EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 659

PHARMACEUTICAL COMMITTEE
26 March 2014
72nd meeting

SUMMARY RECORD

The Pharmaceutical Committee held its 72nd meeting on 26 March 2014, in Brussels, chaired by Sabine Jülicher, Head of Unit SANCO D5 - *Medicinal products – authorisations, EMA*.

Agenda

- **The draft agenda (PHARM 640) was adopted, with two additional items under A.O.B.**

1. Interpretation of Pharmaceutical legislation

➢ 1a) Ongoing court cases

The Commission called the Committee's attention to some pending cases as well as recent rulings of the European Court of Justice and the General Court, especially:

- Case C-512/12, judgment of 13 March 2014 (Octapharma France)

➢ 1b) Off-label use

Commission services presented the document PHARM 655. Member States welcomed the Commission's approach and thanked for the initiative to launch such a study. They emphasised that the off-label use should not as such be seen as negative (referring in particular to paediatric use). It was underlined that in most Member States, it is a national issue, which implies the physicians' decision. Safety was mentioned as an important factor to be considered, but also the cost, which is part of the public health policy. Commission services clarified that they have no prejudged idea on the outcome of the study, which can vary from exchange of best practices between Member States to a more formalised way forward. Member States identified hospitals and pharmacies practices as elements to be considered. Moreover, the study should look into the practices of the marketing authorisation holders that do not extend their marketing authorisation.

EMA proposed to support the work to be carried out through its existing working parties (patients' and consumers' WP, healthcare professionals' WP and pharmacovigilance inspection WP) as well as through the SmPC advisory group which is currently working on a reflection paper on the way to refer to off label use in the PIl and SmPC (in the context of the new pharmacovigilance legislation). EMA also proposed to limit the definition to 'intentional use', in order to distinguish from medication errors.

2. Implementation of Pharmaceutical legislation

➢ 2a) Identification of biological medicinal products - Implementation of Article 102(e) of Directive 2010/84/EC-International Nonproprietary Names (INN) for biosimilar medicinal products

The European Biopharmaceutical Entreprises (Ebe) sent to the European Commission a survey claiming that many Member States have not complied with the obligations to ensure the proper identification of biologicals, as vested in Article 102(e) of Directive 2001/83/EC. On the basis of the survey and the written replies from the Member States, the Commission summarised the situation:

- About 10 Member States have completely transposed Article 102(e) in the national law and have also adopted a number of measures to ensure identification of biologicals (e.g. reference

to good pharmacovigilance practices, specific forms to submit the name and the batch number of the biological, Q&A document);

- About 10 Member States have transposed Article 102(e) but were identified by Ebe as having failed to adopt specific measures. These Member States have replied to the Commission to highlight the measures in place to identify biologicals e.g. education programmes for pharmacists, traceability of biologicals in databases, procedure to go back to the healthcare professionals to obtain the batch number if not available.

- About 8 Member States have not yet replied to the European Commission. It is therefore not possible to take stock of the situation in these MS. The Commission will send again the information by email and invite these Member States to respond to the Commission.

One Member State suggested restricting the identification for certain types of biologicals. However, the legislation does not provide any flexibility to waive certain biologicals. The Member State also asked what measures would be accepted by the Commission to implement the Directive, and whether non-legislative measures would be sufficient for certain medicinal products. The Commission explained that it should be possible to identify all biological medicinal products. The means to do so could vary.

- **2b) Relation between pharmaceuticals regulatory framework and timely access of medicines to patients: Reflection on difficulties and opportunities**

The Commission initiated a reflection process with the Member States on the link between pharmaceuticals regulatory framework and timely access of patients to medicines. The right balance between the need for an evidence-based proof of safety and efficacy of a new medicinal product and the timely availability of promising new therapies to patients is as old as the pharmaceutical legislation. Over the years flexibility has been built in the existing authorisation system in order to facilitate early access of patients to medicines with an accelerated assessment procedure and by means of conditional authorisations and authorisation under exceptional circumstances on the basis of less complete data, in order to address unmet medical needs. In addition the pharmaceutical legislation provides the possibility to make medicines available to patients before a Marketing Authorisation is granted, on grounds of compassionate use and treatment on a 'named-patient basis'.

