Consultation in relation to the Paediatric Report

Ref. PCPM/16 – Paediatric Report

1. PART I - GENERAL INFORMATION ABOUT RESPONDENTS

Your name or name of the organisation/company: European Chiropractors Union: Baiju Khanchandani, DC, and Sue A Weber, BSc, DC, MSc

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Please indicate whether you are replying as:

- A citizen
- A business
- **A non-governmental organisation (NGO)**
- An industry association
- A patient group
- **A healthcare professional organisation YES**
- Academia or a research or educational institute
- public authority
- Other (please specify)

If you are a business, please indicate the size of your business

- Self-employed
- Micro-enterprise (under 10 employees)
- Small enterprise (under 50 employees)
- Medium-sized enterprise (under 250 employees)
- Large company (250 employees or more)

Please indicate the level at which your organisation is active:

- Local
- National
- Across several countries

- **EU YES**
- Global

2. PART II – CONSULTATION ITEMS

(You may choose not to reply to every consultation items)

2.1. More medicines for children

Consultation item No 1: Do you agree that specific legislation supporting the development of paediatric medicines is necessary to guarantee evidence-based paediatric medicines?

Yes we agree. Self-regulation was a lax approach which resulted into the dearth of adequate an appropriate research prior to the Paediatric Regulation of just 10 years ago.

A similarly creative approach needs to be implemented to encourage research into the use of Herbal Remedies which are also monitored by the EMA and other evidence-based and knowledge-based, approaches from other professions, for example chiropractors and naturopaths.

2.2. Mirroring paediatric needs

Consultation item No 2: Do you have any comments on the above? To what extent and in which therapeutic areas has the Regulation contributed to the availability of important new treatment options?

The consultation document admits the limitations of regulation in encouraging innovation in pharmaceutical approaches in some therapeutic areas. Innovation in these neglected areas could be achieved by other mechanisms.

The EU Expert Panel on Investing in Health (EXPH) has published opinions that offer ideas to promote innovation. One EXPH opinion is on **Competition**. Together with the OECD document, Enhancing Beneficial Competition in Health Professions is acknowledged as a driver of innovation in the economy in general and in health in particular. The IMF has highlighted competition and patient choice as the number one driver of efficiency in health systems (1.)

The EXPH opinions on Disruptive Innovation and Primary Care also suggest **increasing portals of entry to the health system** and with more varied gate-keepers. One example could be the introduction of primary care professional experts in musculo-skeletal and spine care in particular. Musculoskeletal conditions have been identified as a top health system priority by the Global Burden Disease project and the eumusc.net project.

Best practice in some countries includes the **integration of new and emerging professions into the health system** offering evidence and knowledge based approaches to health care, including manual care and advice on prevention and health promotion. For example, Denmark and Norway have integrated approximately 700 chiropractors into their health systems while Greece has less than two dozen operating outside the public health system. Health workforce innovation and regulation is used in some countries as a method in addition to pharmaceutical regulation to obtain benefits for health systems and children in particular.

(1)
The Economics of Public Health Care Reform in Advanced and Emerging Economies
Clements, Coady, Gupta International Monetary Fund, 2012

2.3. Availability of paediatric medicines in the EU

Consultation item No 3: In your experience, has the number of new paediatric medicines available in Member States substantially increased? Have existing treatments been replaced by new licensed treatments?

The number of new paediatric medicines has increased.

Some existing treatments have been replaced by new licensed treatments.

Some existing treatments have been replaced by other methods of care (see ref to Denmark and Norway in No. 2). There is a trend in some segments of society to avoid pharmaceuticals in children where possible and an increased emphasis on life-style choices (diet, exercise) while in other segments of society poor diet and lack of physical activity are on the increase, with consequent associated morbidities.

2.4. Reasonable costs

Consultation item No 4: Do you have any comments on the costs for pharmaceutical companies to comply with an agreed paediatric investigation plan?

The costs incurred by pharmaceutical companies are reasonable.

