ЕВРОПЕЙСКИ ПАРЛАМЕНТ PARLAMENTO EUROPEO EVROPSKÝ PARLAMENT EUROPA-PARLAMENTET
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COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY
THE SECRETARIAT

Brussels, February 2013

SUMMARY NOTE

ENVI Delegation to the European Medicines Agency (EMA), London, 11-13 February 2013

I. Composition and Objectives of the Delegation

On 11-13 Feb 2013, the Committee on the Environment, Public Health and Food Safety visited the European Medicines Agency (EMA) in London in order to learn about the latest developments and main current and future challenges concerning the Agency in carrying out its functions.

Full lists of participants on side of EP and EMA, as well as detailed delegation programme are attached at the end of the present report.

II. Structure of the Visit

The visit started in the afternoon of Monday 11 Feb 2013 with a detailed introduction to the Agency ad its functioning, followed by a full day of presentations on Tuesday and the morning of Wednesday when the visit was concluded. All presentations were followed by discussions with the ENVI delegation and/or clarifying questions.

III. In detail

Welcome and outline of the visit to the Agency, Mr Guido Rasi

The Executive Director of the EMA, Mr Guido Rasi, welcomed the ENVI delegation and presented the EMA participants heading most of the key divisions within the Agency. He gave a brief outline of the visit.

The Marketing Authorisation (MA) procedures - National Procedure (NP), Centralised Procedure (CP), Mutual Recognition (MRP) and Decentralised Procedure (DP), Ms Hilde Boone

Ms Boone gave an overview of the 4 different ways of obtaining marketing authorisation for medicinal products in Europe - NP (when meant to obtain authorisation for just one Member State (MS)) or European CP+MRP+DP (if authorisation to be valid in more than 1 or all MSs). There are 4 procedures for the authorisation of medicines:

- **NP**: each MS has its own procedure for the authorisation, within their own territory, of medicines that fall outside of the scope of the CP;
- **MRP**: companies that have a medicine authorised in one MS can apply for this medicine to be recognised in other MSs. In 2012, 267 new applications were received;
- **DP**: companies can apply for the simultaneous authorisation in more than one MS of a medicine that has not yet been authorised in any MS and that does not fall within the CP. In 2012 1183 new applications were received;
- **CP**: this procedure results in a single MA that is valid in all EU countries (and Iceland, Liechtenstein and Norway). The product will have only one trade name and identical product information in 22 languages (package leaflet and labelling). In 2012 96 applications were received. The CP is compulsory for:

    - medicines derived from biotechnology processes;
    - advanced therapy medicines and those intended for treatment of AIDS, cancer, neurodegenerative disorder, diabetes, auto-immune and of viral diseases;
    - Orphan Medical Products,

The CP is still optional for products outside of the 3 categories above but which prove to be either scientific, therapeutic or technical innovation or are considered in the interest of human or animal health.

In the follow up discussion a number of issues were brought up mainly with regards to the "referrals" to EMA and the role of national medicine agencies (NMAs). Members pointed that most problems arise with local products authorised via the DP or MRP thus expressing also concern about the quality of the functioning as well as the responsibility taken up by NMAs. EMA assured the delegation that referrals of the type arising from disagreement among MSs in the scope of MRP occur very rarely as MSs tend to work well together on that front. The other type of "safety referrals" are more problematic given that EMA is not in the driving seat as it depends on a company, MS or COM to refer a case to EMA and then EMA is not in possession of the data upon which the MA is being made, however, things are improving with the new PRAC committee.

EMA and the EU network/Heads of Medicines Agencies, Ms Silvia Fabiani

Established in 1996, HMA is the voluntary network of the Heads of the National Competent Authorities in the EEA MSs (47 in total) with which the EMA and COM cooperate. The HMA is supported by a Management group and a Permanent Secretariat of 4 part-time staff from volunteer agencies. It is divided in various configurations - some 16 working groups - depending upon the subject area covered. Its work output though is entirely voluntary serving to provide example and has no binding effect. Ms Fabiani also spoke about the challenges faced by HMA such as the issue of funding and the competition for resources, the differences among the agencies and bridging their realities, the overlap between HMA and the EMA Management Board (MB). Members expressed a concern about spending already limited resources on a voluntary organisation while these are needed to support actual responsibilities of EMA under its legal statute. In response, EMA assured that it doesn't cover the expenses of

HMA which is supported by each EU Presidency adding that HMA in fact provides a form of simplicity in what is a very complex network of various agents.

