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Reflection paper on working parties (WP) CHMP/EMA group analysis and proposals

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1. Introduction

In accordance with Article 56 (2) of EC Regulation 726/2004 as amended, the CHMP may establish standing and temporary working parties. When establishing working parties, the CHMP shall in its rule of procedure provide for an appointment of members as well as for consultation of these working parties.

CHMP Working Parties (WPs) have played a key role in strengthening the EU regulatory system and their contribution is highly recognised. Since the progressive consolidation of the EU regulatory network, the guidelines produced by the different WPs have been essential instruments for the establishment of a scientifically based EU regulatory policy. In addition to their guidance and training purposes, regulatory guidelines have been critical in promoting the harmonisation, transparency and consistency of regulatory decisions.

Some WPs were put in place early (BWP, EWP, QWP, SWP and Ad-hoc BPWP). Based on growing and new scientific needs, a number of additional WPs were set up later on, with the aim to cover upcoming scientific fields: BMWP, CPWP, GTWP, PgWP and VWP.

By legal mandate, the CHMP established the SAWP, which is intended to provide product-related scientific advice and protocol assistance, and non-product related advice, including on novel technologies (e.g. biomarkers). The PhVWP has a different mandate and reporting system, as well the two other WPs/working groups recently constituted (PCWP, HCPWG). These groups, as well as the NRG, are not in the scope of the present review.

CHMP expectation from the WPs is to get high quality scientific and regulatory input in a number of areas, where the 3 most relevant are: drafting of regulatory guidelines, contribution to Scientific Advice and contribution to specific aspects of dossier evaluation following CHMP request.

After several years of successful and meritorious work, complexity and workload of the system have increased considerably. This fact, together with the creation of new committees has created a need to review, in-depth, the structure, composition and mandate of CHMP WPs with the aim of improving their efficiency and avoiding overlapping and unnecessary competition among them, while stating clearly the role that each stakeholder is expected to play.

The CHMP adopted in 2008 a briefing note (Annex 1) in the context of the CHMP work plan for 2008-2010 as described in item 2.

2. WPs Review project

The CHMP agreed that the mandate, composition, functioning and reporting system of the WPs should be reviewed and therefore a briefing note (Annex 1) was adopted in the context of the CHMP work plan for 2008-2010 and the following non-exhaustive list of key issues was identified:

- Define CHMP's expectation for the various WPs, and the roles of the "players" in the system
- Review of range of working parties, optimising resources and avoiding unnecessary duplication and overlap
- Review of model mandate adapted to specific WP requirements, including a clear delineation of the rules of procedure of each WP
- Review of the composition of working parties
- Review the procedure for appointment and renewal of Chairs and Vice-Chairs of the working parties

- Review of feedback and feed forward mechanisms between the CHMP and its working parties and other Committees
- Review of the role of the EMA secretariat
- Clearly define the roles and responsibilities in the relationship between CHMP WPs and other Committees (CMD, PDCO, HMPC, CAT etc.)
- Review guidance on Drafting Group arrangements and roles of guideline rapporteurs
- Implement monitoring and control systems and review a need for a peer review system e.g. prior to the publication of guidelines
- Optimise efficiencies

It was considered that the appropriateness of the range of CHMP WPs should be assessed in the light of new legislation; such as Paediatric and Advanced Therapies Regulations. Collaboration between the different CHMP WPS as well as the role of briefing meetings has been identified as important issues.

A working group was constituted with E. Abadie, G. Calvo, J-L. Robert and C. Schneider as CHMP Sponsors, and X. Luria as EMA Sponsor. The group has focused on the following WPs: BWP, BMWP, BPWP, CPWP, EWP, GTWP, PgWP, QWP, SWP and VWP.

3. Analysis of the current structure

The above-mentioned issues have been analysed by the group and a number of proposals for improvement (item 4) have been developed.

It is important to note that the CHMP WPs were initially set-up to gather specific expertise that is not represented in CHMP, to reduce CHMP workload, to allow CHMP to consult them on any scientific issue related to their specific field of expertise, to get delegation of certain tasks associated with the scientific evaluation of applications and to draft guidelines as per CHMP request. Therefore, the CHMP expectations from the WPs are high quality scientific and regulatory input in a number of areas, of which the following 3 are the most relevant:

- Drafting regulatory guidelines
- Contribution to Scientific Advice
- Contribution to specific aspects of dossier evaluation following CHMP request

A relevant element that have created further requirements for the WPs is the existence of other Committees as they have also particular expectations from the WPs and needs to be covered by them.

These three main tasks drive the core elements of the mandates of all WPs, however the relative weight on their activities varies considerably. There may be a number of reasons explaining these differences, though the specificity of the scope of each particular WP appears to be the one of the main determinants. For instance, interactions with stakeholders and contribution to other Committees have become key issues in the mandate of some WPs.