2.5. Functioning reward system

Consultation item No 5: Do you agree that the reward system generally functions well and that early, strategic planning will usually ensure that a company receives a reward?

The reward system functions well and should not be made too generous. Where a medicinal product is hugely profitable the money made is rarely capped in free-market advanced economies.

Government incentives to investment in pharmaceutical products distorts the economy; investment and growth in non-pharmaceutical approaches is disadvantaged.

2.6. The orphan reward

Consultation item No 6: How do you judge the importance of the orphan reward compared to the SPC reward?

No opinion

2.7. Improved implementation

Consultation item No 7: Do you agree that the Regulation's implementation has improved

over time and that some early problems have been solved?

The issue of improving children specific research to find pharmaceutical solutions has moved forward. Some of the early problems have been solved. However the issue of missed opportunities in non-pharmaceutical evidence based approaches has not been addressed. See comment on item No 8.

2.8. Waivers and the 'mechanism of action' principle

Consultation item No 8: Do you have any comments on the above? Can you quantify and qualify missed opportunities in specific therapeutic areas in the last ten years?

It is a good idea to waiver research where there is no benefit over existing treatments.

We wish to expand on beneficial non-pharmaceutical treatments and health care approaches. There is no obvious EU mechanism of incentives for non-pharmaceutical evidence and knowledge based approaches, which do have benefits over existing treatments. The Innovative Medicines Initiative (IMI) and the Future Emerging Technologies (FET) projects, together with Paediatric Regulation offer an incentive and regulatory framework for pharmaceutical and technological advances. There is little similar for evidence and knowledge based approaches which are or may be of benefit over existing treatments. This is a neglected area with missed opportunities, where a Future Emerging Professions project may aid the identification and spread of best practice in the utilisation of new and emerging professions.

Examples of areas of opportunity, often non-pharmacological, are articulated here below:
27 October 2016 EMA/231225/2015
Human Medicines Research and Development Support Division 10-year Report to the European Commission General report on the experience acquired as a result of the application of the Paediatric Regulation1 Prepared by the European Medicines Agency and its Paediatric Committee

3.4. Addressing needs of neonates
Analysis by neonatal priorities
(Table 16. Agreed PIPs for additional neonatal indications)
Pain: before medication is prescribed for pain in neonates and children recommend a trial of :

- manual therapy for neonates/children to address biomechancial disorders causing pain
- milk and soy free diet for breastfeeding mother or formula for neonate in pain, and for the child with recurring stomach pain and/or constipation
- make available to families milk, soy and gluten free formulas at a reasonable cost, over the counter

For children not meeting their growth curves,

- recommend a trial of 4 weeks of milk and soy protein free diet.
- For children with a positive HLA-DQ8/2, recommend gluten-free diet

REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

Comments and references:

CHAPTER 2 Waivers Article 11 1. Production of the information referred to in point (a) of Article 7(1) shall be waived for specific medicinal products or for classes of medicinal products, if there is evidence showing any of the following: (a) that the specific medicinal product or class of medicinal products is likely to be ineffective or unsafe in part or all of the paediatric population; (b) that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations; (**c) that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients**. 2. The waiver provided for in paragraph 1 may be issued with reference either to one or more specified subsets of the paediatric population, or to one or more specified therapeutic indications, or to a combination of both.

Chapter 2, article 11, 1 c:

Treatment of GORD or reflux in the infant: before a trial of medication with proton pump inhibitor, the infant should have a 2 week trial of milk protein and soy protein free diet to see if symptoms resolve.

These milk, soy and gluten free formulas should be made available for families over-the-counter and at a comparable price to regular formulas.

Constipation in the infant or child: a 3 week trial of milk protein and soy protein free diet be assessed before prescribing medication.

Before prescribing medication for spinal pain or non-rheumatological joint pain in children, an assessment of function by a chiropractor and if appropriate a trial of chiropractic care should be made available and assessed.

Chapter 2, article 11, 1 a

Before prescribing any medication for excessive infant crying, a trial of paediatric chiropractic care be administered and assessed.

