

Joint Heads of Medicines Agencies /European Medicines Agency Training Project Team

Strategy for Regulatory and Scientific Training within the European Regulatory Network

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1. Executive Summary

A Joint Project Team established by the Heads of Medicines Agencies and the European Medicines Agency (the Joint HMA/EMA Training Project Team –TPT) has developed a strategy for training within the European Regulatory network following a detailed analysis of the history and current situation with regard to the supply of regulatory training and as a result of a number of surveys. The strategy proposes the creation of an EU Office for Regulatory Training that would coordinate training activities on behalf of the network. The office would coordinate the definition of curricula for the different categories of staff working within agencies and would create a register of commercial and non-commercial sources of training. The office would assist the network in the supply of training, in assuring its quality and in promoting harmonisation of standards for assessment, recording of training and quality assurance of staff by national authorities.

2. Introduction and background

Heads of Medicines Agencies (HMA) recognized very early on the need for harmonised training to help ensure that the EEA Medicines Regulatory Network (ERN) achieves on an ongoing basis harmonised high quality performance standard in assessment and inspection. In November 2001 a mandate was given to a project team in an effort to progress in this matter. Belgium volunteered to be project coordinator in this effort and reported to the HMA meeting in Verona in July 2003 with an extensive list of suggested areas for training. The HMA endorsed the report, but follow up was difficult. EMA and MS have invited to valuable training sessions, in addition internal training is given by the Agencies. But no overall strategy has been developed for what is needed.

The HMA strategy, the EMA Roadmap and the Benchmarking of European Medicines Agencies (BEMA) exercise were strong drivers for the issue to be brought up again. Other strong drivers are the Innovative Medicines Initiative, the European Technology Platform for Global Animal Health and the emphasis on continuous professional development (CPD).

At the HMA meeting in Bonn, April 2007, the draft mandate for an ad hoc Training Project Team was adopted. The team reported for the first time to the HMA meeting in Madeira 2007, where slight changes to the mandate and the way forward were endorsed.

3. Objectives

The overall objectives are:

- To improve the quality and consistency of the work of the European Regulatory Network;
- To foster science based, pragmatic and consistent assessment, inspection and laboratory control practices and decision making;
- To promote harmonised interpretation of guidelines and operation of the regulatory framework throughout the European Regulatory Network;
- To provide continuous professional development for staff of regulatory agencies and, possibly, others involved in regulation of medicines.

The mandate of the HMA/EMA Training Project Team (TPT) was therefore agreed as:

- Develop a training strategy that addresses the needs of:

- o experts in human and veterinary medicinal products at all levels of experience;
- o internal and external experts acting on behalf of NCAs;
- o scientific and administrative staff with regulatory responsibilities;
- o different professional backgrounds (e.g. assessors, inspectors, laboratory staff, lawyers).
- Develop a training strategy that includes:
 - o coordinated approach to training;
 - o competence assessment and accreditation;
 - o quality assurance of training provided;
 - o delivery options including role of existing providers;
 - o funding and cooperation with other initiatives (IMI, ETPGAH).

4. Approach adopted by the TPT

4.1. Mandate and Composition of the Team

The Mandate given to the TPT by HMA is given as Annex 1 and the composition of the team as Annex II.

In view of the wide range of staff working in the network and, consequently, the extensive and divergent needs for training that exist, the TPT proposed that the network adopts a phased approach concentrating in the first instance on developing a strategy for the supply of training to assessors and regulatory staff.

4.2. Gap Analysis of Existing Provision

In order better to understand the existing situation regarding external training providers, the TPT contacted a range of known providers and posted a notice on the HMA web site inviting interested providers to supply details of their existing courses and to make proposals for how best they might interact with the network in the future. In addition, the TPT conducted a non-exhaustive survey of existing external sources of training available to the network. The results of this analysis showed that a considerable amount of training is available from a wide variety of sources including universities and centres of higher education, not-for-profit organisations, commercial providers, and professional and learned societies. Internationally recognised qualifications are available in relevant advanced specialities, usually in the form of post graduate masters degrees, but there is little such formal assessment or accreditation of intermediate or basic level training. The TPT concluded that if the network defines the competences and curricula required, this will create a market and existing providers would compete to provide the required training at all levels.

