

CROATIA

Recent and planned changes in pharmaceutical pricing and reimbursement and overview of the medical devices system



P H A R M A C E U T I C A L S	Changes in pricing	Changes in reimbursement																
	Change of reference countries (International comparisons):		<p>There are no changes.</p> <pre> graph TD A[Submit applications (company)] --> B[CHIF (administration obligation)] B --> C[The Committee for Medicinal Products (13 members)] C --> D[CHIF's Management Board (9 members)] </pre> <p>The criteria for inclusion:</p> <ul style="list-style-type: none"> -importance of the medicinal product from the perspective of public health -therapeutic importance of the medicinal product -relative therapeutic value of the medicinal product -assessment of ethical aspects 															
	<table border="1"> <thead> <tr> <th>International comparisons</th> <th>Old Ordinance</th> <th>New Ordinance</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Basic countries</td> <td>Italy</td> <td>Italy</td> </tr> <tr> <td>Slovenia</td> <td>Slovenia</td> </tr> <tr> <td>France</td> <td>Czech Republic</td> </tr> <tr> <td rowspan="2">Reserve (backup) countries</td> <td>Spain</td> <td>Spain</td> </tr> <tr> <td>Czech Republic</td> <td>France</td> </tr> </tbody> </table>			International comparisons	Old Ordinance	New Ordinance	Basic countries	Italy	Italy	Slovenia	Slovenia	France	Czech Republic	Reserve (backup) countries	Spain	Spain	Czech Republic	France
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Internal price referencing:																		
<ul style="list-style-type: none"> -clusters formed at ATC levels 3-5 -Reference price = cheapest molecule, 5% of cluster volume over a 3-month period preceding the reference pricing process 																		
Other changes related to medicines																		
- VAT on drugs from January 2013.																		
M E D I C I N E S	Pricing and reimbursement system of medical devices																	
	<ul style="list-style-type: none"> • Competent authority: Competence for pricing and reimbursement lies with both Croatian Ministry of Health and Croatian Health Insurance Fund; classification, clinical trials and registration (if needed) are with the Agency for Medicinal Products and Medical Devices (HALMED) 																	
	<ul style="list-style-type: none"> • Price regulation: Pricing of medical devices that are not reimbursed by Croatian Health Insurance Fund is statutorily not regulated and can be freely set by the manufacturers. In order to apply for the List of medical devices which are reimbursed by Croatian Health Insurance Fund, applicant needs to comply with price regulation ordinance set by Ministry of Health. 																	
	<ul style="list-style-type: none"> • Reimbursement: Manufacturers or distributors need to make an application for the reimbursement list with Croatian Health Insurance Fund (HZZO) in order to have a medical device reimbursed. It is up to the manufacturers/distributors whether they ask for reimbursement or not. 																	
	<p>Submit application (company) – CHIF ← The Committee for orthopedic devices - CHIF's Management Board ↙ The Committee for general medical-technical devices ✓</p>																	
<ul style="list-style-type: none"> • Price sources/prices known: There is an overview of prices for medical devices which are reimbursed by Croatian Health Insurance Fund (i.e. List of medical devices) 																		

