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BUDGET IMPACT ANALYSIS OF TRIVERAM FOR THE TREATMENT OF HYPERTENSION IN ITALY

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Introduction: Hypertension is a major risk factor for ischaemic and haemorrhagic stroke, myocardial infarction (MI), heart failure (HF), chronic kidney disease, cognitive decline and premature death. In 2008, approximately 40% of adults aged ≥ 25 years had been diagnosed with hypertension worldwide¹. According to the Italian Hypertension Society (SIIA), in Italy there are approximately 14 million of people who have elevated blood pressure (hypertension), but only 3 million receive appropriate therapy and just the 37% of these with controlled blood pressure. CVD is responsible for one-third of global deaths per year (approximately 17 million) and is a leading and increasing contributor to the global disease burden². The high prevalence of hypertension worldwide has significantly contributed to the present pandemic of CVD³.

Objectives: The objective of this study was to perform a Budget Impact Analysis (BIA) assessing the introduction of Triveram for the treatment of hypertension into the Italian market. TRIVERAM is a single pill combination of statin (atorvastatin calcium trihydrate), calcium channel blocker (amlodipine besilate) and angiotensin-converting enzyme inhibitor (perindopril arginine) indicated for the treatment of essential hypertension and/or stable coronary artery disease.

		Patients
Triple therapy	Perindopril+Amlodipine+Atorvastatin	5.395
	Perindopril/Amlodipine+Atorvastatin	21.258
Double therapy	Perindopril+Atorvastatin	31.130
	Perindopril+Amlodipine	24.557
	Atorvastatin+Amlodipine	207.864
	Perindopril/Amlodipine+Atorvastatin	40.610
TOTAL		330.814

		Patients
Triple therapy (100% of the market)	Perindopril+Amlodipine+Atorvastatin	5.395
	Perindopril/Amlodipine+Atorvastatin	21.258
Double therapy	Perindopril+Atorvastatin (60%)	18.678
	Perindopril+Amlodipine (50%)	12.279
	Atorvastatin+Amlodipine (60%)	124.718
	Perindopril/Amlodipine (50%)	20.305
Total		202.633

Table 1. Upper panel: Patients in double or triple therapy
Lower panel: Reference Market

Methods: The BIA compares two different scenarios: one without a triple fixed combination therapy (Scenario 1) vs. another one with the introduction of Triveram (Scenario 2). The study has been conducted considering the perspective of the Italian National Healthcare Service. Population data were obtained from a Local Project Database managed by Cegedim composed by 1.100.000 patients' records originated from software used by 900 Italian GPs. The time horizon considered was 3 years from the introduction of Triveram. Total number of patients in each of the 3 years was the same for the two Scenarios, because the model allows only the switch of patients from the dual (Perindopril+Atorvastatin, Perindopril+Amlodipine, Amlodipine+Atorvastatin) or triple combinations (Perindopril+Amlodipine+Atorvastatin, Perindopril/Amlodipine+Atorvastatin) to the fixed dose treatment with Triveram.

According to the Cegedim database, there are about 331 thousands patients treated with double or triple therapy (Table 1).

The reference market for Triveram is composed by the patients that can switch from the double therapy because they do not reach target blood pressure (according to major clinical trials about 60% of the patients in double therapy with Atorvastatin and 50% of the patients in double therapy with Perindopril and Amlodipine) and by all the patients currently in triple therapy (Table 1). The model assumed that the percentage of patients who switch to Triveram is 26%, 38% and 49% the first, second and third year respectively. The prices used in the model are ex-factory prices (Table 2) as published in AIFA web site after price cuts.

Ex factory prices	Price per day	Price per month
TRIVERAM	€ 0,43	€ 12,90
COVERLAM MEDIA (Perindopril/Amlodipina)	€ 0,31	€ 9,41
PERINDOPRIL	€ 0,13	€ 3,81
AMLODIPINA	€ 0,10	€ 2,93
ATORVASTATINA	€ 0,16	€ 4,68
Perindopril+Atorvastatina	€ 0,28	€ 8,49
Amlodipina+Atorvastatina	€ 0,25	€ 7,61
Perindopril+Amlodipina	€ 0,22	€ 6,74
Perindopril+Amlodipina+Atorvastatina	€ 0,38	€ 11,42