As part of this analysis TPT members and other volunteers carried out an informal assessment of the range of e-learning modules to which access was kindly granted by a leading provider in this area. The results confirmed that e-learning tools could form a valuable part of a blended learning programme for basic to intermediate level training in regulatory affairs.

4.3. Baseline Survey

The TPT conducted a baseline survey to assess what training is given in the different NCAs, their use of external training providers, what the need for training was, and the funding available in the different NCAs. A questionnaire was sent out and 27 NCAs responded. The analysis of the results of the questionnaire and the conclusions drawn have been taken into account in preparing this document.

5. Coordinated approach to training

The main principle underlying this strategy is that basic training should be provided to all the staff members of a competent authority and that additional, specialized, training should also be provided to those that need it. The need to coordinate training activities is very clear. The current un-coordinated approach represents a considerable 'hidden' cost to the network in terms of using experienced staff in individual agencies to train new staff, particularly in view of the high turnover of staff and the resulting constant need to train these new staff.

The main groups of professionals to be included, in a first step, should be **Assessors and Regulatory staff**.

5.1. Core Skills vs. Specialized Training

In relation to **core skills**, there is currently almost no coordination of activities within the network. NCAs assess the skills of new staff relative to the essential competences required for the post and then provide training through a combination of induction training, mentoring and other forms of personal training, and formal, didactic training at agency or network level. This is an area for potential coordination within the network that could lead to considerable resource savings through shared training and the supply of standardized, high quality training material.

In relation to **specialized training**, much activity happens at the national level although there is some coordination at European level and through the HMA. Also, the EMA runs an ongoing program of specialist training that is targeted annually to the needs of the ERN. One of the principle outcomes of any future HMA strategy on training should be a more strategic approach to supply of specialist training.

It could be foreseen to use interesting real cases as a starting point, and CXMP working parties should play a major role.

5.2. Curricula

Regarding the definition of subjects that need to be covered (curricula), these should be defined by suitably composed groups of experts (depending on the professional group) and should be based on the definition of the professional skills needed to perform the core tasks of the network. The potential role for an EU Office of Training in this regard is considered later in this document.

English is the working language of the network. The TPT considered that training provided to, and by, the network should therefore be in the English language. The responsibility for ensuring proficiency in English rests with the individual and the national competent authority for which they work. Nevertheless, the training strategy needs to take into account that trainees will have differing levels of ability in terms of English. Where possible, arrangements should be made for training materials to be provided to national authorities for translation into national languages in advance of training

events and authorities should provide assistance as necessary in terms of verbal translation during events. Translated material is particularly helpful for basic training for junior staff whose first language is not English and who rarely use English as their working language. It is less relevant for more senior staff, particularly those who frequently work in English.

5.3. Industry

The potential for targeting training events to both agency and industrial staff should be considered.

The advantages foreseen are:

- raising awareness by regulators of the challenges faced by industry, this was considered particularly useful as part of basic training of new staff coming into regulatory agencies and coming into contact with industry for the first time;
- raising awareness by industry of the challenges faced by regulators;
- access to a wider range of experts (i.e. those employed by industry who would not otherwise participate in external training events), particularly where such individuals may be opinion leaders in highly specialised fields;
- Effective use of resources by both regulators and industry thereby reducing the financial burden on both.

The disadvantages are:

- increased preparation and care to avoid issues of confidentiality;
- need to avoid and manage any perception that industry was 'grooming' regulators into accepting their position;
- some regulatory authorities may feel uncomfortable with this proposal as being inconsistent with perceptions of 'best practice' in their countries.

In order to avoid the possibility of perceived or actual conflicts of interest, this option will take more preparation and may thus need to be applied less frequently. Great care will need to be taken to ensure that any training material prepared for a joint event does not risk disclosing confidential information. As this material may well be related to actual case assessment, this could constrain the extent to which industry could be involved in this type of training.

Nevertheless, the TPT is of the view that joint training with industry is possible, and even desirable, provided that the following conditions can be met:

- The EU regulatory network should set the agenda for the training event;
- Confidentiality needs to be fully respected and this can limit the extent to which industry can be involved in some discussions/training;
- Joint training will be relevant only for a relatively restricted, optional range of topics within the overall curriculum.