Scientific Advice/Protocol Assistance, Mr Spiros Vamvakas

Since 1996 EMA provides advice to companies on the scientific requirements for new drugs in view of improving the quality of applications coming to EMA. Some 80% of orphan drugs applicants request scientific advice and same 80 % of applicants under the CA. The process takes place within the Scientific Advice Working Party of the CHMP supported by 30 experts from NMAs/universities/hospitals, EMA staff (9 in house scientists) and a network of thousands of EU expert. The advice is prepared in the form of an advice letter of 20-30pages adopted by the CHMP within 1-2 months from when requested. In 2012, some 113 SMEs benefited from this service out of 420 total addressed requests to EMA.

SME Office at EMA, Ms Melanie Carr

Ms Carr presented the work of the SME Office at EMA which since 2006 tailors support to SMEs in the form of fee incentives, regulatory assistance, translations, SME-friendly bulletins and guidelines as well as workshops. In 2012 there were 1098 companies assigned with SME status (up from 120 in 2006) mainly in the field of human therapeutics. SMEs are increasing in numbers and in their activities, such as already mentioned in 2012 113 SMEs sought scientific advices compared to only 20 in 2006, with fees for SMEs reduced by 90% for this service.

Communication at the Agency, Mr Martin Harvey (replaced by Sarah Weatherley)

Since the entry into office of Mr Rasi, EMA's external communication has been further emphasised also necessitated by the new pharmacovigilance legislation. The new ICT strategy, one of the agency's 5 priorities for 2013, focuses on improving EMA's digital presence and streamlining its 14 existing public-facing websites and 2 non-public ones down to 3 (new corporate website in EN only, new intra/extranet in EN only and new European medicines web portal in all official EU languages). The new strategy is meant to promote an understanding of how the agency works and hence boost public confidence in its output, to open access to data and knowledge (such as clinical trials data), to explain the benefits and risks of medicines. The 2011 March survey revealed that only 6% of the 0.5 million web visits per month are of personal nature the rest being for professional reasons. In terms of social media, EMA has a more conservative approach of maintaining no Facebook page but having Twitter account #EMA_News to share (without engaging in dialogue) news and press releases of important events.

Budget, Staff and new EMA Premises, Mr Andreas Pott

Mr Pott presented a detailed account of the current situation with EMA budget and the challenges it is/will face in the coming years. Since 2008, EMA's income growth has stabilised with EU contributions declining since 2005 currently accounting for 10-14% of overall budget. In 2012 almost half of the budget was spent on staff and infrastructure (the latter being quite squeezed since 2011), the rest on operational activities which are gradually increasing due to the PhVigilance responsibilities. Mr Pott emphasised the importance of EMA being allowed to maintain a reserve of EUR5-10million to balance its cashflows as it is a lot dependent on companies' fees payments month on month, which could vary greatly while its monthly expenditure for staff and infrastructure is constant. In the follow up discussion Members were supportive of EMA and the difficulties it faces - there needs to be a legislative change to allow

for such a reserve of perhaps EMA keeping the positive surplus for 2 years in such a reserve (which legally is not a problem for agencies that are 100% fees financed). Mr Pott also raised the issue that due to the cashflow problem, industry fees also cross-subsidise EU expenditure where insufficient such as with orphan drugs. Some Members raised the issue of EMA independence if reliant on industry paying fees, which however did not present a problem for the agency since the indusrty is paying for the service and not for the result. In terms of staffing, EMA is currently recruiting to fill in the 611 posts it has for 2013 putting an effort to recruit from MSs which are under par in terms of geographical representation. EMA is 2/3 women with almost half of its total staff being in the 30-40 age bracket. The leasing on its current premises expires end of 2013 when EMA will move to its new office occupying 1/3 of the new building with open-plan style offices and possibility to expand within the building if needed in the coming years.