Despite the measures which are already in place the issue of earlier access to innovative medicines for patients continues to be raised. In particular adaptive pathways to licensing of medicines are discussed and EMA initiated on 19 March a pilot project on adaptive licensing (AL) in order to gather sufficient knowledge and experience, address a range of technical and scientific questions and further refine how the adaptive licensing pathway should be designed for different types of products and indications: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/03/news_detail_002046.jsp&mid=WC0b01ac058004d5c1

Adaptive licensing is defined as a prospectively planned process, starting with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorisation to expand access to the medicine to broader patient populations.

In addition to technical and scientific aspects, the adaptive licensing involves important legislative and policy aspects which need to be thoroughly considered. The Commission therefore initiated the reflection process with the Member States in the Pharmaceutical Committee in order to better examine the relation between pharmaceuticals regulatory framework and timely access of medicines to patients, in particular with respect to adaptive licensing. More specifically this discussion should focus on the following issues:

1. Analyse the perceived problem of early access of patients to innovative medicines and the reasons for it and to what extent they are related to marketing authorisation procedures or other policy areas

2. Examine whether current approaches to marketing authorisation meet the objective to ensure timely access of patients to new medicines

3. Study if there are ways to improve the situation within the current legal framework

4. Analyse the perceived merits and weaknesses of an adaptive licensing approach from the regulatory/policy point of view, including the acceptable levels of uncertainty, possible change of paradigm and the consequences of shifting evidence gathering to the post-authorisation phase

5. Examine how AL fits within the current legal framework and principles of legislation

6. Consider whether any action would be useful or necessary

Some Member States have in place or are taking measures to ensure early access of patients to innovative medicines. A Member State expressed the view that the Pharmaceutical Committee may not be the right forum for such a discussion.

Member States were asked to give their comments and proposals on the issue, in particular the 6 points mentioned above, and inform the Commission about any studies that have been carried out on this topic or actions considered or taken at national level to ensure timely access of patients to medicines, by 15 June 2014. The issue will be discussed at the next Pharmaceutical Committee together with the possibility if necessary to create an ad hoc working group on this issue.

- **2c) Penalties**

The Commission reminded the Committee that in October 2012 the first ever penalty procedure under Commission Regulation 658/2007 was initiated against a marketing authorisation holder for centrally authorised products. Such procedure may lead to the imposition of financial penalties on companies in case of issues of non-compliance with obligations under EU pharmaceutical law. Any decision of the Commission is preceded by an investigation conducted by the European Medicines Agency. The results of the investigation are reported to the Commission and the marketing authorisation holder, but also to the Member States (via the Permanent Representations).

Member States were reminded of the principles of confidentiality and professional secrecy that apply to any document received in the context of such procedure and should consider

appropriate handling restrictions. The EMA representative explained that Member States are likely to receive information from the EMA on the particular case in the course of April.

- **2d) 2015 – 50 years of Pharmaceutical legislation**:

2015 will mark the 50th birthday of the Pharmaceutical legislation (Directive 65/65). The Commission plans to organise a conference in Brussels to mark this occasion, but also invited Member States to consider communication activities.

As regards such activities Member States were asked to share any information with the Commission (via sanco-pharmaceuticals-D5@ec.europa.eu).

- **2e) Update on the implementation of Directive 2011/62/EU (Falsified Medicines Directive)**

The Committee was informed that the Commission is preparing to refer the 4 Member States that have not yet transposed the Falsified Medicines Directive (FMD) to the European Court of Justice for penalties. The Commission also requested Member States which have not yet done so to send in their notifications pursuant to Art. 117a of Directive 2001/83/EC.

On the application of the FMD the Commission representative provided some clarification as to its application for traditional herbal medicinal products with regard to the legal basis for inspections and the possibility for the Member States to establish sanctions. Furthermore, the Spanish request to reconsider the answer provided on distribution from free warehouses and free trade zones was noted and clarification on the background for the answer was provided with reference to the scope of the Directive 2001/83/EC, as amended.

On the rules for importation of active substances from third countries, the Commission communicated which Member States have notified their intention to apply the waiver 2 (Art. 46(b)(4) of Directive 2001/83/EC) and confirmed that GMP non-compliance statements in the publicly accessible EudraGMDP database supersede any written confirmation issued for the same site.

