

Availability and procurement of generics in hospitals among medium-sized European countries. Brian Godman, BSc, PhD

(Accepted for publication Generics and Biosimilars Initiative Journal)

Brian Godman reviews the paper by Vogler and colleagues on the procurement of generics or originators among European hospitals once multiple sources become available.

Vogler and colleagues have provided valuable insight into the procurement of generic medicines in hospitals among medium-sized European countries [1]. To date, this has been a neglected area with the majority of research and payer focus on ambulatory care as medicine expenditure in hospitals has only been a limited proportion of overall hospital expenditure at 5% to 10% over the years [1], whilst pharmaceutical expenditure in ambulatory care is typically the second highest cost component after physician salaries, with expenditures rising by more than 50% in real terms during the past decade [2]. In addition, there are continual pressures on ambulatory care expenditure driven by well known factors including ageing populations, rising patient expectations and the continued launch of new premium priced technologies [2-4]. This has resulted in multiple policies and initiatives among authorities across Europe to enhance prescribing efficiency for both new and established medicines [2,4]. Policies and initiatives for established medicines include encouraging the prescribing of lower cost generics versus originators and patented products in a class where all or nearly all the products in the class or related classes are seen as therapeutically similar [1,2,5,6]. Classes include the proton pump inhibitors, renin-angiotensin inhibitor drugs as well as the statins [2,5-7]. This takes advantage of an increasing number of products losing their patents in recent years [1,2,5,6].

However as Vogler et al point out, the focus is changing with new premium priced medicines, including biological medicines, initiated in hospitals before patients are discharged [1,8]. This is a concern for the authorities responsible for ambulatory care if physicians are reluctant to change prescriptions to suitable lower cost generics, including generics versus originators, even in countries where there is a high rate of prescribing of generics such as Germany [1,8-10]. This is less of an issue if there is a tradition of international non-proprietary name (INN) prescribing across all sectors (UK) for small molecules [1,6,11], compulsory generic substitution (Sweden) [1,6,12], preference policies for the molecule (Netherlands) [1,2,13], or reference pricing where patients have to cover the additional cost themselves for a more expensive medicine than the quality assured referenced priced medicine [1,14]. However, this is an issue if patients are discharged on premium priced medicines, including originators, where low cost generics (or branded generics) are equally suitable and there is limited potential for switching in ambulatory care, enhanced by hospitals receiving appreciable discounts and sometimes free medicines [1,15].

It was against this background, that the current study was conducted. It was encouraging to see a range of countries were studied in this paper with different healthcare systems, different geographies, different approaches to the tendering of medicines in hospital as well as different approaches to the pricing of generics in ambulatory care and measures to enhance their utilization [1]. In addition, concentrating on just one category of medicines, namely cardiovascular medicines, to provide good insights for the reasons stated. The study also built on the considerable contacts of the co-authors through the PHIS network [1].

The study highlighted a number of interesting findings. These included the fact that typically hospitals only carry one product line, mainly the generic, or at the most two, i.e. both a generic and the originator, for a given molecule (only a minority of hospitals in Norway and Slovakia). The only exception was atorvastatin where apart from Norway the originator was principally supplied. This compares to the ambulatory care sector where there may be multiple presentations available for dispensing from different companies once the patent has been lost [1]. One hospital in Portugal only carried atorvastatin rather than both simvastatin and atorvastatin [1]. This may reflect previously limited demand-side measures in ambulatory care in Portugal preferentially encouraging the prescribing of generic simvastatin rather than patented atorvastatin when it first became available thereby encouraging the manufacturer of atorvastatin to seek its preferential listing in the hospital formulary [1,16]. Secondly, just single doses are often supplied in hospitals versus typically full packs in the community with varying tablet sizes and strengths. Thirdly, Norway was the only country in which the surveyed medicines were exclusively centrally tendered leading to appreciable discounts. This provides an example to other countries, backed up by campaigns supporting generics [1]. There

was also tendering among hospitals in Portugal, with individual hospitals having the potential to negotiate lower prices if able to do so [1]. Discounts of 100% were seen among the majority of surveyed hospitals in Austria, although discounts and cost-free medicines did not apply to new on-patent medicines. Otherwise there was limited headroom for appreciable discounts between the hospitals [1]. Dispensing of originators in Austria will increase costs, with Austria having neither INN prescribing, generic substitution or reference pricing [1, 17]. However, the Sickness Funds in Austria are looking to address this through information and other campaigns in hospitals [1,18].

In conclusion, this study offers valuable insight into the procurement of generics among hospitals in Europe once products lose their patent. It is hoped this study will be repeated for other product classes and other countries to provide further insight given the extensive networks and experience of the co-authors. This is especially important with growing recognition of the need for both ambulatory care and hospital sectors to work more closely together to maximize the health gain of patients with available resources – ‘Interface Management’ [1,8].

