



Hearing Health in Australia

Submission in response to Senate Inquiry

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Introduction

GlaxoSmithKline (GSK) welcomes the opportunity to contribute to the inquiry into hearing health in Australia. Our submission will focus on the hearing health areas identified by the Senate Community Affairs Committee.

Hearing is one of our primary senses. A loss of hearing not only impacts a person's ability to communicate but also their interaction within society. This effect is even more pronounced in children where hearing loss has a profound impact on a child's auditory skills and their subsequent ability to develop speech and language.

GlaxoSmithKline

GSK is a world leading, research-based pharmaceutical company dedicated to meeting the health care needs of people around the world by helping them do more, feel better and live longer. The company is a global leader in the research, development, manufacture and supply of prescription medicines, vaccines, over the counter medicines, oral care products and nutritional health care drinks.

GSK has a strong presence in Australia with operations in all states and manufacturing facilities at Boronia and Port Fairy in Victoria, Ermington and Castle Hill in NSW and Latrobe in Tasmania. GSK currently employs approximately 2,000 Australians.

We are a leading supplier of medicines and vaccines to the Pharmaceutical Benefits Scheme and National Immunisation Program, providing treatments for conditions such as asthma, COPD, diabetes, HIV/AIDS, infections, breast cancer, pain relief and dental care as well as a wide range of vaccines. GSK has been at the forefront of developing vaccine technology, such as combination vaccines to protect against multiple diseases with a single product, thereby improving compliance, coverage and reducing healthcare costs. We have also led innovation in adjuvant technology, which is designed to enhance the strength and duration of the immune protection from our vaccines. Such a response can include a long-lasting and broad- immune response, as in our cervical cancer vaccine, Cervarix[®], or a more powerful immune response, as in our candidate malaria vaccine. Adjuvants can also allow us to greatly increase manufacturing capacity to meet global demand, such as for our pandemic influenza vaccine.

Immunisation is the most cost-effective public health intervention after provision of clean drinking water. GSK Biologicals is a global organisation which has demonstrated its leadership in innovation. Active in the fields of vaccine research, development and

production, globally we have over 30 vaccines approved for marketing and 20 more in development. In 2008 GSK Biologicals distributed 1.1 billion doses of vaccines to 169 countries in both the developed and developing world – an average of 3 million doses a day. Close to 80% of our vaccines were distributed to developing countries. We have consistently been the leading vaccine innovator for, and supplier to, organisations such as UNICEF and the Pan American Health Organization (PAHO). One key outcome is that GSK has made a significant contribution to the eradication of polio in many regions. We are contributing to achieving the Millennium Development Goal Number 4 (MDG4), to reduce under-5 mortality by two-thirds between 1990 and 2015 as our vaccines against diphtheria, tetanus, pertussis (whooping cough), polio, measles, hepatitis B and Haemophilis influenza type b are included in the Expanded Immunisation Programmes (EPIs) for the most vulnerable children around the world.

Locally through the Australian National Immunisation Program (NIP), GSK supplies vaccines for hepatitis B, polio, rotavirus, measles, mumps and rubella (MMR) and pertussis amongst others. Earlier this year GSK introduced a new pneumococcal vaccine into Australia. Synflorix® is a vaccine which protects infants and children against invasive disease, pneumonia and acute otitis media (Synflorix PI). Every child in Australia currently receives a GSK vaccine supplied through the NIP schedule.

In 2008, GSK invested approximately \$37 million in Pharmaceutical R&D and approximately \$6.2 million in Vaccines R&D. GSK is one of the top 15 industrial R&D contributors in Australia. We have one of the strongest vaccine pipelines in the industry with over 20 vaccines in clinical development including vaccines to prevent pneumococcal disease, pandemic flu, new class of cancer immunotherapeutics (ASCIs) and a meningitis combination vaccine.

The extent, causes and costs of hearing impairment in Australia

Hearing loss affects one in six Australians and currently costs the economy in excess of \$11.75 billion per annum (Access Economics, 2006). The most significant cause of hearing loss amongst adult Australians is exposure to loud sounds. Despite understanding that loud sounds could damage their hearing, one in five Australians still frequently visit loud venues and listen to music through headphones. Alarming of those individuals who do listen to music through head phones almost two in three people have the music so loud that people usually have to shout to be heard. Interestingly the same survey found that very few people actually believe they have poor hearing (Australian Hearing survey). With an ageing population hearing loss is predicted to affect one in four Australians by 2050 (Access

Economics, 2006). There are some substantial differences between the levels of ear disease in the Indigenous population compared to the non-Indigenous community. While in loud sounds and normal ageing processes may be a primary cause of hearing loss in the non-Indigenous community, within the Indigenous populations ear disorders are largely due to ear infections rather than noise exposure (Australian Hearing survey).

