

1 Public health

- Council: conclusions on Covid-19
- Council: the economy of wellbeing
- European Commission: expansion of the European Reference Networks
- EXPH: opinion on options to foster health-promoting health systems
- European Commission-OECD-OBS: State of health in the EU
- ECDC: survey of healthcare workers' knowledge and attitudes concerning antibiotic resistance
- EU Health Policy Platform: joint statements
- European Commission: public consultation on Europe's Beating Cancer Plan
- European Commission: tackling the Covid-19 outbreak

2 Health care services in the internal market

- European Commission: toolbox for cross-border healthcare

3 Medicines and medical devices

- Council: the Finnish presidency makes a series of proposals on improving access to medicines
- Council: Regulation on health technology assessment
- Novartis withdraws a patent for an over-priced cancer medication
- EMA: mandatory use of an international format for reporting side effects to EudraVigilance
- EMA and HMA: Ten recommendations to unlock the potential of big data for public health in the EU
- EMA: draft 'Regulatory Science to 2025' strategy
- PPRI: comparative analysis of pharmaceutical pricing and reimbursement policies in the 47 PPRI member countries
- AIM: Fair prices for pharmaceuticals - Why and how?

4 e-Health

- European Commission: European data strategy
- European Commission: White Paper on artificial intelligence
- EPHA: reflection paper on big data and artificial intelligence in health care
- European Parliament: resolution on enabling the digital transformation of health and care
- European Commission: the work programme for European standardisation for 2020

5 Social policy

- European Commission: proposal for a joint employment report 2020
- European Commission: coordination of social security systems at a glance
- European Commission: statistical reports on social security coordination 2019
- European Commission: intermediate report on the feasibility of a guarantee for vulnerable children
- European Commission: a strong social Europe for just transitions

6 Economic policy

- European Commission: publication of the country reports, as part of the European Semester
- European Commission: publication of the Annual Sustainable Growth Strategy 2020
- European Commission: Post-programme surveillance report. Cyprus - autumn 2019
- European Commission: Post-programme surveillance report. Ireland - autumn 2019
- European Investment Bank (EIB): loan to prosthetics producer
- EIB: support to biotech company MolMed SpA for investment in research, development and production of innovative treatments for cancer and rare diseases
- EIB: € 40 million for research and development into cancer treatments

7 Competition

- European Commission: acquisition of General Electric's Healthcare Life Sciences Biopharma Business by Danaher Corporation approved subject to conditions
- European Commission: acquisition of Allergan by AbbVie approved
- European Commission: in-depth investigation into proposed acquisition of GrandVision by EssilorLuxottica
- Latvia: unfavourable pricing mechanism for medicines

8 Court of Justice of the European Union

- Judgment: settlement agreement between a manufacturer of originator medicines and a manufacturer of generic medicines
- Judgment: the Court confirms the right of access to documents contained in the file of a marketing authorisation application for a medicinal product
- Judgment: appeal brought by the 'One of us' European Citizens' Initiative (ECI) dismissed
- Advocate General's opinion: a requirement for civil liability insurance concerning the use of medical devices may be restricted to the territory of a Member State

9 Publications

- WHO: status report on prison health in the WHO European region
- Federal Public Service Social Security: Analysis of the evolution of the social situation and social protection in Belgium
- BTSZ: 60 years of social security coordination from a workers' perspective
- OSE: inequalities in access to healthcare in the European Union Member States
- Médecins du Monde: access to healthcare in Europe for vulnerable people - an alarming situation
- OECD: Performance-based managed entry agreements for new medicines in OECD countries and EU Member States
- Council of Europe: study on shortcomings in the legislation on falsified medicines
- ETUI: Tackling low pay in sectors dominated by women- evidence from health and social care
- EPHA: regional collaboration initiatives concerning access to medicines: BENELUXA et al
- OECD: unmet needs for healthcare: comparing approaches and results from international surveys
- BMJ: Fair pricing of medicines
- OECD: Health at a Glance 2019

10 Miscellaneous

- Johanniter International: European first aid guidelines

1 Public health

Council: conclusions on Covid-19

On the basis of a Presidency steering note, ministers exchanged views on the implications of the outbreak of Covid-19. They adopted conclusions, which insisted on the need for increased cooperation, at both EU and international level.

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Council: the economy of wellbeing

On the basis of a discussion paper, ministers held a discussion entitled "Economy of wellbeing- next steps in investing in health as its key component". The ministers shared their views on health-related subjects, particularly mental health, healthy ageing, and the digital transformation of health and social services.