3.1 Drafting Guidelines

The production of Guidelines is a recognised task of WPs. Roles of each WP were initially easily identifiable when there were a limited number of groups with clearly defined competences – QWP, BWP, SWP, EWP and ad-hoc BPWP. Subsequent establishment of various new WPs has created areas where more than one WP has expertise potentially causing overlapping competences and activities. The biological WPs (BWP, BMWP, BPWP, CPWP, GTWP, and VWP) are most likely affected

on this issue. In the view of pre-clinical and clinical aspects the SWP and EWP initially dealt with all clinical guidelines, however they have now been followed by a number of specific WPs (VWP, GTWP, CPWP, and BMWP). The creation and review process of scientific guidelines needs to be reviewed in the light of limited resources and increasing scientific and regulatory challenges. It should be also considered that new Scientific Committees have been put into place and their needs should be integrated. Finally, the process of planning, monitoring and timely delivery of the guidelines should be improved.

3.2 Scientific Advice

Involvement of assessors with broad regulatory and scientific experience in the provision of Scientific Advice is critical to ensure the quality and consistency of advices given. However, the involvement of the different WPs in the SA process is heterogeneous and, to some extent, insufficiently defined. There may be a number of reasons explaining this fact, by the lack of clearly established procedures regulating their contribution, the heterogeneity in the number of meetings and way of functioning of the different WPs, and the overlapping in areas of expertise between them may at least partly explain why in some cases the contribution is suboptimal.

3.3 Product-related assessment

Some WPs discuss product-related issues on a routine basis, without this having been explicitly requested by CHMP. There appears to be differences between WPs as regards this aspect. Additionally, it is understood that the CHMP (Co)Rapporteurs (for MAA) and SAWP coordinators (for SA) should remain in the driving seat of the respective assessment processes.

The differentiation between the role of WPs and SAGs has been addressed in the draft report of the CHMP working group on SAGs. WPs may, as per CHMP request, discuss and provide input on specific parts of the dossier at an early stage of the procedure, however it does not mean that the WP is required or even entitled to discuss the whole benefit-risk balance.

The current regulatory system has dramatically changed since most of the WPs were set up and the creation of new Committees with complementary objectives and with similar needs to get further scientific support should be integrated in the discussion. It is agreed that WPs should serve as a common resource to the EMA and the interaction with other Committees needs to be defined.

Composition of WPs is to a certain extent an important determining factor, since those with representation from all Member States may have the advantage of its wider representativeness, but not all members participate actively, and in some cases the expertise required couldn’t be provided.

4. Proposals for improvement

In general terms, the recommendations have been developed in accordance with a number of key elements as follows:

- Ensure scientific competence and active contribution from all working party members
- Ensure transparency in the functioning and reporting lines in all WP activities
- Reduce and avoid overlapping responsibilities and unnecessary duplication of work
- Include the tasks of each WP in their respective work programmes as identified by the CHMP. The work programmes are to be adopted and amended, if needed, by the CHMP
- Ensure awareness amongst all WPs and their members that the CHMP is the decision-maker, and that CHMP may disagree and hence not follow the WP recommendation

- The approach to the functioning and outcome of the WPs should be updated due to the existence, expertise and needs of new Scientific Committees
- Oral hearings of applicants during WP meetings should only be held exceptionally and only after CHMP has given a mandate to conduct it
- Review the above mentioned issues related to considerations made above with regard to Drafting Guidelines, Scientific Advice and Product-related assessment

4.1 Working Parties and Drafting Groups

All CHMP Working Parties and Drafting Group are intended to provide service to all Agency's human Committees. Furthermore, it is strongly recommended that other Committees do not create Working Parties or Drafting Groups that could overlap with those existing in the CHMP.

Two main types of WPs have been identified (Annex 2): those with transversal competences – BWP, QWP and SWP - and those with more specific competence linked to a particular kind of product or therapeutic class. The EWP does have transversal activities, most of them focused on therapeutic areas but some other with transversal impact (general ICH guidelines on clinical development, patient reported outcomes, extrapolation of non-EU data to EU population). Transversal WPs have as a common feature a broad range of topics and/or a regular delegation by the CHMP to be involved in product assessment.

Legislation mentions standing and temporary WPs only and therefore it is proposed that those three with well established transversal competence are considered standing (BWP, QWP, SWP) and all other WPs temporary (Therapeutic WP from the previous EWP, Biostatistics WP, BMWP, BPWP, PgWP, PKWP and VWP). This difference will be reflected in the mandate and in the composition.

Temporary WPs are more topic specific (products, therapeutic area or scientific field) and are not supposed to be regularly involved in product assessment and are convened by the CHMP to deliver in a concrete task over a defined timeline (i.e. guideline or to address other specific issues).

In reality both types of WPs can be created and discontinued at any time by CHMP.

Drafting Groups: When a process for reviewing or developing of a particular guideline is adopted and the topic doesn't fit within any of the existing WPs, there is an option to create a drafting group rather that a new WP (see 4.7).