On the delegated act on the safety features, the Commission outlined the outcome of the impact assessment exercise to the Committee. The Commission will now proceed with the drafting of the delegated act in line with the results of the impact assessment, in consultation with the Member State expert group on the delegated act on the safety features.

One Member State asked for the possibility for pharmacies to verify and check out medicines when these enter the pharmacy, rather than just before dispensing them to patients. The need for national competent authorities to get full access to the repository system was also stressed. A request was made so that only price would be considered when assessing the risks of falsification of a medicinal product in order to establish which medicinal products should bear or not the safety features. The Commission pointed out that the criteria for assessing the risks of and arising from falsification are set in the Directive.

The Commission also updated Member States on the work on the logo for online medicines. The Commission is considering consulting the Standing Committee via written procedure.

- **2f) New Regulation on clinical trials, update from the Commission and EMA**

The Commission informed the Committee about the adoption status of the new Regulation on clinical trials: it is expected to be formally adopted by the Co-legislators and published on the Official Journal of the European Union before the summer.

The Committee was also informed that the new Regulation will require Member States to appoint a unique contact point to be communicated to the Commission and EMA. Member States are invited to initiate the internal consultations in view of these appointments.

EMA also gave an update on the ongoing Member States Exeprt Group workshops organised by EMA to prepare for the development of the Clinical Trial Portal and Database.

- **2g) Good Manufacturing Practice (GMP) Guide**

The Commission had consulted the Pharmaceutical Committee on a proposal for revision of "Chapter 6: Quality Control" and on an editorial change to "Chapter 2: Personnel" of the EU GMP Guide; both of which were supported by the Good Manufacturing and Distribution Practice Inspectors Working Group (GMCP IWG). The Veterinary Pharmaceutical Committee has been consulted by written procedure.

The Commission had received no comments from neither committee in writing and no comments were raised in the meeting.

The request to clarify in the introduction the application of the chapter to the EEA in a future revision of "Chapter 2: Personnel" was noted by the Commission.

3. Pharmacovigilance

- **3a) Delegated Act on Post-authorisation efficacy studies**

The Committee was provided with an update on developments regarding the delegated act on post-authorisation efficacy studies. Since the October 2013 meeting of the Pharmaceutical Committee, the Commission has adopted a delegated act based on the advice received during discussion with experts nominated by Member States and EMA. In accordance with Article 290 TFEU, the delegated act will only enter into force if neither Council nor Parliament raise any objections. This scrutiny period ends beginning of April. In case of no objections the act will subsequently be published in the Official Journal of the European Union and enter into force within three weeks of publication.

- **3b) Regulation on fees for Pharmacovigilance and revision of EMA fees**

The Commission gave a short update on the procedural aspects of the legal proposal on fees for pharmacovigilance.

4. Legislative issues

➢ Paediatrics: Best practices to promote at national level clinical trial research with children

Several delegations and the EMA reported initiatives that have been taken to stimulate clinical research in children and to provide information about such research to the public (patients, parents) and sponsors. Activities in this area are considered important to address recruitment issues, which many paediatric trials face. Experiences and best practices in some Members States may encourage other Member States to consider similar activities. A summary of the reported initiatives is annexed to this summary record. The Commission will further discuss the issue with the European Medicines Agency and its Paediatric Committee.

5. International developments

➢ 5a) International Pharmaceutical Regulators Forum (IPRF)

The Commission provided information on the first full meeting of the International Pharmaceutical Regulators Forum which took place on 1 November 2013, in Osaka, Japan. It was explained that the IPRF already existed but under a different format known as "Regulators Forum" whose meetings were organised in parallel with the ones of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In addition, in December 2013 the International Coalition of Medicine Regulatory Authorities (ICMRA) was established.

In accordance with the Commission's aim at increasing not only the access to information but also the involvement of the Member States in the activities of the IPRF in a more structured way, the creation of a specific IPRF sub-group was proposed. This sub-group, with members from the Member States, the Commission and the EMA, will have access to the working documents, be consulted on written contributions and hold teleconferences in order to discuss important developments in the IPRF. An agreement on the creation of the group was reached and the Commission services will proceed with its establishment.