Discussion with Mr Kent Woods - Chairman of EMA MB

Mr Woods has been EMA MB Chair since June 2011 also heading the UK NMA. Thus Members were interested in the spirit of cooperation in the MB by the different representatives there as well as the comparison of EMA with NMAs. Members thus discussed the subject of Conflict of Interest (CoI) of experts nominated by the NMAs to the EMA Committees and the discussions on that at MB level. Mr Woods stated that there is a fine balance between having experts who also have no CoI and no relation to industry where they might have attained their expertise. In the UK, one way of mitigating this conflict is by having expert advisory groups which however have no decision powers. The topic of how medical devices (MDs) should be regulated and if the high risk ones should go via pre-MA by NMAs or EMA was also discussed. Mr Woods was sceptical if the US system (via the FDA) is appropriate since it delays the entry into the market of devices while not necessarily guaranteeing the product will not be withdrawn later due to MDs failing in different ways to medicines. What is needed, according to Mr Woods, is sufficient information on long-term use of the device through post-market surveillance, increased knowledge of notified bodies and unique device identifier.

EMA International activities - Ms Emer Cooke

Globalisation is increasingly posing challenges for the work of EMA (most active substances coming from outside of the EU, clinical trials moving out as well while supply chains become more complex in nature) necessitating that it expands its international cooperation and activities. Bilaterally EMA maintains contacts under confidentiality arrangements with US, CA, JP and AU, it does also work closely with CN, IN, BR and RU, while multilaterally with WHO, ICH, OECD, Council of Europe. EMA has undertaken specific effort in the field of clinical trials in 3rd countries, promoting global approach to GMPs (providing trainings for 3rd country authorities staff at EMA's premises) and better use of international resources through international work-sharing (such as non-duplication of inspections in collaboration with USA, AU, WHO and the COM).

Safety of Medicines, Implementing the Pharmacovigilance (PhVig) legislation and PRAC experience, Mr Noël Wathion and Mr Peter Arlett

EMA's role in the safety of medicines relates to a) data collection (via clinical trials and spontaneous reporting to the EudraVigilance database, some 4million reports to date) and b) analysis and assessment of the data, which feeds into the work of the new PRAC committee. With the PhVig legislation there is an increasing transparency of data mainly as it appears and accumulates in the relevant databases, but also the minutes of the PRAC meetings and detailed

scientific outcomes are now published. Mr Wathion pointed out to a change in the safety direction, currently mainly stemming not from new medicines but from old products, as the environment becomes more and more risk-averse and there are increasing problems with manufacturing and product quality. Article 57 of the PhVig legislation now allows the establishment for the 1st time of a database with all medicinal products authorised in the EU - currently having 370,000 entries in the database.

The PRAC Committee, established in July 2012, has had 6 meetings so far. Its workload is steadily increasing and in its first year some fine-tuning to its processes will naturally be needed. Two high-profile opinions are imminent, one being on the 3rd and 4th generation contraceptives review expected for July 2013 and the other on the Diane35 review expected for May 2013.

In the ensuing discussion Members requested an update on developments with new products marked with a black symbol. Currently, there is a consultation ongoing with patients, consumers, working parties/organisations upon which completion the COM will produce a list of products to be labelled with the symbol and it will focus only on the mandatory scope of the highest risk products. So far communication between EMA and COM on that matter goes smoothly. In this relation, Members expressed a concern about possibly thousands of products being labelled with the black symbol thus devaluing the whole exercise. Furthermore, warning was raised by Members in view of NMAs referring too many cases they could manage nationally to EMA and thus shifting responsibility to EMA. The question of referrals, their quality and the fees for PhVig were well debated.

As for the Eudravigilance database, it has been in operation for 10 years already accumulating almost 4mn reports. The quality of the database depends very much on the quality of the input and some upgrading is needed to which end EUR6.5mn are planned for investing in improving the quality of the data by also supporting industry and MSs in their responsibility of providing the right data.

The second part to this discussion focused on presenting the 2 case studies of oral contraceptives (3rd-4th generation) and off-label use (Diane 35 - acne treatment used as contraceptive as well). Both cases, referred to EMA by the FR authorities, are being currently discussed in PRAC. With regards the first case, EMA is reflecting upon the +/- of organising the 1st public hearing of its kind - in any case, so far most experts at PRAC do not share the views of the FR authorities. As for Diane 35, the PRAC opinion needs to be delivered in May 2013 as the FR NMA decision to withdraw the drug from the FR market kicks in April 2013. The like outcome in this case is that the drug would be kept on the market but with a much improved labelling. Off-label use was greatly discussed - issues with it very much depend on how old the product in question is. On related subject of compassion use, there are guidelines dating from 2006, which as Mr Arlett mentioned, these could be larger in scope indeed. Currently, only FR is starting a compassion use programme, there is no EU harmonisation on that and it is purely national legislation issue. Members expressed concern about these differences among MSs stating that perhaps there is a need for some legislation to channel the divergent situations across MSs.