4.2 Mandate

WPs are all convened by the CHMP, however the standing ones will have a regular ongoing activity, while the temporary WPs are convened in order to carry out specific tasks related to their respective fields.

Their mandate is as follows:

- Drafting Guidelines: according to the new planning system
- Scientific Advice: on SAWP request
- Product-related assessment: following specific CHMP request. Only BWP carries out product evaluation on a regular basis
- Interaction with stakeholders under clear rules and supervision of CHMP
- Contribution to other Committees' needs

4.3 Composition

WPs and Drafting Groups should both be composed of assessors from National Agencies with specific expertise in the area of interest. Approximately half of the members should be senior assessors with accredited experience in the assessment of products and drafting of guidelines. The contribution of less experienced assessors in the group will ensure the continuity of the task in the future. One of the senior assessors should act as a Chair coordinating the workload together with the EMA Secretariat, ensuring communication with other WPs and representing the WP in the Coordination Group. It is highly desirable that at least one CHMP member or alternate should be part of each WP and EG.

Standing WPs will get a composition based on one member per National Agency and Temporary WPs members will be based only on competence and expertise.

In case that one particular Temporary WP considers that it should be composed by members from each National Agency a justified request should be adopted by CHMP

4.4 Standing WPs

Three WPs (QWP, BWP and SWP) will be responsible of keeping a regular ongoing activity in their respective fields as per their mandate.

BWP should continue in its task of reviewing product-related issues (quality aspects and safety aspects related to quality) of biologic products (biological medicinal products including macromolecules extracted from animal or human tissues or fluids, vaccines, plasma-derived medicinal products - so called blood products, biotech products - so called recombinant proteins).

For the other transversal WP (SWP and QWP), the mandate will also include the possibility of regular involvement in major product issues on CHMP request.

No other major changes in their mandates are proposed. Their composition will remain as currently. Details of the mandates, composition and reporting lines of standing WPs are described in Annex 3.

4.5 Temporary WPs

It is proposed that BMWP, BPWP, PgWP and VWP will be Temporary WPs with more uniform and consistent mandate, composition and rules of procedure.

The current EWP Pharmacokinetics and Biostatistics drafting groups will be converted into a Temporary WPs.

The EWP will be converted into a number of Temporary WPs and Drafting Groups (see 4.7). Temporary WPs will be initially Cardiovascular, Central Nervous System, Oncology and Infectious Diseases.

The general criteria for the constitution of a Therapeutic Temporary WP will be a reasonable number of relevant guidelines to be produced and regular involvement on SA requests. Additionally, it should also be considered the intention to build a consistent cluster on the particular field with repercussion on the Agency, European Regulatory Network and internationally. When a reduced number of guidelines are expected in one particular field a Drafting Group should be preferable.

Regarding their mandate, the general principles will apply. Therefore, it is expected that they develop/review guidelines following the new planning system and provide input, upon SAWP request, on SA procedures under their area of expertise. Product related discussions are not expected to take place on a regular basis. On a case by case basis, the CHMP may request input on product-related issues. Nevertheless, briefing on product-related matters relevant to the development and maintenance of guidance is envisaged.

Most of the Temporary WPs have well-established links with stakeholders (Industry, learned societies, patients and health professional groups) and other regulatory authorities including WHO and other European agencies. Furthermore, some of them are involved on organising assessors meetings and workshops. All these activities will be carried on by each WP and coordinated through the Coordination Group.

With regard to Temporary WPs composition, it will be based on competence and expertise. The nominations will be adopted by the CHMP following proposals from CHMP members and EMA. There should be a maximum of 10 members per WP, however by exception more than 10 may be permitted. It is highly desirable that at least one CHMP member or alternate should be in each WP. Since choice of members will be based on competence and expertise, the possibility of more than one member from a Member State is not excluded. Specific requirements on the composition of each WP should be adopted by CHMP (i.e. inclusion of members from other WPs or Committees). Additional experts may be invited in particular circumstances in which specific expertise is required and these should be appointed by the CHMP. Participation as observers of additional experts proposed by individual National Agencies and agreed by the CHMP is expected, but they will not be reimbursed by EMA.

Concerning common WPs rules of procedure, continuity of each Temporary WP should be confirmed once a year. The chairpersons of each WP will be nominated for a term of 3 years, which may be renewed once, in case that the WP is required for a longer period of time. No time limit is proposed for the term of WP members, however (re)nominations should take place every 3 years. The EMA Secretariat will support and coordinate these activities. A work programme for the following 2 years will be adopted by the CHMP at the time of the constitution of the WP. This will be renewed and adopted by the CHMP once a year thereafter with justification for the continuation. Guideline drafting is described in item 8. The maximum number of meetings per year will be 3 with a maximum of 2 days each. Additional meetings will require specific approval from the CHMP and EMA preferably when the work programme is agreed for the following year. The Temporary WPs can be put on hold or their composition modified depending on the ongoing needs.

