EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The Scientific Advice Working Party (SAWP) and its interaction with other WPs and groups

PCWP/HCPWP joint meeting

Presented by Iordanis Gravanis on 3 March 2023
Head of Scientific Advice Office, Scientific Evidence Generation Department, EMA

Outline

- Introduction to the SAWP-main tasks
- SAWP interaction with other WPs
- Patient and HCP involvement in SA

The Scientific Advice Working Party (SAWP)

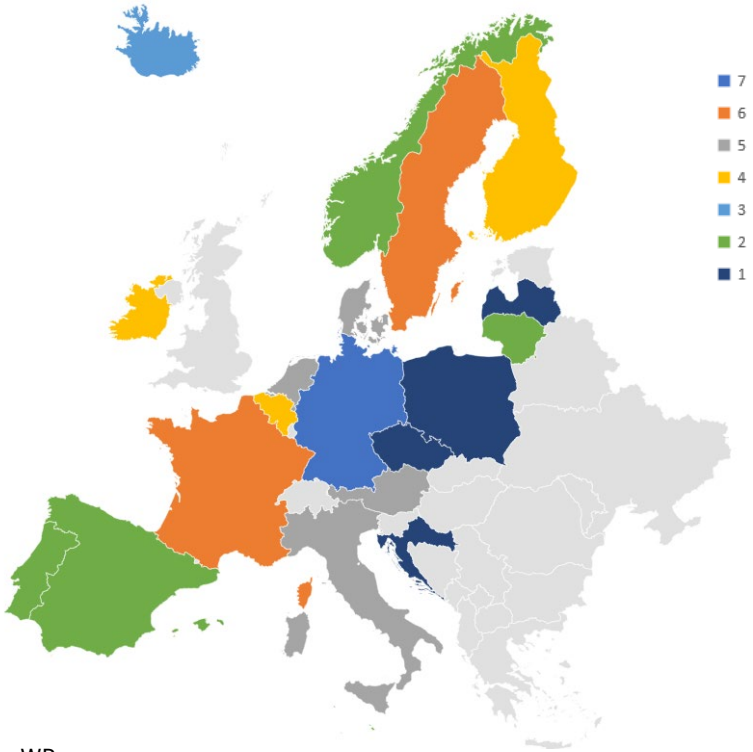
- Standing working party of the Committee for Medicinal Products for Human Use (CHMP) with the sole remit of providing scientific advice

- Meets on a monthly basis 11 times per year (no meeting in early August)

- Consists of 72 members and alternates nominated based on expertise needs including representatives from EMA committees

SAWP and its interaction with other WPs

EU Member State representation at the SAWP

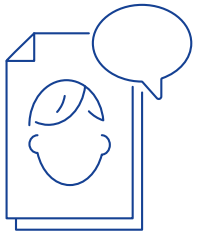


SAWP and its interaction with other WPs

Main tasks of the SAWP

- Provision of scientific advice/protocol assistance (~70 requests/mo)
- Provision of qualification advice/opinion (~2 requests or 5 agenda topics/mo)
- Assessment of PRIME eligibility requests for recommendation to CAT/CHMP (1-7 eligibility requests/mo)

What is scientific advice?



Regulators' advice on the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products

Clarification of scientific requirements for marketing authorisation (MA):

- Manufacture and testing, non-clinical (in vitro and animal) and clinical testing, risk management plans and post-authorisation follow-up (efficacy or safety), methodological aspects (statistics, data analysis, modelling and simulation) etc.
- Type of marketing authorisation, post-authorisation extension of indication, ways to develop generics, hybrids and biosimilars, development in children etc.

Prospective in nature - focusing on development strategies rather than pre-evaluation of data to support a MAA

In the form of specific questions to be answered

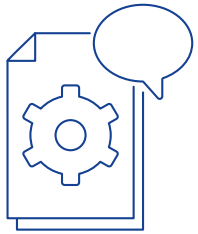
What is protocol assistance?

Scientific advice given on the development of orphan designated medicinal products is called protocol assistance

It can include questions on the plan to demonstrate ‘significant benefit’ of the orphan designated product vs established therapies (pharmaceutical or not) in the target condition which is a requirement for the maintenance of the orphan designation at the time of marketing authorisation (MA)

Qualification of novel methodologies and biomarkers

Framework to guide the development of new more efficient ways to develop drugs, e.g. development of new endpoints for clinical trials



Aim: Speed up/optimise drug development and utilisation

Examples:

- Biomarkers to predict toxicity or enrich a patient population
- Surrogate clinical endpoints
- Patient and caregiver reported outcomes
- Patient/disease registries

Relies on meta-analysis of multiple data sources and qualifies the method for use in a specific Context-of-Use