Transparency and Clinical Trials (CTs) Data, Mr Guido Rasi

The European Medicines Agency is committed to proactive publication of clinical trial data once the marketing authorisation process has ended; the question is not whether data should be published, but how – underlined Mr Rasi.

He explained the background against which EMA's new transparency policy was put in place: following the Tamiflu case where EMA refused to reveal certain data, the Ombudsman stated that public health interest overrode commercial confidentiality. Drawing from this experience, the Agency's policy was changed in 2010 to enable the publication of CT data upon request after marketing authorisation, and to explore how to make date available pro-actively. A joint EMA-Heads of Medicine Agencies document was prepared on what was considered commercially confidential information. On 22 November 2012 EMA held a workshop to consult with the stakeholders. Following the workshop, advisory groups with broad representation from all parties were formed to work on the following topics: protecting patient confidentiality; clinical-trial-data formats; rules of engagement; good analysis practice; and legal aspects. Final advice from the advisory groups is expected by the end of April 2013, and the policy of proactive publication of data is expected to come into force on 1 January 2014. Mr Rasi clarified that legacy would not be concerned by the new policy; there the current legislation would be ruling. He also underlined that transparency was a two-way road as clarity would be needed on who requested information and for what purposes.

Members agreed with the two-way approach and emphasised the need for a robust framework on transparency. The question of what data sets should have been made available and in what format was also raised.

Clinical Trials data and EMA - Mr Fergus Sweeney

Mr Sweeney explained in details the procedure in which clinical trials are authorised, and the role the Agency plays in integrating data, information, and knowledge aspects to support decision making. He underlined that good quality decision leads to a better use of medicines and resources; and that quality data, best evidence and transparency support the decision-making process. He also underlined that the majority of clinical trials are conducted by commercial sponsors, and these are the trials which are of larger scale, i.e. involving more trial subjects. In terms of geographical spread, the trend is the globalisation of trials, with almost two thirds of the subjects coming from outside of Europe, and within that two-third, the Rest of the World is gaining space. Thus, ethical issues and good clinical practice aspects of trials become more and more important. The reflection paper on ethical and GCP aspects of third country trials was endorsed by the committees and the EMA Management Board in December 2011, and by the Heads of Medicines Agencies in February 2012. Finally, he referred briefly to the new legislative proposal on clinical trials, which is currently under codecision, and which aims at simplifying the authorisation of trials, and increasing transparency. In the following discussion it was emphasised that prior to a new clinical trial, it has to be looked into whether a trial has already been conducted in that field, and if so, what data have been generated; thus, availability of data from previous trials, a solid methodology to analyse existing data, and a common format making data searchable play a pivotal role in the pre-trial phase.

EMA Databases - Ms Sabine Brosch, Ms Noemie Manent, Mr David Cockburn

Ms Brosch gave an overview on the functioning of the EudraVigilance database holding 3.9mn adverse reaction reports related to medicinal product authorised in the EU. She underlined particularly the new tasks and features brought by the new pharmacovigilance legislation such as patient reporting and signal assessment by PRAC. PRAC, the newly established Pharmaceutical Risk Assessment Committee, already reviewed 36 signals in 2012. Another important work for the past year was the international standardisation work on identification of

medicinal products, resulted in five new standards to harmonise description of substances and medicinal products. She emphasised the significant progress both EMA and the regulatory agencies had made last year with the data collection and management activities, transparency and communication, and the implementation of the new signal management process. She also explained that the existing 18 databases were in the process of being streamlined and merged into only three databases.

The discussion which followed the presentation focussed on, in particular, the role and responsibility of the national competent authorities for reporting but also for processing and cleaning the reports, and the upcoming legislative proposal on EMA fees.

