

CZECH REPUBLIC

Recent and planned developments in pharmaceutical policies 2016

Special topic: Pricing and reimbursement policies for biosimilars

D E V E L O P M E N T S	CHANGES IN PRICING	CHANGES IN REIMBURSEMENT
	<ul style="list-style-type: none"> • No relevant system changes in 2016 • <u>Conclusion of 3rd wave of price review:</u> <ul style="list-style-type: none"> ○ No. of Administrative procedures: 491 ○ No. of medicinal products: 4637 ○ Lead to a price decrease in: 54 % 	<ul style="list-style-type: none"> • No relevant system changes in 2016 • Ongoing 2nd wave of complex reimbursement reviews • Ongoing 3rd wave of complex reimbursement review • 01/09/2015: Extension of period between complex reimbursement reviews from 3 years to 5 years
	OTHER CHANGES	
	<ul style="list-style-type: none"> • Preparation of an amendment of the Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts: <u>regulation of re-export</u> - selected medicinal products published in bulletin, sanctions up to 20 million CZK 	
S P E C I A L T O P I C	POLICIES FOR BIOSIMILARS	
	<p>The price for biosimilars is set on the same procedure as for generics, but the price decrease for biosimilars is different from the generics.</p> <p><u>1st follower: at least 15% priced below originator.</u></p> <p>The reimbursement procedure is the same as for all other medicines, but the reimbursement decrease for biosimilars is different from the generics.</p> <p><u>1st follower: at least 15% reimbursement decrease of the whole reference group.</u></p> <p>A special short-time procedure for generic pricing/reimbursement is available to speed up the availability of generics.</p> <p>There are no specific rules for substitution of biosimilars in the Czech Republic. Substitution within the same active ingredient is allowed. Biosimilar is not considered the same active ingredient as original product that is why biosimilars could not be substituted at pharmacy. Switch is not usually performed by physicians in patients who are undergoing treatment.</p>	