



EUROPEAN COMMISSION

SECRETARIAT-GENERAL

PV(2023) 2454 final

- English translation of the French version which is authentic -

Brussels, 7 June 2023

TEXTE EN

MINUTES

of the 2454th meeting of the Commission

held in Brussels

(Berlaymont)

on Wednesday 26 April 2023

(morning)

PV(2023) 2454 final

- English translation of the French version which is authentic -

EN

TABLE OF CONTENTS

Attendance list	7–8
1. AGENDAS (OJ(2023) 2454/FINAL; SEC(2023) 2454/FINAL)	9
2. WEEKLY MEETING OF HEADS OF CABINET	9
3. APPROVAL OF THE MINUTES (PV(2023) 2450; PV(2023) 2450, 2 ND PART)	9
4. INTERINSTITUTIONAL RELATIONS (RCC(2023) 96)	9
5. COORDINATION OF EXTERNAL ACTION (RCC(2023) 19).....	12
6. MONITORING THE APPLICATION OF EUROPEAN UNION LAW	12
STATE AID AND OTHER COMPETITION RULES	12
7. WRITTEN PROCEDURES, EMPOWERMENT AND DELEGATION OF POWERS.....	12
7.1. WRITTEN PROCEDURES APPROVED (SEC(2023) 151 ET SEQ.).....	12
7.2. EMPOWERMENT (SEC(2023) 152 ET SEQ.)	12
7.3. DELEGATION / SUBDELEGATION OF POWERS (SEC(2023) 153 ET SEQ.)	13
7.4. SIGNIFICANT WRITTEN PROCEDURES (SEC(2023) 154 AND /2)	13
8. ADMINISTRATIVE AND BUDGETARY MATTERS (SEC(2023) 155).....	13
8.1. DG HEALTH AND FOOD SAFETY – APPOINTMENT OF A DIRECTOR AT GRADE AD14/15 (PERS(2023) 39 TO /3)	13
8.2. DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY – ADOPTION OF A LIST OF CANDIDATES FOR THE POST OF EXECUTIVE DIRECTOR OF THE ‘SMART NETWORKS AND SERVICES’ JOINT UNDERTAKING (SNS JU), AT GRADE AD14 (PERS(2023) 40 TO /3)	14

8.3. EUROSTAT – AUTHORISATION OF THE INTERNAL AND INTERINSTITUTIONAL PUBLICATION, AT GRADE AD14/15, AND EXTERNAL PUBLICATION, AT GRADE AD14, OF A DIRECTOR POST (PERS(2023) 41)	14
8.4. OFFICE FOR INFRASTRUCTURE AND LOGISTICS IN BRUSSELS – EXTENSION OF THE DIRECTOR’S TERM OF OFFICE	15
8.5. DG MOBILITY AND TRANSPORT – EXTENSION OF THE TERM OF OFFICE OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN MARITIME SAFETY AGENCY (EMSA)	15
9. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE EFFECTIVE COORDINATION OF ECONOMIC POLICIES AND MULTILATERAL BUDGETARY SURVEILLANCE AND REPEALING COUNCIL REGULATION (EC) N° 1466/97 (COM(2023) 240 AND /2; RCC(2023) 103).....	16
10. PROPOSAL FOR A COUNCIL REGULATION AMENDING REGULATION (EC) N° 1467/97 ON SPEEDING UP AND CLARIFYING THE IMPLEMENTATION OF THE EXCESSIVE DEFICIT PROCEDURE (COM(2023) 241 AND /2; RCC(2023) 103).....	16
11. PROPOSAL FOR A COUNCIL DIRECTIVE AMENDING DIRECTIVE 2011/85/EU ON REQUIREMENTS FOR BUDGETARY FRAMEWORKS OF THE MEMBER STATES (COM(2023) 242 AND /2; RCC(2023) 103).....	16
12. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS – REFORM OF THE PHARMACEUTICAL LEGISLATION AND MEASURES ADDRESSING ANTIMICROBIAL RESISTANCE (COM(2023) 190 TO /3; RCC(2023) 100; RCC(2023) 101)	22

13. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN UNION PROCEDURES FOR THE AUTHORISATION AND SUPERVISION OF MEDICINAL PRODUCTS FOR HUMAN USE AND ESTABLISHING RULES GOVERNING THE EUROPEAN MEDICINES AGENCY, AMENDING REGULATION (EC) N° 1394/2007 AND REGULATION (EU) N° 536/2014 AND REPEALING REGULATION (EC) N° 726/2004, REGULATION (EC) N° 141/2000 AND REGULATION (EC) N° 1901/2006 (COM(2023) 193 TO /3; SWD(2023) 192; SWD(2023) 193; SWD(2023) 194; SEC(2023) 390; RCC(2023) 100; RCC(2023) 101).....22
14. PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE UNION CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE (COM(2023) 192 TO /3; SWD(2023) 191; SWD(2023) 192; SWD(2023) 193; SEC(2023) 390; RCC(2023) 100; RCC(2023) 101) 23
15. PROPOSAL FOR A COUNCIL RECOMMENDATION ON STEPPING UP EU ACTIONS TO COMBAT ANTIMICROBIAL RESISTANCE IN A ONE HEALTH APPROACH (COM(2023) 191 AND /2; SWD(2023) 190; RCC(2023) 100; RCC(2023) 101) 23
16. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON STANDARD ESSENTIAL PATENTS AND AMENDING REGULATION (EU) 2017/1001 (COM(2023) 232 TO /4; SWD(2023) 123; SWD(2023) 124; SWD(2023) 125; SEC(2023) 174; RCC(2023) 102) 30
17. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON COMPULSORY