SAWP and its interaction with other WPs

PRIority MEdicine (PRIME) scheme

- Intended to foster the development of medicines with **major public health interest** and in particular from the viewpoint of **therapeutic innovation** in areas of **unmet medical need**
- Eligibility request assessed by the SAWP towards recommendation to CAT/CHMP towards granting the PRIME designation
- Reinforced scientific and regulatory advice via **early CAT/CHMP Rapporteur appointment** and **scientific advice**
- Optimised development for robust data generation in order to enable **accelerated assessment**

SAWP and its interaction with other WPs

SAWP referrals to committees, WPs and OEGs

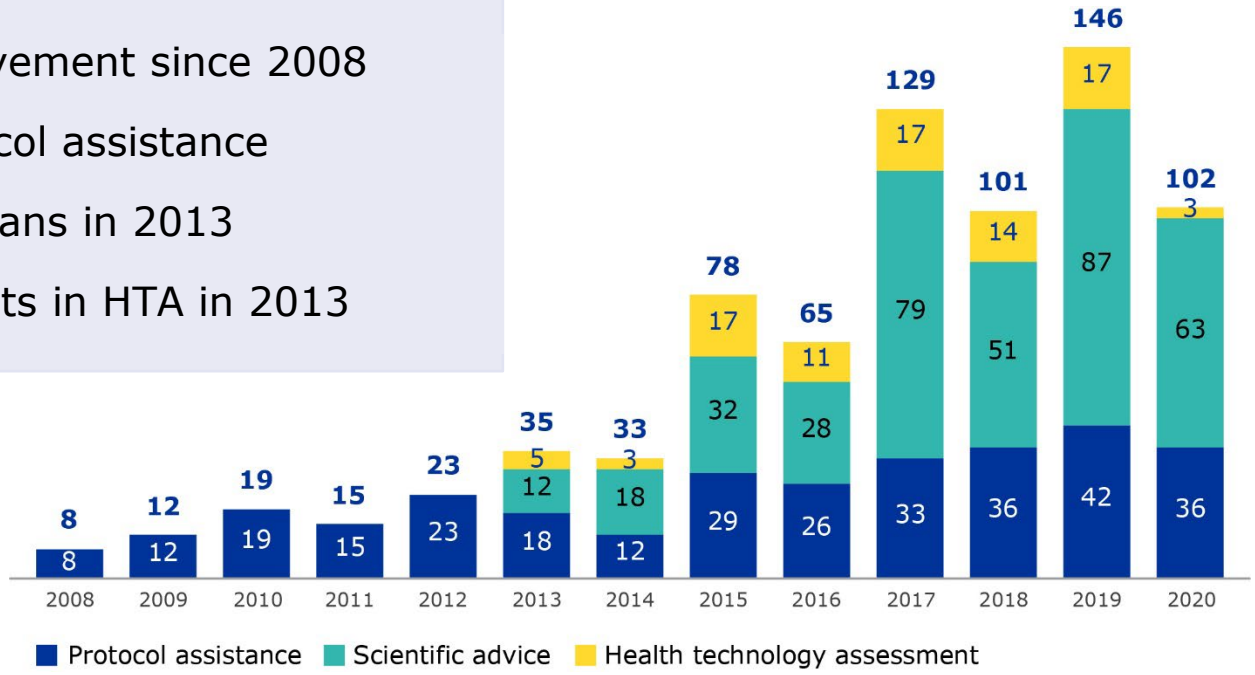
Action	(To) Whom?	What?
delegates	BWP/QWP core team	Quality
delegates	COMP	Significant benefit
systematically involves	PDCO	Paediatric with PIP
systematically involves	CAT	ATMPs
systematically involves	PRAC	PASS
systematically involves	BSOEG	Statistics (all clinical)
systematically involves	MSOEG	M&S (all clinical)

SAWP referrals to WPs (cont.) and other groups

Action	(To) Whom?	What?
ad hoc involves	PDCO	Paediatric without PIP
ad hoc involves	NCWP	Non-clinical
ad hoc involves	MWP	Pharmacokinetics
system. involves	GMP-IWG	GMP
system. involves	CTCG	Qualifications of innovative or decentralised Clinical Trial designs
system. involves	GCP-IWG	Qualifications involving Digital Health Technologies (DHTs)

Patient involvement in scientific advice over the years

- Data for patient involvement since 2008
- First patients in protocol assistance
- Extended to non-orphans in 2013
- Involvement of patients in HTA in 2013