Ms Manent explained how the EudraCT and the EU Clinical Trials Register worked. The first database includes records of CT protocols as of May 2004, and is accessible only to the competent authorities, EMA and COM. COM issued guidelines in October 2012 on the posting and publication of information on the result of clinical trials; the database, allowing sponsors to provide information in a structured format directly to EudraCT will be launched in Q4 2013. In order to ensure transparency, the EU CT Register was launched in March 2011 to give access to the general public on CT information. The Register has a broad scope in terms of both substance and geographic coverage: it includes trials with at least one trial site in the EEA; and it makes it possible to search for information on any paediatric trial, any adult trial except the ones on healthy volunteers, and any trials listed in the Paediatric Investigation Plan. The Register is a primary registry in the WHO network.

Mr Cockburn presented the EudraGM(D)P database. The database related to Good Manufacturing Practices was already in function for a while; the part on Good Distribution Practice, a novelty brought in by the Falsified Medicines legislation, was due to be launched at the end of Feb 2013. The database is accessible to the general public as well, with some restrictions applied for the protection of commercially confidential information or personal data; the publication policy re non-compliance statements were planned to be changed soon.

New Pharmaceutical legislation (CTs, MDs) and Implementation of current one (Falsified medicines) - Mr Fergus Sweeney, Ms Marie-Helene Pinheiro, Mr David Cockburn

Mr Sweeney highlighted briefly the main features of the clinical trials proposal. He emphasised, in particular, that it foresaw a single dossier and a single application portal for the EU, including both regulatory and ethics review. Assessment would be done in two parts: joint assessment for certain issues and national assessment for some others, with a single decision per trial and per Member State.

On medical devices Ms Pinheiro emphasised that the legislative proposal did not foresee that EMA became an EU Governance Body but proposed to have limited scope for certain combination products (single use MDs with medicinal products or ancillary medicinal products, companion diagnostics). She voiced EMA's public health concerns over borderline products status, and interaction and collaboration between the two sectors.

Mr Cockburn first summarized the state of play with the implementation of the Falsified Medicines Directive. The legislation foresaw a unique identifier, whose detailed regulation us subject to future delegated acts; he added that EMA's involvement in the unique identifier repository system was not yet clear. He also referred to the strengthened provisions for distribution through the Good Distribution Practice element of the GMDP database, and

through the regulation of internet sales where COM, EMA and Ms would cooperate in a public awareness campaign. He also raised the issue of active substance importation from third countries which had not applied to be listed, and where there were uncertainties whether some third country authorities were willing or able to issue written conformations. There was a growing concern that disruption of the supply of active substances would lead to product shortages. To mitigate such shortages, authorities in the major exporting countries should be involved in active dialogue with COM, EMA and MSs; EMA should map the sources of active substances of centralised products, and run a risk analysis; and EMA and MSs should work on a coordinated inspection plan to use waiver provided by EU GMP certificate.

EMA reorganisation and increased efficiency, Mr Guido Rasi

Mr Rasi spoke the changing environment within which EMA needs to operate with growing pressures from external sources as well as internal ones spurred by the need to respond to these new challenges of increasing responsibilities with stagnant resources. How to put the available resources to their best use of coordinating and aligning EMA's services for greater efficiencies is the main objective of the on-going internal reorganisation. The new Communication strategy is part of this overall exercise as well the streamlining of the 18 existing databases which need to be better integrated. Some areas for improvement have already been identified, such as better presentation of EMA's scientific opinions. While the expertise is there, proper presentation of the results needs to be improved. With regards to the scientific coordination amongst the EMA 7 committees, that is ensured by the Scientific Coordination Board (SciCoBo) which consists of the Chairs of the committees plus the Scientific Advice Working Party (CHMP) and relevant Agency staff meeting 2-3 times per year. The aim of the board is to ensure smooth communication between the committees and the Agency senior management as well as best use of the common resources (the 3,500 experts) and to coordinate common issues for all committees such as the CoI.

Innovation - Advanced Therapy Medicines (ATMs), Personalised Medicines (PMs), Mr Patrick Celis and Ms Marisa Papaluca Amati

Currently, only two ATMs have been authorised, 4 being under review however a substantial number are expected in the coming years - most are still in very early stages of development. In the field of ATMs around 60% come from academia and the rest from pharma industry. These are very complex products that come as a result of scientific innovation and regulation of "one fits all" does not reflect the specifics of this field, which faces a different level of testing, development, clinical trials and follow-up & traceability. Thus existing procedures and legislation should be adaptable to the needs of this sector in order for it to be stimulated and better supported. The COM has currently launched a public consultation on the functioning of the ATM Regulation (deadline 31.3.2013) with EMA providing specific input to the expected COM report on the subject.

