Index

abortion, ECHR, 287-88 abuse of dominant position AstraZeneca, 655-59 competition law, 358-62, 364-65, 655-59,666 generic competition, 655-59, 666 GlaxoSmithKline, 666 services of general economic interest (SGEI), 364-65 advertising ban Tobacco Advertising Directive, 99-100 tobacco control, 99-100, 262-65 After the Services Directive, governance, 121-28 agencies, see also regulatory agencies; supranational agencies EU. 150 European Union Agency for Fundamental Rights, 308–12 key area, EU legal and policy developments in health, 45-49 overview, 45-49 risk analysis, 165 aims, this book's, 1 Altmark package public procurement, 384-89, 396-97 state aid, 384-89 ambulance services, public procurement, 397-98 'amenable mortality', policy, 5 anti-competitive agreements Commission Inquiry, 660-61 generic competition, 660-61 AstraZeneca abuse of dominant position, 655-59 competition law, 655-59 regulatory pathway, 655-59

award procedures closed awards, 413-14 competitive awards, 415-16 no contractual relationship, 412-13 open awards, 414-15 public procurement, 412-16 balance, need for, 83 barriers, free movement of services, 468 - 77Bettercare case, competition law, 345 - 46Biomedicine Convention, health care law, 285-86 bio-similar medicines/products, generic competition, 653-55 Blood Safety Directive, public health policy, 238-39 Bolkestein Directive governance, 121-28 Netherlands, 431-33 private health insurance, 431-33 border regions access, treatment abroad, 538-40 'brain drain' ethical recruitment guidelines, 622-23 health professionals, 622-23 budget, public health policy, 90-92 BUPA financial transfers, 440-45 Ireland, 440-45 risk equalization schemes, 440 - 45CAP, see Common Agricultural Policy cartels

competition law, 350–58 exclusions, 355–58

case-law ECJ, 516-21 free movement of patients, 516-21 centralized/decentralized licensing regime, pharmaceuticals market, 644 - 46CFI. see Court of First Instance challenges policy, 4-19 supranational solidarity, 22-24 variety in approaches, 22 welfare, 22-24 Charter of Fundamental Rights of the European Union, see EU Charter client politics (diffuse/concentrated), 8 - 9clinical trials patent protection, 647-48 pharmaceuticals market, 647-48 closed awards, award procedures, public procurement, 413–14 **Commission Inquiry** anti-competitive agreements, 660 - 61generic competition, 659-61 patent protection, 659-61 Commission's role, new governance, 226 - 28Committee for Proprietary Medicinal Products (CPMP) health protection, 158-59 pharmaceuticals policy and law, 158 - 59Common Agricultural Policy (CAP), public health policy, 234 common health care objectives new governance, 207 OMC, 207 common values and principles, policy, 14 - 18communicable disease control ECDC, 252-56 goods, restrictions on movements, 249 - 50IHR, 247-49 networks, EU, 254-55 people, restrictions on movements, 250 - 51public health policy, 247-57 restrictions on movements of goods, 249 - 50

restrictions on movements of people, 250-51 summary, 256-57 surveillance/response system, 251-56 communication, health professionals, 599-600 community framework free movement of patients, 551-56, 558-59 safe, high-quality, efficient care, 551-56, 558-59 competition competition policy 'toolkit', 638-39 consequences, 642-44 intra-brand competition, 642, 662-63 parameters, 640-44 pharmaceuticals market, 635-38 policy, 25 competition law, 337-78 abuse of dominant position, 358-62, 364-65, 655-59, 666 applying, 338-49 AstraZeneca, 655-59 Bettercare case, 345-46 cartels, 350-58 Commission Inquiry, 659-61 conclusions, 334-36, 376-78 Constitutional Treaty, 332-34 damage claims, 374-76 decentralization of enforcement, 670 - 72ECJ, 30-32, 322-25 economic activity, 319 e-health, 571-72 enforcement, 367-76 enforcement analysis, 368-69 European Commission, 330-34 exclusion, social solidarity, 320-25 exclusionary abuse, 359-62 Finnish Competition Authority (FCA), 347 Foundation Trusts (FTs), 346-47 free movement of services, 101-2 fundholding scheme, UK, 344-45 generic medicines, 655-59 German Competition Authority (GCA), 347–48 health insurance market, 365-67 health insurers, 342

