



Reliability and impact of Drug Authentication at the point of Dispensing

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**RELIABILITY AND IMPACT OF DRUG
AUTHENTICATION AT THE POINT OF DISPENSING**

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Summary

Background and Objective: Authentication processes based on mass serialization technology have been developed with a view to securing the drug supply to patients. This paper aims to assess the reliability and the impact of the AegateProtect™ service, a drug authentication system implemented in Belgian and Greek community pharmacy. The findings of this study may inform community pharmacists, pharmaceutical associations and policy makers about the potential of the AegateProtect™ service and, in general, the approach of authentication using mass serialization as a means to protect patients from harmful products. To the best of the authors' knowledge, this is the first study undertaking an analysis of the reliability and impact of an operational drug authentication system.

Methods: A prospective analysis assessed the reliability of the service in a sample of Belgian community pharmacists by means of a mystery shopper audit. A retrospective analysis of the service in place in Belgian and Greek community pharmacies evaluated the impact of the service in terms of the number of scans relating to authentic, recalled, expired, and suspicious products.

Results and Discussion: The AegateProtect™ service attained a sample reliability of 100% (95% confidence interval: 99.8%-100%) in Belgium. Out of the total of 219,897 scans tested in Belgium during June-August 2008, the AegateProtect™ service identified 211,544 scans relating to authentic products (96.20% of scans); 1,639 scans relating to

recalled products (0.75%); 6,630 scans relating to products that may be recalled (3.01%); and 84 scans relating to expired products (0.04%). No scans relating to suspicious products were identified. Similar results were observed in Greece.

Conclusion: The AegateProtect™ service has been shown to be reliable and effective in identifying authentic, recalled, expired and suspicious drugs in community pharmacy at the point of dispensing. However, the coverage of the Aegate databases needs to be increased in the future by increasing the volume of drug serialization codes.

Keywords: drug supply, authentication, mass serialization, reliability, impact, community pharmacy.