The Finnish presidency also informed the ministers of the outcomes of the conference organised on this subject.

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European Commission: expansion of the European Reference Networks

841 new clinical units in hospitals across Europe have asked to become members of the European Reference Networks (ERNs) of centres offering highly specialised care. An evaluation process will be used to decide which of the applicants will be accepted into the ERNs. The ERNs currently have 953 members, and have recently accepted 247 Associated National Centres and 4 National Coordination Hubs as affiliated partners.

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EXPH: opinion on options to foster health-promoting health systems

The Expert Panel on effective ways of investing in health (EXPH) published an opinion on options to foster health-promoting health systems.

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European Commission-OECD-OBS: State of health in the EU

The European Commission, in cooperation with the OECD and the European Observatory on Health Systems and Policies (OBS) published reports describing the profiles of health systems in thirty countries. These country health profiles, describing the "State of Health in the EU", compare the health systems in the various countries. A companion report has also been published, presenting some of the major trends in the changing face of health systems.

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ECDC: survey of healthcare workers' knowledge and attitudes concerning antibiotic resistance

Generally speaking, knowledge and awareness of antibiotic resistance and related issues are high among European healthcare workers, according to a European survey carried out by the European Centre for Disease Prevention and Control (ECDC). The survey, however, also reported significant gaps in knowledge.

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EU Health Policy Platform: joint statements

At its annual meeting, the EU Health Policy Platform discussed joint statements, prepared by thematic networks, on the following topics:

- Healthcare in cross-border regions
- Improving organ donation and transplantation in the EU
- Nobody left outside: improving access to healthcare for vulnerable and marginalised groups
- Improving integrated people-centred healthcare solutions

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European Commission: public consultation on Europe's Beating Cancer Plan

The European Commission launched an EU-wide public consultation on Europe's Beating Cancer Plan. The consultation will help shape the plan, identify key areas and explore future action.

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European Commission: tackling the Covid-19 outbreak

The European Commission is supporting the efforts being made to tackle the Covid-19 outbreak, in various ways. It is coordinating with Member States to share information, assess needs and ensure a consistent EU-wide response. The Commission is also financing research, offering support through the EU civil protection mechanism, and supporting China with emergency medical supplies.

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2 Health care services in the internal market

European Commission: toolbox for cross-border healthcare

This toolbox contains relevant information on the legal framework for cross-border healthcare. It is divided into two main parts: one for patients and one for National Contact Points (NCPs).

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3 Medicines and medical devices

Council: the Finnish presidency makes a series of proposals on improving access to medicines

On the basis of a presidency note, the ministers held a debate on how to strengthen cooperation and coordination in order to improve access to medicines throughout the EU.

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Council: Regulation on health technology assessment

The presidency informed ministers about the on-going discussions on the Regulation on health technology assessment.

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Novartis withdraws a patent for an over-priced cancer medication

On 3 July 2019, the organisations Doctors of the World (Médecins du Monde) and Public Eye filed a patent opposition at the European Patent Office against a patent covering Kymriah®, a gene therapy for cancer from Novartis. The aim was to denounce an abusive patent intended to strengthen a monopoly which would allow an exorbitant price to be imposed. At the end of November 2019, Novartis announced that it was withdrawing the patent.

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EMA: mandatory use of an international format for reporting side effects to EudraVigilance

The European Medicines Agency (EMA) has decided to require the use of a consistent international format, the ISO ICSR format, for reporting individual cases of suspected side effects in patients. The use of the new international standard will be mandatory for all reports made to EudraVigilance, the European database on suspected side effects of medicines authorised in the European Economic Area (EEA).

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EMA and HMA: Ten recommendations to unlock the potential of big data for public health in the EU

The joint Big Data Task Force of EMA and the Heads of Medicines Agencies (HMA) is proposing ten priority actions to make the best use of big data to support innovation and public health, by evolving the approach taken to data use and evidence generation.

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EMA: draft 'Regulatory Science to 2025' strategy

This is a plan for advancing the EMA's engagement with regulatory science over the next five to ten years. The draft strategy aims to build a more adaptive regulatory system that will encourage innovation in human and veterinary medicine.

