Access to newly licenced medicines

Supplementary Submission Alliance Scotland

The ALLIANCE would like to express our thanks to the Committee for their invitation to take part in the evidence session on access to newly licenced medicines on 29 January 2013.

Witnesses in the Committee’s second oral evidence session made some extremely valid points about the nature of the IPTR process and access to new medicines which related to the experiences of people who live with rare conditions. Many of these experiences echo the experiences of people who live with long term conditions across Scotland.

The ALLIANCE would like the Committee to note the following additional points:

- We would support the comments made by Dr Mark Roberts about the rigorous and difficult process and the potential damage this causes to the doctor-patient relationship (Official Report, Health and Sport Committee, 29/01/13, pg. 3242). This is a symptom of the process that we recognise as equally applicable to other long term and more prevalent conditions.

- Alastair Kent made the point that where patients are not allowed to have access to medication in the first place it is difficult to determine whether a new medicine is as useful in practice as clinical trial data suggests (pg. 3242). Such a situation also applies to access to new medicines intended to treat a whole range of long term conditions.

- We share Marion Ferguson’s concerns around proof of exceptionality being established on an individual basis (pg. 3244) and the cost implications of such an approach. This difficulty applies beyond rare conditions and is, in fact, magnified and even less cost effective among other more prevalent long term conditions.

- Alastair Kent also pointed to systems currently operating in Australia and Netherlands that act as a system of coverage with evidence development and “in which the presumption that the drug will be licensed but with certain stop criteria in place” (pg. 3245). We would encourage the Committee to look in more detail at the nature of these systems and the potential value of their operation in Scotland.

- We support the comments of Mr Kent that “the issue is being clear that the criteria for evaluating whether a particular intervention is effective take account of the patients’ experience and views about the salience of various elements of the condition” (pg. 3246). As we mentioned in our initial written response to the Committee, ensure that support of an individual’s quality of life is critical. The ALLIANCE is calling for the current system to be enhanced with the consideration of social elements, for instance considering the impact on an individual's employability or
evidence that a treatment supports a preventative approach. One example of such an approach is the STAR\textsuperscript{1} system.

- Marion Ferguson called for a more centralised system "especially for specialised, rarer diseases – it would make the process much simpler and avoid the need to go round different boards" (pg. 3248). We would like the Committee to note that this situation occurs for many people who live with long term conditions and see specialists in a neighbouring Health Board while being registered with a GP near their home. Children who live with long term conditions are particularly affected as they are often treated in tertiary centres, for instance Glasgow’s Yorkhill or Edinburgh Royal Hospital for Sick Children which will often be in a different Health Board area to the one in which they live

- Mark McDonald MSP asked whether there was a particular concern for rare conditions that “there is not enough of a voice to advocate publicly… with the result that they are not thought about first” (pg. 3251). This applies to advocacy in relation to many more prevalent well known long term conditions where capacity in the third sector is still very limited.

In some cases UK-wide organisations only submit to NICE and bypass the SMC because of a lack of resource in Scotland or lack of awareness of a separate process. Many third sector organisations offering support and advice across the UK and those based in Scotland staffed entirely by volunteers do not have capacity to make patient submissions to SMC and have no awareness of the IPTR process. We are concerned that this does not ensure that the voice of people who live with long term conditions is heard in the decision-making process.

- Dr Richard Simpson MSP asked the witnesses “Do we have the model for rare diseases completely wrong? Should the model look at the service as a whole?” (pg. 3254). We agree that drugs are integral part of the services offered to people who live with long term conditions. Ideal service models are often promoted (e.g. through the work of Managed Clinical Networks and in SIGN guidelines) but they do not exist consistently in every clinical or geographical area. While there are undoubtedly specific challenges in relation to rare diseases, this issue also applies more broadly across long term conditions.

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