Genomics, or the science of better predicting what choices in medicines and at what doses will achieve better results with certain patients, has turned out the approach in disease treatment for certain cases, focusing on the characteristics of the patients in determining his/her treatment. So far 20 PMs have been approved by the COM. The issue with the further development of these is that the predictive tools needed have not entered the market yet. There is a strong need for coordination on EU level, as what is available is not yet coherent, and EMA can provide that coordination by pulling the academic and regulatory expertise via its Pharmacogenomics Working Party. In the follow up discussion Members raised the issue of funding the R&D in

that field. While for ATMs it is still SMEs that mainly operate in the field for PMs increasingly the big pharma industry is stepping in. There was an agreement over the significance of using ATMs and PMs, especially for cancers, which could save as much as dozens of times the money invested in producing these drugs.

Scientific expertise and Conflict of Interest (CoI), Mr Noel Wathion

CoI with regards to experts, staff and MB members is an issue for many European Agencies. EMA has been strengthening its CoI policy, also adopting a Breach of Trust procedure, for the past few years. The policy focuses on direct CoI with a risk-based approach (stricter controls for higher profile positions). The quality (ex post) control that EMA has undertaken (in context of 2010 Discharge) looking at ad hoc sample of declarations of interest of experts has absorbed 700 hours of work at a cost of almost EUR80,000. While that subject was touched upon earlier with Mr Kent Woods, the discussion once again focused on finding the right balance between having experts with sound experience which has though been gained with minimum industry interaction. This is especially pertinent when it comes to representatives of civil society sitting on the scientific committees or MB. Often such organisations enjoy very little public support and thus industry to a great extent finances their activities. Mr Rasi shared that perhaps a good solution to this problem is to establish a fund (still funded by industry) which will pool resources and from which then civil society organisations will be financed, yet like that, industry will not be linked directly to any particular organisation.

Veterinary pharmaceutical legislation - Mr David Mackay

The main goal is to increase the availability of veterinary medicines through reducing administrative burden, creating a single market for veterinary medicines, and introducing tools to reduce the risk of antimicrobial resistance. To achieve this, Mr Mackay explained, veterinary legislation should be allowed to diverge from legislation applicable to human medicines where necessary; administration should be reduced by simplifying the system and reducing duplication; barriers for companies to introduce new drugs or existing ones to new MSs should be removed; and medicines already on the market should be progressively harmonised. All these should be done while maintaining the safety of animals, owners, consumers and the environment.

Members posed questions about the Action Programme, and voiced their concerns about the use of antimicrobials for breeding purposes.

Antimicrobial Resistance (AMR) - Mr Marco Cavaleri and Mr Jordi Torren-Edo

The EU's AMR strategy, set by the Commission, makes the Union the most restricted area in the world with regard to the use of antimicrobials. EMA cooperates closely with the Commission and other European agencies (ECDC, EFSA) on the implementation of the strategy and the related Commission Action Plan. The Agency, together with ECDC and EFSA, is currently analysing the relationship between antimicrobial sales and resistance; the first report on the subject is due in 2014.

With regard to human medicines, EMA revised its guidance documents to streamline the development of new ABs, and issues a new guidance for new antibiotics that target infections

caused by resistant bacteria for which there is an unmet medical need. Concerning veterinary use, the focus is on responsible use, which is emphasised both in the requirements for authorisation, as well as in EMA guidelines. Members were particularly concerned about the implications for the food chain, and the use of AMs for breeding purposes.

Incentives for targeting AMR are still needed. According to a study conducted by EMA and the LSE, incentives could include price, patent protection, administrative protection, research incentives (including innovative forms of PPP into drugs and diagnostic), and the control of use and off-label use. Members raised concerns in particular about patent and administrative protection which might work against generics, and were worried that a reduction in administrative fees would still make it necessary to cover the reduction from elsewhere.