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PPRI: comparative analysis of pharmaceutical pricing and reimbursement policies in the 47 PPRI member countries

This 2018 report provides an overview of pharmaceutical pricing and reimbursement policies in the 47 Pharmaceutical Pricing and Reimbursement Information (PPRI) member countries.

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AIM: Fair prices for pharmaceuticals - Why and how?

The International Association of Mutual benefit societies (AIM) organised an event entitled 'Fair prices for pharmaceuticals - why and how?', to discuss the challenges of the current pharmaceutical pricing model and possible solutions. At this event, AIM presented a proposal on fair and transparent prices for pharmaceuticals.

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4 e-Health

European Commission: European data strategy

The Commission presented its ideas and actions for digital transformation by means of a European data strategy and policy options to ensure the human-centric development of artificial intelligence (AI). Its communication on a data strategy makes specific reference to a Common European health data space (from p. 29). The Commission states that for high-risk cases, such as in health, policing or transport, AI systems should be transparent and traceable and should guarantee human oversight.

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European Commission: White Paper on artificial intelligence

In the White Paper accompanying the European data strategy, the Commission (Action 6) states its intention to launch sector dialogues, giving priority to healthcare, rural administrations and public service operators, in order to present an action plan. The sector dialogues will be used to prepare a specific 'Adopt AI programme', that will support public procurement of AI systems and help to transform public procurement processes themselves.

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EPHA: reflection paper on big data and artificial intelligence in health care

This reflection paper from the European Public Health Alliance (EPHA) examines the potential of artificial intelligence (AI) - and the big data used for this purpose - in the context of the on-going digital transformation of health and healthcare within the EU. According to the paper, it is vitally important that AI and related technologies should serve, first and foremost, the needs of their end users: healthcare providers, policymakers, patients and the general public.

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European Parliament: resolution on enabling the digital transformation of health and care

The purpose of the resolution is to give citizens a greater say and to promote health. It calls on the Commission to make a proposal on sharing information and data governance, to tackle the implications for national health systems. Some of the points emphasised are:

- access to and exchange of personal data, ensuring compliance with the data protection rules (GDPR)
- better health data
- better digital instruments

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European Commission: the work programme for European standardisation for 2020

The Commission is asking the European standardisation bodies to support the implementation of the recommended format for exchange of European electronic health records, by developing state-of-the-art standards to protect health data and ensure the security of network and information systems on which such electronic health record systems rely. This will help to avoid data breaches and minimise the risk of security incidents.

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5 Social policy

European Commission: proposal for a joint employment report 2020

The European Commission published the European Semester autumn package. This includes the proposal for a joint employment report 2020, which also discusses the challenges in relation to access to healthcare in the Member States.

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European Commission: coordination of social security systems at a glance

The common rules to coordinate the national social security systems cover anyone who moves to another country to settle permanently, work temporarily or study, and even those who are going on holiday. This report provides an overview and assessment of the functioning of the coordination rules during the reference year 2018. Cross-border healthcare is one of the topics addressed.

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European Commission: statistical reports on social security coordination 2019

These reports provide an overview of the data submitted by the Member States on the functioning of these rules.

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European Commission: intermediate report on the feasibility of a guarantee for vulnerable children

The Commission commissioned a report to study the feasibility of a child guarantee for vulnerable children. An interim report has now been published, with initial conclusions and recommendations. Access to healthcare is one of the five pillars of the child guarantee.

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European Commission: a strong social Europe for just transitions

The Commission presented a Communication on building a strong social Europe for just transitions. It sets out how social policy will help deliver on the challenges and opportunities of today, proposing actions at EU level for the months to come. Affordable healthcare is one of the points addressed.

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6 Economic policy

European Commission: publication of the country reports, as part of the European Semester

The country reports analyse economic and social policy challenges for the Member States, including their health systems.

According to the country report for Belgium, the Belgian health system is effective in its delivery of acute hospital care; however, many aspects of broader public health and prevention policy could be strengthened, in order to improve health and reduce health inequalities.

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European Commission: publication of the Annual Sustainable Growth Strategy 2020

As part of the European Semester, the European Commission published the Annual Sustainable Growth Strategy 2020, which sets out its priorities for the coming year. With regard to healthcare, the document says that, due to population ageing, investment in healthcare and long-term care is becoming increasingly important, bearing in mind the need to ensure the sustainability of the social protection system and thus guarantee intergenerational justice.

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European Commission: Post-programme surveillance report. Cyprus - autumn 2019

This report presents the findings of the seventh post-programme mission to Cyprus, and identifies the remaining challenges for the Cypriot economy following the end of the economic adjustment programme. The report also discusses the healthcare reforms.