health policy, 337-78 health providers, 342 health system reforms, 372-73 imperium principle, 341 internal market, 101-2 key area, EU legal and policy developments in health, 57-62 legal crossroads, 338-39 markets, 315-18 NCAs, 367-76, 377 Netherlands, 372-73 overview, 57-62 pharmaceuticals market, 655-59 pharmaceuticals pricing, 373 political reform, 330-34 predatory pricing, 360-62 privatization, 340-41 prohibited conduct, 350-67 public services, 315-36 public/private sectors, 344-48 scope, 319-25 SGEI, 325-29, 362-67 social insurance institutions, 343 social solidarity exclusion, 315-18, 320 - 25state regulation, 362-67 competition parameters, pharmaceuticals market, 640-44 competition types, pharmaceuticals market, 640-44 competitive awards, award procedures, public procurement, 415 - 16complementary cover government intervention, 432 - 35private health insurance, 432–35 concertation procedure, health protection, 159 'constitutional asymmetry' policy, 5-7 'constitutional asymmetry', 79 Constitutional Treaty, competition law, 332-34 constraints, policy, 7-11 constructivism, policy, 9 continuing professional development (CPD), Directive 2005/36/EC, 613-18 continuity of care, health professionals, 590

Contracting Directive, Distance, e-health, 569-70 contracting entities public procurement, 404–12 SGEI, 404-12 contractual arrangements free movement of patients, 528 planned care, treatment abroad, 540 - 44contradictions, policy, 4-19 cooperation initiatives, free movement of patients, 528 coordination routes adjustments, treatment abroad, 535-38 Court of First Instance (CFI) GlaxoSmithKline, 663-66 pharmaceuticals market, 663-66 pricing and marketing, 663-66 CPD, see continuing professional development CPMP, see Committee for Proprietary Medicinal Products cross-subsidies, policy, 12-19 damage claims, competition law, 374-76 data exclusivity, generic competition, pharmaceuticals, 650-51 Data Protection Directive, e-health, 563-66, 576-79 'de minimis Communication', public procurement, 390-92 decentralization of enforcement, competition law, 670-72 decentralized/centralized licensing regime, pharmaceuticals market, 644-46 deregulation, see also free movement of services; internal market policy, 25 differential treatment of insurers government intervention, 450 private health insurance, 450 Directive 2004/27/EC, generic competition, 649-50 Directive 2005/36/EC, 603-20 automatic recognition, 604-8 background, 603-4 common platforms, 609 CPD, 613-18 disciplinary matters, 619-20

Directive 2005/36/EC (cont.) establishment vs. provision of services, 610-13 general system, 608-9 health professionals, 603-20 practices allowed, 618 professional qualifications, 603-20 pursuit of the profession, 610-13 qualifications recognition, 613-18 qualifications, professional, 603-20 quality, 613-18 recognition, automatic, 604-8 specific provisions, 606-8 training, minimum conditions, 604 - 8disciplinary matters Directive 2005/36/EC, 619-20 health professionals, 619–20 discrimination, EU law, 25-26 disease control, communicable, see communicable disease control Distance Contracting Directive, e-health, 569-70 'Doctors' Directives', health professionals mobility, 592-93 dominant position abuse, see abuse of dominant position dual pricing, GlaxoSmithKline, 663-66 EACP, see 'Europe against Cancer' programme EC rules national health care, 393-416 public procurement, 393-416 ECDC, see European Centre for Disease Control; European Centre for Disease Prevention and Control ECHR, see European Convention on Human Rights ECJ, see European Court of Justice E-commerce Directive, e-health, 566-68 economic activity, competition law, 319 economic differences, Member States, health professionals, 589-90

Economic Policy Committee (EPC), governance, 112–13 e-Europe initiative, e-health, 572-73 EFSA. see European Food Safety Authority e-health, 561-88 applications, 561-62, 575-82 competition law, 571-72 conclusions, 587-88 Contracting Directive, Distance, 569 - 70Data Protection Directive, 563-66, 576-79 defining, 561-62 Distance Contracting Directive, 569 - 70E-commerce Directive, 566-68 e-Europe initiative, 572-73 EHR, 575-79 Electronic Signatures Directive, 570-71 genetic data/tissue, 580-82 health grids, 579-80 health systems, policy impact, 572-75 key area, EU legal and policy developments in health, 70-73 legal challenges to promote, 575-87 legal framework, 561-88 legal instruments, 563-72 liability legal framework, 585-87 Medical Device Directives, 568-69 overview, 70-73 platforms, 575-79 policy impact, 572-75 Product Liability Directive, 586-87 promoting, 575-87 scope, 561-62 status, 70-73 telemedicine legal framework, 585-87 telemedicine reimbursement criteria, 582-84 telemedicine services, 574-75 Working Group on Health Telematics, 573 EHR. see electronic health records electronic health records (EHR), e-health, 575-79 Electronic Signatures Directive, e-health, 570-71

