Implementation of NICE clinical guidelines and lessons learned from European cases on how to ensure that health services do not fall short of their obligations

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Objectives

It is a sad fact that public bodies sometimes move the goal posts. This can happen even midway through the reimbursement process. Consequently, companies need to have a well considered, proactive plan to identify and mitigate risks. As well as seeking advice from specialists in health technology assessment (HTA), they should also draw on legal and public affairs expertise.

Healthcare bodies can drive off-label use when licensed alternatives exist, for example in recent legislative changes in France and Italy. Similarly, even where national authorities approve a treatment, issues of uptake by local commissioners arise. In the UK for instance, clinical commissioning groups (CCGs) do not necessarily comply with the guidelines developed by the National Institute for Health and Care Excellence (NICE). We seek to demonstrate that use of legal remedies can be effective in taking such authorities to task where they breach either EU or national laws.

Methods

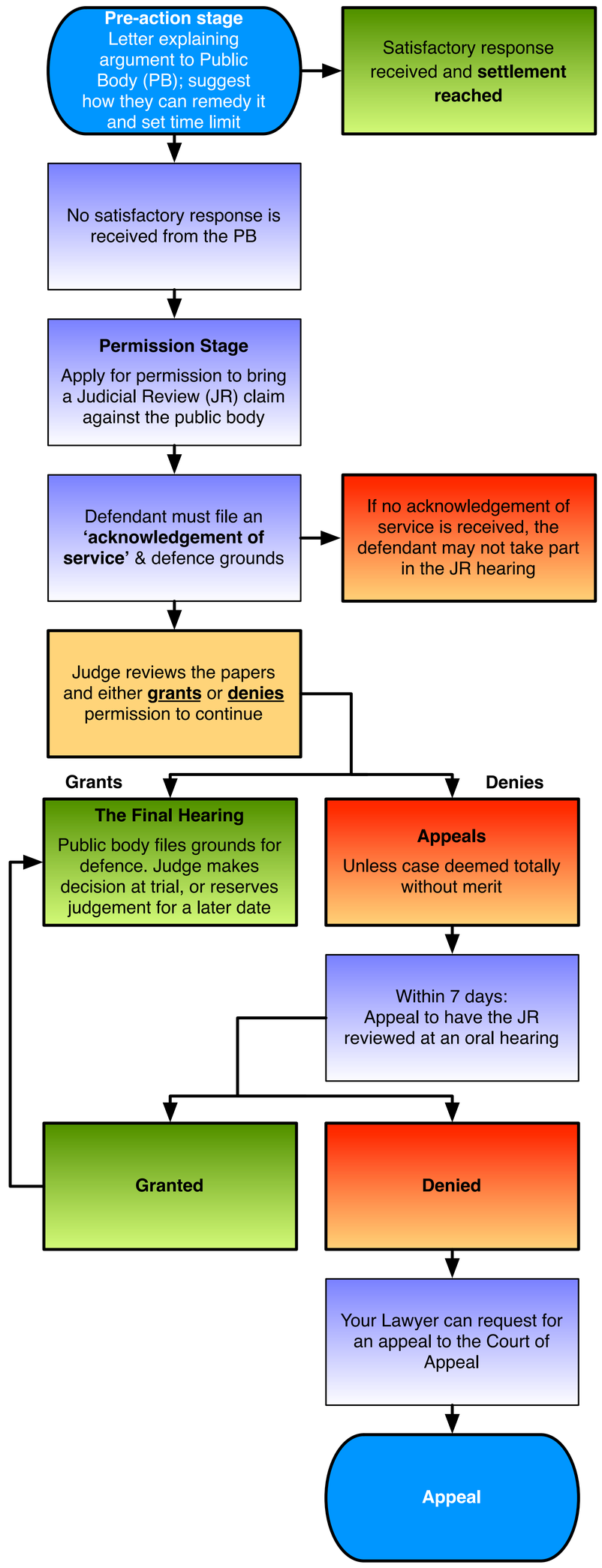
Case law and legislation are reviewed to address enforceability of:

- The general principle, identified in EU case-law, that protection of public health must take precedence over economic considerations; and
- National clinical guidelines (CGs) (as opposed to technology appraisal guidance (TAG), where there is an obligation to make treatment available e.g. NICE in the UK).

In the UK decisions by public bodies can be challenged on a number of grounds including:

- The public body does not have the power to make a particular decision, or it has used a power which it does have for an improper purpose;
- The decision is irrational;
- The procedure followed by the public body is unfair or biased;
- The decision taken is in breach of the Human Rights Act;
- The decision taken is in breach of European Community Law;
- The public body failed to comply with one of its legal duties, for example, the public sector equality duties.

Figure 1: Summary of the Judicial Review Process



Results

Under EU law, the supply of medicines for unauthorised use is only permitted as an exception to the requirement that a medicinal product should have a marketing authorisation in order to fulfil special needs (Art. 5.1 of Directive 2001/83/EC).

In Commission v Poland the Court of Justice[1] confirmed that financial reasons do not justify derogation from the marketing authorisation requirements. This principle was reiterated by the Director General of DG SANCO[2], stating that "Financial considerations must not take precedence over the safety of patients."

There is a legal obligation to comply with NICE TAG accompanied by a funding direction; but it has generally been considered that this was not the case for Clinical Guidelines (CGs). In the recent UK Rose v Thanet CCG case, a UK court considered that the CCG was under an implied obligation to give reasons for any general policy not to fund a particular intervention[3]. This suggests that CGs are effectively mandatory unless there are special grounds for exemption.

Conclusions

In most jurisdictions including at national and EU levels as well as the US, there are well developed rights for those adversely affected by the decisions of administrative bodies to go to court to challenge those decisions. For instance, the EU General Court may hear actions to contest decisions taken by institutions of the EU and national courts. In the UK, one could argue on the basis of unreasonableness, procedural unfairness or that the public body exceeded its powers in reaching its decision.

These remedies reflect the powers of the US courts to determine whether an administrative regulation contradicts existing law at the State and Federal levels, but may also test it for consistency with the US Constitution.

The use of such actions in relation to the reimbursement, or the availability, of medical treatment is increasing. Companies should develop a detailed understanding of the process and its implementation so that if there are grounds for complaint, or they are dissatisfied with the outcome, they are in a position to take timely action. Figure 1 provides an example of the judicial review process from the UK perspective. A coordinated approach involving legal, HTA and public affairs expertise could prove to be of critical importance in turning around a lost position.

References:
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