

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 obstrtrics, neonatal, pediatric, emergenyc and ambulatory wards.

1. We agree that paeditaric regulation has paved the way for paediatric development, making an integral part of the overall product development of medicines in the European Union.
2. We also can say that too few paediatric investigations have been completed, and that is due to the too recent regulation, the lack of fundinf for resaerch and the long development cycles of medicinal products, even more curtailed due to secondary concluded effects.
3. In terms of "output", the PUMA (paediatric use marketing authorisation) is disappointing for the percentage of onlabel paediatric drugs remains around 10%.
- 4.Through that, the paediatric 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 paediatric obligation.
- 5.As paediatric develoment is in facts dependent on adult developemnt and even this is in difficult position, the peadiatric needs will and are very slowly encountered and attained.
6. A mor adequate research and greater and more fundings for this research, balanced between animal models and human beings should improve the situation.
7. All theses facts, together with an insufficient receptive healthcare professionnal part, is actually perhaps a resistance to the developement of pediatrics 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 paediatric intensive care.

Sincerely,

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