EMEA, see European Medicines Agency employment rights, EU law, 25-26 entrepreneurial politics (concentrated/ diffuse), 8-9 environmental policy, public health policy, 234 environmental tobacco smoke, tobacco control, 269-72 EPC, see Economic Policy Committee equality EU Charter, 302 fundamental rights, 302 ERDF, see European Regional Development Fund erosion/protection of national social policies, 19-28 ESF, see European Social Fund establishment vs. provision of services Directive 2005/36/EC, 610-13 health professionals, 601-2 ethical recruitment guidelines, health professionals, 622-23 EU agenda, slow move of health care to the EU agenda, 106-21 EU Charter equality, 302 fundamental rights, 282-83 health care law, 296-308 health policy, 296-308 personal data, 301-2 solidarity, 303-8 torture, 300-1 EU institutions' roles, new governance, 226-28 EU law, see also European Court of Justice (ECJ) cross-fertilization with governance, 131 direct effect, 92-94 discrimination, 25-26 effects on health systems, 92-105 employment rights, 25-26 free movement of services, 94-101 governance, cross-fertilization, 131 health care law, 283-94 health professionals, 73-75 hybrid approaches, 82-83 internal market, 94-101 legal-policy patchwork, 92-105

national social policies, 19-28 supremacy, 92-94 Tobacco Advertising Directive, 99 - 100tobacco control, 275-77 'Europe against Cancer' programme (EACP), tobacco control, 257-62 European Centre for Disease Control (ECDC) development, 81-82 role, 81-82 shortcomings, 81-82 European Centre for Disease Prevention and Control (ECDC), communicable disease control, 252 - 56European Commission competition law, 330-34 political reform, 330-34 European Convention on Human Rights (ECHR) abortion, 287-88 health care law, 286-90 reproductive technology, 288-90 European Court of Justice (ECJ), see also EU law case-law, ECI, 516-21 competition law, 30-32, 322-25 free movement of patients, 516-21 free movement of patients, policy response to ECJ rulings, 521-27 free movement of services, 30–32 impact, 18-19 interpreting law, 32-34 jurisprudence, 27-28 policy response to ECI rulings, free movement of patients, 521-27 role, 28-34 SGEI, 326-29 soft law, 34 European Food Safety Authority (EFSA), 35-37 accountability, 176-77 cf. EMEA, 164-82 core functions, 165-70 governance, 171-81 health protection, 161-62 health systems, 181-82 independence, 171–76 industry's role, 180-81

European Food Safety Authority (EFSA), (cont.) participation, 179-80 politics of scientific advice, 165-70 regulatory agencies, 135-37 transparency, 177-79 European Medicines Agency (EMEA), 35 - 37accountability, 176-77 centralized/decentralized licensing regime, 645–46 cf. EFSA, 164-82 core functions, 165-70 governance, 171-81 health protection, 159-60 health systems, 181–82 independence, 171-76 industry's role, 180-81 licensing regime, 645-46 origin, 159-60 participation, 179-80 pharmaceuticals market, 645-46 politics of scientific advice, 165-70 regulatory agencies, 135-37 transparency, 177-79 European Regional Development Fund (ERDF), public health policy, 91-92 European Social Charter, fundamental rights, 290-92 European Social Fund (ESF), public health policy, 91–92 European social model, welfare, 21 - 22European Union Agency for Fundamental Rights, health rights, 308-12 Europeanization health protection, regulatory agencies, 154-64 welfare, 20-21 exclusionary abuse, competition law, 359 - 62FCA, see Finnish Competition Authority FCC, see French Competition Council financial transfers BUPA, 440-45 government intervention, 437–47