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European Commission: Post-programme surveillance report. Ireland - autumn 2019

According to this report, the financial sustainability of the Irish healthcare system is not certain.

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European Investment Bank (EIB): loan to prosthetics producer

The European Investment Bank (EIB) is providing financing of up to € 100 million to Ottobock SE & Co. KGaA, a world-leading manufacturer and supplier of prosthetic limbs, orthotics and wheelchairs. Ottobock will use these funds for its European-based RDI programme.

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EIB: support to biotech company MolMed SpA for investment in research, development and production of innovative treatments for cancer and rare diseases

The European Investment Bank and the biotechnology company MolMed SpA (MLMD.MI) have signed a financing agreement which will provide MolMed, in the coming years, with a credit line of up to € 15 million to support its development plan for sustainable growth.

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EIB: € 40 million for research and development into cancer treatments

The European Investment Bank is providing € 40 million to ITM Isotopen Technologien München AG (ITM), a producer of innovative diagnostic and therapeutic radiopharmaceuticals for use in precision oncology. ITM will use this new funding to invest in research and development of a proprietary portfolio of Targeted Radionuclide Diagnostics and Therapies, to treat a number of forms of cancer.

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7 Competition

European Commission: acquisition of General Electric's Healthcare Life Sciences Biopharma Business by Danaher Corporation approved subject to conditions

The European Commission has approved Danaher Corporation's acquisition of General Electric's Healthcare Life Sciences Biopharma Business. Both companies are active in the manufacturing of products and services used in the bioprocessing industry. The acquisition is conditional on the divestment of certain activities.

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European Commission: acquisition of Allergan by AbbVie approved

The European Commission approved AbbVie's acquisition of Allergan. The approval is conditional on the divestment of a product under development by Allergan to treat inflammatory bowel diseases.

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European Commission: in-depth investigation into proposed acquisition of GrandVision by EssilorLuxottica

The European Commission launched an in-depth investigation into the proposed acquisition of GrandVision by EssilorLuxottica, with reference to the EU Merger Regulation. The Commission is concerned that the acquisition could reduce competition in the wholesale supply of ophthalmic lenses and eyewear, and in the retail supply of optical products.

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Latvia: unfavourable pricing mechanism for medicines

The Latvian Competition Council (CC) has concluded that even when manufacturers in Latvia set lower prices for medicines than in Lithuania or Estonia, medicines may be more expensive for Latvian customers, due to the existing pricing mechanism. The CC is therefore encouraging the responsible institutions to develop a new mechanism which would make reimbursable and non-reimbursable medicines financially more accessible to Latvian consumers.

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8 Court of Justice of the European Union

Judgment: settlement agreement between a manufacturer of originator medicines and a manufacturer of generic medicines

In case C 307/18, the Court ruled on a settlement agreement between a manufacturer of originator medicines and a manufacturer of generic medicines, in which the manufacturer of generic medicines undertook not to enter the market for a medicine with a specific active ingredient during the period covered by the agreement, in return for transfers of value in its favour from the manufacturer of originator medicines. The Court found that, in certain circumstances, this constitutes an agreement which has as its object the prevention, restriction or distortion of competition.

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Judgment: the Court confirms the right of access to documents contained in the file of a marketing authorisation application for a medicinal product

In judgments C-175/18P and C-178/18P, the Court confirms the right of access to documents from a file of a marketing authorisation application for a medicinal product. Any objection to such access must explain the nature, purpose and scope of the data whose disclosure would undermine commercial interests.

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Judgment: appeal brought by the 'One of us' European Citizens' Initiative (ECI) dismissed

The organisers of the 'One of us' European Citizens' Initiative (ECI) wished to prevent EU financing of activities which destroy human embryos, including the funding of abortions. They collected the necessary million signatures in 2014. Since the European Commission declared that it would take no action on the ECI, the organisers brought an action seeking annulment of the Commission's communication. The Court confirmed the Commission's stance. In case C418 / 18 P, it has now dismissed the appeal brought by the 'One of us' European Citizens' Initiative ('ECI') against the original Court judgment.