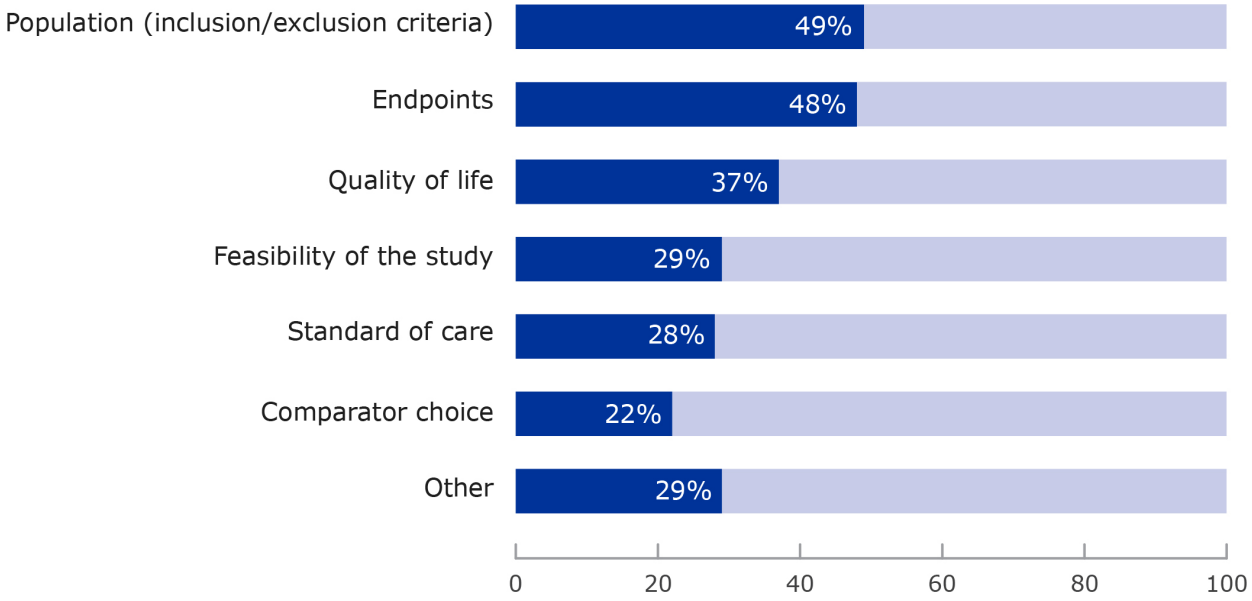


SAWP and its interaction with other WPs

Patient involvement in scientific advice 2017-20 survey analysis

- Involved in 1 in 5 procedures with clinical questions (20%)
- Reasons for requesting patients included:
  - study population (77%)
  - endpoints (74%)
  - study feasibility (52%)
  - quality of life (48%)
  - other aspects such as PROs, biomarkers and safety issues

Where patients gave input



Patient input resulted in further reflection in 52% of cases.

"Other" areas included general insights into the condition, its daily impact and treatment options.

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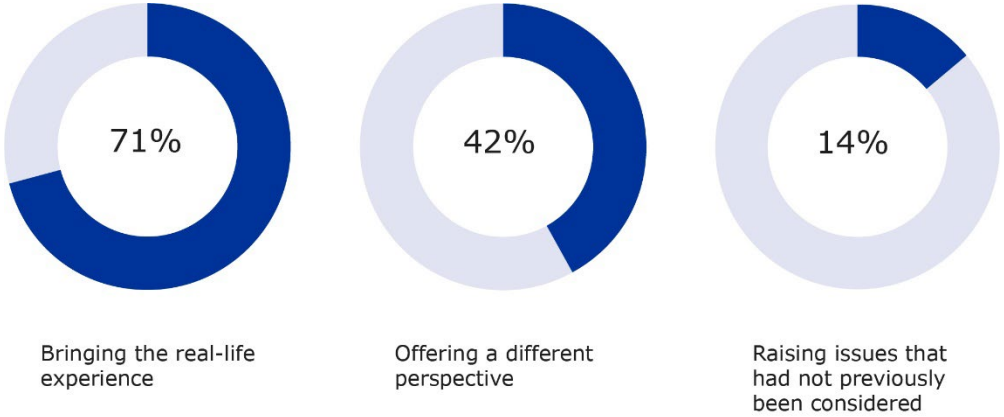
Added value of patient input and involvement



Patient input:

- **complements** the scientific and medical contributions to the specific questions.
- contributes to **future recommendations** in the same therapeutic area.

SAWP and its interaction with other WPs

Impact of patient input and involvement

20% of cases - recommendations made to the developer were modified based on patient contributions.

>85% cases where patient input did not change the final advice correlated to patient **agreement** with the proposed development plan.

HCP involvement in SA

- Not as well developed as patient involvement
- Overlap with expert involvement in SAWP coordinators' teams at national level
- Occasional EMA-proposed additional HCP involvement for rare diseases for which there is lack of or little expertise in the network
- HCPs interested to regularly participate in SA should approach their NCA
- 8 of the current 68 SAWP members have a primary academic affiliation and many SAWP members are working in hospital settings

Any questions?

Further information

iordanis.gravanis@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 7821
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