25 June 2012
EMA/428590/2012
Patient Health Protection

General comments received from public consultation on good pharmacovigilance practices (GVP)

The first seven good-pharmacovigilance-practice (GVP) modules on prioritised topics were released for public consultation between 21 February and 18 April 2012. The modules have been revised, taking the comments received into account.

Those who participated in the public consultation were asked to submit comments using the specific templates for each module and the definition annex.

The comments received are published for each module, identifying the sender's organisation (but not name). Where a sender has submitted comments as an individual, the sender's name is published.

The European Medicines Agency thanks all those who participated in the public consultation for their contributions.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date of submission>

Submission of general comments on 'Good pharmacovigilance practices (GVP)'

Comments from:

Name of organisation or individual
British Association for Quality Assurance (BARQA)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	The Modules keep referring to the “Commission Implementing Regulation”, but to our knowledge this document has not been published even in its draft form and it difficult to understand how this links with other regulatory texts. It would be useful to know what the plans are regarding this document in terms of public consultation and implementation date.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18. April 2012

Submission of general comments on 'Good pharmacovigilance practices (GVP)'

Comments from:

Name of organisation or individual
Bundesverband der Pharmazeutischen Industrie e. V. (BPI) - German Pharmaceutical Industry Association

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	All citations related to the document “Commission Implementing Regulation on the performance of Pharmacovigilance activities provided for the Regulation (EC) No 726/2004 and Directive 2001/83/EC” needs to be checked as most of them do not refer to the right section anymore (example I: Module II, Line 322, refers to “IM Art 4(1)” but in fact the right section is “IM Art 3 (3)”; example II: In module GVP VII PSURs Annex III.1(6) in line 232 is referenced but in fact this reference leads to "Clinical Study Protocol", the correct reference is Annex II; that is also true for several citations within the other GVP-Modules). Furthermore, all abbreviations should be explained directly in the text (e.g. there is no explanation for “IM” – does “IM” stands for “implementing measure” and if so, why does a “IM” citations refers to a document which is named “Implementing Regulation”?).

17.04.2012

Submission of general comments on 'Good pharmacovigilance practices (GVP)'

Comments from:

Name of organisation or individual
CIS bio international/IBA

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	I fear that the time limit between the GPV finalisation by EMA and the implementation by MAH will be definitely short.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18-April-2012

Submission of general comments on 'Good pharmacovigilance practices (GVP)'

Comments from:

Name of organisation or individual
The European Pharmacovigilance Working Group (EPVWG)
The EPVWG has been in existence for more than 12 years and consists of 19 PV experts from both regulatory agency and broad industry backgrounds. During the past couple of years, the members of this Group have closely followed and participated in the development of the new PV legislation, directly as company representatives and/or indirectly through professional associations and networks. The EUPVWG welcomes the new legislation with its goals of simplification and harmonization of the EU PV legislation in order to better protect public health. The following comments on the draft GPV modules have been prepared by the Group and are focused on key areas for clarification or improvement**.**

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	Comment 1: The staggered release of the draft GPV modules means that it is not possible to assess the GVP guidance as a whole and in particular, to evaluate the Modules for consistency and coherence. Further, the revision of the draft Implementing Measures/Regulation and release (subsequent to the release on consultation of the first wave of GVP Modules and close to the end of the consultation period, also means that it has not been possible thoroughly to consider the GVP Modules in the context of the proposed Implementing Regulation, which is also still in draft.
	Comment 2: Consideration of the available GVP Modules indicates that there are inconsistencies within Modules and between Modules. The Annex to the draft GVP Modules is designed to contain a set of definitions of central terms. However, definitions are also provided in the individual Modules with potential for inconsistencies and errors across the Modules. For example: • Comparison of GPV Modules V and VIII shows discrepant definitions of “registries” with the definition in the Risk management systems Module V (line 1067-8): “registries are prospective non-interventional cohort studies...”) being incorrect and not aligned with the definition in the Post-authorisation safety studies Module VIII (line 779): “A registry should be considered a structure within which studies can be performed”). A registry is a systematic data collection without the specification of any specific epidemiological study design. The incorrect definition in Module V is also followed by the requirement “to follow appropriate standards and scientific guidelines” which differ for cohort studies and registries. “Registry” is not defined in Annex 1. • The Risk management systems Module V refers (line 405 and also 622) to “off-label use” which cannot be found among the definitions in Annex 1 and is not consistent with the terminology in the legislation (Article 101) (“use outside the terms of the marketing authorization”).
	Recommendations regarding Comments 1 and 2: Staggered implementation/application of new standards and requirements should be allowed for industry as well as Competent