Table 2. Ex-factory prices (AIFA)

Results: The study shows that the introduction of Triveram leads to a reduction in the quantity of pills taken by patients ((247.893.255, 270.691.934 and 287.356.690 in Scenario 1 and 224.916.946, 222.121.000 and 214.892.239 in Scenario 2, respectively in year 1, 2 and 3). (Figure 1). With a cost of 12,90 €/month, the introduction of Triveram generates savings for the Italian NHS equal to 10.6, 22.4 and 33.5 €/millions respectively in year 1, 2 and 3 over the total expenditure of 95, 114.8 and 126.1 €/millions related to the year 1, 2 and 3 in the first scenario.

(Figure 2). As the majority of patients with hypertension require two or more agents to achieve their BP targets, simplifying treatment by reducing pill burden through the use of SPCs is one of the most straightforward and effective ways of improving adherence⁴.

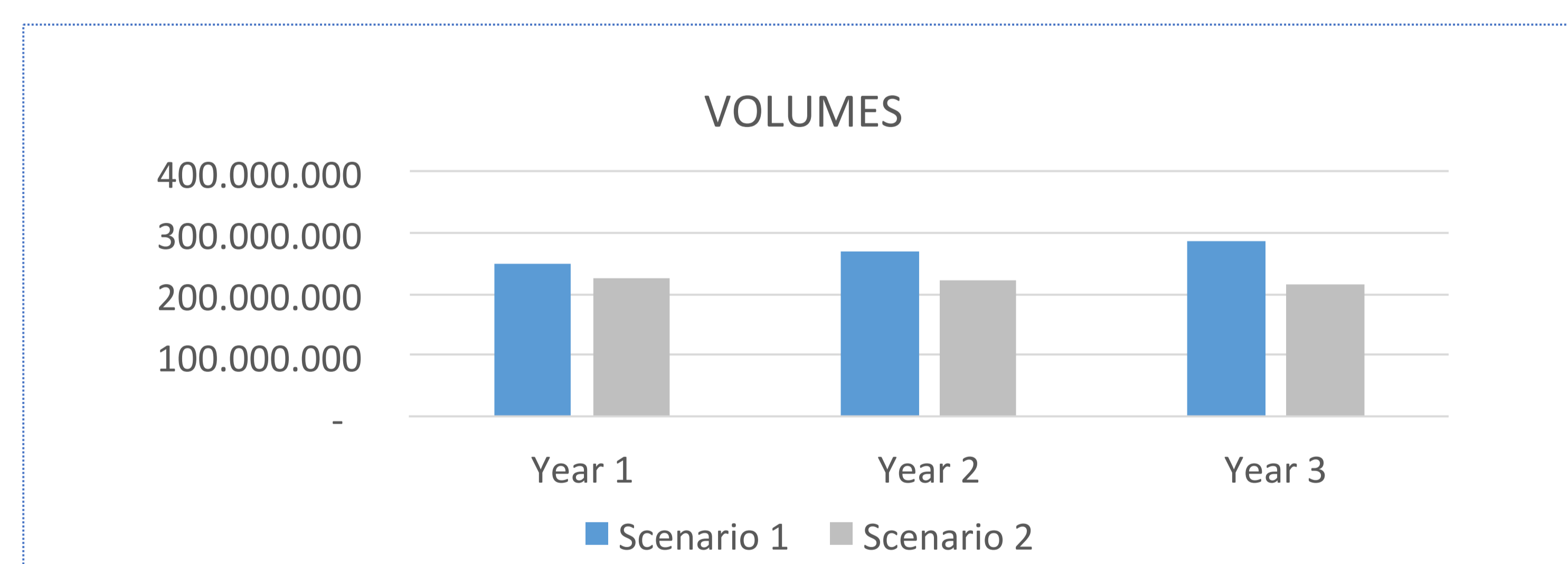


Figure 1

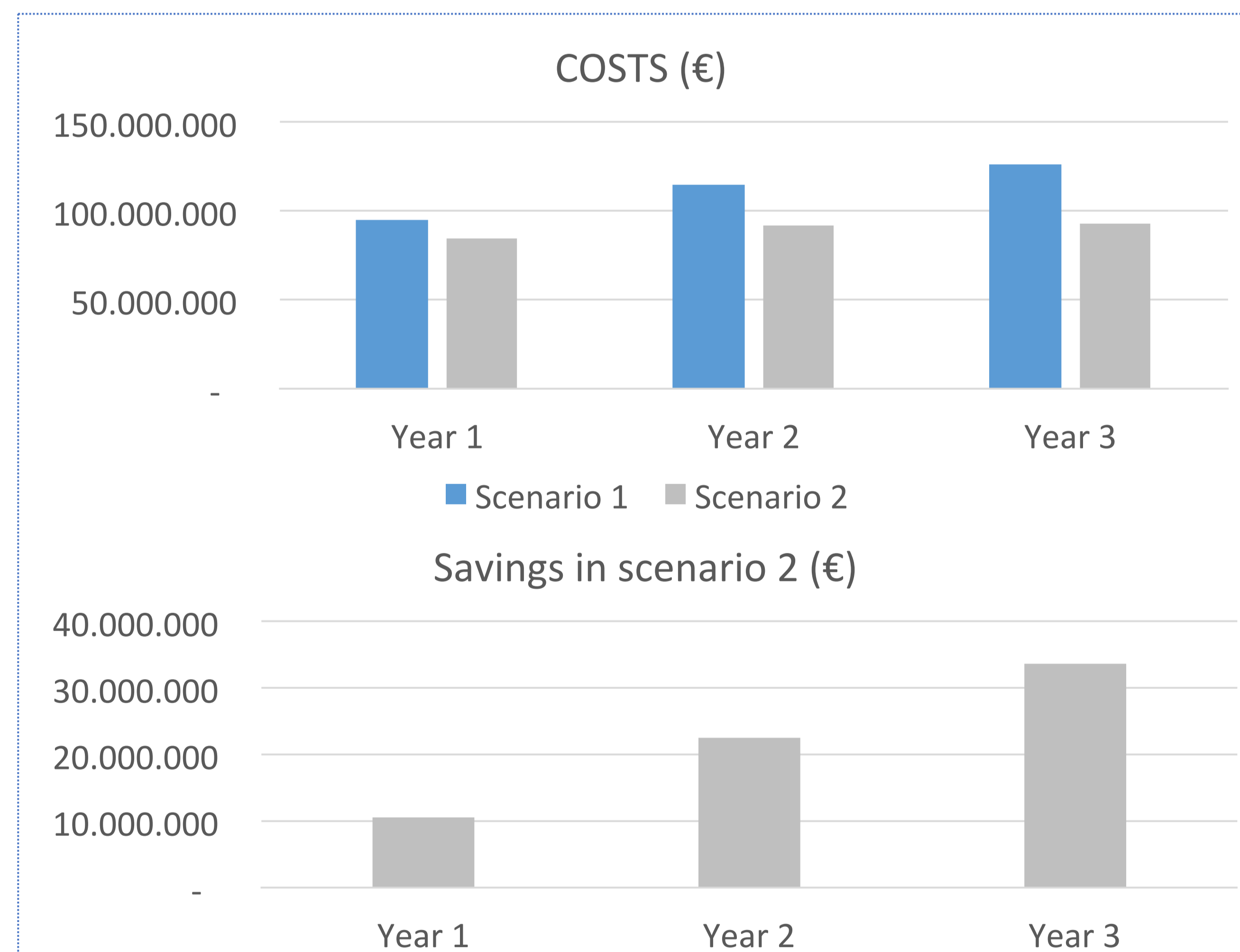


Figure 2

Conclusions: The present study indicates that the introduction of Triveram has two important effects:

1. It does not imply additional treatment costs; from the first year, actually, it generates a saving for the NHS.
2. The introduction of Triveram represents a benefit for the patients, especially for the elderly, because it improves the adherence to the therapy, thanks to the reduction in the number of pills taken. Better adherence is also linked to a reduction in the number of hospitalizations caused by therapy interruption and, consequently, permits to avoid the related costs.

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3. Kearney PM, Whelton M, Reynolds K et al. Global burden of hypertension: analysis of worldwide data. Lancet 2005; 365: 217-23.
4. Erdine S. How do compliance, convenience, and tolerability affect blood pressure goal rates? Am J Cardiovasc Drugs 2012; 12(5): 295-302.

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