

BMS comments on the Assessment Report: Storage of Donated Kidneys

Confidential information is highlighted and underlined, e.g. Viaspan

Approved Name of Medicinal Product:	University of Wisconsin Solution
Brand Name:	Viaspan
Company:	Bristol-Myers Squibb Pharmaceuticals Ltd
Submitted by:	[REDACTED]
Position:	[REDACTED]
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Bristol-Myers Squibb (BMS) appreciates the opportunity to comment on the Assessment Report (AR) on the effectiveness and cost-effectiveness of methods of storing donated kidneys from deceased donors; our comments are detailed below.

Viaspan vs. Machine Perfusion (LifePort)

- A significant amount of data pertaining to the comparison of Viaspan versus LifePort was obtained from the PPART and MPT trials is marked as confidential in the AR; this prevents us from providing a comprehensive response to the issues raised in this part of the assessment.
- Separate cost-effectiveness analyses were conducted based on data from the two trials mentioned above; these provide opposing estimates: Viaspan dominates LifePort (i.e. is both more effective and less costly) in the analysis based on the PPART trial and LifePort dominates Viaspan in the analysis based on the MPT trial. Without being able to examine the underpinning efficacy data, it is impossible to comment on the merits of these analyses. Thus, BMS strongly believes that given the significant uncertainty surrounding many of the inputs and assumptions used in the economic analysis, as detailed by the Technology Appraisal Group (TAG), needs to be thoroughly explained to the members of the Appraisal Committee. Further, should any recommendations be based on these cost-effectiveness results, they need to be considered with particular caution as there appears to be no strong basis for preferring one storage method over another.

Viaspan vs. Marshall's Soltran Solution

- The TAG concluded that no significant differences in efficacy parameters were found between Viaspan and Marshall's Soltran. As there appear to be no safety concerns related to cold storage solutions of donated kidneys, the two solutions were deemed equivalent. Again, efficacy parameters alone appear insufficient to support a choice of one solution over another. However, the submission from the British Transplant Society highlighted that Marshall's Soltran solution may not be a safe choice when other organs are retrieved with the kidneys. Given that a number of kidneys in the UK are obtained during multi-organ retrievals, BMS

would urge the Appraisal Committee to carefully consider this point as it seems that Viaspan should, indeed, be a preferred choice for the NHS.

- Cost-effectiveness estimates suggest that Viaspan dominates Marshall's Soltran Solution (i.e. both more effective and less costly). Although there is considerable uncertainty surrounding this analysis, as outlined by the TAG, the trend, together with the potential safety concerns, could lead to an overall preference for Viaspan.

BMS recognized the difficulties associated with conducting comparative efficacy and cost-effectiveness analyses in an area with significant variability in the quantity and quality of available data. It appears that the TAG's analyses is as comprehensive as the available evidence allows.