Ireland, 438-39, 440-45

Netherlands, 438-39, 439-40 Slovenia, 438-39, 445-47 Finnish Competition Authority (FCA), competition law, 347 foodstuffs EFSA, 161-62 EFSA cf. EMEA, 164-82 European dimension, health protection, 157-62 Platform on diet, nutrition and physical activity, 194 priorities, balancing, 162-64 SCF, 160-61 Forum, Pharmaceutical, see Pharmaceutical Forum Foundation Trusts (FTs), competition law, 346-47 fragmentation, pharmaceuticals market, 637-38 free movement of patients, 509-60, see also restrictions on movements of people; treatment abroad access arrangements, 529-51 authorization, 530-35 border regions access, 538-40 case-law, 516-21 challenges, 559 community framework, 551-56, 558-59 conceptual construct, 511-14 conclusions, 556-60 contractual arrangements, 528 contractual arrangements, planned care, 540-44 cooperation initiatives, 528, 556 coordination routes adjustments, 535 - 38ECJ case-law, 516-21 fear of harm, 553-54 governance, 511-28, 558 informed choice, 554-55 overview, 67-70 planned care, contractual arrangements, 540-44 policy response to ECJ rulings, 521-27 private patients, 544 retired people, 550-51 safe, high-quality, efficient care, 551-56

social security coordination. 514-16 temporary stays abroad, 544-51 tensions, 513-14 treatment abroad, 529-44 types, 529-51 free movement of services, 461–508, see also deregulation; internal market; restrictions on movement of goods barriers, 468-77 competition law, 101-2 conclusions, 505-8 ECI, 30-32 economic nature of health care, 465 - 68EU law, 94-101 generic (social services of general interest) approach, 502-5 health care as economic activity, 465 - 77health systems approach, 499-502 HLG, 499-502 horizontal (internal market) approach, 497-99 internal market, 94-101 internal market approach, 497-99 justified restrictions, 477-93 key area, EU legal and policy developments in health, 64-67 legal certainty, 493-96 national actors, 493-96 Necessity Test, 479-82 overview, 64-67 policy challenge, 493-505 policy responses, EU level, 497-505 Proportionality Test, 482-93 public health policy, 232-33 sectoral (health systems) approach, 499-502 social and employment law, 102-5 social services of general interest approach, 502-5 types, see *also* deregulation; internal market; restrictions on movements of goods unjustified restrictions, 477-93 free movement of students, see also health professionals quotas, 620-22 training access, 620-22

French Competition Council (FCC), supply quotas, pharmaceuticals market, 668-69 FTs, see Foundation Trusts fundamental rights, 282-314 conclusions, 312-14 ECHR, 286-90 equality, 302 EU Charter, 282-83 European Social Charter, 290 - 92European Union Agency for Fundamental Rights, 308-12 health care law, 283-94, 294-312 key area, EU legal and policy developments in health, 54-56 Member States, 292-94 overview, 54-56 personal data, 301-2 solidarity, 303-8 torture, 300-1 fundholding scheme, UK, competition law, 344-45 funding ERDF, 91-92 ESF, 91-92 public health policy, 90-92 future governance, 131-33 new governance, 224-30 public health policy, 277-80 GCA, see German Competition

Authority general directives health professionals mobility, 597-603 shortcomings, 598-603 general interest services, see services of general economic interest generic (social services of general interest) approach, free movement of services, 502-5 generic competition, see also intrabrand competition; patent protection; pharmaceuticals market abuse of dominant position, 655-59,666 anti-competitive agreements,

660–61

generic competition (cont.) bio-similar medicines/products. 653 - 55Commission Inquiry, 659-61 data exclusivity, 650-51 Directive 2004/27/EC, 649-50 marketing exclusivity, 651-53 pharmaceuticals market, 641-42, 649-61 Regulation 726/2004/EC, 649-50 regulatory pathway, 649-61 generic medicines competition law, 655-59 defining, 652-53 NCAs, 371 pharmaceuticals policy and law, 371 pharmaceuticals pricing, 371 regulatory pathway, see also pharmaceuticals market genetic data/tissue, e-health, 580-82 German Competition Authority (GCA), competition law, 347-48 GlaxoSmithKline abuse of dominant position, 666 CFI, 663-66 dual pricing, 663-66 marketing pathway, 663-66 pharmaceuticals market, 663-66 supply quotas, 666-69 goods, restrictions on movements, communicable disease control, 249 - 50governance, see also new governance; regulatory agencies After the Services Directive, 121–28 Bolkestein Directive, 121–28 cross-fertilization with EU law, 131 EFSA, 171-81 EMEA, 171-81 EPC, 112-13 EU law, cross-fertilization, 131 free movement of patients, 511-28, 558 future, 131-33 Health Policy Forum, 115–16 HLG, 122-28, 130-31 HLPR, 116-21, 130-31 legal-policy patchwork, 105-28 new forms of, 34-42, 80