One of the main characteristics of the future work of the WPs should be based in the use of IT facilities in order to improve efficiency and minimising costs. Use of tools such as email, teleconference, web sharing and VITERO should improve the ability of WPs to hold dynamic discussions, keeping assessors properly involved and replying to CHMP, other Committees and SAWP request in a timely basis.

4.6 GTWP and CPWP

Both WPs were established by the CHMP at a point in time when these scientific areas became progressively more relevant and therefore there was a need for further expertise. This situation has been evolving up to the point that the new Regulation on Advanced Therapies has significantly upgraded the importance of gene-, cell- and tissue therapies thought the creation of a Committee for Advanced Therapies (CAT). As a consequence and in order to be consistent with previous similar situations, it is proposed that both, the GTWP and CPWP would be discontinued and the main body responsible to deal with issues in these respective fields will be the CAT.

Following the proposed system to agree and plan guideline production (item 8), the CHMP and the CAT shall be involved in the process and when the guidelines to be drafted belong to the scope of the CAT, a Temporary WP or Drafting Group would be organised, following the criteria, mandate and composition set up for all WPs and Drafting Groups.

In order to ensure adequate coordination with other WPs, the CAT chairperson and WPs chairs, if any, will participate in the monthly teleconference of the Coordination Group (item 10).

4.7 Drafting Groups

CHMP can create specific ad-hoc Drafting Groups to deal with a very particular and short term matter. Their mandate will be limited to the specific task commissioned by the CHMP and the rules of procedures will follow those of the Temporary WPs. Their composition could be limited to very few members as agreed by the CHMP.

Drafting Groups could be a useful tool to support very specific therapeutic areas where the main workload is to maintain and create new guidelines. Guidelines for rare therapeutic areas usually need a reduced number of members, 2 to 5. In case that there is a need to get contributions from other WPs or Drafting Groups, this will be discussed at the Coordination Group. To set up a peer review system on a case by case basis is for discussion at the Coordination group.

4.8 Production of guidelines (including a system for planning and adoption)

EMA will continue the task of keeping the CHMP guidelines, including preparatory documents, updated.

It is recognised that the regulatory environment in the EU has been changing over recent years and today the CHMP, due to its responsibility in the decision making process for granting marketing authorisations in the EU, should lead and ensure the consistency of all scientific guidelines. However, other Committees and WPs should be actively involved in the process of identification, planning, production and adoption of guidelines.

EMA will collect proposals on guidelines to be produced and/or reviewed on the year + 2 from CHMP, CAT, PDCO, SAWP, WPs and EGs and EMA scientific secretariat. Taking into consideration all suggestions, prioritisation criteria and available resources, the EMA will make a proposal to the Chairs of CHMP, CAT, PDCO and SAWP. Such proposal will include year + 2 guidelines to be created and/or reviewed and confirm/modify those for the year + 1. The final proposal will be adopted by the CHMP and should then be transposed into the work programmes of relevant WPs and Drafting Groups. The time schedule for this process will be clearly announced by EMA.

When unplanned guidelines are suddenly required, the work programme may be amended by the CHMP on an ad hoc basis.

A tracking system of guidelines accessible by CHMP members and assessors will be set up.

4.9 Relationship with other WPs, Committees and groups

WPs will interact with each other as needed through the Coordination Group.

Requests from SAWP will be sent directly to WPs and in case of a request that is not covered by any of the existing WP, it will be sent to the CHMP and managed by the Coordination Group. SAWP requests (and product-related topics to a lesser extent) require very quick timelines. It could be an issue to respond on time for those therapeutic areas without specific WP or ongoing Drafting Group. Therefore, EMA will progressively build a catalogue of assessors that eventually can be convened within a short period of time by the CHMP.

WPs will provide service to Committees or other groups (e.g. PDCO, CMDh) and to the Pharmacovigilance WP and all requests should be sent directly to the relevant WP a simultaneously to the CHMP.

Representatives of Committees and other groups should also be involved in the drafting of guidelines when it concerns their area of expertise. It is recommended that mixed Drafting Groups are organised with members from more than one Committee when the topic is relevant for both.

4.10 Coordination Group

The EMA will be responsible for the coordination of WPs, including setting up and managing the new system of planning and producing guidelines.

The Coordination Group will be created in order to integrate all related Committees and WPs. The Coordination Group has only functional objectives, such as coordination of activities among the respective WPs, avoiding overlapping and ensuring horizontal activities (i.e. ICH), training of assessors and relationship with stakeholders. CHMP can delegate to this group some of its functions with regard to WP operations. It is not expected that the Coordination Group carry out detailed and lengthy discussions/presentations from WPs chairs and it should not enter in the scientific acceptance of guidelines. The current Bio-Coordination Group (BCG) functions will be taken over by the Coordination Group.

