1	Preamble					
2	Investments in Medical Institutions					
	2.1	General Regulations		3		
		2.1.1	Investment Policy for Investments in Medical			
			Institutions	3		
		2.1.2	Medical Institutions Under Chinese Law	5		
		2.1.3	Forms of Investment	7		
	2.2	Establishment of Medical Institutions as Joint Ventures		10		
		2.2.1	Requirements	10		
		2.2.2	Review and Approval Procedures	12		
		2.2.3	Special Provisions for Service Providers from Hong Kong,			
			Macao and Taiwan	19		
	2.3	Establ	lishment of Medical Institutions as a Wholly-Owned			
		Subsic	diary ("WFOE")	22		
		2.3.1	Special Arrangements in the Shanghai FTZ	23		
		2.3.2	Pilot Project for the Construction of Hospitals			
			as WFOE in Seven Provinces	25		
		2.3.3	Special Provisions for Service Providers from Hong Kong,			
			Macao and Taiwan	27		
	2.4	Opera	tion of the Foreign-Invested Medical Institution	33		
		2.4.1	Employment of Chinese and International Personnel	33		
		2.4.2	Acquisition of Medical Devices	38		
		2.4.3	Acquisition of Medicinal Products	43		
		2.4.4	Application of Medical Technology	45		
		2.4.5	Tax and Fee Regulations	49		
		2.4.6	Advertising for Medical Institutions and Services	61		



vi Contents

		2.4.7 2.4.8	Provisions on the Price of Medical Services	64 65		
		2.4.9	Treatment Errors	65		
3	Dist	ributio	n of Medical Products in China	69		
	3.1	Overv	iew	69		
	3.2	Appro	oval Procedures for Medical Devices	69		
		3.2.1	General Requirements for the Approval of Medical			
			Devices	70		
		3.2.2	Classification of Medical Devices	77		
		3.2.3	Logging Procedures for Category I Medical Devices	87		
		3.2.4	Registration Procedures for Category II and III Medical			
			Devices	92		
		3.2.5	Registration Procedures for In Vitro Diagnostic Medical			
			Devices	96		
		3.2.6	Special Examination and Approval Procedures for			
			Innovative Medical Devices	101		
		3.2.7	Approval Procedures in Emergencies	103		
	3.3	Import of Medical Devices		104		
		3.3.1	Prerequisites	104		
		3.3.2	Procedure	105		
	3.4	Distril	bution in the Chinese Market	106		
		3.4.1	Designated Agents	106		
		3.4.2	Representative Office Established in China	106		
		3.4.3	Establishment of a Subsidiary as Representative	106		
	3.5	Advertising for Medical Devices				
	3.6	Price Cap				
	3.7	Procus	rement Procedure for the Purchase of Medical Equipment			
		by Pu	blic Hospitals	109		
	3.8	Recall	of Defective Medical Devices	110		
	3.9	Dome	estic Production of Medical Devices	110		
		3.9.1	Investment Policy at a Glance	110		
		3.9.2	Licencing Regime for the Manufacturing of Medical			
			Devices	111		
		3.9.3	Competent Authority	112		
		3.9.4	Application Procedure	112		
		3.9.5	Advantages and Disadvantages of the Review and			
			Approval Process	112		

Contents vii

4	Lega	al Fran	nework for Investment in Retirement and Nursing		
	Homes in China				
	4.1	Genera	al Regulations	115	
		4.1.1	Investment Policy for Investment in Retirement		
			and Nursing Homes	115	
		4.1.2	Forms of Investment	117	
	4.2	Licensing, Registration and Operating Licence Requirements			
		4.2.1	Limitations	118	
		4.2.2	Qualifications	119	
		4.2.3	Approval Procedure	119	
	4.3	Nursir	ng Staff	125	
		4.3.1	Legal Regulations/Requirements	125	
		4.3.2	Special Requirements	125	
	4.4	Buildi	ng Permit Requirements	127	
		4.4.1	Norms of Construction Plans for Retirement and Nursing		
			Homes	127	
		4.4.2	Standards of the Construction Plans for the Residential		
			Building for the Elderly	127	
		4.4.3	Building Standards for Old People's Homes and Nursing		
			Homes	128	
		4.4.4	Barrier-Free Design Regulation	128	
	4.5	Preferential Taxes and Other Benefits		128	
		4.5.1	Exemption from Value Added Tax	128	
		4.5.2	Reduction of Administrative Fees	129	
		4.5.3	Lower Costs for Electricity, Water and Heating	129	
	4.6	Practical Examples of Foreign Investment		130	
		4.6.1	RIEI Co., Ltd. (Japan)	130	
		4.6.2	Colisée Group (France)	130	
		4.6.3	Orpea- Group (France)	130	
		4.6.4	Merrill Gardens (United States)	131	