- LICENSING FOR CRISIS MANAGEMENT AND AMENDING
REGULATION (EC) 816/2006 (COM(2023) 224 AND /2;
SWD(2023) 120; SWD(2023) 121; SWD(2023) 122; SEC(2023) 173;
RCC(2023) 102).....30
18. PROPOSAL FOR A REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL ON THE SUPPLEMENTARY
PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS
(COM(2023) 231; SWD(2023) 117; SWD(2023) 118; SWD(2023) 119;
SEC(2023) 172; RCC(2023) 102).....30
19. PROPOSAL FOR A REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL ON THE SUPPLEMENTARY
PROTECTION CERTIFICATE FOR PLANT PROTECTION
PRODUCTS (COM(2023) 223 AND /2; SWD(2023) 117;
SWD(2023) 118; SWD(2023) 119; SEC(2023) 172; RCC(2023) 102) 30
20. PROPOSAL FOR A REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL ON THE UNITARY
SUPPLEMENTARY CERTIFICATE FOR MEDICINAL PRODUCTS,
AND AMENDING REGULATION (EU) 2017/1001, REGULATION
(EC) N° 1901/2006 AS WELL AS REGULATION (EU) N° 608/2013
(COM(2023) 222; SWD(2023) 117; SWD(2023) 118; SWD(2023) 119;
SEC(2023) 172; RCC(2023) 102).....30
21. PROPOSAL FOR A REGULATION OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL ON THE UNITARY
SUPPLEMENTARY PROTECTION CERTIFICATE FOR PLANT
PROTECTION PRODUCTS (COM(2023) 221 AND /2; SWD(2023) 117;
SWD(2023) 118; SWD(2023) 119; SEC(2023) 172; RCC(2023) 102) 31

22. OTHER BUSINESS.....	33
-------------------------	----

<i>IMPORTS OF AGRI-FOOD PRODUCTS FROM UKRAINE</i>	<i>33</i>
---	-----------

Single sitting: Wednesday 26 April 2023 (morning)

The sitting opened at 9.09 with Ms von der LEYEN, President, in the chair.

Present:

Ms von der LEYEN	President	
Mr TIMMERMANS	Executive Vice-President	
Mr DOMBROVSKIS	Executive Vice-President	Items 9/11 to 22
Mr ŠEFČOVIČ	Vice-President	Items 9/11 (in part) to 22
Ms JOUROVÁ	Vice-President	
Ms ŠUICA	Vice-President	
Mr SCHINAS	Vice-President	
Mr HAHN	Member	
Ms GABRIEL	Member	
Mr SCHMIT	Member	Items 9/11 (in part) to 22
Mr GENTILONI	Member	
Mr WOJCIECHOWSKI	Member	
Mr BRETON	Member	
Ms FERREIRA	Member	
Ms KYRIAKIDES	Member	
Mr REYNDERS	Member	
Ms DALLI	Member	
Ms JOHANSSON	Member	
Mr LENARČIČ	Member	
Ms VÁLEAN	Member	
Ms URPILAINEN	Member	Items 1 to 16/21 (in part)
Ms SIMSON	Member	
Mr SINKEVIČIUS	Member	
Ms McGUINNESS	Member	

Absent:

Ms VESTAGER	Executive Vice-President
Mr BORRELL i FONTELLES	High Representative / Vice-President
Mr VÁRHELYI	Member

The following sat in to represent absent Members of the Commission:

Ms SOEWARTA	Head of Cabinet to Ms VESTAGER
Mr BRIENS	Deputy Head of Cabinet to Mr BORRELL
Mr KRISTÓFFY	Head of Cabinet to Mr VÁRHELYI

The following also sat in:

Mr SEIBERT	Head of Cabinet to the PRESIDENT	
Mr CALLEJA CRESPO	Director-General, Legal Service	
Ms AHRENKILDE HANSEN	Director-General, DG Communication	
Mr MAMER	Head of the Spokesperson's Service and Chief Spokesperson of the Commission	
Ms PETKOVA	Director of Coordination and Administration in the PRESIDENT's cabinet	
Ms HOPMEIER	A member of the PRESIDENT's cabinet	Items 9/11
Ms WERNER	Deputy Secretary-General	Item 22
Ms ALLOUIS-LE LOSTEC	Head of Unit in the Secretariat-General	
Mr VALERO	Secretariat-General	

Secretary: Ms JUHANSONE, Secretary-General, assisted by Ms DEPREZ, Director in the Secretariat-General.

1. AGENDAS

(OJ(2023) 2454/FINAL; SEC(2023) 2454/FINAL)

The Commission took note of that day's agenda and of the tentative agendas for forthcoming meetings.

2. WEEKLY MEETING OF HEADS OF CABINET

The Commission took note of the conclusions, presented by the Secretary-General, of the weekly meeting of Heads of Cabinet which took place on Monday 24 April and Tuesday 25 April 2023.

3. APPROVAL OF THE MINUTES

(PV(2023) 2450; PV(2023) 2450, 2ND PART)

The Commission approved the minutes of its 2450th meeting of 14 and 16 March 2023 and decided to hold over approval of the minutes of its 2451st, 2452nd and 2453rd meetings of 22 and 29 March and 18 April 2023 until a later meeting.

4. INTERINSTITUTIONAL RELATIONS

(RCC(2023) 96)

The Commission took note of the record of the meeting of the Interinstitutional Relations Group (IRG) held on Friday, 21 April 2023 (RCC(2023) 96).

The Commission approved the lines proposed for the following points:

- **2023 Commission Work Programme: withdrawal of pending proposals and publication of the list in the Official Journal**

Line set out in SPI(2023) 18.