Stakeholder number *(To be completed by the Agency)*	General comment
	Authorities over the course of the next six months (see also Comment 3). If it is not possible, due to time constraints, for all documents to be available for consultation simultaneously before final release, robust mechanisms for review and correction should be introduced during a defined transition period so that clarity, consistency and compatibility across the GVP modules in respect of requirements, concepts and terminology can be achieved. Key terms should be defined in the Annex 1 to the Modules and cross-checking of terms used and definitions quoted within individual Modules should be undertaken with the aim of ensuring accuracy and consistency. The references to the Implementing Regulation contained in the draft Modules must be updated so as to reflect accurately the binding elements of the guidance contained in those Modules.
	Comment 3: The use of “shall” (binding) or “should” (guidance) throughout the Modules was welcomed. However, there is a need for clarification as to the application of the guidance by Competent Authorities in particular with regard to standards to be applied upon inspection immediately after July 2012 where the GVP Module relevant to certain PV activities is not yet available, or finalised, or has been finalised only just prior to the introduction of the new legal requirements.
	Recommendation regarding Comment 3: Guidance on the application of new standards (date of application and the regulators’ expectations of the performance of activities by Marketing Authorisation Holders) should be issued prior to July 2012 and should represent the interim position of all Member State inspectorates.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 April 2012

Submission of general comments on 'Good pharmacovigilance practices (GVP)'

Comments from:

Name of organisation or individual
EuropaBio

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	EuropaBio, the European Association of Biotechnology Industries, thanks the European Medicines Agency (EMA) for the opportunity to submit comments on the first wave of draft GVP modules. EuropaBio's mission is to promote an innovative and dynamic biotechnology based industry in Europe. EuropaBio, has 62 corporate and 7 associate members operating worldwide, 2 Bioregions and 19 national biotechnology associations representing some 1800 small and medium-sized enterprises. EuropaBio broadly supports the comments provided by EFPIA, the European Federation of Pharmaceutical Industries and Associations, and would like to provide some additional general comments of specific importance to its members. Our comments focus on important aspects related to the expected business impact for small and medium-sized enterprises, as well as to advanced therapy medicinal products. EuropaBio welcomes the alignment with existing ATMP-specific guidance (e.g. guideline on safety and efficacy follow-up – Risk management of ATMPs – EMEA/149995/2008), which brings a certain level of stability in the legal framework for companies operating in the field. We would like to highlight that specifically for SMEs adequate transitional periods and proportionate implementation of the significant system changes are necessary while avoiding unnecessary administrative burden.
Module II PSMF – Transition from the DDPS	We strongly welcome the introduction of the PSMF independent from a specific marketing authorisation and we recommend a simple and pragmatic transition process for products with existing DDPS. As a PSMF is required for any new MAA and for all renewals due after the implementation date, we believe that many MAHs would have an interest in moving to PSMF for all authorised products at once to avoid maintaining both a PSMF and a DDPS in parallel as well as reducing the number of variations to be submitted.

Stakeholder number *(To be completed by the Agency)*	General comment
	The change-over is currently proposed to occur for each product including a DDPS via a Type IB Variation. In order to reduce administrative burden for Industry and Regulators, we recommend using a Type IB worksharing procedure per group of MAHs sharing the same PSMF and including a list of all affected products authorised in the EEA regardless of their specific registration route covering one Type IB fee. We strongly encourage the national competent authorities to immediately implement the outcome of the worksharing procedure into all national authorisations without any further national process. This will ensure a consistent and pragmatic phasing in of the new PSMF across EEA without unnecessary administrative burden. The management of changes to the PSMF should completely be delinked from the Variation regulation and any specific MAAs. The summary of the PSMF covering location and contact details of the EU QPPV person should solely be managed through notification of required updates to the EVMPD and not trigger any variation process.
Module II PSMF – Co-licensing/Co-marketing scope	The scope of description and documentation of co-licensing and co-marketing arrangements in the PSMF is unclear. However, the expectations for inspections need to be explicit. Within the current Volume 9A it has until now been applicable to arrangements within the EEA. Please clarify that the scope is being limited to commercial arrangements applicable to markets within the European Economic Area.
Module V RMP – ATMP section	Duration of exposure to the medicinal product may be a challenging subject to describe for ATMPs, as the kinetics of cells and genes are different as compared to classical molecules. E.g. Manipulated cells can be used in a single administration to initiate a biological repair process. It is however unknown what proportion of these cells will actually become an intrinsic component of the repair tissue and for how long these cells will be retained. Please specify how exposure duration should be calculated and how relevant is this parameter is in such case.
Module V RMP vs Module VII PSUR - document structure and interchangeable modules	The scope and purpose of PSUR and RMP are not always clear, because of the focus and the overlap in some modules of both documents. Although the PSUR is considered to be mainly used for post-authorisation information reporting, it is also expected to capture pre-market experience. This applies vice versa to the RMP where post-authorisation data are reported. We propose to clarify and simplify both document purposes and structures. The RMP should focus on the pre-authorisation strategy including the binding commitments for post-authorisation development, while the PSUR should focus on the post-authorisation phase reporting the results or the development activity and monitoring of the adverse events. Emerging post-

