nederland | Bachelor |
| Österreich | Fachhochschuldiplom (6-7 Semester) |
| Polska | Licencjat – Inzynier |
| Portugal | Bacharelato |
| România | Diplomă de Licenţa |
| Slovenija | Diploma o Pridobljeni Visoki<br>Strokovni Izobrazbi |
| Slovenská Republika | Diplom o ukončení<br>Bakalárského štúdia |
| Suomi/Finland | Kandidaatti / Kandidat examen<br>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) |