CORRESPONDENCE

Off-label Use of Prescription Drugs in Childhood and Adolescence–an Analysis of Prescription Patterns in Germany

by Prof. Dr. med. Bernd Mühlbauer, Dr. rer. pol. Katrin Janhsen, Dr. hum. biol. Josef Pichler, Dr. rer. nat. Petra Schoettler in volume 3/2009

The Doctor Is Responsible

The doctor treating a minor is obliged to inform the parents or their representatives if he is using a drug "off-label". Even if he believes that he has adequate information about possible risks for the individual underage patient, it is only possible in exceptional cases for him to obtain the necessary "informed consent" for studies on efficacy, safety and dose finding.

These days, both the public and doctors expect that manufacturers will only include recommendations in their summaries of product characteristics for which there are clear supporting data. It would be desirable for the summary of product characteristics to refer to published scientific data or to provide the data if requested. As no placebo-controlled studies on pregnant women or children have been performed for most available drugs, manufacturers are obliged to state that they cannot be used in this context.

The doctor retains responsibility for the treatment he provides, whatever his legitimation or knowledge. This may have serious consequences, both after treatment or if no treatment is provided. This problem cannot be solved by the manufacturer either. Even the valuable efforts of Dr. Seyberth (1, 2) and the German Society for Pediatrics and Adolescent Medicine (3) remain wishful thinking, as long as there are no evidence-based data available. Any legal regulation would be of little or no use. We must therefore search for new approaches for "drug studies" and drug approval for the unborn, neonates, babies, infants and schoolchildren.

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The author declares that no conflict of interest exists according to the guidelines of the International Committee of Medical Journal Editors.

In Reply:

One has to agree with Dr. Helwig's plea. There can be no reliable information on the benefit and risk of a drug in the target population unless there are data from well controlled studies. For many years, almost all participants—the registration authorities, pharmaceutical companies, pediatricians and the parents of sick children—have offered an enormous variety of excuses for not demanding, performing or supporting good study projects. Good clinical research can cost much less than is usually thought, as can be seen in the pediatric study projects supported by the HEXAL initiative for pediatric medicines (1).

As already mentioned in article (2), a new ordinance came into force in the European Union in 2007 (Regulation [EC] No. 1901/2006; http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm). The elements of this are intended actively to support clinical research on children. We must hope that the planned or already introduced measures will not be structured in such a clumsy manner that years will have to pass before data on pediatric drugs will attain a standard which is regarded as a matter of course for most indications in adult medicine.

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