Stakeholder number *(To be completed by the Agency)*	General comment
	authorisation data should not require updating of both documents, but rather require only one document update. A specific section for risks associated with a Medical Device is necessary for the use of Drug Delivery Systems and better linkage with the Risk Management Systems of such devices that follow different methodologies. For the sake of clarity, we propose that all post-authorisation studies, whether they are PASS or PAES, are included into one Annex to the RMP. Both study types usually include safety parameters and may not easily be distinguishable. The significant expansion of the RMP content and the administrative burden of producing an updated RMP document should be taken into account by the Regulators. We discourage establishing a practice of "routine" updates to an RMP in the absence of any new information that materially affects the product's benefit-risk balance and, consequently, the absence of any need for modifications to the pharmacovigilance and risk minimisation activities.
Module V RMP – comprehensive review process including local inputs	A comprehensive process to include additional national risk minimisation activities or drug utilisation studies within the RMP needs to be thought through in detail as multiple ongoing parallel discussions in the post-authorisation phase might unnecessarily slow down market access for innovative products and can prove to be especially challenging for SMEs. The PRAC is responsible for assessing the overall RMP and as such involves representatives from all Member States. We recommend that this process should ensure that any specific local requirements are included during the PRAC assessment process. In addition, drug utilisation studies to be recorded within the RMP should be strictly limited to the EEA region.
Module V RMP and Module VII PSUR – submission schedule for updates and document life-cycle management	The schedule for submissions of RMP updates is not well defined, and may differ from the schedule for submission of PSURs. The data intervals under review may therefore differ between the 2 documents, limiting the "interchangeability" of the overlapping content. A clear co-ordination and document life-cycle management process needs to be established for both documents to maximise their value and avoid any confusion or redundancy. To ensure consistency, the same rapporteur should be utilised for the assessment of PSURs and RMPs as well as any product related PASS. The assessment process for PSURs may last beyond 6 months. This will pose challenges for products requiring very short PSUR submission cycles and taking into account the data lock points and adequate time to analyse and prepare the following PSURs. We strongly welcome the new proposal that any changes recommended as a consequence of a PSUR review are implemented into

Stakeholder number *(To be completed by the Agency)*	General comment
	the product information without any subsequent variation submissions.
Module VI ICSR - webmonitoring	In support of a proportionate implementation of the new requirements, we propose that the monitoring of ICSRs from websites should be focused on company-sponsored sites. Active screening of non-sponsored websites for adverse reactions is a resource consuming and challenging task, especially for SMEs. In addition, the scientific validity of such sources is often not quantifiable. The added value of such reports over scientific publications is questioned in relation to the additional effort required to capture, analyse and assess the information from blogs, forums, etc.
Module VI ICSR – Validation of reports	Under the new requirements patient or consumer reports should be handled as spontaneous reports irrespective of any subsequent 'medical conformation'. The only requirement for a reporter to be considered identifiable is the availability of contact details in order to confirm or follow-up the case. We are concerned that a MAH or Regulatory Agency may not be able to distinguish genuine, authentic adverse reactions reported by a patient/consumer from fake reports that may have been submitted under a fake email address (identifiable reporter with contact details). Some clarification regarding the confirmation of the existence of a reporter needs to be established.
Transitional periods	As a general rule, new processes or templates should become mandatory for use 6 months after they have been finalised to allow companies adapting their internal processes and documents. Changes involving adaptations to IT systems should be phased in with at least 18 month transitional periods as significant re-programming, validation and company investment are required for their implementation.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 April 2012

Submission of general comments on 'Good pharmacovigilance practices (GVP)'

Comments from:

Name of organisation or individual
Janssen Pharmaceutical Companies of Johnson & Johnson

