

GLOBAL PHARMACEUTICAL STANDARDS: A NEW REGULATORY PARADIGM?

MELANIE SAMSON

FEBRUARY 7, 2012

ABSTRACT

One of the constant features of legal scholarship in the past few years has been an increasing attention paid to what is usually described as the transformation of global regulatory experience. Evidence of such transformation which is commonly pointed to includes the fragmentation of rule-making processes, the lack of legitimacy of decision-making, increasing de-differentiation between legally binding rules and voluntary rules of conduct and so on. This paper aims to test the transformation thesis in light of a particular example of global pharmaceutical standards. More specifically, the research task which is being addressed in this paper is to determine the extent to which global pharmaceutical standards depart from the traditional regulatory paradigm at the international level. My research hypothesis is as follows: while global pharmaceutical standards testify to the transformation of traditional regulative frameworks, it seems, on a closer examination, that the thesis of radical departure from traditional regulatory paradigm which has been at work in the global arena needs to be qualified. For instance, although technically voluntary, pharmaceutical standards enjoy a significant degree of practical efficiency. At first sight, this can be seen as a remarkable novelty as a matter of regulatory philosophy. However, it seems that reasons which account for such a phenomenon have been at work in what is conceived of as traditional regulatory experience. Similar remarks can be offered as regards the sort of legitimacy that pharmaceutical standards enjoy because of the authority of science in modern societies. By “re-familiarizing” pharmaceutical standards in this way, I do not intend to deny that they pose various new practical and conceptual challenges. My aim is simply to show that these standards also exhibit some features which can be traced back to more traditional legal experience. Although the focus of this paper is primarily analytical, such a theoretical prospect is not devoid of practical interest: as is well known, proper identification of a problem is central to its successful resolution.