The Coordination Group will be composed by CHMP, CAT and PDCO Chairs, WPs Chairpersons (or their back-ups) and the respective EMA secretariats and will be chaired by the CHMP Chair (or vice-chair). A monthly teleconference before the CHMP week will be arranged and in principle no face to face meetings are planned. The TC will have a common agenda, but differentiating three parts: matters specific for Biological WPs (BWP, BPWP, VWP, BMWP and CAT and its WPs if any), general matters and Therapeutic WPs matters (SWP, CV, CNS, any other existing therapeutic WPs and Drafting Groups, Biostatistics WP and PKWP). QWP and SAWP will also participate.

The monthly TC of the Coordination Group will be open to all CHMP members. In particular this could be used by those coming from National Agencies with limited number of assessors in WPs to keep track of the ongoing activities and get information on the future plans. Minutes will be drafted by EMA and circulated for comments before they are forwarded to CHMP.

A specific Coordination Group mandate will be adopted and it will include

- Discussing work plan and fulfilment
- Approving WPs meeting agendas
- Ensuring WPs activities stick to their mandate and rules of procedure and discussing deviations
- Ensure adequate training activities for assessors
- Identifying and avoid (solving) overlapping
- Identifying and discussion of potential gaps
- Relationship with stakeholders

4.11 Consistency Group

It will review all draft guidelines before they are discussed at the CHMP in order to maintain regulatory and scientific consistency.

The Group will be composed by few senior CHMP members or assessors or members from other Committees and senior EMA staff. The members should be senior assessors with regulatory experience with a wide scientific background.

They will develop a high level review of all clinical and methodological guidelines, with specific attention to key sections (i.e. endpoints, design of pivotal studies, placebo vs. active control). It is not expected that they carry out detailed revision of the text of the document nor editorial check and should avoid unnecessary delays in the guidelines drafting process.

Normally when a WP or DG adopts a final draft guideline, EMA will circulate it to Consistency Group. A predefined time for reaction and comments is of 1 month. The group will interact directly with WPs chairs, but they can also be involved in the WP discussions. If there are no major issues, the guideline will be submitted to the CHMP for adoption prior consultation. If there are major discrepancies, a presentation to the CHMP will be carried out by a member of the Consistency Group and the chair of WP or DG or by the Rapporteur. No face to face meetings of the Consistency Group are planned although occasionally a meeting could be arranged.

In principle the Consistency Group will be focused on therapeutic and methodological guidelines, but its composition could be adapted to the need of reviewing other guidelines (i.e. biological, non-clinical) as agreed by the CHMP.

4.12 Working Parties (WPs) and Scientific Advisory Groups (SAGs)

The WPs are mainly composed by assessors, hence experts belonging to national agencies and therefore with further regulatory component. Their functions are related with those set up in the WPs mandate.

The SAGs are basically composed by independent experts and they are intended to answer specific questions from the CHMP in relation to the evaluation of medicinal products regulatory procedures.

It is beneficial for the whole European Regulatory System that WPs and SAGs mutually contribute to common scientific fields, therefore it is expected that the CHMP involves SAGs in preliminary discussions of guidelines and promotes cross-fertilization between WPs and SAGs.

4.13 Ensuring integration of the whole EU Regulatory Network

Participation as observers of additional experts proposed by individual National Agencies and agreed by the CHMP is expected, but they will not be reimbursed by EMA (see 4.5).

Meetings (face to face or by video/teleconference) will be arranged in such way that allows participation of members. Workload will be distributed among all members.

Agenda and minutes will be distributed to all CHMP members and information regarding all WPs activities will be widely circulated to all MS.

Assessor inputs on guidelines could be provided through specific meetings or video/teleconferences.

Implementation of guidelines should include activities on assessors training and additionally one of more members of the WP or DG could be committed into an implementation initiative (including email box for questions) in order to ensure that it is effectively enforced.

4.14 Relationship with stakeholders and briefing meetings

WPs should not organise meetings with pharmaceutical and related companies or academic groups, unless this has been agreed by the CHMP. Meetings with trade associations should also be previously endorsed by CHMP.

Requests for briefing meetings are received and managed by the Innovation Task Force secretariat and they organise the meetings. ITF is an EMA's multidisciplinary group that includes scientific, regulatory and legal competences. When the briefing meeting is related to specific scientific issues, they are carried out with the appropriate WP. When they are concerning ATMPs, ITF will involve CAT members.

Both meetings with stakeholders and briefing meetings will be brought to the Coordination Group for information and it will ensure appropriate coordination if needed.

4.15 Clinical trials and manufacturing issues

Some of the current WPs have had in some context, a different wider mandate, for instance from the Commission and HMA regarding clinical trials and from the Commission, HMAs and CVMP regarding quality and manufacturing issues. For this reason, they also have links with GCP, GMP, PhV and GLP IWGs, HMPC PAT, CTFG, Commission Ad hoc working group on clinical trial guidelines etc.

It is important that regular involvement of the CHMP through its WPs and EGs on clinical trials should be organised.