operationalization, 121-28 pharmaceutical industry priorities, 111 - 12regulatory agencies, NMG, 135, 137 - 54slow move of health care to the EU agenda, 106-21 soft law, 34-42, 80 government intervention benefits, 447-50 circumstances of, 430-37 complementary cover, 432-35 differential treatment of insurers, 450 financial transfers, 437-47 Ireland, 438-39, 440-45 legal challenges, 438-39 Netherlands, 431-33, 438-39, 439 - 40private health insurance, 429-55 risk equalization schemes, 437-47 Slovenia, 438-39, 445-47 soft law, see also regulation solvency requirements, 450-52 tax treatment, 453-55 types, 437-55 Greek Syfait Case, pharmaceuticals market, 666-68 health and safety, public health policy, 233 - 34health care as economic activity barriers to free movement of services, 468-77 economic nature of health care, 465-68 free movement of services, 465-77 health care law Biomedicine Convention, 285–86 ECHR, 286-90 EU Charter, 296-308 fundamental rights, 283-94, 294-312 health grids, e-health, 579-80 health insurance market, competition law. 365-67 health insurers, competition law, 342 health policy, see also public health policy competition law, 337-78

EU Charter, 296-308 new governance, 191-93, 198 - 212Health Policy Forum, governance, 115 - 16health professionals, 589-634 'brain drain', 622-23 communication, 599-600 conclusions, 632-34 continuity of care, 590 CPD, 613-18 Directive 2005/36/EC, 603-20 disciplinary matters, 619-20 distrust, 598-99 'Doctors' Directives', 592-93 economic differences, Member States, 589-90 establishment vs. provision of services, 601-2, 610-13 ethical recruitment guidelines, 622-23 EU law, 73-75, 589-634 free movement of students, 620-22 general directives, 597-603 Hungary, Working Time Directive, 628 information exchange, 600 key area, EU legal and policy developments in health, 73-75 Member States' economic differences, 589-90 mobility, 591-623 non-discrimination rule, 600-1 overview, 73-75 payment issues, 602 practices allowed, 618 qualifications recognition, 613-18 qualifications, professional, 603-20 recruitment guidelines, ethical, 622 - 23recruitment system failure, 622–23 reimbursement issues, 602 sectoral directives, 593-97 service provision vs. establishment of services, 601-2, 610-13 telemedicine, 603 training access, 620-22, 622-23 training, minimum conditions, 604 - 8Working Time Directive, 623–32

health protection concertation procedure, 159 CPMP, 158-59 EFSA, 161-62 EMEA, 159-60 European dimension, 157-62 Europeanization, 154-64 foodstuffs, European dimension, 157-62 pharmaceuticals policy and law, 158 - 59pharmaceuticals, European dimension, 157-62 priorities, balancing, 162-64 regulatory agencies, 134-85, 154 - 64SCF, 160-61 health providers, competition law, 342 health rights, European Union Agency for Fundamental Rights, 308-12 health system reforms, competition law, 372-73 health systems best practices, 78-79 constrained competence, 79-80 EFSA, 181-82 e-health, policy impact, 572-75 EMEA, 181-82 EU law effects, 92-105 evolving, 78 public procurement, 379-418 similarities, 12-19 state aid, 379-418 health systems approach, free movement of services, 499-502 High Level Group on Health Services and Medical Care (HLG) free movement of services, 499-502 governance, 122-28, 130-31 new governance, 194-95 'High Level Process of Reflection' (HLPR), governance, 116–21, 130 - 31HLG, see High Level Group on Health Services and Medical Care

HLPR, *see* 'High Level Process of Reflection'

horizontal (internal market) approach. free movement of services. 497-99 Hungary health professionals, 628 Working Time Directive, 628 IHR, see International Health Regulations imperium principle, competition law, 341 information exchange, health professionals, 600 informed choice, treatment abroad, 554 - 55institutions' roles, EU, see EU institutions' roles insurance, private health, see private health insurance interest group politics (concentrated/ concentrated), 8-9 intergovernmentalism, policy, 9-10 internal market, see also deregulation; free movement of services competition law, 101-2 EU law, 94-101 free movement of services, 94-101 private health insurance, 419-60 public health policy, 235 public procurement, 389-93 regulating, 389-93 social and employment law, 102-5 Tobacco Advertising Directive, 99-100 internal market approach, free movement of services, 497-99 International Health Regulations (IHR), communicable disease control, 247-49 international/national issues relationship, public health policy, 231 - 32interpreting law, ECJ, 32-34 intra-brand competition, see also generic competition marketing pathway, 662-63 pharmaceuticals market, 642, 662-63 Ireland

