Pharmaceutical quality of generic Atorvastatin products compared with the innovator product: A need for revising pricing policy in Palestine

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Abstract
Atorvastatin reduces morbidity and mortality due to cardiovascular events. This study was conducted to assess the prices and pharmaceutical quality of innovator atorvastatin 20 mg with its locally available generics in Palestine and to assess the suitability of their interchangeability. The prices of innovator and generic atorvastatin 20 mg were determined and compared. Innovator atorvastatin and four generic products were
tested for their pharmaceutical quality. Tablets were tested for their drug contents, weight uniformity, hardness, disintegration and dissolution. Three out of four generics were less expensive than the innovator. Pharmaceutical quality assessments were satisfactory and within limits for all atorvastatin tested products. The average weight ranged from 206.6 ± 8.40 to 330 ± 3.92 mg and the %RSDs were within the permitted limits as per USP. Tablet hardness ranged from 102 ± 1.41 to 197.4 ± 6.88 kg and drug contents ranged from 92.2% to 105.3%. All products disintegrated within permitted time limits and showed very rapid dissolution. Products released more than 85% of their drug contents in less than 15 min. Our results showed that all tested innovator and generic atorvastatin products were of good pharmaceutical quality. Despite the lack of in vivo evaluation, our results indicate that these products are equivalent in vitro. Considering the in vitro release characteristics, these products might be used interchangeably. However, regulatory authorities permit the use of in vitro data in establishing similarity between immediate release oral dosage forms containing biopharmaceutical classification system class I and III drugs only.