However, concerns were raised by Member States with regard to the membership of this specific IPRF group and the contact points. The Commission recognised the need to define this group and its members in a more detailed way.

On the question on the participation in the Technical Expert Group on Biosimilars, the European Medicines Agency clarified that the European Union is represented with two experts appointed by Germany and Austria.

The next meeting of the IPRF will take place in June 2014, in the United States of America

➢ 5b) Transatlantic Trade and Investment Partnership or TTIP

The Commission provided a state-of-play of the 4th round of negotiations that took place in Brussels on 10-14 March 2014. The main topics under discussion are GMP inspections, biosimilars, generics, transparency of clinical trial data, and pricing and reimbursement.

The objectives of the next steps (i.e. rounds in May, July and the September Stock taking) were presented.

Concerns were expressed on the real added value of the TTIP which could end up being a prolongation of the existing cooperation between the EMA and the Food and Drug Agency (FDA). The Commission was also asked whether the area of mutual recognition of marketing authorizations and IPR issues/patent protection will be explored. The Commission services clarified that the marketing authorizations are not part of the negotiations but hopefully an overall positive and ambitious outcome will be achieved through the TTIP.

- **5c) International Nonproprietary Name (INN) for biosimilar medicinal products**

The Commission updated the Committee on the latest developments prior to the next meeting of the INN Expert Group 7-10 April 2014 in Geneva. The purpose of the Biological Qualifier (BQ) is to avoid different national or regional schemes for identification of biosimilars. Apparently, the INN policy will remain unchanged and the BQ will not be part of the INN as such. The BQ would be voluntary and could be used for the purposes suitable to the needs of the regulator in question. It is not clear if the BQ would be for biosimilars only or for all biological medicinal products.

Concerns were expressed about the risk that the BQ would hinder uptake of biosimilars in EU and that the BQ would not be necessary in the EU. It was suggested that the problem would lie with the reporting parties which do not always provide all information necessary for an unambiguous identification. The introduction of an additional voluntary parameter to the INN would not solve this basic problem. Questions were also raised about the membership of the INN Expert Group. The Commission will reflect on the possibilities to make the EU point of view heard in the expert group.

6. A.O.B.

- **6a) Consultation of Standing Committee**

The members were reminded of their obligation and right to be consulted for certain draft Commission Implementing decisions by written procedure. In 2012 the Commission sent a letter to the Permanent Representations explaining the situation. The members were asked once again to confirm whether the functional mailboxes used are actively checked and report any problems.


Letter to ambassadors on writt


Letter to ambassadors on writt

- **6b) Update on the availability of medicinal products study**

The Commission reminded the Committee members to send comments to the external study on availability. A summary of the comments will be presented by the Commission to the

Committee at the next meeting. The comments will be published thereafter with the study report.

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The next meeting of the Pharmaceutical Committee (human) is **tentatively** planned for **22 October 2014. (no travel arrangements should be made until final date is confirmed by the Commission in September 2014).**

Annex

Paediatrics: Best practices to promote clinical trial research with children

Ireland

Molecular Ireland and the Irish Platform for Patient Organisations, Science & Industry (IPPOSI) to better inform patients/public about clinical research. They have developed a website in this regard: www.clinicaltrials.ie. Part of this website which is still in development informs children about research. This is the link to the website: http://clinictrials.scoilpac.com/.

Sweden

The Swedish government adopted a National Strategy for Medicines to be carried out by several health authorities over a period of 3 years (2011 – 2014). Within the strategy there are several priority areas, one of which is dedicated to paediatric medicines, entitled Expanding the knowledge of paediatric medicines and their use which has been assigned to the Medical Products Agency.

Whereas the assignment includes several activities, such as fostering safer handling of medicines in paediatric care, identification of therapeutic areas with insufficient evidence in paediatrics, compilation of existing evidence and best practice in paediatrics, performing inventories of paediatric use of medicines etc, the need for more clinical trials in children and adolescents has also been identified. Identification and recruitment of children or adolescents with a certain disease/diagnosis into a clinical trial remains a challenge for a country with a limited population, and therefore, networking is of particular importance. The Medical Products Agency is currently taking an active interest in the development of national and Nordic networks supporting clinical research concerning medicines for children in the Nordic countries.