In particular, the Therapeutic Coordination Group should consider effective management of efficacy/therapeutic transversal guidelines, including general clinical trial guidance, ICH E series, EU guidelines on DSMBs, etc.

The WPs with the need for a clear link with GCP and GMP IWGs in their mandate should be identified.

Both QWP and BWP have contributed to the reflexion of some quality aspects for the IMPs through 1 and 2 guidelines, respectively. Furthermore, both WPs have regular meetings with inspectors and some common initiative has been developed to discuss new quality approaches such as PAT, QbD, and implementation of ICH Q8, Q9 and Q10 in the daily practice.

In this respect, to ensure consistent implementation and acceptance of these guidelines, discussion has started on developing a formal role of the PAT team, possibly as an Expert Working Group, in scientific advice procedures and in the assessment phase of applications that include the use of these new ICH quality approaches. Details as to how this would work in practice require further discussion at this time.

5. Implementation plan

The final distribution of WPs and Drafting groups is as follows:

Standing WP:	Biologicals (B)
	Safety (S)
	Quality (Q)
Temporary WP:	Blood Products (BP)
	Biosimilar (BM)
	Vaccines (V)
	Pharmacogenomics (PG)
	Pharmacokinetics (PK)
	Biostatistics (BS)
	Cardiovascular (CV)
	Central Nervous System (CNS)
	Infectious Diseases (ID)
	Oncology (ONC)

Drafting Group: Endocrinology, Rheumatology/Immunology, Respiratory, Gastroenterology

The three standing WPs (BWP, QWP and SWP) will continue their tasks and activities as of today. BWP is meeting on a monthly basis, except in August.

Concerning the temporary WPs and DG:

- Mandates: Standard mandate for Temporary WP and DG will be presented to CHMP in June 2010 for adoption in July 2010
- Composition: Members of the Temporary WPs and DG will be proposed before June CHMP for a first discussion at the June CHMP and for adoption in July 2010
- Chairs: Election will be carried out according to the new WP mandate at the first meeting (face to face or by video/teleconference)
- Work Programmes: Those of 2010 will not be changed in terms of guidelines, meetings and activities, but those for 2011 will be adapted to this Reflection Paper

Planned meetings for 2010 according to the respective Work Programmes are as follows:

- BMWP: meetings 30 June-1 July 2010 and 27-28 October 2010
- BPWP: meetings 30 September–1 October 2010 and 25-26 November 2010
- PGWP: meetings 6-7 October 2010 and 6-7 December 2010
- VWP: meetings 30 June, 1,2 July 2010, 28-30 September 2010 and 30 November-2 December 2010
- EWP: 6-7 July 2010 (final plenary meeting)

The Coordination Group mandate will also be presented to the CHMP in June for adoption in July 2010. Its kick off meeting will be in September 2010. In case that a WP still has not elected the chair at the timer of the first Coordination Group, the current chair of the WP or DG (for EWP's DGs) will participate.

The Consistency Group mandate will be presented to the CHMP in July for adoption in September 2010. Members will be proposed before September CHMP for a first discussion at the September CHMP and for adoption in October 2010

Guidelines planning: No changes are introduced for those planned for 2010 and 2011. EMA Secretariat will start to develop the new planning system on January 2011 and a first draft of Guidelines for 2012 and 2013 will be available in April 2011 and adoption will be in September/October 2011.