6. Competence assessment, recording of training and quality assurance of personnel

First of all, the basic skills to take part in the work of the network need to be defined. As a first step a standard set of competence criteria for assessors and regulatory personnel need to be defined. This

could be done by creating a group of experts in the different fields that could agree and define the standards at various levels. Then the curricula's can be decided in the same manner. The potential role of an EU Office of Training in coordinating these activities is discussed later in this document. A set of standard modules are foreseen. The core training should provide a platform for people to take part in the procedures with an option for additional training for continuous development according to the needs of the individual and the Agency. There is a need to avoid bureaucracy, but also a need to make the training more formal.

There is a basic level of knowledge that is necessary and this is usually based on formal qualifications. For example, to work as an assessor either a master's degree in a relevant subject (natural sciences, civil engineers, pharmacy, MD, DVM, DDM) or a first degree supplemented by relevant experience is normally required. For regulatory staff, the formal qualifications should be more flexible.

The NCAs will be interested in the highest standards of the personnel. There will be a need for flexibility for the Agencies, but the system should be transparent. For core competencies therefore assessment of individuals should remain the responsibility of the agencies based on the harmonised curricula and standards agreed within the network.

For training leading to a formal qualification, external accreditation by universities and other centres of higher education is preferable with extensive input from agencies as to the curriculum and standards.

There is a need for a system within the agencies to assess and record competence. In each Agency a competence plan should be developed (such as already exists for inspectors) covering basic education, basic training and continuous training. It will be the responsibility of each NCA to see to the continuous development of the competence of their staff. This will be inherently linked to the quality system in operation at the agency where continuous improvement is a requirement of any quality policy. The proposals link closely to the BEMA initiative and should be seen as a complementary activity to the other aspects of quality assurance.

7. Quality assurance of training provided

It should be the task of the network to set the quality standards against which they and external organizations can assess the quality of training provided.

It is crucial to ensure both consistency and continuation while making the training available at a reasonable cost to all member states. External providers of Basic Training should be encouraged to establish links to a number of universities that can issue internationally recognised qualification, such as a Master degree in Drug Regulatory Sciences, and can also help to run the courses and examinations at different locations across Europe. This would increase the availability and reduce travelling costs.

A potential role for the proposed EU Office of Training should be explored in terms of promoting harmonised standards for training once the necessary requirements and curricula have been defined.

8. Delivery options including role of existing providers

Training of regulators and scientific experts in the National Competent Authorities (NCAs) is essential for the operation and maintenance of the quality of the European Regulatory Network. This regards training of new staff (in some agencies there is a turn-over rate of 25-50%), but the changing legislative and scientific environment requires also continuous education of existing staff and experts.

The following options are available for training of staff. Some are more suitable for the training of new regulators and experts, some seem more appropriate for follow up training.

8.1. Available training options

8.1.1. On the job training/mentoring

8.1.2. Traditional taught courses

8.1.3. Distance learning/e-learning

8.1.4. Twinning projects/Regional cooperation projects

8.1.5. 'Train the trainers' approach

Important factors for assessing the suitability of a certain training option are:

- Cost- including both the cost of the training course and travelling/hotels
- Time- of trainers and trainees
- Effectiveness
- Quality of training
- Consistency in standards
- Number of experts to be trained
- Focus: national or European

The respective benefits and disadvantages of these options are discussed below.

8.1.1. On the job training/mentoring

Traditionally most new staff members are trained by their senior colleagues. This can include both practical training and theoretical training such as explanation of legislation and Guidance documents.

Most agencies have formal curricula that lay down the required topics for training and expected knowledge/experience before a new staff member is allowed to work on their own. The introduction and job training should be linked to the overall quality assurance system of the agency. Practical experience can mainly be gained by training on the job, based on the handling of applications and assessment of dossiers. Some agencies have standard ‘Handbooks’ with a compilation of important Guidelines and national agreements to facilitate the work of assessors. Sharing of this documentation between agencies could increase the transparency and save resources.

8.1.2.Traditional taught courses

Many topics that are important for regulators/ assessors are given in traditional taught courses. The courses can be organized by Agencies/EMA/CXMP Working parties or a group of Agencies.

Non-for profit external providers such as DIA and TOPRA offer Regulatory training and Courses consisting of different Modules or different topics such as Statistics/Epidemiology Academia often offer Regulatory training courses for certain regions (Germany, Denmark, Netherlands, but these trainings are open for all agencies). There are also many Commercial Training providers which offer short trainings on specific topics. Some training courses offer a Master diploma, or have their own examination of the programme.