France

Entre 2009 et 2012, des réunions visant à optimiser la coordination et le partage d'information et d'outils existants ont été organisées par l'ANSM, regroupant des représentants d'associations de patients et de sociétés savantes, des institutions publiques (CENGEPS, INSERM, INCA…), des réseaux d'investigation cliniques, des praticiens hospitaliers et des représentants de l'industrie pharmaceutique. Un état des lieux a été dressé et un "Manuel Opératoire Qualité de la Recherche Clinique", clarifiant la réglementation tout en restant didactique, réalisé et utilisé dans un des cancéropôles implantés en France, a été diffusé.

L'ANSM, dans le cadre de ses missions, peut financer des recherches scientifiques sur la sécurité d'emploi des produits de santé, indépendamment de l'industrie. Les projets soumis dans le cadre de l'appel à projets de recherche doivent apporter de nouvelles connaissances sur la sécurité d'emploi des produits de santé dans la vie réelle et doivent s'inscrire dans des domaines limités, dont l'analyse de la balance bénéfice/risque des produits de santé dans des groupes ou populations présentant une vulnérabilité et des risques particuliers. La recherche pédiatrique peut donc être potentiellement concernée.

Les comités d'éthiques nationaux devraient rendre des avis plus homogènes sur les protocoles de développement pédiatrique proposés, afin de rendre plus facile leur aboutissement.

Les associations de patients pourraient également apporter d'avantage leur contribution à l'application de la réglementation en facilitant l'inclusion des enfants (guide des consentements, cf. le livret développé en France par le CERPED sur l'information et le consentement dans le cadre des essais en pédiatrie, avec la contribution de l'Agence), ou en apportant des solutions pratiques, car de plus en plus les patients sont hospitalisés à domicile.

UK

The UK Government provides support for the NIHR Medicines for Children Research Network (MCRN), which provides infrastructure across all of England to aid the delivery of paediatric medicines studies although not direct funding.

From its establishment in 2006 to the end of 2013, the MCRN has supported a total of 280 industry studies, 61 of which were taken on in 2013. 209 public (academic/health service) studies have been taken on by the Network since 2006, 27 in 2013, with grants awarded under a number of European, UK and other research programmes (http://public.ukcrn.org.uk/Search/Portfolio.aspx?level1=4).

On its website (http://www.mcrn.org.uk/ MCRN published specific information for children and parents as well as industry. This includes a small video, in which two children report their experience with clinical trials: http://www.youtube.com/watch?v=KvamYWTDwQA&feature=player_embedded

Netherlands

To support studies in children, the Dutch Ministry of Health, Welfare and Sport has supported the set-up of a Dutch division of the Medicines for Children Research Network (http://mcrn.nl/).

Spain

The Spanish Agency of Medicines and Medical Devices co-organized recently a multidisciplinary workshop to identify main obstacles in Spain to clinical trials in neonatology and paediatrics. Main obstacles and potential solutions were:

(a) Financial obstacles.- Paediatric CT have an elevated cost due to difficulties in raising a needed sample size, need of high sensible techniques and sophisticated statistics. Clinical trials usually compete with routine health care. There are only a few CT sponsored by industry and few public funding for doing such research in academic or non-commercial settings.

> *The **Institute of Health Carlos III** (ISCHI) is part of the Spanish Strategy for Science, Technology and Innovation 2013-2020 and the State Plan for Scientific Research, Technology and Innovation 2013-2016. To implement such strategy, the ISCHI offers the Strategic Action for Health, which is proposed as a programmatic action whose activities are managed by the Institute, the policy of their own centres, foundations, networks and consortia. Scientific Platforms Services and Common Techniques, as well as concerts with the regional governments and other institutions (http://www.eng.isciii.es/ISCIII/es/contenidos/fd-investigacion/planificacion-2.shtml).*
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> *Especially relevant is the **Spanish Clinical Research Network** (SCReN) whose objective is funding of collaborative network structures in specific transversal areas like paediatrics and/or neonatology. This Network, supported by the ISCHI, will promote clinical research and its projection into healthcare innovation, contribute to solving clinicai problems, and promote national and international collaborative activities.*

(b) Methodological obstacles: Recruitments are slow in paediatric CT, obtaining informed consent is sometimes difficult, and long periods of follow-up are needed in these population. Approval is sometimes delayed due to regulatory overload. Alternative designs to CT have not been completely explored. As a result of the lack of information about ontogeny and maturation processes as well as evolution of diseases, needs for sophisticated statistics methods are necessary. There is also a need of non-invasive techniques for obtaining samples.