ANNEX 1

London 7th April 2008
Doc. Ref.: EMA/103263/2008

CHMP Briefing Note – CHMP Work plan 2008-2010

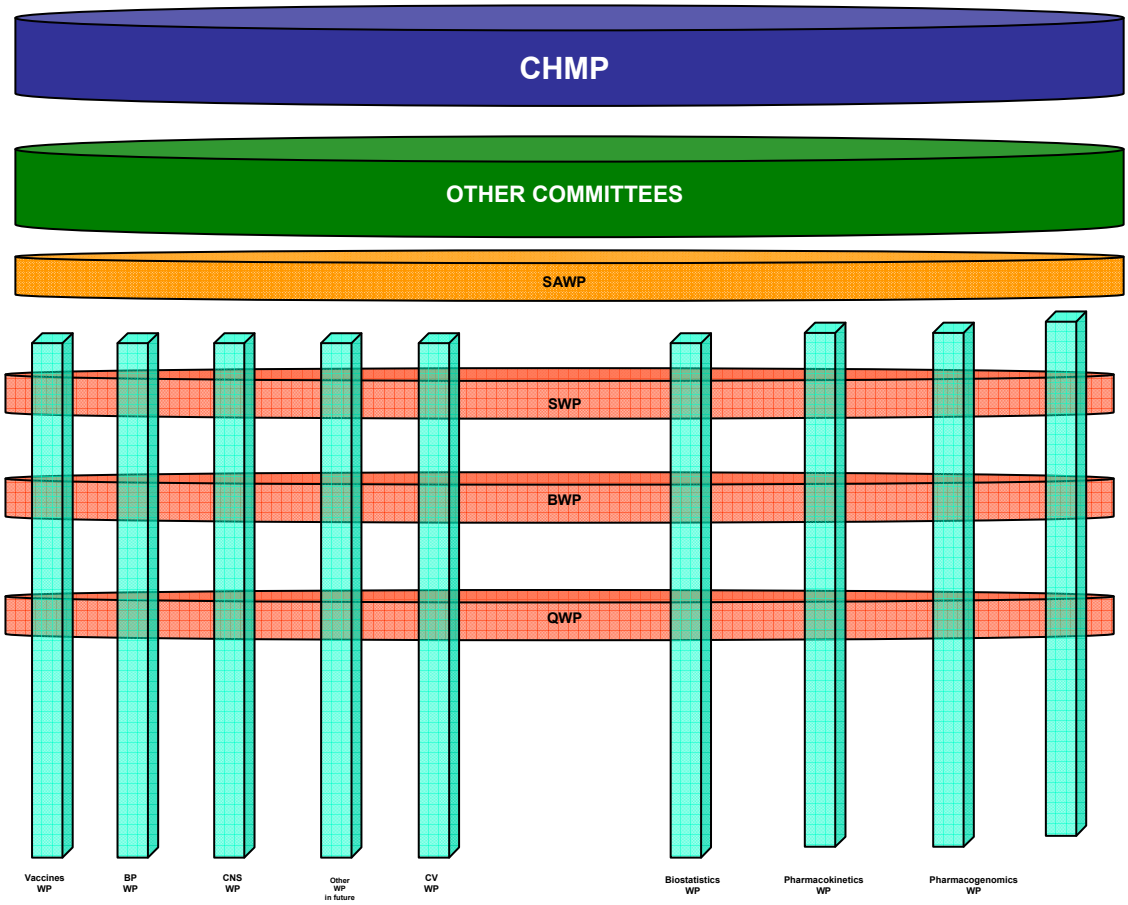
Review of CHMP Working Parties Mandate, Composition and Reporting Structures

Criteria	
Problem statement	In the light of new developments (e.g. legislation, new committees) a need to critically examine and possibly review the mandate, composition and reporting arrangements for CHMP working parties has been identified. Issues to be addressed include the following: - To define what the expectation of the CHMP for the various WPs is, and to define the roles of the "players" in the system. - Whether or not the composition and mandate of the different working parties need to be individually reconsidered in the light of the specific tasks requested by CHMP, (issues with general application vs specific requirements for CAPs, product related issues vs general guidance documents, etc). - Whether the current range of CHMP working parties continues to be appropriate in the light of new developments such as the Advanced Therapy Regulation or Paediatric Regulation. - The procedure for appointment and renewal of Chairs and Vice-Chairs of the working parties. - How to ensure effective feedback and feed forward mechanisms between the CHMP and its working parties, and consistency of decisions including guidelines and to avoid unnecessary overlap of activities. This should include also feedback to CHMP/SAWP Rapporteurs. - The need for better monitoring and control systems. - Relationships and effective working relationships between CHMP working parties, and other committees (CMD, PDCO, HMPC, CAT etc). - Planning and reporting – including input into the EMA budgetary reporting cycle. - Rules for drafting group formation. - Collaboration between the different CHMP Working Parties. - The role of briefing meetings
Objectives to be achieved	Review of mandates, composition, terms of reference, procedures to take into account outcomes of discussions on the issues described above. Improvement of efficiency taking into account HMA's concern about the resource implementations of WPs.

Potential concerns, pitfalls, limitations, barriers	Due to the large number of working parties and the extensive amount of issues to be addressed, it is expected that this will be a resource intensive exercise. In 2003, the EMA established a cross-agency working group to develop a harmonised approach to the management of working parties, expert groups and their outputs. One of the outcomes was a model mandate and terms of reference agreed by CHMP, CVMP and HMPC. The impact on these cross-agency agreements will need to be addressed. A differentiated approach for the PhVWP will be necessary.
Actions proposed to meet objectives	A working group with members appointed by the CHMP, including representatives from the EMA Secretariat to meet to agree on present and future CHMP needs with respect to WPs, a project plan and mandate for the group's activities.
Expected impacts	- Review of range of working parties, optimising resources and avoiding unnecessary duplication and overlap - Review of model mandate adapted to specific WP requirements, including a clear delineation of the rules of procedure of each WP (need for Drafting Groups, guideline discussion, etc) - Review of composition of working parties - The procedure for appointment and renewal of Chairs and Vice-Chairs of the working parties - Review of feedback and feed forward mechanisms between the CHMP and its working parties - Review of role of EMA secretariat - Clear definition of roles and responsibilities in the relationship between CHMP WPs and other Committees (CMD, PDCO, HMPC, CAT etc.) - Guidance on drafting group arrangements and roles of guideline rapporteurs - Implementation of monitoring and control systems, need for peer review system before guidelines publication etc. - Optimisation of efficiencies
Links with other stakeholders / Committees	Collaboration with CVMP, HMPC, PDCO, CAT, possibly CMD(h) and CMD(v) will need to be considered. Ongoing project work on SAGs may also need to be considered to ensure that SAG and WP/drafting group concepts remain clearly differentiated.
Required Delivery Date	To be determined based on priorities identified by CHMP.
CHMP Sponsors & EMA Sponsors	CHMP Sponsor: Eric Abadie Other CHMP participants: G Calvo, J-L Robert, C Schneider, EMA Sponsor: Emer Cooke*

