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National Assembly for Wales
Children, Young People and Education
Committee Inquiry into Children's rights in
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Response from: Noah's Ark Children's Hospital
for Wales

Access to medicines and good quality paediatric research: children's human rights implications and considerations for the Welsh context

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1. Introduction

To the Children and Young People's Committee, National Assembly for Wales, for the purposes of its short inquiry on children's rights in Wales to review the impact of the Rights of Children and Young Persons (Wales) Measure 2011.

This evidence concerns Welsh Government's decision-making on allocation of resource for health services and research in Wales in general and specifically on the issue of access to medicines and research into medicines for children.

We submit that there is as yet little evidence of implementation in practice of the duty of due regard to the requirements of the UNCRC in the published documents and statements on these issues.

2. Why is access to medicines and good quality paediatric research a children’s human rights issue?

Access to essential medicines is entrenched in the right to the highest attainable standard of health, which is enshrined in international law and the development of essential medicines requires good quality paediatric research. States are obliged under international human rights law to respect, protect, and fulfil the right to health, which includes an obligation to adopt legislative, administrative, and budgetary measures to facilitate access to medicines that are affordable, accessible, culturally acceptable, and of good quality. There are a core set of *minimum obligations* which are not subject to progressive realization, including access to essential medicines.¹²

United Nations Convention on the Rights of the Child (UNCRC)

With respect to the UNCRC and the provisions of the *Rights of Children and Young Person’s Wales Measure*, the two key articles of the United Nations Convention on the Rights of the Child in relation to the child’s right to health are:

Article 6 of the UNCRC states that:

1. States Parties recognize that every child has the inherent right to life.
2. States Parties shall ensure to the maximum extent possible the survival and development of the child.

Article 24 of the UNCRC states that

“States Parties must recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.”

¹[U.N. Doc. E/C.12/2000/4 (August 11, 2000)]

²Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights have elaborated, the progressive realization of rights also suggests that states, regardless of their level of economic development, are obligated to take measures immediately and “move as expeditiously as possible” towards the realization of those rights. See <https://www.escri-net.org/docs/i/425445>.

Additionally the UN Committee on the Rights of the Child General Comment No. 15 explains that services should comply with their obligation to adhere to what is commonly referred to as the AAAQ framework.³⁴ States should ensure that all children's health services and programmes comply with the criteria of availability, accessibility, acceptability and quality. According to General Comment No. 15 of the UNCRC, realizing the right to access medicines is contingent upon the realization of these four interrelated elements.

There are many articles of the UNCRC that are essential to realising a child's right to health. In considering the implications of this response we would like the Committee to take into account these further articles, summarised below:

Article 2: No child should be discriminated against on any grounds.

Article 3: The best interests of children should always be considered in individual care decisions, but also in the planning, delivery, and setting of service standards

Article 4: Economic, social and cultural rights (including the right to health) must be implemented to the maximum extent of available resources.

Article 12: All children should be involved in decisions that affect them, from individual care decisions through to shaping health services that they might use.

Article 23: All children with disabilities have the right to be involved, which includes having appropriate communication support.

Article 27: Every child should have a standard of living adequate for the child's physical, mental, spiritual, moral and social development.

Article 28: Every child has the right to education, including as an inpatient, structuring services to avoid missing school due to participation in clinic appointments.

³ United Nations Committee on the Rights of the Child (2013) General Comment No. 15 paras. 113-116

⁴See also the WHO, "Equitable Access to Essential Medicines: A Framework for Collective Action" in *WHO Policy Perspectives on Medicines Bulletin* (2004), <http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf>, 2.

Article 31: Every child has the right to rest, relax and play when engaging with health services.

3. The Problem

3.1 Inadequate paediatric research across the UK

“Children are not small adults; they need biomedical and health services research that takes account of their changing physiology, and addresses their problems directly, generating evidence to improve the quality of the treatments and healthcare they receive, and the policies that affect their wellbeing” (Royal College of Paediatrics and Child Health (RCPCH) 2012)

The prevailing Research and Development (R&D) model is currently ill-prepared to respond to the child population which has little purchasing/voting power, which sees children health research neglected overall and a lack of development of medicines across the UK (and globally). The UK ranks 19th in Europe for neonatal mortality and 20th for under 5 mortality dropping significantly from its position in 1990.⁵ Paediatric research is critically important as many interventions still lack a robust evidence base. Improvements in health care in children will potentially have the longest (lifetime) impact.

