Title: General dealings between SAWP Secretariat and working parties, SAGs, committees and patients' organisations		
Applies to: Scientific Advice Section; working party, SAG and PDCO/COMP secretariats; nominated patients' representatives; SAWP		
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1. Changes since last revision

- Updating of organisational denominators
- Introduction of detailed procedure for PDCO involvement in SA/PA
- Addition of a related document for the BPWP
- Changes to the procedure for interaction with the patients' representatives:
  addition of new step 7.
  renumbering of former step 7 as new step 8.
  replacement of former step 8 by new steps 9 to 11.
  renumbering of former steps 9 to 16 as new steps 12 to 19.

2. Records

Written comments from the expert groups are saved in the relevant product folder in EDMS.

3. Related documents

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- EMEA/CHMP/SAWP/69686/04 (as revised): Mandate, objectives and rules of procedure of the SAWP
- WIN/H/3042: Organisation of discussion meeting for Scientifc Advice and Protocol Assistance
- WIN/H/3073: Check of experts for scientific advice/protocol assistance
- WIN/H/3195: Organisation of Scientific Advcie Working Party meetings
- List of Blood Products: documentum\Docbases\EDMS\Meetings\Scientific Meetings\B P W P\04 - Projects\04-1 - Product related issues\01 - Scientific Advice\List of Blood Products

4. Definitions

BPWP: Blood Products Working Party
BWP: Biologics Working Party
CAT: Committee for Advanced Therapies
CHMP: Committee for Medicinal Products for Human Use
COMP: Committee for Orphan Medicinal Products
CPWP: Cell-based Products Working Party
DM: Discussion meeting
GTWP: Gene Therapy Working Party
PA: Protocol assistance

PDCO: Paediatric Committee
PgWP: Pharmacogenomics Working Party
QWP: Quality Working Party
SA: Scientific advice
SAA: Scientific advice administrator
SAG: Scientific Advisory Group
SAWP: Scientific Advice Working Party
Sec: Secretary
SWP: Safety Working Party
VWP: Vaccine Working Party
WP(s): Working party(ies)

5. Groups consulted by SAWP

Several groups are involved in giving expert opinion to the SAWP.

WPs of the CHMP

The following WPs are involved in the provision of SA and PA.

Biologics Working Party
The BWP is systematically consulted on all quality questions on biotechnology and biological medicinal products, including quality issues for blood products. Each SA/PA request is discussed during the BWP meetings. The BWP report is then incorporated in the final advice letter.

Vaccine Working Party
The VWP is systematically consulted on clinical questions on vaccines (except cancer vaccines). The VWP mainly comments in writing, however, when suitable the discussions are held during one of the VWP meetings.

Quality Working Party
The QWP is systematically consulted on all quality questions on chemical medicinal products. The QWP mainly comments in writing.

Safety Working Party
The SWP is included in mailings for SA/PA requests on preclinical questions. The SWP mainly comments in writing.

Cell-based Products Working Party
The CPWP is systematically consulted on all questions on cell therapy products (including cancer vaccines). The CPWP mainly comments in writing, however, when suitable the discussions are held during one of the CPWP meetings.

Blood Products Working Party
The BPWP is systematically consulted on clinical questions on plasma-derived and recombinant blood products. The BPWP mainly comments in writing, however, when suitable the discussions are held during the planned BPWP meetings or via teleconference. When requested individual BPWP members also provide scientific expertise during SAWP meetings with companies. Refer to "List of Blood Products" for a detailed description of all products that should be addressed by the BPWP.

Gene Therapy Working Party
The GTWP is systematically involved in all questions on gene therapy products. The GTWP mainly comments in writing, however, when suitable the discussions are held during one of the GTWP meetings.

Pharmacogenomics Working Party
The PgWP is systematically involved in all questions on pharmacogenomics. The PgWP mainly comments in writing.

Paediatric Committee

The PDCO is systematically involved in all paediatric-related questions. The PDCO mainly comments in writing, however, when required, discussions are held during one of the PDCO meetings. PDCO members can also participate in SAWP meetings.

Committee for Advanced Therapies

The CAT is systematically consulted on all procedures related to advances therapies. Each SA/PA request is discussed during CAT meetings and is commented on in writing.

Scientific Advisory Groups of the CHMP

The SAGs are involved on an ad hoc basis if specific expertise is required. Comments are made in writing.

Patients' Organisations

Patients' representatives are invited to contribute to all protocol assistance requests through the member of the COMP representing them (in line with Article 78(2) of European Parliament and Council Regulation (EC) 726/2004 and Article III.5.1 of the SAWP Mandate).

6. Process of involvement

CHMP WPs and CAT

During the initial validation of the SA/PA requests WPs/CAT are identified and noted in the validation cover sheet. The relevant WP/Committee secretariats are contacted during the validation process when necessary.

At the start of the procedure (just after SAWP day 0) an email is sent to the respective WPs/ CAT secretariats with a link to the full product dossier and information on the timelines. The Coordinators' first reports (include locator to file with all first reports) and the agenda are also sent to WPs/ CAT secretariats in premails before the second SAWP (day 30) meeting.

