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Public questionnaire for the 2019 Evaluation of the Research & Development and Specialisation Block Exemption Regulations

Fields marked with * are mandatory.

1
Introduction

Background and aim of the public questionnaire

Article 101(1) of the Treaty on the Functioning of the European Union ('the Treaty') prohibits agreements between undertakings that restrict competition unless they generate efficiencies in line with Article 101(3) of the Treaty. Agreements generate efficiencies in line with Article 101(3) of the Treaty if they contribute to improving the production or distribution of goods or services, or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefits; they only impose restrictions that are indispensable for the attainment of these objectives and do not eliminate competition in respect of a substantial part of the product in question. The prohibition contained in Article 101(1) of the Treaty covers, amongst others, agreements entered into between actual or potential competitors (so-called 'horizontal agreements').

Commission Regulations (EU) No 1217/2010 (Research & Development Block Exemption Regulation - 'R&D BER') and 1218/2010 (Specialisation Block Exemption Regulation - 'Specialisation BER'), together referred to as the 'Horizontal block exemption regulations' (or 'HBERs'), exempt from the prohibition contained in Article 101(1) of the Treaty those R&D and specialisation agreements for which it can be assumed with sufficient certainty that they satisfy the conditions of Article 101(3) of the Treaty. The Commission Guidelines on horizontal cooperation agreements ('HGL') provide binding guidance on the Commission for the interpretation of the HBERs and for the application of Article 101 of the Treaty to other horizontal agreements. The HBERs will expire on 31 December 2022.

This public questionnaire represents one of the methods of information gathering in the evaluation of the HBERs, together with the HGL, which was launched on 5 September 2019. The purpose of this questionnaire is to collect views and evidence from the public and stakeholders on how the current rules work for them. The Commission will evaluate the current HBERs, together with the HGL, based on the following criteria:

- Effectiveness (Have the objectives been met?),
- Efficiency (Were the costs involved proportionate to the benefits?),
- Relevance (Do the objectives still match current needs or problems?),
- Coherence (Does the policy complement other actions or are there contradictions?), and
- EU added value (Did EU action provide clear added value?).

The collected information will provide part of the evidence base for determining whether the Commission should let the HBERs lapse, prolong their duration without changing them or prolong them in a revised form, together with the accompanying HGL.

The responses to this public consultation will be analysed and the summary of the main points and conclusions will be made public on the Commission's central public consultations page. **Please note that your replies will also become public as a whole, see below under Section 'Privacy and Confidentiality'.**
Nothing in this questionnaire may be interpreted as stating an official position of the Commission.

Submission of your contribution

You are invited to reply to this public consultation by answering the questionnaire online. To facilitate the analysis of your replies, we would kindly ask you to keep your answers concise and to the point. You may include documents and URLs for relevant online content in your replies.

While the questionnaire contains several questions of a more general nature, notably Section 4 and 5 also contain questions that are aimed at respondents with more specialised knowledge of the HBERs and HGL. We invite all respondents to provide answers to the questionnaire. In case a question does not apply to you or you do not know the answer, please choose the field 'Do not know' or 'Not applicable'.

For your information, you have the option of saving your questionnaire as a 'draft' and finalising your response later. In order to do this you have to click on 'Save as Draft' and save the new link that you will receive from the EUSurvey tool on your computer. Please note that without this new link you will not be able to access the draft again.

The questionnaire is available in English, French and German. You may however respond in any EU language.

In case of questions, you can contact us via the following functional mailbox: COMP-HBERS-REVIEW@ec.europa.eu .
In case of technical problem, please contact the Commission's CENTRAL HELPDESK.

Duration of the consultation

The consultation on this questionnaire will be open for 14 weeks, from 6/11/2019 to 12/2/2020.

Privacy and confidentiality

* 1.1 Publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**
  Only your type of respondent, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.

- **Public**
  Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

Please note that your replies and any attachments you may submit will be published in their entirety even if you chose 'Anonymous'. Therefore, please remove from your contribution any information that you will not want to be published.

☑ 1.2 I agree with the personal data protection provisions

2 About you

* 2.1 Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- (•) English
- Estonian
- Finnish
- French
- Gaelic
- German
- Greek
- Hungarian
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

* 2.2 First name

Hannelore

* 2.3 Surname

Wiame

* 2.4 Email (this won't be published)

* 2.5 I am giving my contribution as

- ○ Academic/research institution
- ◉ Business association
- ○ Company/business organisation
- ○ Consumer organisation
- ○ EU citizen
- ○ Environmental organisation
- ○ Non-EU citizen
- ○ Non-governmental organisation (NGO)
- ○ Public authority
- ○ Trade union
- ○ Other

2.6 Other - please specify

If you chose “Other”, please specify whether you are contributing as lawyer/law firm, economic consultancy or something else:

N/A

* 2.7 Organisation name

255 character(s) maximum

The European Federation of Pharmaceutical Industries and Associations (EFPIA)

If available, please provide your ID number of the EU Transparency Register. If your organisation is not registered, we invite you to register, although it is not compulsory to be registered to reply to this consultation.