According to the *Royal College of Paediatrics Turning the Tide report 2018*:⁶

- Consultant academic paediatricians are still a very small percentage of the UK paediatric workforce
- Consultant paediatricians have limited time for research in their work plans.
- Children’s interests are not currently represented adequately in the UK life sciences industry’s strategy
- Not enough paediatricians on national research boards or committees promoting the interests of children.
- Funding for child health research is decreasing year on year since 2012

⁵ See ONS data 2017

⁶Royal College of Paediatrics and Child Health (2018)Turning the tide-five years on https://www.rcpch.ac.uk/sites/default/files/2018-03/turning_the_tide_-_five_years_on_2018-03

It is discriminatory and not in the best interests of children as a social group that they are not gaining the benefits of good quality research. This is a breach of their rights as laid out in most globally ratified human rights treaty the United Nations Convention on the Rights of the Child (UNCRC) and concurrently our own domestic legislation the *Rights of Children and Young Person's Wales Measure 2011*. A progressive programme of work has been undertaken by the European Union through the 'Paediatric Regulation' that has encouraged increased access to medicines for children since 2007. However given that the UK could be about to leave the European Union, a clear framework of accountability for children is essential. Research has demonstrated that with legal systems with legislative provisions in place the availability of a higher number of new paediatric medicines for children has been achieved.⁷ According to the RCPCH, if the UK is; 'not completely aligned with the European Paediatric Regulations, the volume of commercial research in the UK will be reduced with strong negative impacts on child health'.⁸

3.2 Welsh Health Research Infrastructure neglects Paediatric Research

This is set against a context whereby paediatric research in Wales is already underrepresented and resourced. From 2010-2015 children's paediatric research was included in the Welsh Health Infrastructure⁹ through the Children and Young People's Research Network; however, the change from the old infrastructure to the new Centres and Units in 2015 resulted in a loss of focus on paediatric research. The creation of a Clinical Research Facility for children was one of the National Centre for Population Health and Wellbeing's objectives, however no funding was made available for this and Cardiff and Vale University Health Board moved forward with this as a solo project. Since 2015 paediatric research across Wales has been supported in 2 ways: a) through the Children's Speciality Lead and b) through Activity Based Funding (ABF). This is wholly inadequate; the Speciality Lead (currently held at the Noah's Ark Children's Hospital for Wales (NACHfW)) is funded for one session of consultant time (3.75 hours) a week to encourage and increase paediatric research across Wales and the ABF model does not

⁷European Commission (2017) State of Paediatric Medicines in the EU 10 years of the EU Paediatric Regulation. COM https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/2017_childrensmedicines_report_en.pdf p. 9,

⁸ Royal College of Paediatrics and Child Health (2018)

https://www.rcpch.ac.uk/sites/default/files/201803/turning_the_tide_-_five_years_on_2018-03.pdf p.7

⁹ Please see map of the Welsh Research Health Infrastructure <https://www.healthandcarerresearch.gov.wales/research-infrastructure-map/>

compensate for the complexity of paediatric trials and the fact that numbers will always be a very small proportion of adult studies.

Despite these challenges, in 2017 the Children and Young Adults' Research Unit (CYARU), the first Clinical Research Facility in Wales dedicated to children was opened. Initially funded by Cardiff and Vale University Health Board at risk but now with two research nurses funded through ABF allocation, CYARU has doubled the number of children recruited into clinical research studies in Wales.

The aim is to build on the work of the CYARU and the work of the Speciality Lead and develop Wales-wide paediatric research; however, for this to happen, core funding must be secured. In April 2019 the Children's Hospital in partnership with Wales, wide collaborators put forward an application to the Health and Care Research Wales infrastructure fund. The application, after being considered by an External Review Board (ERB) failed to receive funding. Basic feedback regarding the ERB's decision was offered in the outcome letter; however the letter also stipulated that no further feedback would be forthcoming. The Wales wide collaborators understand the competitive nature of research funding, however, without further feedback it is impossible to determine whether due regard was paid to the UNCRC when the funding decision was made.

We are concerned that access for children to good quality clinical research have not been embedded effectively across Welsh Government health portfolios and policy. We also question whether Welsh Government is failing to ensure that its duties within the Measure are translated into the public bodies it provides funding to? We are therefore pleased that the National Assembly's Children and Young People's Education Committee are taking the opportunity to scrutinise this issue.

3.3 Activity Based Funding Model: Discriminatory towards children

Activity Based Funding (ABF)¹⁰ is a Welsh Government formula for paying for each patient recruited in to a portfolio study. Portfolio studies are those deemed of sufficient quality to qualify for such recognition and are placed on an All Wales register of research studies. Studies are categorised in to three bands and funded per patient recruited: interventional (£976), observational

¹⁰ The ABF model is currently under review by Health and Care Research Wales.