8.1.3.Distance learning

Some commercial providers offer courses that can be followed via the internet or on the computer. One provider (Zenosis) offers a wide range of different Modules suitable for Regulators and scientific assessors. The courses can be used for in-house individual training of new staff, but also to inform staff on new developments.

Many universities have already experience with this form of training, often with interactive Q and A sessions that allow students to discuss topics and answer questions. In Regulatory affairs there is limited experience but some organisations such as TOPRA announce the use of e-learning for future courses.

Advantages are reduction of travelling time and costs. Another advantage is that it is custom made; the individual student can study at his/her tempo.

It may be possible to create a ‘Knowledge Warehouse’ containing training material and other relevant information supplied by NCAs. Trainees could then use ‘self service’ to access these materials and then self certify that they have read and understood the various components.

E learning can be expensive to set up and takes considerable time and resource to maintain. It should therefore be focused on subject matter that does not require frequent updating e.g. rules, legislation and procedures.

The TPT conducted a survey of the modules made available by a leading supplier of e-learning tools to the regulatory network. In summary, the modules were found to be well constructed and well designed for the intended purpose of self-directed learning. All modules examined related exclusively to human medicinal products and procedures and the TPT is not aware that similar modules exist in the veterinary sector. In addition, modules do not exist for all areas that would be required to provide a comprehensive set of e-learning tools for new staff coming into the regulatory area. However, the system for producing new modules is quick and efficient and the network, possibly through the proposed Office of Training (Section 9.2.2.) could negotiate with one or more providers to extend the range of modules available to cover veterinary and other topics. In addition, there is

the potential for such modules to act a revenue stream to the network if suitable agreements can be reached. It is essential that a mechanism exists to ensure that modules are continuously maintained and this is a relatively expensive and resource intensive task. For this reason, this method of training is well suited to areas of knowledge where there is little change over time and a large, ongoing demand, such as basic regulatory affairs. It is less well suited to highly specialised areas where knowledge is rapidly changing and where demand for specialist knowledge is relatively limited.

Other technologies, such as 'webinars' and other web based tools are becoming more widely used and have a great potential to reduce the need for travelling. These technologies should therefore be explored as part of the approach to 'blended learning' (see below).

8.1.4.Twinning projects/ regional cooperation

Twinning projects are projects financed by the European Commission. In these projects new member States are trained by experts from experienced member states to explain European Guidelines, procedures etc. They are often a mix of theoretical presentations and training on the job such as writing of assessment reports.

Twinning projects have been organised before accession, but they are also possible after accession.

Regional cooperation is a form of bilateral cooperation between Member States offering training to new regulators or assessors. This can be practical training on the job or theoretical training courses. It is not known at the moment which agencies have this form of cooperation.

An extension of this could be the creation of a European Apprenticeship scheme, whereby trainees from one agency could visit other agencies to receive training in particular areas (similar to Erasmus Scheme). The possibility of obtaining EU funding for such a scheme should be explored.

8.1.5.'Train the trainers' approach

Training offered at European level, for example by EMA or Working Parties, is important to achieve a harmonised view at EU level in the assessment of dossiers or interpretation of Guidelines. As there are 30 agencies it is only possible to invite 1 or 2 representatives from each Agency to such a training or Workshop. However, the benefit is limited if these experts do not give the feedback at home on the outcome of the training. They should be the trainers who afterwards train their colleagues. The trainers can be supported by making training material available (presentations, videos, papers) that can be used for their own training activities.

8.1.7.Discussion

There are many options available to train scientific staff. The Team considers that there is sufficient available training at the European level to cover the need of the European Network but there is a lack of coordination and communication of what training is available. Based on the submitted documentation and reports from external providers, the TPT group also concluded that there is considerable training available on regulatory procedures, but little on skills and science of assessment. In addition, the availability of sufficient training at individual Member State level is not consistent. Training might not always be available when needed. The lack of coordination means that

the objectives of the training strategy may not always be achievable in a timely and consistent manner by each agency. Which options are chosen will depend mainly on available resources and possibilities to travel or not. Many agencies have limited resources available for training.

The TPT concluded that a way should be found to provide the network with a comprehensive suite of e-learning tools covering the entire curriculum necessary to provide basic regulatory training to new staff coming into regulatory network.

However, e-learning alone will not meet the training needs of the network. The term 'blended learning' is often used to indicate that training consists of a mix of available training options: training on the job, e-learning, traditional courses and other available commercial courses. The TPT concludes that 'blended learning' is the appropriate delivery mechanism for this training strategy.