- **Measures for a high common level of cybersecurity at the institutions, bodies, offices and agencies of the Union (Regulation) – VIRKKUNEN report – 2022/0085 (COD)**

Line set out in SI(2023) 113.

- **Fluorinated greenhouse gases: amendment of Directive (EU) 2019/1937 and repeal of Regulation (EU) N° 517/2014 (Regulation) – EICKHOUT report – 2022/0099 (COD)**

Line set out in SI(2023) 116/2.

- **Substances that deplete the ozone layer and repeal of Regulation (EC) N° 1005/2009 – POLFJÄRD report – 2022/0100 (COD)**

Line set out in SI(2023) 117/2.

- **Union guidelines for the development of the trans-European transport network, amendment of Regulation (EU) 2021/1153 and Regulation (EU) 913/2010 and repeal of Regulation (EU) 1315/2013 (amended proposal for a Regulation) – THALER & RIQUET report – 2021/0420 (COD)**

Line set out in SI(2023) 118/2.

- **Establishment of a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act) (Regulation) – NICA report – 2022/0032 (COD)**

Line set out in SI(2023) 119.

- **Consumer credits (Directive) – KONEČNÁ report – 2021/0171 (COD)**

Line set out in SI(2023) 115.

- **Joint proposal for a Council Regulation concerning restrictive measures in view of the situation in the Republic of Moldova – 2023/0116 (NLE)**

Line set out in SI(2023) 120.

- **Application of certain transposition requirements in indirect management under the Financial Regulation and the proportionality principle**

Line set out in SPI(2023) 10.

- **EU position with a view to consultations (i) with the United Kingdom, with a view to reaching an agreement on fishing opportunities for sprat in the English Channel, (ii) with the United Kingdom and Norway, with a view to reaching an agreement on fishing opportunities for sprat in the North Sea, the Skagerrak and the Kattegat, and (iii) with Norway, with a view to reaching an agreement on fishing opportunities for Northern prawn in the Skagerrak, the Kattegat and deep sea areas off Norway for 2023 and, if appropriate, 2024**

Line set out in SI(2023) 114.

The Commission approved the line proposed for the following point, for transmission to the European Parliament:

- **Commission replies to the non-legislative resolutions adopted by the European Parliament at its February II and March I 2023 part-sessions**

Line set out in SP(2023) 219/3.

The Commission took note of the following point:

– **Results of European Parliament’s April 2023 part-session**

Information set out in SP(2023) 205.

**5. COORDINATION OF EXTERNAL ACTION
(RCC(2023) 19)**

The Commission took note of the operational conclusions in RCC(2023) 19 of the meeting of the Group for External Coordination (EXCO) held on Wednesday 19 April 2023.

**6. MONITORING THE APPLICATION OF EUROPEAN UNION LAW
*STATE AID AND OTHER COMPETITION RULES***

The Commission’s decision on this item is recorded in the special minutes.

**7. WRITTEN PROCEDURES, EMPOWERMENT AND DELEGATION OF
POWERS**

**7.1. WRITTEN PROCEDURES APPROVED
(SEC(2023) 151 ET SEQ.)**

The Commission took note of the Secretariat-General’s memoranda recording decisions adopted between 17 and 23 April 2023.

**7.2. EMPOWERMENT
(SEC(2023) 152 ET SEQ.)**

The Commission took note of the Secretariat-General's memoranda recording decisions adopted between 17 and 23 April 2023.

7.3. DELEGATION / SUBDELEGATION OF POWERS
(SEC(2023) 153 ET SEQ.)

The Commission took note of the Secretariat-General's memoranda recording decisions adopted under the delegation and subdelegation procedures between 17 and 23 April 2023 archived in Decide.

7.4. SIGNIFICANT WRITTEN PROCEDURES
(SEC(2023) 154 AND /2)

The Commission took note of the significant written procedures for which the time limit expired between 24 and 28 April 2023 and of a finalisation written procedure.

8. ADMINISTRATIVE AND BUDGETARY MATTERS
(SEC(2023) 155)

ADMINISTRATIVE MATTERS
(PERS(2023) 38)

8.1. DG HEALTH AND FOOD SAFETY – APPOINTMENT OF A
DIRECTOR AT GRADE AD14/15
(PERS(2023) 39 TO /3)

The Commission had before it applications under Article 29(1)(a)(i) and (iii) of the Staff Regulations for the post of Director of the 'One Health' Directorate in DG Health and Food Safety (PERS(2023) 39).

It took note of the opinions of the Consultative Committee on Appointments of 20 December 2022 and 1 March 2023 (PERS(2023) 39/2 and /3).

The Commission proceeded to compare the applicants' qualifications for the post. On a proposal from Mr HAHN, in agreement with the PRESIDENT, and after consulting Ms KYRIAKIDES, it then decided to appoint Ms Roser DOMENECH AMADO to the post.

This decision would take effect on a date to be determined.

8.2. DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY – ADOPTION OF A LIST OF CANDIDATES FOR THE POST OF EXECUTIVE DIRECTOR OF THE ‘SMART NETWORKS AND SERVICES’ JOINT UNDERTAKING (SNS JU), AT GRADE AD14 (PERS(2023) 40 TO /3)

On a proposal from Mr HAHN, in agreement with the PRESIDENT, and after consulting Mr BRETON, the Commission decided:

- to approve the list of three candidates, presented in alphabetical order, set out in point 1 of PERS(2023) 38, for the post of Executive Director of the ‘Smart Networks and Services’ Joint Undertaking (SNS JU) in DG Communications Networks, Content and Technology, and to consider this list as the Commission proposal;
- to ask Mr BRETON, the Member of the Commission responsible, to communicate this decision to the Governing Board of the ‘Smart Networks and Services’ Joint Undertaking.