> *Development of a **Hospital Network of Excellence for Paediatric CT** with strong relationships with International consortiums (European Network for Paediatric Research at the European Medicines Agency), conducting national or international clinical trials funded by public competitive calls, designing projects for the Network, contacting and validating project with officials at the national and European level...*

(c) Regulatory obstacles: Multiple evaluations by ethics committees and regional agencies with a high level of premature abandon of the CI. Need of expertise in ethics committee, continuity of research groups.

> *The Spanish Agency of Medicines and Medical Devices (AEMPS) is preparing a **new national regulation** that, besides European regulation, simplifies authorization*

processes by the AEMPS and Ethics Committees, recognize academic and non-commercial research and exempts them for fees, redefines the role of Ethics Committees including among their members paediatricians and other experts, as well as patients. The AEMPS have also an ***Office for helping and promoting non-commercial investigation.*** *Finally, the AEMPS has settled the* ***Spanish Registry of Clinical Studies*** *publishing in its website all CT authorized in Spain. The AEMPS is also in charge of classifying observational studies with medicines and will promote the development of observational studies and data collection strategies to improve the information available on the efficacy and safety of off-label uses in children (http://www.aemps.gob.es/investigacionClinica/medicamentos/oficinApovo.htm)*

(d) Logistic obstacles: lack of labour recognition or integrity of health care/research structures, interference of CT with scholarship of children and work of parents, lack of paediatric formulation, biological samples recollection.

The collaboration of ***transversal health professional societies*** *(clinical pharmacologists or hospital pharmacists) has been achieved in order to save costs and internalize some research activities like manufacturing, conditioning and labelling, distribution and/or formulation.*

(e) Social perception: Misinformation of society in general and parents in particular on research activities and CT in Spain, resulting in fear of children and their parents to participate. There is no awareness of the huge number of medicines in which there are no data on efficacy and safety in children. The image of vulnerability and the actual vulnerability of children makes participation in trials were initially rejected. Parents of children with severe diseases use to collaborate but it is not the same case for parents of children with milder diseases.

The AEMPS will set up an annual multidisciplinary workshop to assess how the things progress making public documents that contribute to surpass barriers in paediatric investigation.

Italy

The Italian Medicines Agency is finalizing a communication campaign dedicated to the correct use of medicines in children that is scheduled to be launched in next June and in Autumn on all the media (billboards, tv, radio, press, etc.). The campaign is part of a scientific project primarily aiming at disseminating the correct information among general public and healthcare professionals on the medicinal products that are authorized for paediatric usage and those that are not and therefore to discourage the inappropriate use in children of medicines authorised only for adults. As a second step of this awareness campaign, the other message that is intended to be circulated is on the promotion of the clinical trials in the paediatric population in order to increase the amount of medicinal products tested in children and approved for them.

The campaign will be supported by a dedicated website where a database on medicines classified in “in-label” and “off label use” for children will be also available.

Austria

In 2013, as part of a public-private partnership between the health ministry, academia and the industry, Austria has created OKIDS (‘Organisation Kinderarzneiforschung’). OKIDS is a network for the development of medicinal products for children in Austria and intended to offer several services for the conduct of paediatric trials, including a ‘one stop shop’ for trial sponsors, sufficient resources and know-how, predictable patient recruitment.

The website set up to support the project also provides information for children and patients: http://www.okids-net.at/Seiten/Kinder-Familie.aspx.

European Medicines Agency

The European Network for Paediatric Research at EMA (Enpr-EMA) has conducted a survey among its members to obtain information on involvement of young people and families in the Enpr-EMA networks: http://www.emea.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000303.jsp&mid=WC0b01ac05801df74a

Involvement of young people and families in the Enpr-EMA networks Engaging and involving young people and family members in clinical research has many benefits, including greater understanding of young people’s perspectives, and improvements in study design and the quality of clinical research.

Additionally, the European Agency is currently considering some communication activities on the basis of experience with a similar campaign regarding the black symbol (pharmacovigilance).