Communication and coordination

Article 43, number 2ù
2. In establishing the inventory of therapeutic needs, account shall be taken of the prevalence of the conditions in the paediatric population, the seriousness of the conditions to be treated, **the availability and suitability of alternative treatments for the conditions in the paediatric population**, including the efficacy and the adverse reaction profile of those treatments, including any unique paediatric safety issues, and any data resulting from studies in third countries.

Alternative treatments for spinal pain and joint pain to include chiropractic care before medication is prescribed.

Alternative treatment for the excessively crying infant is paediatric chiropractic care

Lifschitz & Szajewska. Cow's milk allergy: evidence-based diagnosis and management for the practitioner. Eur J Pediatr (2015) 174:141–150

DOI 10.1007/s00431-014-2422-3.

Dobson D, Lucassen PLBJ, Miller JE, Vlieger AM, Prescott P, Lewith G. Manipulative therapies for infantile colic. Cochrane Database of Systematic Reviews 2012, Issue 12. Art.
No.: CD004796. DOI: 10.1002/14651858.CD004796.pub2.

Ndetan H, Evans MW, Hawk C, Walker C. Chiropractic or osteopathic manipulation for children in the United States: an analysis of data from the 2007 National Health Interview Survey. J Altern Complement Med. 2012 Apr;18(4):347-53. doi: 10.1089/acm.2011.0268.
Epub 2012 Mar 2.

2.9. Deferrals

Consultation item No 9: Do you agree with the above assessment of deferrals?

We agree with the deferral policy.

2.10. Voluntary paediatric investigation plans

Consultation item No 10: Do you have any comments on the above?

The concept of rewarding pharmaceutical companies for voluntary paediatric investigation is good.

A similar mechanism needs to be studied and implemented to reward non-pharmaceutical, evidence and knowledge based approaches to paediatric health care.

2.11. Biosimilars

Consultation item No 11: Do you have any comments on the above?

No.

Lack of funding for non-pharmaceutical research may be an obstacle to researching these options.

2.12. PUMA — Paediatric-use marketing authorisation

Consultation item No 12: Do you share the view that the PUMA concept is a disappointment? What is the advantage of maintaining it? Could the development of off-patent medicines for paediatric use be further stimulated?

The PUMA concept could be expanded to include non-pharmaceutical interventions, such as herbal remedies (monitored already by the EMA) and food supplements. The PUMA "kite-mark" would be wider known in the general population and medical and health care community. The PUMA kite-mark would be better known and more useful for marketing too.

There should not necessarily be a need to charge a premium for the PUMA branding. While the prescribing medical practitioner may prescribe an equivalent non-PUMA product, there would still

be an opportunity at the level of the sale in the Pharmacy/Chemists for the serving pharmacist to encourage sales of PUMA marked products.

2.13. Scientifically valid and ethically sound — Clinical trials with children

Consultation item No 13: Do you have any comments on developments in clinical trials with children following the adoption of the Regulation and in view of the above discussion?

No comments.

2.14. The question of financial sustainability

Consultation item No 14: Do you have any views on the above and the fact that the paediatric investigation plan process is currently exempt from the fee system?

A perusal of the company reports over the last decade documents the profits made and dividends paid by pharmaceutical companies. It would be legitimate to introduce a fee system.

It would also be legitimate to widen the search for appropriately qualified experts to appoint to the Paediatric Committee. The approach used to involve Civil Society to recruit members to the EMA Herbal Medicine review process could be used as an example.

2.15. Positive impact on paediatric research in Europe

Consultation item No 15: How do you judge the effects of the Paediatric Regulation on paediatric research?

In essence, it is early days. 10 years is not a long time. More needs to be invested in prevention, and the field of non-pharmaceutical approaches to musculoskeletal disorders.

There has been little or no impact of the Regulation on prevention and health promotion. Pharmaceutical prescription is not always the first line choice of therapy according to the evidence (2, 2a). Yet pharmaceuticals are often the therapy of first choice.