These decisions would take effect immediately.

8.3. EUROSTAT – AUTHORISATION OF THE INTERNAL AND INTERINSTITUTIONAL PUBLICATION, AT GRADE AD14/15, AND EXTERNAL PUBLICATION, AT GRADE AD14, OF A DIRECTOR POST (PERS(2023) 41)

(26 April 2023)

On a proposal from Mr HAHN, in agreement with the PRESIDENT, and after consulting Mr GENTILONI, the Commission decided to authorise the internal and interinstitutional publication, at grade AD14/15, and external publication, at grade AD14, of the vacancy notice in PERS(2023) 41 for the post of Director of the ‘Government Finance Statistics (GFS)’ Directorate in Eurostat, in accordance with Article 29(1)(a)(i) and (iii), Article 29(1)(b) and Article 29(2) of the Staff Regulations.

This decision would take effect immediately.

**8.4. OFFICE FOR INFRASTRUCTURE AND LOGISTICS IN BRUSSELS –
EXTENSION OF THE DIRECTOR’S TERM OF OFFICE**

On a proposal from Mr HAHN, in agreement with the PRESIDENT, and after consulting the Management Committee of the Office for Infrastructure and Logistics in Brussels (OIB), the Commission decided to extend Mr Marc BECQUET’s term of office as OIB Director for a maximum period of 24 months or until his retirement, if that came earlier.

This decision would take effect on 1st May 2023.

**8.5. DG MOBILITY AND TRANSPORT – EXTENSION OF THE TERM OF
OFFICE OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN
MARITIME SAFETY AGENCY (EMSA)**

On a proposal from Mr HAHN, in agreement with the PRESIDENT and after consulting Ms VĂLEAN, the Commission decided:

- to propose to the Administrative Board of the European Maritime Safety Agency (EMSA) that it extend Ms Maja MARKOVČIĆ KOSTELAC’s period of office as Executive Director of EMSA by 4 years, as of 1st January 2024, in accordance with Article 16(2) of Regulation (EC) N° 1406/2002;

- to ask Ms VĂLEAN, the Member of the Commission responsible, to communicate this decision to the Administrative Board of the European Maritime Safety Agency.

These decisions would take effect immediately.

- 9. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE EFFECTIVE COORDINATION OF ECONOMIC POLICIES AND MULTILATERAL BUDGETARY SURVEILLANCE AND REPEALING COUNCIL REGULATION (EC) N° 1466/97
(COM(2023) 240 AND /2; RCC(2023) 103)**
- 10. PROPOSAL FOR A COUNCIL REGULATION AMENDING REGULATION (EC) N° 1467/97 ON SPEEDING UP AND CLARIFYING THE IMPLEMENTATION OF THE EXCESSIVE DEFICIT PROCEDURE
(COM(2023) 241 AND /2; RCC(2023) 103)**
- 11. PROPOSAL FOR A COUNCIL DIRECTIVE AMENDING DIRECTIVE 2011/85/EU ON REQUIREMENTS FOR BUDGETARY FRAMEWORKS OF THE MEMBER STATES
(COM(2023) 242 AND /2; RCC(2023) 103)**

The PRESIDENT introduced the legislative package on economic governance, highlighting the huge amount of work done by the departments and cabinets concerned. She noted that when the Stability and Growth Pact had been introduced in 1997, the debt level in most Member States had been below 60% of GDP. She also stressed two central features of the existing pact, namely a ‘one-size-fits-all’ approach with a debt ceiling of 60% for all Member States and sanctions for non-compliance so drastic that they had never been imposed.

She pointed out, however, that successive crises had profoundly altered the economic situation in the EU, noting in particular the triggering of the pact's general escape clause during the COVID-19 pandemic. The vast majority of Member States now had debt levels above 60% of GDP and were therefore directly affected by the rules of the European economic governance framework being adjusted to the new post-pandemic reality.

Mr DOMBROVSKIS, in turn, stressed that the EU had changed a great deal since it had first drawn up its fiscal rules in the 1990s and that the world was now a very different place, in terms of both challenges and priorities. In particular, public debt had risen sharply and the EU's debt-to-GDP ratio had reached 84% in 2022, roughly 20% more than 20 years previously. Some Member States had public debt ratios well above 100% of GDP.

The EU also faced massive reform and investment needs for the twin green and digital transitions, and to strengthen social, economic and energy resilience. Reformed fiscal rules were therefore needed to reinforce the sustainability of Member States' public debt through gradual and realistic fiscal consolidation, and to boost sustainable and inclusive growth through ambitious reforms and investments.

In this regard, the Commission had launched the process of reviewing the EU economic governance framework in February 2020 by means of a wide-ranging consultation of EU institutions, national governments and many other interested parties. The Commission had then published its orientations for the review in November 2022. In March 2023 EU finance ministers had agreed on a number of core elements to be included in a revised framework. They had also asked the Commission to consider further elements, in particular relating to common safeguard provisions and quantitative benchmarks.

Mr DOMBROVSKIS noted that the Commission proposals presented that day represented a balanced approach based on all the contributions received. This

approach was underpinned by four key principles: simplicity, ownership, safeguards and enforcement.

As regards simplicity, fiscal policy coordination would be based on a single indicator – government net expenditure. This was observable and under government control, so the objectives could be easily achieved.