The onset of this hearing loss is usually varied, it may occur suddenly or gradually over time. The timing of onset will have a direct impact on the language skills of a person, education and their employment opportunities (Access Economics, 2006). Depending on which part of the ear is affected, hearing loss is categorised into two areas: conductive or sensorineural hearing loss. Conductive hearing loss is caused by blockage or damage in the outer or middle ear. People affected with this disorder usually lose amplitude (quality and volume). Some of the causes leading to conductive hearing loss are: outer/middle ear infection, glue ear (common in children), perforated ear drum, otosclerosis (hereditary) and partial or complete closure of the ear canal. The degree of hearing loss will vary in these individuals however; a person cannot go completely deaf from a conductive hearing problem. People affected by conductive hearing loss may find some relief from surgical procedures or amplification provided by a hearing aid (Australian Hearing, May 2003).

Sensorineural hearing loss results due to damage of the cochlea or the hearing nerve within the ear. This condition can be acquired or congenital. Several circumstances can lead to acquired sensorineural hearing loss some of which are: ageing process, excessive noise exposure, meningitis, viral infections such as mumps and measles, ototoxic drugs and head injuries. Congenital (condition that is present at or soon after birth) sensorineural hearing impairment occurs as a result of inherited hearing loss, prematurity, birth trauma, exposure of foetus to a virus such as German measles and jaundice (Australian Hearing, May 2003). A person affected by sensorineural hearing loss usually leads not only to a loss of loudness but also clarity of sound. This dual impact can sometimes limit the benefit a hearing aid offers. In addition there is a lack of medical treatment for this condition hence the effects are usually permanent.

In 2005, the real financial cost of hearing loss was \$11.75 billion. Nearly half the people who suffered hearing loss are of working age and here in lies the largest financial cost component – productivity loss which accounts for 57% of all financial costs (\$6.7 billion).

These costs are relatively conservative as they do not include the costs of otitis media, the costs of which can be substantial in some sub populations such as Indigenous children. One of the main differences between this disability and others is that it is invisible and therefore, often isn't understood (Access Economics, 2006).

Causes, prevalence and costs of treating otitis media (OM) in Australia

Hearing loss in children can either be conductive or sensorineural in nature. A large proportion of sensorineural losses occur due to infections such as meningitis occurring early in life whereas conductive losses are a result of eustachian tube dysfunctions and otitis media. Up to 30% of children are affected by OM in the winter months. Most people often experience this problem when suffering from severe head colds. However, the problem can lead to more serious complications such as fluid in the middle ear or OM where bacteria or a virus infects the middle ear or ear drum (Access Economics, 2006).

The lack of universal definitions of OM together with a high degree of diagnostic uncertainty creates difficulties in determining the incidence and prevalence of OM and its associated costs (Access Economics, 2008). In the first study of its kind analysing the costs of OM in Australia, Taylor and colleagues estimated that that up to 659,495 people (approximately 3% of the total population) were projected to experience between 1 and 2.4 million episodes of OM per annum. Of this approximately 78% of children aged up to 12 months will have at least one episode of OM (approximately 195,000 Australian infants). In 2008, the predicted treatment cost of OM in Australia ranged from \$100 million to \$400 million. This range is reflective of the differing data sources and indicates a need for robust Australian epidemiological data (Taylor *et al*, 2009).

Whilst some respiratory viruses are linked to OM, bacterial infections are the primary causes of the condition. The bacteria most commonly associated with OM are *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*. Infants and preschool children are more likely to develop OM than adults (Access Economics, 2008). The condition is commonly associated with symptoms such as pain, fever and irritability that not only affects the child but can also cause concern for their family. General Practitioners (GP) or the Emergency Department are the primary ports of call for OM conditions. In 2006-07, over a million cases of OM were managed by GPs. Of these 74% of presentations were for children aged 0-14 years (Access Economics, 2008). While there is no universally agreed treatment algorithm for OM in Australia, the usual approach is to initially observe the child for a 'safe' period, and if the condition does not improve to administer antibiotics. The utilisation of antibiotics is contentious in the management of OM particularly due to potential bacterial

resistance. In 2008, ten percent of all medications (antibiotics and other medicines) prescribed by GPs to children less than 15 years were antibiotics prescribed for OM (Taylor *et al*, 2009).

Prevention of OM can be attained through avoidance of non-hereditary risk factors such as environment exposure to pollutants, exposure to tobacco smoke and other health factors. While the environmental risk factors can be avoided a large number of other factors are pre-determined and thus cannot be avoided. Another means of prevention of OM is through vaccination. Two pneumococcal vaccines (Prevanar[®] and Pneumovax[®]) are currently used in Australia that may prevent a proportion of OM cases (Taylor *et al*, 2009). Although introduction of vaccination has been concurrent with a reduction in OM requiring surgery in non-Indigenous children (6-23%) the overall cost burden of the disease is still significant and warrants further attention (Jardine, 2009 and Roche, 2008).

In 2009, the TGA approved a new vaccine for Australian children, Synflorix[®], which protects infants and children against invasive disease, pneumonia and acute OM (Synflorix PI). The new vaccine offers additional benefits over the currently available pneumococcal vaccines through coverage of serotypes not contained in those vaccines. Importantly, the Government's vaccine advisory group, ATAGI, has recognised that Synflorix[®] also protects against middle ear infection, which remains an area of unmet need in Australia. The PBAC have recommended that Synflorix[®] be added to the immunisation schedule. The vaccine is currently waiting approval for inclusion in the National Immunisation Program (NIP).