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Advocate General's opinion: a requirement for civil liability insurance concerning the use of medical devices may be restricted to the territory of a Member State

A patient received defective breast implants in Germany, manufactured by Poly Implant Prothèse SA ('PIP'), a French company. PIP had taken out civil liability insurance, which is mandatory in France, with the French insurance company Allianz IARD. The insurance contract, however, restricts the coverage to damage caused in France only. The Advocate General's opinion in case C 581/18 is that an obligation to take out civil liability insurance for the use of medical devices may be limited to the territory of a Member State.

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9 Publications

WHO: status report on prison health in the WHO European region

This report presents an analysis of data collected on the health status of people in prison and prison health systems in 39 countries in the WHO European region.

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Federal Public Service Social Security: Analysis of the evolution of the social situation and social protection in Belgium

This report, "Analysis of the evolution of the social situation and social protection in Belgium, 2019 - slowly falling behind", analyses the evolution of the social situation and social protection in Belgium, in the European context. One of the aspects addressed is access to healthcare.

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BTSZ: 60 years of social security coordination from a workers' perspective

This edition of the Belgisch Tijdschrift voor Sociale Zekerheid (Belgian Social Security Journal (BTSZ)) takes stock of the various aspects of European coordination of social security systems, as the legislation regarding this coordination turns 60. Cross-border access to healthcare is one of the points discussed.

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OSE: inequalities in access to healthcare in the European Union Member States

This article in the BTSZ analyses inequalities in access to healthcare in the EU Member States. It was also published in Dutch, as a chapter in "the Poverty Yearbook".

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Médecins du Monde: access to healthcare in Europe for vulnerable people - an alarming situation

Médecins du Monde reported on the living conditions, health and access to healthcare of the most vulnerable people in Europe. This report is the outcome of a survey of 29,359 people in 7 European countries who called on the services of Médecins du Monde.

The report shows that the EU does not have an appropriate tool to assess the scope of the problem, since these groups are not covered by the social scoreboard or the data in the EU SILC survey.

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OECD: Performance-based managed entry agreements for new medicines in OECD countries and EU Member States

Managed entry agreements (MEAs) are arrangements between firms and healthcare payers that allow for coverage of new medicines while managing uncertainty around their financial impact or performance. Many OECD countries and EU Member States also use these agreements, which make payments to firms conditional on product performance. The OECD investigated these countries' experience to date with the use of performance-based MEAs.

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Council of Europe: study on shortcomings in the legislation on falsified medicines

A recent study, carried out under the Council of Europe MEDICRIME convention, has highlighted shortcomings of current legislative approaches to the protection of patients against falsified medicines in Europe.

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ETUI: Tackling low pay in sectors dominated by women- evidence from health and social care

The European Trade Union Institute (ETUI) published a working document on low pay in the health and social care sectors, which are dominated by women. The publication argues that the wage penalty for working in female-dominated sectors can be explained by the underfinancing and privatisation of social care, weaker bargaining power in these sectors, and the fact that care work is subject to the general undervaluation of what often is still seen as 'women's work'.

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EPHA: regional collaboration initiatives concerning access to medicines: BENELUXA et al

This reflection paper analyses multi-level cooperation in the form of intergovernmental regional initiatives to cooperate in access to medicines policy, focusing on the BeNeLuxA coalition, the most advanced regional European cluster. The paper looks at the progress achieved so far and tries to foresee the challenges and opportunities along the way for these alliances in Europe.

DOC [EN](#) HTML

OECD: unmet needs for healthcare: comparing approaches and results from international surveys

This document compares the approaches and results of international surveys of unmet needs for healthcare.

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BMJ: Fair pricing of medicines

It is challenging to find agreement on a single definition of fair pricing, and health systems have struggled to achieve a balance between affordability and need. This collection of articles outlines evidence and further research that is needed to balance affordability and innovation of medicines.

DOC [EN](#) HTML

OECD: Health at a Glance 2019

Health at a Glance provides the latest comparable data and trends on different aspects of the performance of health systems in OECD countries. It provides striking evidence of large variations across countries in indicators of health status and health risks, as well as in the inputs and outputs of health systems.

DOC [EN/FR](#) HTML

 **Johanniter International: European first aid guidelines**

Johanniter International presented a set of common, European-wide first aid guidelines. The JOIN guidelines are intended for first aiders, the general public, and health professionals. Developed by an international team of experts, they can be used as a basis for setting up a European-wide framework for first aid, and are designed to be applied in every European country.

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Editors: Rita Baeten and Boris Fronteddu

E-mail: baeten@ose.be

Website: <http://www.ose.be>

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