On national ownership, Mr DOMBROVSKIS pointed out that the Commission's proposals promoted greater appropriation by Member States by giving them more leeway to take their specific situation into account. Each Member State would thus have to commit to implementing a medium-term fiscal-structural plan, which was a real departure from the current 'one-size-fits-all' approach.

The plan would need to contain clear fiscal targets to achieve a gradual and sustained reduction in public debt ratios or to maintain debt at prudent levels in low-debt countries. As a rule, the plans would have to apply for 4 years. However, a Member State could extend this period if it committed to structural reforms and investments meeting certain criteria, namely boosting growth, improving fiscal sustainability and contributing to EU priorities.

On safeguards, Mr DOMBROVSKIS explained that the added leeway for Member States was constrained by a set of common EU rules to ensure transparency and equal treatment. In particular, the Treaty reference values remained in place, i.e. 3% of GDP for the public deficit and 60% of GDP for public debt. For Member States that exceeded either of these figures, the Commission would issue 'technical trajectories' as a basis for each plan, providing for a gradual reduction in the ratio of public debt to GDP over the period covered by the plan. Member States whose public deficit remained above 3% of GDP would have to carry out a minimum fiscal adjustment of 0.5% of GDP per year. Finally, Member States would not be allowed to push back fiscal adjustments or the required reforms and investments to a date later than that set out in their respective plans. Each plan would need to be approved

by the Commission and the Council to ensure transparency and multilateral surveillance.

On enforcement, he noted that the deficit-based excessive deficit procedure would remain unchanged, while the debt-based excessive deficit procedure would be strengthened. For Member States that faced substantial public debt challenges, departures from the agreed fiscal adjustment path would by default lead to the opening of an excessive deficit procedure. Member States would face tighter fiscal requirements if they failed to carry out the reforms and investments which they had committed to, and financial sanctions could also be imposed.

Mr DOMBROVSKIS concluded his presentation by stressing that it was essential to reach political agreement on the proposals quickly so that the new fiscal rules could be in place as soon as possible. In this context, the Economic and Financial Affairs Council aimed to complete the legislative process by the end of 2023.

Mr GENTILONI emphasised above all the need for the EU to have common economic governance rules. While the Stability and Growth Pact had contributed to addressing the major economic challenges of the previous 25 years, it had not achieved its main objectives of reducing debt and promoting growth. Average debt in euro area countries had risen from 60% when the pact was introduced to more than 90% at present, and Member States had experienced a prolonged period of low public investment and weak growth following the global financial crisis. He also noted the widening gaps between Member States' respective debt levels.

In this context, the aim of the Commission's proposals that day was to outline a new approach to economic governance, based on the concept of a 'plausible downward path' for debt. The financial markets were less interested in the precise debt figures than in the question of whether the debt of high-debt countries was falling and whether the EU as a whole was promoting growth through investment in common priorities. It was not about more flexible rules, therefore, but more effective ones. If

the new rules were successfully implemented, Member States could see the biggest fall in their public debt for more than 30 years.

Mr GENTILONI then emphasised the medium-term approach underlying the new rules, which included Member State fiscal-structural plans lasting at least 4 years. The fiscal adjustment included in these plans could be extended up to 7 years through reforms and investments, including in four key sectors for the EU: the European Green Deal, the European Pillar of Social Rights, the Digital Decade Policy Programme 2030 and the Strategic Compass for Security and Defence.

The Commission would provide a common framework with technical trajectories for each Member State, and changes in net expenditure would be the only operational indicator used. The framework would therefore be halfway between the non-binding recommendations of the European Semester and the very strict conditions and parameters of the Recovery and Resilience Facility.

A debt-based excessive deficit procedure had never been opened, owing to overly ambitious debt reduction rules. The proposed new framework therefore set out a more realistic, differentiated and gradual approach. The fiscal-structural plans to be proposed by Member States should improve compliance. In particular, it would be easier to open an excessive deficit procedure if Member States deviated from the plan agreed with the Commission and accepted by the Council. The corrective arm would not be applied in all circumstances, and there was provision for a general escape clause and national escape clauses.

In conclusion, Mr GENTILONI welcomed the proposals presented that day, which were designed to reduce debt and increase public investment. He highlighted the Commission's key role in defending the proposals and enabling an agreement to be reached in the Council given the considerable differences in Member States' views on certain issues.

In the course of the discussion that followed, the Commission raised the following main points:

- full support for the intensive work carried out by the Commission, in coordination with stakeholders, on the complex and sensitive subject of European economic governance, as well as for the resulting balanced proposals;
- the need to demonstrate clearly to investors that the EU was able to repay its debts, while providing the necessary flexibility to allow Member States to make public investments in the general interest of the Union;
- the unequal contribution of different Member States to the EU's priorities, and the observation that debt levels might be comparable if debt incurred in connection with green or defence-related measures were added to traditional debt;
- in this context, the importance of providing a country-specific downward path for debt that would be seen as credible by the financial markets;
- the reminder that the economy is cyclical in nature, and hence that a medium-term time horizon of 4 to 7 years would be required to avoid a pro-cyclical fiscal policy;
- the need for the EU to give itself a permanent common fiscal capacity to meet future challenges, modelled on NextGenerationEU;
- the welcome reference to the rule of law and good governance.

The PRESIDENT concluded by thanking the Members of the College for these sound and balanced proposals. She highlighted the experience gained in exceptional public finance management during the pandemic and the related activation of the general escape clause. The present challenge was to return to an effective structural framework applicable to all Member States.

Finally, the PRESIDENT urged both the Commission and the Member States to draw on the very positive lessons learned from NextGenerationEU, which had enabled country-specific plans to be drawn up for the first time, subject to

conditions related to investments and reforms. This model could usefully serve as a basis for the application of the new economic governance rules.