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	Each of the GVP Modules refers extensively to the articles contained within the Commission Implementing Regulation on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC. As the public do not yet have sight of the final version of this document it was very difficult to assess the true impact of these draft modules. Much of the guidance provided relies on details yet to be elaborated in the implementing measure. It is, therefore, essential that the final Implementing Regulation be released prior to implementation of the final versions of these Modules.
	As numerous countries with numerous languages will work with these documents, we recommend the use of “must” rather than “shall” to denote legally required actions. Experience has shown us that the words “shall” and “should” are often seen in the same context and perceived to have the same meeting when users are not native English speakers. We recognise that the Agency has already clarified the interpretation of “shall” and “should,” but still feel that replacing “shall” with “must” will provide further clarity around what is legally required versus what is merely recommended.

17 April 2012

Submission of general comments on 'Good pharmacovigilance practices (GVP)'

Comments from:

Name of organisation or individual
Kuros Biosurgery AG

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	This guidance documents seem mostly targeted towards products that already have gained access to the market. However, given that the Introduction references the Directive 2001/83/EC relating to medicinal products for human use and not to the 2001/20/EC that determines the safety reporting process in clinical trials, the company proposes that the Agency clarifies whether these guidelines apply to product under investigation as well as marketed products. It would also be helpful that, if the guideline pertains in some ways to medicinal product under investigation, these specific chapters should mention clinical trials. It would also be useful to indicate when the processes should start, e.g. with the first human experience? It would then be advisable to use some of the provisions of the pharmacovigilance guidance in the product development phase already. The company would like to be reassured that the guidelines for safety monitoring and reporting during the post marketing phase are in alignment with the guidelines and directives for safety monitoring and reporting in the development phase. Consequently, EMA should consider making references to clinical trials regulations in these guidance documents.
	The company very much welcomes the effort of the EMA in revising the pharmacovigilance legislation and publishing such extensive and comprehensive guidance on this subject. However, there is a concern that this is not paralleled by a similar effort from the authorities in other territories, especially the US-FDA. A lack of harmonisation would represent additional hurdles for manufacturers willing to enter international market.
	Are the principles and the processes behind these pharmacovigilance guidelines applicable for devices as well as drugs?

02/04/2012

General comments applicable to all draft modules

Submission of comments on 'GVP Module I – Pharmacovigilance systems and their quality systems' (EMA/541760/2011)

Comments from:

Name of organisation or individual
Nilesh Sheth (MRPharmS), Regulatory Consultant

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	The following general comments apply to all of the draft modules It is evident that a huge amount of work has been undertaken by all parties involved in the preparation of these draft modules to support the revised legislation. Without taking anything away from this substantial effort, it is very worrying and disappointing to see that there are what appear to be a large number of grammatical, spelling and punctuation errors in sections of all of the draft documents. Unnecessarily long sentences have been employed on many occasions to the point where it affects the readability of the documents. It might have been more appropriate to use bullet points in some of these instances to explain concepts/guidance more accurately and concisely. It is important that guidance documents should facilitate understanding of the subject matter rather than creating confusion and doubt as appears to be the case due to the poor use of grammar and punctuation. Whilst it is probably not be the case, the nature of the errors strongly suggests that the documents may not have been drafted or proof read entirely by persons with sufficient knowledge of the English language and in some instances, the subject matter.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		Comment: Proposed change (if any):

Please add more rows if needed.

Pharmacovigilance documents 2012-02-22

EMA

Sir

Today I got your new Pharmacovigilance docuents for inspection.

Since I have been Pharmacovigilance officer first at Pharmacia Diagnostics, Uppsala Sweden and then ALK-Abelló, Hørsholm, Demark, I looked for ay mentioning of biologics an especially allergenic extracts.

I have the following comments

1. The reports obtained using the regular reporting forms seldom gives any help, why I developed my own forms.
2. Authorities in most European countries had no insight or engagement in how biologicals work and which precautions should be taken and considered.
3. I believe it is a need for chapters on biologics in general and as exemplified by allergenic extracts preparations
4. To avoid reactions like those in UK using biological product at an early stage in a totally incorrect manner, immunologists/allergists, with experience form the clinical use of such products and basic knowledge on their action, must be involved in this part of the work.

Furthermore I did not find Module III and IV.

Sincerely yours

Sten Dreborg

Sten Dreborg, MD, PhD, FAAAAI, HDFACAAI
Professor Pediatric Allergology
Department of Women's and Children's Health
Department of Pediatric Allergology
University Hospital
Uppsala University
SE-751 85 Uppsala
Sweden

[redacted]