Improved quality and consistency at a reasonable cost will require central co-ordination of training activities and evaluation of training options, as discussed below.

9. Funding

9.1. Current Situation

Funding for regulatory and scientific training within the European Regulatory Network (ERN) is currently fragmented. The overwhelming majority of direct funding originates from the budgets of National Competent Authorities (NCAs). This is supplemented with additional direct funds coming from the European Commission through its funding of EMA training activities. Indirect funding of training originates from not-for-profit organisations such as DIA and TOPRA through their sponsorship of meetings (which would otherwise be more expensive) and from the pharmaceutical industry who generally contribute 'in kind' through the supply of experts free-of-charge to training events organised by, or for the benefit of, the ERN.

Expenditure takes place on the basis of two main drivers. First, expenditure in relation to individual members of staff by their parent organisation to ensure that they attain and retain the core skills necessary to perform their work (henceforth termed 'core skills' training in this document). Second, specialised training organised at NCA or network level with a view to enhancing the knowledge and skills of the network in relation to particular, specialised areas of expertise (henceforth termed 'specialist skills' training in this document).

Due to apparent inconsistency in the way in which agencies responded to the questionnaire, little clear data was obtained from the survey conducted in relation to expenditure by NCAs on external training. However, it is clear from the table below that there is considerable variation between agencies in annual expenditure and that some agencies spend large amounts. The figures provided apparently relate to the total spent on training and therefore include both direct cost and indirect costs, such as travel and subsistence. However, the amounts given do not represent the complete costs to agencies of providing training to employees such as on-the-job training, in-house training, specialist training etc. and the amounts would be considerably higher if these 'inapparent' costs were also included.

	Range (Euros)	Mean (Euros)	Median (Euros)
Joint (n = 8)	14 000 – 680 000*	178 000	117 000
Human (n = 6)	25 000 – 425 000*	131 667	64 000
Vet (n = 4)	10 000 – 164 575*	86 838	86 388

* The cost of travel and subsistence related to this figure for the overall cost of training was not specified in the majority of cases

9.2. Options for the Future

The objectives of the HMA Training Strategy in terms of funding should be both to maximise benefit from the resources committed to training and to identify and utilise all potential sources of funding.

Three funding options have been identified and are explored further below:

9.2.1.Option 1: Current system

The least radical option would be for training to continue to be provided predominantly by NCAs for their own staff with a greater emphasis given to coordination of training, particularly in the area of specialist skills. Likewise, the EMA would continue to organise specialist training on behalf of the network, predominantly through the CXMP working parties. This option would be cost neutral in the short term but would fail to take advantage of potential cost saving from either of the other options which would reduce duplication within the network.

9.2.2.Option 2: Creation of a coordination office for training

This option envisages the creation of a central 'EU Office of Training' with the mandate to coordinate training within the ERN. The office would work with the network to identify the core and specialist skills required by scientific and regulatory experts. The office would then liaise with NCAs, existing not-for-profit organisation and the EMA to create a program of training activities to meet the needs identified. In this model, competence assessment, recording and assuring the quality of trainees would remain the responsibility of the NCAs or of the training providers with a quality assurance and coordination role for the Training Office and the network.

The TPT proposes that the office is run in a similar manner to the HMA Permanent Secretariat with HMA members contributing defined allocations of the time of identified members of staff to running the activities of the office. Provided that matching commitment could be found from the network, the EMA would be willing to explore the possibility of both providing a contribution to the staffing of the office and to providing a physical location for the office at the EMA premises in London, should this be the wish of the Network. Alternatively, another NCA may wish to offer to host the office or it may remain a 'virtual office'. In contrast to the HMA PS, however, the TPT considers that a physical rather than a virtual office would have considerable advantages in terms of rapidly getting the office operational and established both as a physical identity and as a recognised asset of the network.

An alternative option would be for the office to be funded by direct contributions from the NCAs through a levy similar to that currently charged for the CTS. The objective would be that the office

would be either cost-neutral or represent a saving to NCAs when compared to the current system due to reduction of duplication.

In terms of funding, two possibilities have been discussed in this paper but other options may exist and should be explored once a decision has been reached in principle to go ahead with creating an office. One possibility might be that the office might charge for its services and identify a range of revenue streams such as royalties, licences and others.