Following these presentations, the Commission:

- adopted the proposal for a Regulation in COM(2023) 240/2 for transmission to the European Parliament, the Council, the European Central Bank and the national parliaments;
- adopted the proposal for a Council Regulation in COM(2023) 241/2 for transmission to the European Parliament, the Council, the European Central Bank and the national parliaments;
- adopted the proposal for a Directive in COM(2023) 242/2 for transmission to the European Parliament, the Council and the European Central Bank and, for information, to the national parliaments.

**12. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS – REFORM OF THE PHARMACEUTICAL LEGISLATION AND MEASURES ADDRESSING ANTIMICROBIAL RESISTANCE
(COM(2023) 190 TO /3; RCC(2023) 100; RCC(2023) 101)**

13. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN UNION PROCEDURES FOR THE AUTHORISATION AND SUPERVISION OF MEDICINAL PRODUCTS FOR HUMAN USE AND ESTABLISHING RULES GOVERNING THE EUROPEAN MEDICINES AGENCY, AMENDING REGULATION (EC) N° 1394/2007 AND REGULATION (EU) N° 536/2014 AND REPEALING REGULATION (EC) N° 726/2004, REGULATION (EC) N° 141/2000 AND

REGULATION (EC) N° 1901/2006

**(COM(2023) 193 TO /3; SWD(2023) 192; SWD(2023) 193; SWD(2023) 194;
SEC(2023) 390; RCC(2023) 100; RCC(2023) 101)**

**14. PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL ON THE UNION CODE RELATING TO MEDICINAL
PRODUCTS FOR HUMAN USE**

**(COM(2023) 192 TO /3; SWD(2023) 191; SWD(2023) 192; SWD(2023) 193;
SEC(2023) 390; RCC(2023) 100; RCC(2023) 101)**

**15. PROPOSAL FOR A COUNCIL RECOMMENDATION ON STEPPING UP
EU ACTIONS TO COMBAT ANTIMICROBIAL RESISTANCE IN A ONE
HEALTH APPROACH**

(COM(2023) 191 AND /2; SWD(2023) 190; RCC(2023) 100; RCC(2023) 101)

The PRESIDENT introduced the package of measures on EU pharmaceutical legislation, pointing out that this was the first reform on this scale in more than 20 years. She congratulated the Members of the Commission responsible for the quality of the work carried out and invited Mr SCHINAS and Ms KYRIAKIDES to present the proposed measures.

Mr SCHINAS hailed the historic progress made by the Commission in the field of health during the current term of office, particularly taking into account the EU's limited competence in this area. He referred in particular to the establishment of the European Health Union announced by the PRESIDENT in 2020, the strengthened mandates of the European Medicines Agency (EMA) and of the European Centre for Disease Prevention and Control (ECDC), the EU's first health programme (EU4Health), the establishment of the Health Emergency Preparedness and Response Authority (HERA) and the establishment of a European Health Data Space.

He explained that the package presented that day, which reviewed one of the oldest pieces of European legislation in force, was intended as the penultimate health-

related initiative of the Commission's term of office, ahead of the adoption of a Communication on mental health in June. The aim of this reform was to make medicines more accessible, affordable and available across the EU. It would support innovation and boost the competitiveness and attractiveness of the EU pharmaceutical industry, while promoting higher environmental standards. In addition to this reform, the Commission was proposing that day a Council Recommendation to step up the fight against antimicrobial resistance (AMR).

As far as access to medicines was concerned, Mr SCHINAS highlighted how the situations of EU citizens depended on where they lived, with rates of access to new medicines ranging from 90% in the larger Member States to 10% in the Member States with least coverage. New incentives would encourage companies to make their medicines available to patients in all EU Member States and develop products that addressed unmet medical needs.

With regard to the affordability of medicines, Mr SCHINAS stressed that high prices for innovative treatments remained a major problem for patients and healthcare systems. The proposed measures thus aimed to create a single market for medicines that would ensure access to safe, effective and affordable medicines for all patients in the EU, including by making more generic medicines available faster.

In order to increase the availability of medicines, the proposals put forward aimed to address shortages of medicines and enhance security of supply. Mr SCHINAS noted that the reform introduced new requirements for the monitoring of potential shortages of medicines by national authorities and by the European Medicines Agency, as well as an enhanced coordination role for the latter. He noted that a list of critical medicines would be drawn up at European level, accompanied by an assessment of the vulnerabilities in the supply chain of these medicines and specific recommendations on the measures to be taken by the companies and other stakeholders concerned.

Mr SCHINAS also stressed the need to provide an attractive and innovation-friendly framework for research, development and production of medicines in the EU, in order to support the competitiveness of European industry. The proposed measures would significantly reduce the administrative burden through simplified procedures and increased use of digitalisation. The European Medicines Agency (EMA) would provide better early regulatory and scientific support for developers of promising medicines to facilitate fast approval and help SMEs.

However, he underlined that the highest standards of quality, safety and efficacy for the authorisation of medicinal products would be maintained. He said that the reform also provided for better enforcement of current environmental standards, so as to limit the potentially harmful effects of medicines on the environment and on public health.

Mr SCHINAS concluded by highlighting the considerable health threat posed by antimicrobial resistance (AMR). He explained that the excessive or improper use of antimicrobials caused them to be less effective, thereby making infections more difficult, if not impossible, to treat. In this context, he welcomed the incentives offered by the proposed reform, in particular the transferable vouchers for companies investing in new antimicrobials able to treat resistant pathogens.