BUPA, 440-45 financial transfers, 438-39, 440-45 government intervention, 438-39, 440 - 45private health insurance, 438-39, 440 - 45risk equalization schemes, 438-39, 440 - 45key areas, EU legal and policy developments in health, 42 agencies, 45-49 competition law, 57-62 e-health, 70-73 free movement of patients, 67-70 free movement of services, 64-67 fundamental rights, 54-56 health professionals, 73-75 legal-policy patchwork, 42-45 pharmaceuticals policy and law. 75-77 private health insurance, 62-64 public health, 52-54 soft law, 49-51 labelling, tobacco control, 265-69 law, EU, see EU law legal certainty, free movement of services, 493-96 legal challenges government intervention, 438-39 private health insurance, 438–39 legal instruments, e-health, 563-72 legal-policy patchwork, 84-133 EU law effects on health systems, 92-105 governance, 105-28 key area, EU legal and policy developments in health, 42-45 overview, 42-45 predicament, 84-87 public health policy, 87-92 liability legal framework, e-health, 585-87 liberalization, policy, 25 licensing regime centralized/decentralized, 644-46 pharmaceuticals market, 644-46 regulatory pathway, 644-46

lobbving, industry, tobacco control, 261-62, 268-69, 275-77 local government policies, NCAs, 371-72 majoritarian politics (diffuse/diffuse), 8 - 9market, internal, see internal market market-building policies, 2-3 market-correcting policies, 2-3 market-cushioning policies, 2-3 marketing exclusivity, generic competition, pharmaceuticals, 651-53 marketing pathway GlaxoSmithKline, 663-66 implications, 669-72 intra-brand competition, 662-63 pharmaceuticals market, 661–72 pricing and marketing, 661–62 refusals to supply, 666-69 supply quotas, 666-69 markets competition law, 315-18 social solidarity, 315-18 markets classification, private health insurance, 422 Medical Device Directives, e-health, 568 - 69mobility, see also free movement of patients; free movement of services health professionals, 591–623 Monti-Kroes package, see Altmark package national competition authorities (NCAs) authority differences, 370 competition law, 367-76, 377 generic medicines, 371 local government policies, 371–72 pharmaceuticals policy and law, 371 pharmaceuticals pricing, 373 pressures, 369-72 national regulation, pharmaceuticals market, 636-37 national social policies

erosion/protection, 19-28 EU law, 19-28 protection/erosion, 19-28 national/international issues relationship, public health policy, 2.31 - 32NCAs, see national competition authorities Necessity Test, free movement of services, 479-82 Netherlands Bolkestein Directive, 431–33 competition law, 372-73 financial transfers, 438-39, 439-40 government intervention, 431-33, 438-39, 439-40 health system reforms, 372-73 private health insurance, 431–33, 438-39, 439-40 risk equalization schemes, 438-39, 439 - 40networks, EU communicable disease control, 2.54 - 5.5OMC, 218-20 new governance ambiguity of instruments, 212-24 Commission's role, 226-28 common health care objectives, 207 defining, 191–93 development, 190-91, 198-212 EU institutions' roles, 226–28 future, 224-30 health care on the agenda, 199-202 health policy, 191-93, 198-212 High Level Group on Health Services and Medical Care, 194 - 95instruments' ambiguity, 212-24 mechanisms, 202-12 objectives, common health care, 207objectives, overarching health care, 207-12 OMC, 193-98 overarching health care objectives, 207-12 persistence, 228-30