Specific issues affecting the Indigenous community

Ear disease (particularly OM) and subsequent hearing loss remains a significant problem with the Indigenous community. Rates of hearing loss range between 10-41% with this community. Comparatively hearing loss in the western population is usually around 5-7% (Access Economics, 2006).

The rate at which Indigenous Australians experience OM is twice that of non Indigenous Australians. While OM is more common in young people (0-14 years), this effect is even more pronounced in Indigenous children where the rates of OM are up to 12.8%. Indigenous children are also more likely to have severe OM (Morris *et al*, 2005 and Mackenzie *et al*, 2009). Up to 61% of Indigenous children suffer from some form of middle ear problem (Thorne *et al*, 2003). For example up to half of all Central and Northern rural Indigenous infants 2.5 years of age will have experienced a tear in their ear drum due to the severity of the middle ear infection (Morris *et al*. 2005 and Mackenzie *et al*, 2009). Similarly the costs of

OM within the young Indigenous community are also high, \$38.7 million annually. Whilst the cost of treating OM within the Indigenous community was based on the same average as all Australians, this cost is likely to be an under estimation of the true costs of treating OM particularly due to the higher costs of health-service provision in remote areas and issues related to access and treatment (Taylor *et al*, 2009).

For children with persistent OM with effusion, hearing, speech and language checks are absolutely necessary. In some children grommit tubes may be inserted depending on the severity of the condition. The need for services becomes even more pertinent within the Indigenous community where supportive pre- and post-operative care is crucial (Taylor *et al*, 2009).

In the area of prevention, the Northern Territory (NT) recently updated their childhood vaccination schedule. As of October 1st, 2009 children from 6 weeks to 2 years of age will receive Synflorix[®] for protection against some of the pathogens that cause OM. In doing so the NT becomes the first Australian state or territory to implement this vaccination for young children.

Implications of hearing impairment for individuals and communities

Hearing is one of our primary senses. As a result one of the major impacts of hearing loss is on a person's ability to communicate and interact with society. Reduced communication skills impact a person's opportunities in life including in their education, employment and relationships. Australians are required to stay productive longer into their working lives and as such any impact on their productivity has large economic implications for society (Access Economics, 2006). In 2008, the productivity loss associated with reduced employment due to permanent hearing loss caused by OM was \$1,323,597. In addition around \$16.8 million was lost in potential tax revenue (Access Economics, 2008).

Studies have also found that people with hearing loss delay seeking help for their disability for up to 6 years from when they first realise they are experiencing difficulties. Two factors drive a person to seek help – first when their hearing problem becomes unmanageable and secondly when they are driven by family members to seek help (Access Economics, 2006).

The effect of hearing impairment is even more pronounced in children where hearing loss poses additional difficulties. For example, in children hearing is not only essential for the development of auditory skills but also for the development of speech and language. Understanding speech is the most significant and challenging task for the auditory-linguistic

system (Aithal *et al*, 2008). The motor pathways that control speech undergo a critical development period within the first 5-7 years of life. Most children with hearing loss also suffer from additional disabilities such as visual impairment and learning difficulties. As a result hearing loss in children directly impacts their literacy, education and employment prospects later in life (Access Economics, 2006).

RECOMMENDATIONS

- There is a clear requirement for robust Australian epidemiological studies and consistent definitions of the types of OM and terminology. Current estimates from the ABS, National Health Survey and National Aboriginal and Torres Strait Islander Health Survey (NATSIS) are based on self-reporting rather than clinical diagnosis. Recognised in this study is a need to identify the nature of both types of hearing loss and its effects on learning and development.
- GPs are the first point of call for most people with OM. In 2006-07, over a million cases of OM were managed by GPs. Of these 74% of presentations were for children aged 0-14 years (Access Economics, 2008). Despite this there is no universally agreed treatment algorithm for OM in Australia. There is an obvious need for tools and guidance on accepted diagnostic, preventative and treatment algorithms which would help healthcare professionals accurately diagnose and treat this condition. The Government may also want to consider the role of nurse practitioners in providing assistance, education and care to families and children with recurrent OM.
- One of the most effective ways of treating hearing loss is through prevention. Preventative measures include a wider understanding of the causes of the disability and strategies to avoid or minimise the risks. Attention may need to be given to awareness and education campaigns that inform people on the risk factors leading to hearing loss and how to avoid these factors. Another effective preventative measure is by protecting children, through vaccination, from bacteria and viruses that lead to conditions such as OM. Bacterial resistance increases with the use of antibiotics. This is particularly evident in children as they tend to harbour more resistant pneumococcal strains due to high use of low dose antibiotics and higher rates of transmission of the bug from one child to another (Access Economics, 2008). Introduction and maintenance of an effective immunisation program and continuing sensible use of antibiotics will be crucial to maintaining effective control of antibiotic resistance.

Conclusion

GSK's submission addresses a number of key areas that should be considered as part of the inquiry into ear health in Australia. Our recommendations reflect the interest we share with the Government and other stakeholders in ensuring that Australia's health system remains world-class and at the frontier of policy reforms designed to make it more efficient, effective and equitable.

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