References

- [1] Vogler S, Zimmermann N, Mazag J. Availability and procurement conditions of originator and generic medicines in hospitals – An exploratory study in five medium-sized European countries. *Generics and Biosimilars Initiative Journal (GaBI Journal)*. 2014 ???
- [2] Godman B, Wettermark B, van Woerkom M, Fraeyman J, Alvarez-Madrado S, Berg C, et al. Multiple policies to enhance prescribing efficiency for established medicines in Europe with a particular focus on demand-side measures: findings and future implications. *Frontiers in pharmacology*. 2014;5:106
- [3] Garattini S, Bertele V, Godman B, Haycox A, Wettermark B, Gustafsson LL. Enhancing the rational use of new medicines across European health care systems. *European journal of clinical pharmacology*. 2008;64(12):1137-8.
- [4] Malmstrom RE, Godman BB, Diogene E, Baumgartel C, Bennie M, Bishop I, et al. Dabigatran - a case history demonstrating the need for comprehensive approaches to optimize the use of new drugs. *Frontiers in pharmacology*. 2013;4:39
- [5] Godman B, Wettermark B, Bishop I, Burkhardt T, Fürst J, Garuoliene K et al. European payer initiatives to reduce prescribing costs through use of generics. *Generics and Biosimilars Initiative Journal (GaBI Journal)*. 2012;1(1):22-7
- [6] Godman B, Auelkhair M, Vitry A, Abdu S, Bennie M, Bishop I et al. Payers endorse generics to enhance prescribing efficiency; impact and future implications, a case history approach. *Generics and Biosimilars Initiative Journal*. 2012;1(2):21-35.
- [7] Moon J, Godman B, Petzold M, Alvarez-Madrado S, Bennett K, Bishop I, Bucsecs A, Hesse U, Martin A, Simoens S, Zara C, Malmstrom RE. Different initiatives across Europe to enhance losartan utilisation post generics: impact and implications *Frontiers in pharmacology*. 2014;5(Article 219):1-10
- [8] Björkhem-Bergman L, Andersén-Karlsson E, Laing R, Diogene E, Melien O, Jirlow M, et al. Interface management of pharmacotherapy. Joint hospital and primary care drug recommendations. *European journal of clinical pharmacology*. 2013;69(1):73-8.
- [9] Godman B, Sakshaug S, Berg C, Wettermark B, Haycox A. Combination of prescribing restrictions and policies to engineer low prices to reduce reimbursement costs. *Expert Review of Pharmacoeconomics & Outcomes Research*. 2011;11(1):121-9.
- [10] Simmenroth-Nayda A, Hummers-Pradier E, Ledig T, Jansen R, Niebling W, Bjerre LM, et al. Prescription of generic drugs in general practice. Results of a survey of general practitioners [Article in German]. *Med Klin*. 2006;101(9):705-10.
- [11]. Godman B, Bishop I, Finlayson AE, Campbell S, Kwon HY, Bennie M. Reforms and initiatives in Scotland in recent years to encourage the prescribing of generic drugs, their influence and implications for other countries. *Expert review of pharmacoeconomics & outcomes research*. 2013;13(4):469-82
- [12]. Andersson KA, Petzold MG, Allebeck P, Carlsten A. Influence of mandatory generic substitution on pharmaceutical sales patterns: a national study over five years. *BMC health services research*. 2008;8:50
- [13] Woerkom Mv, Piepenbrink H, Godman B, Metz Jd, Campbell S, Bennie M, et al. Ongoing measures to enhance the efficiency of prescribing of proton pump inhibitors and statins in The Netherlands: influence and future implications. *Journal of comparative effectiveness research*. 2012;1(6):527-38.
- [14] Vogler S. The impact of pharmaceutical pricing and reimbursement policies on

- generics uptake: implementation of policy options on generics in 29 European countries—an overview. *Generics and Biosimilars Initiative (GaBI) Journal*. 2012;1(2):93-100.
- [15] Vogler S, Zimmermann N, Habl C, Mazag J. The role of discounts and loss leaders in medicine procurement in Austrian hospitals - a primary survey of official and actual medicine prices. *Cost Effectiveness and Resource Allocation*. 2013;11(1):15.
- [16] Godman B, Shrank W, Andersen M, Berg C, Bishop I, Burkhardt T, et al. Comparing policies to enhance prescribing efficiency in Europe through increasing generic utilization: changes seen and global implications. *Expert review of pharmacoeconomics & outcomes research*. 2010;10(6):707-22
- [17] Godman B, Burkhardt T, Bucsics A, Wettermark B, Wieninger P. Impact of recent reforms in Austria on utilization and expenditure of PPIs and lipid-lowering drugs: implications for the future. *Expert review of pharmacoeconomics & outcomes research*. 2009;9(5):475-84
- [18] Vogler S, Zimmermann N. How do regional sickness funds encourage more rational use of medicines, including the increase of generic uptake? A case study from Austria. *Generics and Biosimilars Initiative Journal (GaBI Journal)*. 2013;2(2):65-75.