ENVI COMMITTEE DELEGATION
European Medicines Agency
London, UK 11-13 February 2013

COMPOSITION OF THE EP DELEGATION

Members of the European Parliament - in quota:

Mr Matthias Groote (Chair)	(S&D) (DE)
Ms Dagmar Roth-Behrendt (EMA Contact person)	(S&D) (DE)
Ms Françoise Grossetête	(EPP) (FR)
Ms Margrete Auken	(Greens) (DK)

Members of the European Parliament - locally UK elected:

Ms Linda McAvan	(S&D) (UK)
Ms Marina Yannakoudakis	(ECR) (UK)

Political advisors:

Ms Majella McCone (S&D advisor)

European Parliament Information Office in the UK

Mr Björn Kjellström - Head of UK Office

ENVI Secretariat

Ms Nora Kovacheva - Administrator

Ms Zsuzsanna Laky - Administrator

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

List of EMA Participants

Guido Rasi	Executive Director
Andreas Pott	Deputy Executive Director and Head of Administration
Kent Woods	Chair of the EMA Management Board
Patrick Le Courtois	Head of Human Medicines Development and Evaluation
Noël Wathion	Head of Patient Health Protection
David Mackay	Head of Veterinary Medicines and Product Data Management
Emer Cooke	Head of International and European Cooperation
Peter Arlett	Head of Pharmacovigilance and Risk Management
Martin Harvey Allchurch	Head of Communications
Fergus Sweeney	Head of Compliance and Inspection
Tomasz Jablonski	Acting Head of Legal Service
Nerimantas Steikünas	Head of Office of the Executive Director
Marisa Papaluca Amati	Head of Scientific Support and Projects
Spiros Vamvakas	Head of Scientific Advice
Marco Cavaleri	Head of Anti-Infectives and Vaccines
Melanie Carr	Head of SME Office
David Cockburn	Head of Manufacturing and Quality Compliance
Anthony Hamphreys	Head of Sector for Regulatory, Procedural and Committee Support
Riccardo Ettore	Head of Sector for IT Operations
Hilde Boone	EU Institutional Liaison Officer
Silvia Fabiani	HMA Liaison Officer
Sabine Brosch	Bussiness Lead EudraVigilance and International Standardisation in Pharmacovigilance
Marie-Hélène Pinheiro	Regulatory Adviser, Regulatory Affairs Section
Noémie Manent	Scientific Administrator, Clinical and Non-Clinical Compliance Section
Jordi Torren Edo	Scientific Administrator, Animal and Public Health Section
Patrick Celis	Scientific Administrator, Scientific Committee Support Section (CAT)

PROGRAMME
ENVI Delegation to EMA, London, 11-13 Feb 2013

MONDAY, 11 FEB 2013

Schedule	*Topics*
14.00-14.45	Arrival at EMA
15.00-17.00	Outline of the ENVI visit programme Setting the scene: the Agency and its environment Reflections on the EMA's Management Board Interactive presentation on: - EMA and the EU authorisation process - Scientific Advice & Protocol Assistance - EMA and the EU network / Heads of Medicines Agency - Support to SMEs - International activities - Communication - Budget, staffing, new staff regulation - Move to the new office building in 2014
17.00-18.00	Safety of medicines Implementation PhVig legislation & PRAC experiences Case studies / examples: - Oral contraceptives case - Off-label use
18.00-19.00	Transparency and clinical trial data

TUESDAY, 12 FEB 2013

Schedule	*Topics*
08.45-09.30	Information for the public based on EMA Databases, including a practical demonstration *(EudraVigilance, EudraCT + Register, EudraGMP)*
09.30-11.00	New pharmaceutical legislation: - under review at Council and Parliament o Clinical Trials o Medical Devices - implementation stage: o Falsified medicines / new API import rules

	Coffee break
11.15-12.30	EMA re-organisation & increased efficiency Increased consistency & coordination between Committees Case studies / examples: Glybera, Orphacol
12.30-13.30	Innovation: - Advanced Therapies products: experience to date - Personalised Medicine - Nanotechnology
	Lunch
14.30-15.30	Scientific Expertise/ Conflicts of Interests
15.30-17.30	Parallel satellite meetings on specific topics for individual MEPs (e.g. on Paediatrics)

WEDNESDAY, 13 FEB 2013

Schedule	*Topics*
9.00-10.00	Availability of veterinary medicines Revision of the veterinary pharmaceutical legislation
10.00-11.30	Managing the risks of Antimicrobial resistance for humans and animals
11.30	Departure from EMA