Ms KYRIAKIDES referred to the major progress made since the PRESIDENT announced the construction of a European Health Union in her 2020 State of the Union address, noting the concrete initiatives proposed by the Commission in accordance with the Treaties and the respective competences of the Member States and the EU.

She stressed that the reform of the pharmaceutical rules proposed that day was based on the principles of equality and fairness in access to medicines and health systems for all citizens across the EU. These principles were also at the heart of other Commission proposals in this area, be it Europe's Beating Cancer Plan or the digitalisation of EU health services.

In preparing these proposals, the aim had been to reconcile the interests and concerns of the various stakeholders by adopting an inclusive approach, so as to ensure access to medicines for all European citizens while supporting innovation and the competitiveness of European industry. Against this background, she presented the four key pillars of the proposal.

The first was to improve access to innovative and affordable medicines for patients and national health systems. The reform would transform the current system into a single market for medicines, which would no longer be based on ‘one-size-fits-all’ regulatory protection but on a more effective framework for innovation incentives that would also promote societal and public health interests. To this end, a minimum regulatory protection period of 8 years would be offered to pharmaceutical companies, which could be extended if the medicines were to be marketed in all Member States, if they were to address unmet medical needs, if comparative clinical trials were to be conducted or if a new therapeutic indication was to be developed.

Ms KYRIAKIDES felt that the combination of existing intellectual property rights and new periods of regulatory protection would also preserve the EU’s competitive edge in pharmaceutical development, which would remain among the most protective in the world. The reform would allow research and development to focus on the most important needs of patients and on faster and fairer access to medicines for around 70 million more citizens than at present.

Secondly, the reform aimed to promote innovation and the EU’s global competitiveness through an effective and simplified regulatory framework that was both industry-friendly and patient-centred. Authorisation times for medicines would be considerably shortened to ensure they reached patients more quickly. The average time taken by the European Medicines Agency to complete its scientific assessment and authorisation of medicinal products would be reduced to 180 days from an average of around 400 days at present. In addition, regulatory sandboxes would be established to support the development of innovative medicines.

Ms KYRIAKIDES felt that the reform would thus create an innovation-friendly regulatory environment for the development of new medicines and the use of existing medicines for other purposes. The regulatory burden would be reduced, in particular by removing the obligation to renew the marketing authorisation in most cases and by introducing simpler procedures for generic medicines. She also referred to the gradual digitalisation of health services, in particular with regard to the electronic submission of applications or the provision of electronic product information. It was estimated that the introduction of these simplification measures would save companies almost EUR 100 million per year.

Thirdly, she said that the reform sought to address the problems of medicine shortages that had become apparent during the COVID-19 pandemic. Companies would face stronger obligations, as they would be required to report earlier on shortages and withdrawals of medicines and to draw up plans to prevent shortages. In addition, the Commission would be able to adopt legally binding measures to strengthen the security of supply of certain critical medicines and to impose requirements for emergency stockpiling and joint procurement.

Finally, Ms KYRIAKIDES said that the package presented that day also included a proposal for a Council Recommendation containing additional measures to combat antimicrobial resistance in the fields of human health, animal health and the environment. The Recommendation would encourage Member States to set concrete and measurable targets for the prudent use of antimicrobials, while promoting the implementation of national action plans based on the One Health principle.

She explained that developing new drugs able to fight multi-drug resistant pathogens was of little interest to investors due to limited sales prospects. To address this market failure, the reform proposed to grant ‘transferable data exclusivity vouchers’ to developers of new antimicrobials, granting an additional year of data protection for the medicinal product covered by the voucher.

Ms KYRIAKIDES concluded by stressing the paradigm shift in the field of health at

European level and praising the collaborative work on these proposals, which had made it possible to strike a good overall balance.

In the course of the discussion that followed, the Commission raised the following main points:

- the full support of the College for the proposed package of measures, considered to be very comprehensive and perfectly balanced;
- the difficulties faced by patients in the case of orphan diseases in the absence of sufficient research and investment;
- the critical shortages identified in the EU in connection with the fight against COVID-19;
- a reminder of the leading role of European industry in medical research and the crucial importance of maintaining the EU's competitiveness in this field;
- the distinction to be made between expenditure and investment in the field of health;
- the need for a framework on the use of antimicrobial products, in particular in the context of general practitioners' consultations;
- the concerns expressed by medium-sized pharmaceutical companies about guarantees for the repayment of investments that could prove risky;
- the substantial differences in the financial capacities of Member States' health systems, which might limit access to certain medicines if prices were too high.

Ms KYRIAKIDES explained that the proposed measures included specific provisions to support SMEs. She also stressed that the package would not affect the current system of pharmaceutical patents, but only adjust the period of protection of companies' data.

Following these presentations, the Commission:

- approved the Communication in COM(2023) 190/3 for transmission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions and, for information, to the national parliaments;
- adopted the proposal for a Regulation in COM(2023) 193/3 for transmission to the European Parliament, the Council, the European Economic and Social Committee, the Committee of the Regions and the national parliaments, and, for information, to the European Data Protection Supervisor, together with the staff working document, the impact assessment, the summary thereof and the opinion of the Regulatory Scrutiny Board in SWD(2023) 192, SWD(2023) 193, SWD(2023) 194 and SEC(2023) 390, the contents of which were noted;
- adopted the proposal for a Directive in COM(2023) 192/3, for transmission to the European Parliament, the Council, the European Economic and Social Committee, the Committee of the Regions, the European Data Protection Supervisor and the national parliaments, together with the staff working document, the impact assessment, the summary thereof and the opinion of the Regulatory Scrutiny Board in SWD(2023) 191, SWD(2023) 192, SWD(2023) 193 and SEC(2023) 390, the contents of which were noted;
- adopted the proposal for a Recommendation in COM(2023) 191/2 for transmission to the Council and, for information, to the European Parliament, the Economic and Social Committee, the Committee of the Regions and the national parliaments, together with the staff working document distributed as SWD(2023) 190, the contents of which were noted.