Following SAWP meeting, the Table of Decisions is sent to WPs/CAT secretariats for information.

The reports or written comments from the WPs /CAT should be sent by the agreed deadline for incorporation into the draft advice letters.

Finally the adopted final advice letters and Table of Decisions are sent to WPs/CAT secretariats for information at the end of the procedure.

PDCO

The PDCO members who volunteer as experts for SA/PA are regarded as individual experts and no consolidated view from the whole PDCO is adopted for the final advice letter.

Step	Action	Responsibility
At validation before SAWP 1 (day 0)		
1	Tick the box for PDCO involvement on the validation cover sheet if the advice relates to any paediatric issues.	SAA
Subsequent PDCO meeting		
2	Comple a list of all SA/PA wich require PDCO involvement.	PDCO secretariat
3	Send the list to the PDCO members.	PDCO secretariat
4	Receive the answers from the PDCO members and enter the volunteers into the list.	PDCO secretariat
5	Send the final list to the SAWP secretariat	PDCO secretariat

Step	Action	Responsibility
Before SAWP 2 (day +30)		
6	For each procedure: Send the full briefing package to the PDCO member.	SAA (can be delegated to Sec)
7	Contact the PDCO member via email or phone to explain the procedure and confirm his/her level of involvement: • Comments on briefing package in writing • Comments on 1st reports in writing • Participation during the discussion of the 1st reports (telephone or in person) • Participation at discussion meeting (if applicable: telephone or in person) • Review of final advice letter Note: If the PDCO member attends the SAWP meeting he/she is handled as any other expert (see WIN/H/3042, WIN/H/3073, WIN/H/3195)	SAA
8	Send the relevant 1st reports to the PDCO member.	Sec
During SAWP 2		
9	Comments from the PDCO expert are expressed during the discussion on the 1st reports.	SAA/PDCO member
Finalisation of final advice letter		
10	Send final advice letter to PDCO member for information.	Sec/SAA

Scientific Advisory Groups

The SAGs' expert input is requested on an ad hoc basis. If comments from a SAG are required by the SAWP the responsible scientific administrator will contact the SAG secretariat and decide how the request should be dealt with.

Patients' Organisations (only for PA procedures)

Step	Action	Responsibility
At SAWP 1 (day 0)		
1	Send SAWP agenda and briefing documents for PA procedures to the responsible COMP member representing patients' organisations (Eurordis contact point) and copy the 3 SAWP/COMP members (Eudralink 1).	Sec
Before SAWP 2 (day +30)		
2	Identify requests which can benefit from patient representation and send specific names of patients' representatives, if available, to SAWP secretariat.	Eurordis contact
3	If requests and patient representatives are identified go to step 4. If not, end of the procedure.	SAA/ Sec
4	Check status of identified patient representatives. If they are included in the expert database go to step 6; if not, go to step 5.	Sec
5	Contact patient representative and send documents for nomination as an expert. Upon receipt of full original documentation, patients' representative is nominated by the EMEA and inserted into EMEA experts database.	SAA/ Sec

Step	Action	Responsibility
6	Check patients' representative's declaration of interests for potential conflicts of interest (see WIN/H/3073). Set up a Eudralink account for patients' representative.	SAA/ Sec
7	Forward to the patients' representative and Eurordis contact the relevant final request for PA, letter of intent and 1st reports.	SAA/ Sec
During SAWP 2		
8	Has a DM been requested? If no, go to step 9. If yes, go to step 12.	Sec
After SAWP 2		
9	Forward to the patients' representative and Eurordis contact the Joint report. Inform the patients' representative and Eurordis contact point of the outcome. Inform SAA comments can be expressed in writing and provide as deadline the Wednesday before the CHMP meeting.	Sec
10	Provide written comments (optional).	Patients' representative
11	Forward comments (if applicable) to SAA and SAWP coordinators. Go to step 18	Sec
12	Send email to inform Coordinators, Eurordis contact point and patients' representative on involvement of patients representatives.	Sec
13	Forward to the patients' representative and Eurordis contact the list of issues, the, written responses from the applicant to list of issues (if applicable), a timetable of the PA procedure and approximate date of discussion meeting with sponsor. Include a note stating that views on the proposed PA request can be expressed in writing and provide as deadline the Friday before the DM.	Sec
14	Send invitation for reimbursed participation to patients' representative for involvement in discussion meeting (at SAWP 3). Contact the patients' representative to make sure that he/she understands his/her involvement in the procedure.	Sec/SAA
Before DM at SAWP3		
15	Provide written comments (optional).	Patients' representative
16	Forward comments to the attention of SAWP Coordinators, SAA and include in a mailing to the SAWP for information.	Sec
After DM at SAWP 3		
17	E-mail final list of SAWP attendees to contact point in Medical Information Sector for their records.	Sec
18	Send a short feedback about patients' representative's contribution to the Eurordis contact point after the adoption of the final advice letter from CHMP.	SAA
19	After CHMP adoption send final advice letter, applicant's DM minutes and acknowledgement letter signed by SA team leader to patients' representative and Eurordis contact point for information.	Sec