

Introducing The ENCePP Working Group On Health Technology Assessment Enhancing the Generation of Additional Evidence for HTA Processes

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Background

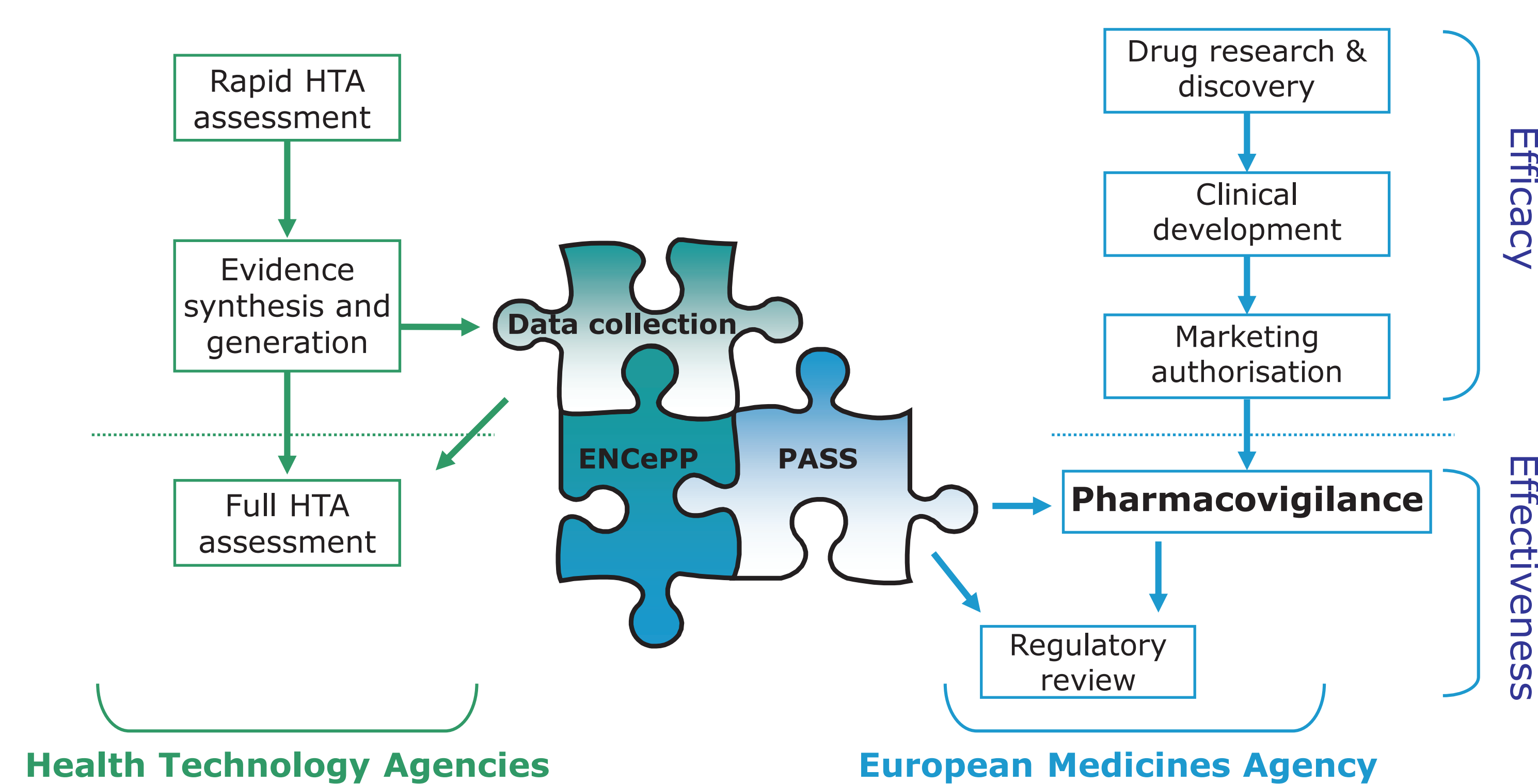
As well as the introduction of new pharmacovigilance legislation many other factors are changing the agenda for post-authorisation studies in the EU.

Factors changing the agenda for post-authorisation studies in the EU

- Development of new pharmaceutical technologies
- Globalisation and international collaboration
- IT development
- Increasing evidence needs
- Growing emphasis on reimbursement/coverage with evidence development
- Rising interest in HTA
- Expanding societal demands
- Getting better value for healthcare spend

Currently however, decision makers are often faced with the challenge that long-term, real-world data on safety, effectiveness and cost effectiveness is lacking at the time of marketing authorisation. This creates uncertainty around a new medicine's risk-benefit profile at a time when manufacturers, health care providers, and patient groups may be exerting pressure for early decisions and rapid access. Decision makers may therefore be unduly delaying potential benefits to patients by waiting for stronger evidence, or may endorse medicines that later turn out to have a less robust benefit-risk ratio, to be ineffective, cost-ineffective, or even harmful.

Providing a potential bridge between Medicines Regulation and HTA



To reduce some of the uncertainties many countries have developed mechanisms that allow temporary access to promising medicines while concurrently requesting the generation of additional evidence. Nevertheless, responsiveness and rigour is required when making any trade-off between different stakeholder needs as well as the flexibility to revise decisions on access when new evidence becomes available. It is also important where practical to conduct post-authorisation studies that potentially link the evidence requirements of regulators with those of HTA agencies.

Rationale for setting up the ENCePP HTA WG

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) is a collaborative network

co-ordinated by the European Medicines Agency (EMA). It brings together over 180 academic and hospital based research centres, providers of healthcare data, and specialised networks across Europe in a functioning network of excellence. The network aims to further strengthen the post-authorisation monitoring of medicinal products in Europe by facilitating the conduct of multi-centre, independent post-authorisation studies focusing on safety and benefit/risk assessment.

The European Network for Health Technology Assessment (EUnetHTA) is working to create a sustainable system of HTA knowledge sharing and promoting good practice in HTA methods and processes.

Recently the ENCePP Health Technology Assessment (HTA) working group (WG) has been established. The WG has representation from academia, research centres, owners of healthcare databases and/or electronic registries and Contract Research Organisations encompassing pharmacoepidemiological expertise, real world observational research experience, knowledge and access to healthcare databases. The WG with support from the EMA and EUnetHTA will provide a forum for consultation, as appropriate, on the development of guidance including post-authorisation efficacy studies and HTA. This consolidated expertise is to be used to support further development of research resources and practices to conduct studies that potentially provide not only new safety data but also concurrent evidence of effectiveness for marketed medicines.

The ENCePP WG on HTA has the potential therefore to become a capacity bridging tool for regulatory and HTA agencies to develop research structures aimed at generating complementary evidence. Through research infrastructure development it creates a real possibility to improve timely access to effective medicines and reduce sponsor costs.

Remit of the ENCePP HTA WG

The WG will inform, where applicable, future activities of ENCePP in terms of health technology assessment with areas of focus including:

- Exploring the capacity bridging for post marketing studies of health technologies which supplement the efficacy and safety aspects of medicines taking account of existing guidance
- Enhancing the generation of additional evidence for HTA processes through research practices
- Providing a forum of academics and service providers for consultation on relevant guidance
- Responding to specific queries on HTA from the ENCePP Steering Group

Areas of collaboration

Two main areas for initial joint working have been proposed

- Development of ENCePP Research Resources Database to include details of expertise and resources to conduct studies for HTA
- Development of a concept paper on current practices in research for HTA

For more information contact the Secretariat at encepp_secretariat@ema.europa.eu