new governance (cont.) Platform on diet, nutrition and physical activity, 194, 218 regulatory agencies, 135, 137-54 resources, scarce, 225-26 scarce resources, 225-26 soft law, 188-91 usefulness, 228-30 varieties, 193 Working Time Directive, 204 'new modes of governance' (NMG), see new governance non-discrimination rule, health professionals, 600-1 objectives common health care, 207 public health policy, 89 OMC, see open method of coordination open awards, award procedures, public procurement, 414-15 open method of coordination (OMC) as learning, 215-22 as soft law, 222-24 common health care objectives, 207 'delivery gap', 214-15 indicators, 210-12 launch, 202-12 networks, EU, 218-20 new governance, 193-98 objectives, common health care, 2.07objectives, overarching health care, 207 - 12overarching health care objectives, 207 - 12overview, 195-97 soft law, 193 soft law example, 39-42 steering instruments, 193 target setting, 220-22 operationalization, governance, 121 - 28overarching health care objectives new governance, 207-12 OMC, 207-12 overview agencies, 45-49 competition law, 57-62

e-health, 70-73 free movement of patients, 67-70 free movement of services, 64-67 fundamental rights, 54-56 health professionals, EU law, 73-75 legal-policy patchwork, 42-45 pharmaceuticals policy and law, 75 - 77private health insurance, 62-64 public health, 52-54 soft law, 49-51 Paris Court of Appeal, supply quotas, pharmaceuticals market, 668-69 patchwork, legal-policy, see legalpolicy patchwork patent certificate regime pharmaceuticals market, 646-49 SPaC regime, 646-49 patent protection, see also generic competition clinical trials, 647-48 Commission Inquiry, 659-61 harmonization, remaining gaps, 648 - 49pharmaceuticals market, 646-49 pharmacovigilance, 647-48 patient information, Pharmaceutical Forum, 677-80 patient mobility, see free movement of patients payment issues, health professionals, 602 people, restrictions on movements, communicable disease control, 250-51 personal data EU Charter, 301-2 fundamental rights, 301-2 Pharmaceutical Forum patient information, 677-80 pharmaceuticals market, 672-80 pricing, 674-76 REAs, 676-77 pharmaceutical industry governance, 111-12 priorities, 111-12 pharmaceuticals market, 681-82, see also generic competition; generic medicines; pharmaceuticals pricing

bio-similar medicines/products. 653-55 centralized/decentralized licensing regime, 644-46 CFI, 663-66 clinical trials, 647-48 competition, 635-38 competition consequences, 642-44 competition law, 655-59 competition law decentralization. 670-72 competition parameters, 640-44 competition policy 'toolkit', 638-39 competition types, 640-44 conclusions, 681-82 data exclusivity, 650-51 decentralization, competition law enforcement, 670-72 EMEA, 645-46 forum, 672-80 fragmentation, 637-38 generic competition, 641-42, 649 - 61GlaxoSmithKline, 663–66 Greek Syfait Case, 666-68 intra-brand competition, 642, 662-63 licensing regime, 644-46 marketing exclusivity, 651-53 marketing pathway, 661-72 national regulation, 636-37 parameters for competition, 640 - 44patent certificate regime, 646-49 patent protection, 646-49 patient information, 677-80 Pharmaceutical Forum, 672-80 pharmacovigilance, 647-48 policy objectives, 635-38 REAs, 676-77 refusals to supply, 666-69 regulatory pathway, 644-49 SPaC regime, 646-49 supply quotas, 666-69 therapeutic competition, 640 pharmaceuticals policy and law CPMP, 158–59 EMEA, 159-60 EMEA cf. EFSA, 164-82 European dimension, health protection, 157-62

generic medicines, 371 key area, EU legal and policy developments in health, 75-77 NCAs, 371 objectives, 635-38 overview, 75-77 priorities, balancing, 162-64 pharmaceuticals pricing CFI, 663-66 competition law, 373 dual pricing, 663-66 generic medicines, 371 NCAs, 373 Pharmaceutical Forum, 674-76 pharmaceuticals market, 661-62, 663-66 pharmacovigilance patent protection, 647-48 pharmaceuticals market, 647-48 planned care, contractual arrangements free movement of patients, 540-44 treatment abroad, 540-44 Platform on diet, nutrition and physical activity, new governance, 194.218 policy 'amenable mortality', 5 challenges, 4-19 client politics (diffuse/ concentrated), 8-9 common values and principles, 14-18 competition, 25 'constitutional asymmetry', 5-7 constraints, 7-11 constructivism, 9 contradictions, 4-19 cross-subsidies, 12-19 deregulation, 25 entrepreneurial politics (concentrated/diffuse), 8-9 interest group politics (concentrated/concentrated), 8-9 intergovernmentalism, 9-10 liberalization, 25 majoritarian politics (diffuse/ diffuse), 8–9 quality element, 80-81 rationalist perspectives, 8-9 soft law, 34-42