- 16. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON STANDARD ESSENTIAL PATENTS AND AMENDING REGULATION (EU) 2017/1001**
(COM(2023) 232 TO /4; SWD(2023) 123; SWD(2023) 124; SWD(2023) 125; SEC(2023) 174; RCC(2023) 102)
- 17. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON COMPULSORY LICENSING FOR CRISIS MANAGEMENT AND AMENDING REGULATION (EC) 816/2006**
(COM(2023) 224 AND /2; SWD(2023) 120; SWD(2023) 121; SWD(2023) 122; SEC(2023) 173; RCC(2023) 102)
- 18. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS**
(COM(2023) 231; SWD(2023) 117; SWD(2023) 118; SWD(2023) 119; SEC(2023) 172; RCC(2023) 102)
- 19. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE SUPPLEMENTARY PROTECTION CERTIFICATE FOR PLANT PROTECTION PRODUCTS**
(COM(2023) 223 AND /2; SWD(2023) 117; SWD(2023) 118; SWD(2023) 119; SEC(2023) 172; RCC(2023) 102)
- 20. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE UNITARY SUPPLEMENTARY CERTIFICATE FOR MEDICINAL PRODUCTS, AND AMENDING REGULATION (EU) 2017/1001, REGULATION (EC) N° 1901/2006 AS WELL AS REGULATION (EU) N° 608/2013**
(COM(2023) 222; SWD(2023) 117; SWD(2023) 118; SWD(2023) 119; SEC(2023) 172; RCC(2023) 102)

21. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE UNITARY SUPPLEMENTARY PROTECTION CERTIFICATE FOR PLANT PROTECTION PRODUCTS (COM(2023) 221 AND /2; SWD(2023) 117; SWD(2023) 118; SWD(2023) 119; SEC(2023) 172; RCC(2023) 102)

Mr BRETON began by pointing out the importance for companies of intellectual property rights, and of patents in particular. He stressed that they were intangible assets that were crucial for the competitiveness and growth of the European economy.

Despite its importance, patent law remained highly fragmented at European level between the various national legal systems. While stressing that the launch of the unitary patent in 17 Member States on 1st June 2023 would constitute a significant improvement in terms of simplifying and reducing the administrative burden, he noted nevertheless that there was an urgent need to upgrade the European patent framework. The aim was to align this framework with the unitary patent and to prepare it for the economy of the future, as announced by the Commission in its action plan on intellectual property adopted in 2020.

The proposals for Regulations tabled that day fell into three categories: a proposal on standard-essential patents, a proposal on compulsory licensing in times of crisis and four proposals on the supplementary protection certificate for pharmaceutical and plant protection products. These regulations would create a more transparent, efficient and sustainable framework for intellectual property rights.

Mr BRETON referred in particular to the proposal on standard-essential patents, namely patents covering technologies that are essential to the implementation of a technical standard adopted by a standardisation body. This was an area characterised by a lack of transparency, high levels of litigation and considerable uncertainty over access to new technologies. However, this area was of particular importance for the competitiveness of European industry and its capacity to innovate, in particular with

the roll-out of the Internet of Things. Companies wishing to invest in this market had to comply with connectivity standards, which required access to protected technologies on the basis of a licence that needed to be granted on fair, reasonable and non-discriminatory terms. Consequently, an effective system that facilitated access to technologies while rewarding innovation was crucial for the Union's technological sovereignty.

Mr BRETON felt that the proposal would benefit all parties – patent holders and standard implementers alike – as it would promote transparency and predictability. It would also incentivise good faith negotiations rather than recourse to litigation.

He then referred to the proposal on compulsory licences, which provided for a new instrument for compulsory licensing at European level. He stressed that the Commission had learned the lessons of the COVID-19 crisis and that it was therefore important to be able to make temporary use of such an instrument in the future in the event of a new crisis. These new rules further strengthened the Union's resilience to crises by ensuring access to critical patented products and technologies in the event of a crisis, if voluntary agreements were unavailable or inadequate.

In the course of the brief discussion that followed, the Commission mainly referred to the significance of the proposals for the implementation of the twin transition and to the strong interest expressed during the preparatory phase by a number of major European companies holding patents.

Following these presentations, the Commission, on a proposal from the PRESIDENT, agreed that the proposals for Regulations currently set out in COM(2023) 232/4, COM(2023) 224/2, COM(2023) 231, COM(2023) 223/2, COM(2023) 222 and COM(2023) 221/2 would be formally approved by finalisation written procedure, the deadline for which was set for Thursday 27 April 2023 (PE/2023/2662, PE/2023/2531, PE/2023/2560, PE/2023/2556, PE/2023/2565 and PE/2023/2562).

22. OTHER BUSINESS

IMPORTS OF AGRI-FOOD PRODUCTS FROM UKRAINE

Mr DOMBROVSKIS reported on the latest developments regarding imports of certain agri-food products from Ukraine against the backdrop of the restrictions put in place by certain Member States bordering Ukraine. In this context, he outlined the various measures envisaged to address the concerns of the Member States in question and allow the smooth transit of Ukrainian grain to world markets.

The Commission took note of this information.

*

* *

The Commission's other discussions on certain agenda items are recorded in the special minutes.

*

* *

The meeting closed at 10.59.