It may also be appropriate for the office to start with a pilot project in a defined area, such as training for quality assessors. The office could work through the model for defining the curriculum required and establish the corresponding criteria for assessing competence with a group of relevant experts. An appropriate training program could be assembled and provided. Once experience has been gained in a limited area this could then be applied to the roll-out of the strategy as a whole.

The possibility of linking the work of the office with the training activities within the Innovative Medicines Initiative (IMI) should be explored. The objectives of the network for the Office for Training in terms of improving the training of the staff of the regulatory network are fully aligned with the Education and Training Pillar of the IMI which aims to close existing training gaps in the drug development process. A number of consortia have been successful in the first round of calls in the areas of providing training in the fields of safety sciences, pharmaceutical medicine and pharmacovigilance. One role for the office might be to establish links with actual or potential consortia to ensure that the needs of the network are met where these are aligned with those of the pharmaceutical industry, as reflected in the work programme of the IMI.

The Office could also play a role in acting as the point of focus for supply of trainers to third countries, where this occurs in response to the strategic need of the network to invest in raising competence in relevant areas. Currently, requests for the provision of training in key areas such as clinical trials, GMP, quality requirements for active substances etc. may be received by the European Commission, by the EMA or by NCAs from a wide range of third countries including in particular China, India and South East Asia. It could be envisaged that, in future, all such requests would be redirected to the Office of Training who would coordinate with the EMA, its scientific committees and with NCAs how best to respond to these demands in a strategic fashion that meets the objectives of the network and allows the network to provide the training with a distinctive EU Regulatory Network 'brand'.

9.2.3. Option 3: Creation of a 'European Academy for Regulatory Training'

This option envisages the creation of a self-funding European Academy. The academy would levy charges for the services it provides to the ERN which would be paid by the NCAs utilising them. The academy would charge for supplying training, for assessing the competence of experts and for the activities of certifying and maintaining registers of competence. The academy would be a not-for-profit organisation. It is envisaged that the benefit to the network would be the establishment of a recognised system for continuing professional development and that there may be saving in the longer term from the central organisation and supply of training when compared with the current disseminated model that leads to considerable duplication.

10. Conclusions

The HMA-TPT favours Option 2 and has obtained the endorsement of HMA, in principle and subject to the outcome of the consultation procedure, to develop this proposal further through the creation of a dedicated steering group to follow up the work of the TPT in relation to establishing an EU Office of Training.

The following tasks are envisaged for the office:

1. Create and maintain a register of relevant existing training provided by the network and by external providers;
2. Establish one or more 'Blue Ribbon' groups of experts to define:
 - the curricula and competence requirements for the different categories of staff within the regulatory network, starting with the needs of assessors and regulatory staff
 - the quality standards for training providers
 - criteria for harmonised assessment of competence to be applied within the network;
3. Work with external training providers to supply with the necessary tools for e-learning;
4. Work with all stakeholders to ensure the availability of the tools needed for effective blended learning.

It is important that the office starts with a clear but relatively limited mandate with a view that its activities and scope may grow with time. The aim of the office is not to replicate or replace the training provided by external providers but to work with them, and with experts in NCAs, to ensure that the needs of the network are met. This recognises that the skills required for delivery of education and training are different from the skills needed for medicines regulation. The office will therefore ensure that the expertise of professional educators and trainers is effectively harnessed to meet the training requirements of the network. Depending on how successful the office becomes, it is possible that it may migrate into some form of 'European Academy for Regulatory Training' (Option 3) through 'natural evolution' with time.

11. ANNEXES

11.1. *ANNEX I: Mandate of the HMA Training Project Team*

Mandate of the Joint Heads of Medicines Agency/EMA Training Project Team (HMA/EMA TPT)

Mission/ Mandate

In support of the efforts of the European Regulatory Medicines Network (ERMN) with regard to public health and animal health and welfare, the HMA Training Project Team (HMA TPT) shall develop a strategy for training and continuous professional development (CPD) of scientific and regulatory staff of the EU/EEA national competent authorities (NCAs) and EMA. The strategy will further foster science based, pragmatic and consistent assessment, inspection and laboratory control practices and decision making as well as harmonised interpretation of guidelines and the regulatory framework throughout the ERMN. To this end, the HMA TPT will look into existing training opportunities and needs within the ERMN and outside, including universities, learned societies and other external training providers, and will draft a range of options whereby this strategy could be realised so that HMA will be in a position to make an informed choice as to the future direction of initial training and CPD within the network..

