

From: Oreste Battisti
Sent: Thursday, November 15, 2012 3:23 PM
To: SANCO PHARMACEUTICALS D5
Subject: EMA paediatric questionnaire

Dear,

hereby we give our opinions concerning the pediatric regulation on drugs.

We give our opinions concerning neonates and children being treated in obstetrics, neonatal, pediatric, emergency and ambulatory wards.

1. We agree that pediatric regulation has paved the way for pediatric development, making an integral part of the overall product development of medicines in the European Union.
2. We also can say that too few pediatric investigations have been completed, and that is due to the too recent regulation, the lack of funding for research and the long development cycles of medicinal products, even more curtailed due to secondary concluded effects.
3. In terms of "output", the PUMA (pediatric use marketing authorisation) is disappointing for the percentage of on-label pediatric drugs remains around 10%.
4. Through that, the pediatric obligations have no impact on timelines in adult development, as there is no evidence for delays in marketing authorisation applications for reasons of compliance with the pediatric obligation.
5. As pediatric development is in fact dependent on adult development and even this is in a difficult position, the pediatric needs will and are very slowly encountered and attained.
6. A more adequate research and greater and more funding for this research, balanced between animal models and human beings should improve the situation.
7. All these facts, together with an insufficient receptive healthcare professional part, is actually perhaps a resistance to the development of pediatric pharmacology.
More trials are needed.
8. We suggest to focalize the efforts on 2 demanding populations:
 - one concerning those in the perinatal life (and this is concerning the pregnant, the fetus and the neonates),
 - and those in pediatric intensive care.

Sincerely,

Oreste Battisti, MD, PhD
Academic Professor of Pediatrics and neonatal medicine
Faculty of Medicine University of Liège
visit "orbi.ulg.ac.be"