ERA-NET 2006

Coordination Action

PRIOMEDCHILD

Treat Your Children Well

"This is an excellent opportunity to combine European forces around a common agenda for medicines development, for one of the most important target groups, our children."

Please note that this fact sheet replaces the previous one, known as Priority Medicines and included in Series 1 of this publication.

Since children constitute one-fifth of the European population, their health and well being is an important factor in the future of a viable Europe. Yet, despite this fact, there has been inadequate research pertaining to medicine for children. In order to better ensure that children are treated with properly evaluated and effective medicine, research related to medicine for children needs to be improved. PRIOMEDCHILD is working towards building the European Research Area by establishing a European sub-area for the research, development and innovation of priority medicine for children, in order to boost the different types of medicine available specifically to this group.

This Coordination Action builds on the ERA-NET SSA Priority Medicines (FP6-2002-ERANET-SSA-Priority Medicines-003214), and the outcomes of the WHO study, Priority Medicines for the Citizens of Europe and the World.

Therapeutic medicine has made huge advances over the last century, as a result of a vast research effort. From aspirin to antibiotics, most of us regularly rely on medicines, and with the advent of functional genomics, the potential for new drug development has never been greater. But certain areas of medical research have received less emphasis. One case in point is research regarding new and better medicines for children. Publicly funded research has an important role to play in filling these gaps, partly to ensure that all social groups (including children, from birth to the age of 17) benefit from new technology.

To facilitate targeted research at European level, the Dutch Health Ministry and the Netherlands Organisation for Health Research and Development (ZonMw) have established the European Research Agenda of an ERA-NET on priority medicines for children. The aim is to network national programmes and programme managers in order to exchange expertise, set the European Research Agenda, and work towards a joint research programme to boost the number of medicines for children, that are both available and safely evaluated.

For children only

Priority medicines are those on which, from a public health point of view, research and development should concentrate. The Dutch Health Ministry commissioned the World Health Organisation in Geneva to compile a list of diseases urgently requiring medicines in Europe and the rest of the world. The need for new and improved medicines for children was seen as a major issue across pertinent disease categories. Some of these include infectious diseases, asthma, mental disorders and obesity. It is evident that children are subject to many of the same diseases as adults, and are subsequently treated with the same drugs. This poses a serious problem, since children should not be treated as small adults regarding pharmacotherapy. They differ from adults in pharmacokinetic, dynamic and toxicological aspects, as well as in their adherence to the therapy, effectiveness and safety of medicines used. Additionally, numerous medicines used on children are not licensed, or are prescribed off-label, which can consequently place children at risk of underdosing or overdosing, or create a delayed risk of long-term adverse effects.

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"The concepts that are developed in this project might well be suitable not only for European children, but for all children in the world, for instance where poverty-related diseases are at stake."

Full title:
Coordination of research on priority medicines for children

Research field:
Priority Medicines

Coordinator:
The Netherlands: The Netherlands Organisation For Health Research And Development (ZONMW)

Partners:
- France: The National Institute For Health And Medical Research (INSERM)
- Institut National de la Santé et de la Recherche Médicale)
- Italy: The Italian National Institute Of Health (ISS)
- Poland: The Polish Ministry Of Education And Science (MES), Department of European Integration; Children's Memorial Health Institute
- Sweden: The Swedish Research Council (SRC)
- Spain: The Institute Of Health Carlos III (ISCIII)
- United Kingdom: The Medical Research Council (MRC)
- Estonia: The Estonian Science Foundation (ETF)

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Coordination of Research Activities
http://www.cordis.lu/coordination/home.html

There is a 25% to 50% incidence of unlicensed drug use in children. In the case of off-label drug use, the range lies between 15% and 40%. This is most common in treatment for neonates. For example, in intensive care units, 90% of babies receive an unlicensed off-label drug. Antiobiotics and vitamins are the most widely used off-label medicines in this group.

Eliminating obstacles

There is clearly a lack of data regarding research for drug treatment in children; moreover, safe drug treatment in children cannot be linearly abstracted from adult data. There are many obstacles for those wishing to conduct research in relation to children. These include financial, ethical and practical issues, not to mention the general resistance to the participation of minors in research. If children are to be treated with sufficiently evaluated and effective medicines, research in medicines for children must be vastly improved. Furthermore, to reduce the burden of childhood diseases, it is crucial that they are recognised as an important cause of morbidity, economic cost and mortality worldwide.

A coordinated European research approach to the issue of medicines for children, is an important step towards creating the appropriate framework and stimulating specific areas of need. Indeed, it has been proven numerous times in the past, that clinical trials specifically for children have resulted in a significant improvement in child medication.

A healthier future

This new proposal focuses on the challenges ahead for paediatric medicines research. Due to the attention focused on priority medicines in general, and the more recent focus on priority medicines for children, public research programmes on these and related issues are now rapidly developing in many European Member States.

PRIOMEDCHILD will contribute to the strengthening and streamlining of these national activities. The project will also facilitate public and private cooperation on a European scale, by coordinating and developing public research programmes based on public health priorities, and aligning them with industrial efforts in this field. In addition, the European regulation on Medical Products for Pediatric use passed in 2006 will facilitate the development of medicines for our kids.

Research into determining more effective medicines for children has far-reaching potential impacts, including a better understanding of the effects that medicine use by pregnant women has on unborn children. The PRIOMEDCHILD consortium has planned awareness-raising strategies to inform target groups and the general public of the results of its findings; the final outcome of these activities will contribute to a healthier future for our children.