Terms of reference

The TPT will consist of senior assessors and regulatory experts from the EU/EEA Medicines Agencies and the EMA. The remit of the team covers the whole range of scientific and regulatory training. The team will endeavour to propose priority areas of interest, ensuring criteria pertaining to the following target audiences are taken into account:

- experts in human and veterinary medicinal products,
- internal and external experts acting on behalf of the NCAs,
- experienced and novice experts,
- scientific and administrative staff with regulatory responsibilities
- different professional backgrounds (e.g. assessors, inspectors, laboratory analysts, lawyers).

The scheme will utilise the modalities organised by EMA, NCAs, EC (Phare) or by independent training providers, in cooperation with industry and academia (where relevant), thus providing options for on site or remote training (e-learning), formal and informal training sessions, with or without accreditation and with or without registration fees.

To this end, the group will:

- analyse previous experience in the light of the strategic orientations laid out in the HMA Strategy Paper
- identify relevant initiatives already existing or emerging within the Network with regard to training;
- explore various mechanisms that may be envisaged to foster development of a consistent training scheme, with a view to providing high quality training to the experts involved in the different aspects of human and veterinary medicines regulation across the EMRN.

The reflections and proposals of the group will be formulated into a strategy that takes due account

of the need to make the most efficient use of resources by focusing on time and cost saving in considering training methods. The aim will be to promote consistency and excellence within the Network. The proposals to be elaborated by the HMA TPT as part of the strategy will include all identified training options, an analysis of feasibility and requirements for each option, as well as an assessment of the respective financial impact.

Deliverables:

- Analysis of former experience and existing training provision
- Proposal for a Training Strategy
- Options analysis for delivering a coordinated approach to providing training and CPD
- Proposals for options to assess the competence¹ of staff and the quality of training provided to the network
- Proposals for a range of options to deliver future training (e-learning, distance learning, taught courses, workshops etc) for a viable training scheme for experts including a variety of training options that might be developed by HMA
- To cooperate with, and identify opportunities for funding from, the Innovative Medicines Initiative and the European Technology Platform for Global Animal Health within FWP 7.

Support and Resources for the HMA/EMA TPT

The TPT is supported by the national competent authorities through the contribution of experienced assessors and regulatory experts.

The TPT will need to consult with education professionals at appropriate stages in the development of the training strategy.

Operating procedures of the HMA/EMA TPT

The rules of procedure of the project team shall be endorsed by the HMA.

Composition/membership

The HMA TPT is an ad hoc group and will be composed of experienced assessors or regulatory experts of NCAs and the EMA and will be chaired by a Head of Agency. In the case of resignation of the chair the HMA-MG may nominate an interim replacement until a new chair has been elected at the next HMA meeting. As an ad hoc group, the TPT will be disbanded once the deliverables have been provided to and adopted by HMA.

Meeting frequency

As an ad hoc group, the HMA TPT will meet on an 'as needed' basis. Face-to-face meetings will be hosted by the chair. Between meetings the group will keep itself permanently updated via means of electronic communication. The use of email and teleconferences as a means for information exchange and discussion is encouraged and foreseen to underpin the work of the group.

Expenses and accommodation

Each agency bears the costs of its representative to the TPT. Attendees pay their own cost of accommodation and travel. The chair is expected to provide meeting facilities for the meetings.

¹ Competence in this context refers to the range of skills possessed by an individual and not their performance in a particular role.

Revision of the mandate

The mandate should be updated in line with the aims and objectives of the training strategy once this has been adopted by HMA but can be reviewed at any time point at the request of the TPT or HMA.

11.2. *ANNEX II: The composition of the TPT*

Chair: Gro Ramsten Wesenberg, NoMA, Norway

Members: Gabriele Unger, PEI, Germany

Gert Ragnarsson, MPA, Sweden

Usfeya Muazzam, BfArM, Germany

Gabriel Beechinor, IMB, Ireland

Ruth Kearsley, VMD, UK

David Mackay, EMA

Dina Lopes, Infarmed, Portugal

Truus Janse-de Hoog, CBG-MEB, Netherlands

Alar Irs, Estonian State Agency of Medicines, Estonia

Contact points: Françoise Felize and Greet Munch, FAGG-AFMPS, Belgium