(£311) and large sample studies (£89). ABF does not work for low recruiting, highly complex studies that are prevalent in paediatric research.

The ABF model should be assessed for compliance with the UNCRC. Although the model may not be prima facie discriminatory against children however when practically applied there is a discriminatory impact. This can result in accessing fewer opportunities to develop critical and age appropriate medicines. This indirect discrimination may breach a child's best interests (article 3 of the UNCRC) the child's right to survive and develop (article 6) to their fullest potential and to the highest attainable standard of health (article 24). Any health funding model should treat all patients equally and without discrimination.

It is also discriminatory because of the resulting limited opportunities to participate in a clinical study in the Welsh context. Early Phase Paediatric Oncology research is a prime example of this issue. Children and their caregivers who, following discussions with clinical teams have decided they would like to consent to participate in early phase studies currently have to travel out of Wales to participate in such studies. Adult patients do not have to do this. Children and caregivers may have to travel long distances to participate in clinical studies, take longer periods of time off work and face negative impacts on their household economy (Article 27). This may also have a negative impact on the child, who consequently does not have regular access to siblings, extended family and to friends who can offer support to the child and the caregiver, in addition to their education (Article, 28 of the UNCRC).

Children's views and perspectives should be considered and in particular the children who are directly affected by these funding decisions (article 12 UNCRC) and is an important aspect of compliance with the Measure. In Wales, there are currently few mechanisms allowing children's views to be heard in the production of research for conditions they are affected by. This is also demonstrated by other mechanisms e.g. Health Wise Survey that does not consult children who are under the age of 16. The 2019 Parliamentary Review of Health and Social Care recommend, "*Strengthening through voice and control in health and care and ensuring all ages and communities have equal involvement*", additionally the Prudent Health Care Principles emphasise the importance of co-production. Children currently do not have equal involvement in health care decision making that affects them.

3.4 Lack of transparency with regards to health budget decision making

We are concerned that there is still a lack of visibility of children in the Welsh Government health research budget. We would urge more detailed analysis on specific areas of spend in particular in relation to health research.

Although requested from the Health and Care Research Wales Support Centre, the figure for what is currently spent by Welsh Government on paediatric research is not forthcoming. The lack of transparency in public expenditure on paediatric research means that it is currently not possible to tell without more detailed analysis, whether the Welsh Government is using sufficient levels of expenditure to fulfil children's right to the highest attainable standard of health. Under article 4 of the UNCRC, Ministers have a clear obligation to demonstrate whether it is fulfilling children's economic, social and cultural rights 'to the maximum extent of available resources'. We believe that transparent evidence of spending on children in relation to health research is an essential tool in both meeting this obligation and evidencing how planned spending and indeed spending cuts are impacting on the outcomes for children and young people in the enjoyment of their rights. We urge that in accordance with the Children's Scheme that all decision making, including budgetary decisions are assessed for compliance with children's rights i.e. a Children's Rights Impact Assessment is undertaken.

4. Conclusion

Even though there is a strong national commitment to the human rights of children in Wales, it is apparent that currently health policy and decision making around access to medicines and paediatric research has not incorporated the accountability framework of children's human rights and international human rights treaty obligations. These obligations could have greater significance given the UK may be about to leave the European Union and the protections and regulatory framework the EU Paediatric Regulation provides.

Welsh Government must urgently dedicate funding to the development of paediatric research and the development of a paediatric academic workforce. The current Welsh Government funding models for funding clinical research in Wales unfairly impact on the paediatric population. The Welsh Government should urgently harness and incorporate the positive elements of the EU Paediatric Regulation and also take this critical opportunity to honour their obligations under the *Rights Measure 2011*. Working with other public bodies they should commit funding and an

action plan to ensure Wales become world leaders in paediatric research and medicinal development for children. A fully funded Wales-wide Research Infrastructure for paediatrics will be essential to delivering this goal and should be underpinned by a children's human rights approach.

Key recommendations

1. Children's human rights should never be an afterthought but a primary consideration and central to any decision making and actions taken regarding research and development and access to medicines for children in Wales.
2. Welsh Government should review their health budget and policies for their compliance with 'due regard' to the principles and provisions of the Rights of Children and Young Persons (Wales) Measure 2011, through conducting a children's rights impact assessment and publish the findings.
3. Welsh Government should introduce a public sector duty, for all public bodies (including health bodies) to have due regard to the UNCRC.
4. Welsh Government should urgently develop a time bound action plan and dedicate funding to the "maximum extent of available resources" to the development of
 - paediatric research,
 - medicine development
 - the academic paediatric workforce in Wales.