** Replaced by Xavier Luria in January 2009*

ANNEX 2


CHMP
OTHER COMMITTEES
SAWP
SWP
BWP
QWP
Vaccines WP
BP WP
CNS WP
Other WP in future
CV WP
Biostatistics WP
Pharmacokinetics WP
Pharmacogenomics WP

ANNEX 3

SUMMARY OF MANDATES, COMPOSITION AND REPORTING LINES

BWP

This WP should be considered as transversal as it has a specific mandate to deal with all quality aspects relating to the whole range of biological products.

It is thus not necessary to reconsider this mandate and the way the BWP is organised (monthly meeting, systematic report to the CHMP for MAA/SA activities and production of guidelines) and composed. It should be noted that, with the implementation of the CAT, the BWP has now two reporting lines depending on the products covered.

WP	Mandate	Composition	Reporting line
BWP	1- Biological or biotech products Quality aspects and safety aspects related to quality Dossier evaluation for quality aspects → report to the CHMP Scientific advice Guidelines 2- for ATMPs Quality aspects and safety aspects related to quality Dossier evaluation for quality aspects → report to the CAT Scientific advice Guidelines	One member per MS plus alternate. National assessors funded by MS Additional specific experts invited by BWP on an ad hoc basis Contact person with other WPs	CHMP/SAWP CAT and then CHMP

Regarding the interaction with BWP activities to cover quality-related matters for ATMPs and for the sake of consistency and maintaining the necessary complementary approach, it is proposed to reorganise the rolling plan of the BWP meeting by setting fixed time slot at which the ATMPs issues (quality aspects) will be scheduled, so as to allow CAT members to contribute, preferably by TC, so this will strengthen the link between BWP and CAT while avoiding duplicating the meetings and discussion on the same topic.

SWP

This WP should be considered transversal as it has a specific mandate to deal with all non clinical issues.

It is thus not necessary to reconsider this mandate and the way the SWP is organised and composed.

WP	Mandate	Composition	Reporting line
SWP	Scientific advice Guidelines Product specific issues on CHMP request	One member per MS plus alternate National experts funded by MS Contact person with other WPs	CHMP/ SAWP

QWP

This WP should be considered transversal as it has a specific mandate to deal with all quality aspects relating to the whole range of chemical products.

It is thus not necessary to reconsider this mandate and the way the QWP is organised and composed.

WP	Mandate	Composition	Reporting line
QWP	Scientific advice Guidelines Product specific issues on CHMP request	One member per National Competent Authority (Human and Vet) possibility of participation of other experts funded by Member States, observers from EDQM, accession countries and, on an ad hoc basis, Mutual Recognition Agreement partners. EMA staff responsible for the secretariat	CHMP/ CVMP

Temporary WPs

	Mandate	Composition	Reporting line
Temporary WPs	Guidelines Contribution to the scientific advice and protocol assistance for Non-clinical and Clinical aspects Product specific issues on CHMP request Vaccines WP: Advice to PDCO, CMDh for vaccine dossiers. Activities on VISI initiative and	Up to 10 assessors Additional assessors where specific expertise is required Possibility of participation of other experts funded by Member States, observers from accession	CHMP

	relationship with WHO, ECDC, etc. Blood Products: Preparation, review and update of Core SPCs for blood products	countries and mutual recognition agreement partners Vaccines WP: PDCO will propose members to CHMP	

ANNEX 4

WP	Working Parties
BWP	Biological Working Party
BMWP	Similar Biological (Biosimilar) Medicinal Products Working Party
BPWP	Blood Products Working Party
CPWP	Cell-based Products Working Party
CMD(h)	Co-ordination Group for Mutual Recognition & Decentralised Procedures – Human
EWP	Efficacy Working Party
GTWP	Gene Therapy Working Party
HCPWG	Healthcare Professionals' Working Group
QWP	Joint CHMP/CVMP Quality Working Party
PCWP	Patients' and Consumers' Working Party
PgWP	Phamacogenomics Working Party
PhVWP	Pharmacovigilance Working Party
SWP	Safety Working Party
SAWP	Scientific Advice Working Party
VWP	Vaccine Working Party
ATMP	Advanced Therapy Medicinal Product
PDCO	Paediatric Committee
SA	Scientific Advice
SAG	Scientific Advisory Group
SPC	Summary Product Characteristics
TC	Teleconference
MS	Member State