The EU needs to provide incentives for an integrative health care approach and correct framing of any pharmaceutical intervention as much as seeking to improve paediatric pharmaceutical regulation.

(2) Exercise as medicine - evidence for prescribing exercise as therapy in 26 different chronic diseases; Pedersen, Saltin; Scand J Med Sci Sports 2015: (Suppl. 3) 25: 1–72 doi: 10.1111/sms.12581 http://onlinelibrary.wiley.com/doi/10.1111/sms.12581/epdf

(2a) Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Qaseem A, Wilt TJ, McLean RM, Forciea MA; Ann Intern Med. 2017 Feb 14. doi: 10.7326/M16-2367. [Epub ahead of print]

2.16. "Mirror, mirror on the wall" - Emerging trends and the future of paediatric medicines

Consultation item No 16: Are there any emerging trends that may have an impact on the development of paediatric medicines and the relevance of the Paediatric Regulation?

Emerging health care trends include a predictive, preventive, personalised, patient-centred approach. These emphasise a non-pharmaceutical approach to health care, which can frame and enhance the effect of any pharmaceutical intervention.

The brain based paradigm in health care is coming to the fore, promoted by a variety of stakeholders ranging from the European Brain Council to new and emerging professions such as chiropractic.

Emerging trends including but not limited to screen use of children of all ages needs to be addressed from a biomechanical point of view to reduce future disability of neck and back pain. Interventions geared towards ergonomics, posture and guidelines for healthy screen time, sleep time, and movement time are needed. These measures have the potential to reduce spinal pain and further reduce opiate dependence in future generations.

The emerging trend of obesity is important from a musculo-skeletal perspective. These children have abnormal movement strategies and are at risk for future musculoskeletal complaints and disability, again a risk for opiate dependency with over prescription of medication. Exercise forms which do not strain the joints and classes aimed at teaching proper movement strategies should be a focus (3).

The trend of over training the developing child who is not skeletally mature results in spinal injury, pain and future disability (again risk for opiate addiction). Intervention on an international level would level the playing ground. Making guidelines based on skeletal development to aid coaches and parents could reduce spinal injury in this subset of children (4).

Preventive and patient-centred care and the advancement of the brain based paradigm together an emphasis on knowledge-based approaches including manual care will impact the development of paediatric medicines.

Another important trend includes the health workforce. This has been studied by the WHO and OECD and more recently by the EU Joint Action on Health Workforce planning. Demographic pressures mean the health sector will suffer competition for workers from other economic sectors. And within the health sector many countries face a shortage of paediatricians.

One solution, echoed by the EU Expert Panel on Investing In Health, is to expand the types of health care operators offering primary care, including paediatric care. This has been done with some success in Denmark and Norway as illustrated in an earlier reply. Together with an increase in digital literacy in the general population, wider access to health information and options of care, and a trend away from a purely pharmaceutical approach, together with a declining birth rate, paediatric pharmaceutical approaches will face increasing competition from other, often more efficient health care and life-style approaches.

3. PROFILING MOVEMENT QUALITY AND GAIT CHARACTERISTICS ACCORDING TO BODY-MASS INDEX IN CHILDREN (9–11 Y). CLARK C, BARNES C, HOLTON M, STRATTON G. HUMAN MOVEMENT SCIENCE 2016. 49:291-300. DOI: 10.1016/J.HUMOV.2016.08.003
4. THE ROLE OF INTENSE ATHLETIC ACTIVITY ON STRUCTURAL LUMBAR ABNORMALITIES IN ADOLESCENT PATIENTS WITH SYMPTOMATIC LOW BACK PAIN. SCHROEDER GD, LABELLA CR, MENDOZA M, DALEY EL, SAVAGE JW, PATEL AA, HSU

WK. EUR SPINE J. 2016 SEP;25(9):2842-8. DOI: 10.1007/S00586-016-4647-5.

2.17. Other issues to be considered

Consultation item No 17: Overall, does the Regulation's implementation reflect your initial understanding/expectations of this piece of legislation? If not, please explain. Are there any other issues to be considered?