2.8 Transparency register number

255 character(s) maximum

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

EFPIA is registered under “II – In-house lobbyists and trade/business/professional associations” with public ID number 38526121292-88

* 2.10 Organisation size

- ○ Micro (1 to 9 employees)
- ○ Small (10 to 49 employees)
- ◉ Medium (50 to 249 employees)
- ○ Large (250 or more)

2.11 The main activities of your organisation:

* *Text of 1 to 250 characters will be accepted*

EFPIA represents the European pharmaceutical industry (through its direct membership of 36 national associations and 39 leading pharmaceutical companies). Its mission is to promote pharmaceutical discovery and development in Europe.

* 2.12 Please describe the sectors where your organisation or your members are conducting business:

Text of 1 to 250 characters will be accepted

The pharmaceutical sector.

* 2.15 Country of origin

Please add your country of origin, or that of your organisation.

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa

- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom

- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

3 General Questions on the Horizontal Block Exemption Regulations and the Guidelines on horizontal cooperation agreements

* 3.6 How often do you consult the **R&D BER** for guidance on a horizontal cooperation agreement?
  - (•) Frequently (several times per year)
  - ( ) Occasionally (once or twice per year)
  - ( ) Never

* 3.7 How often do you consult the **Specialisation BER** for guidance on a horizontal cooperation agreement?
  - ( ) Frequently (several times per year)
  - (•) Occasionally (once or twice per year)
  - ( ) Never

* 3.8 How often do you consult the **HGL** for guidance on a horizontal cooperation agreement?
  - (•) Frequently (several times per year)
  - ( ) Occasionally (once or twice per year)
  - ( ) Never

4 Effectiveness (Have the objectives of the current HBERs and HGL been met?)

In this section, we would like to have your opinion on the extent to which the HBERs and the HGL have met their objectives.

The **purpose of the EU competition rules** is to ensure that competition is not distorted to the detriment of the public interest, individual undertakings and consumers. In line with this objective, the Commission's policy is to leave companies maximum flexibility when concluding horizontal co-operation agreements in order to increase the competitiveness of the European economy while at the same time promoting competition for the benefit of European businesses and consumers.

The **purpose of the HBERs and the HGL** is to make it easier for undertakings to cooperate in ways which are economically desirable and without adverse effect from the point of view of competition policy. The specific objectives of the HBERs and HGL are to ensure effective protection of competition and providing adequate legal certainty for undertakings.

* 4.1 In your view, do you perceive that the HBERs and the HGL have contributed to promoting competition in the EU?
  - ○ Yes
  - ◉ Yes, but they have contributed only to a certain extent or only in specific sectors
  - ○ They were neutral
  - ○ No, they have negatively affected competition in the EU
  - ○ Don´t know

* 4.2 Please explain your reply, distinguishing between sectors where relevant: (1500 characters max.

Text of 1 to 1500 characters will be accepted

The R&D BER is helpful but of limited assistance due to its rigidity. Amongst the limiting factors are the European Commission's narrow approach to the concept of "(potential) competitors" and market definition and the somewhat arbitrary 25% market share threshold. This leads to R&D agreements in the pharmaceutical sector falling outside the application of the R&D BER more easily than what would perhaps be the case in other sectors. Thus, an assessment under the HGL / Art. 101(1) and (3) TFEU, rather than the R&D BER, is more frequently required. This may delay or disincentivise innovation collaboration. Multiple collaboration arrangements are common and pro-competitive and do not necessarily fit neatly in any BE regime. For example, co-promotion agreements, essentially entailing a rented sales force, are common and, provided safeguards are in place to ensure no commercially sensitive information is exchanged, will ordinarily fall outside Art. 101(1) TFEU altogether. Furthermore, while the HBERs and HGL ("Horizontal Rules") have contributed to legal certainty, there are concerns about inconsistent application of the rules by NCAs and national courts, especially in relation to the topic of information exchange. It would benefit legal certainty if the European Commission were to intervene more frequently to ensure the correct and uniform interpretation and application of the Horizontal Rules.

Legal certainty provided by the HBERs and the HGL

*

4.3 In your view, have the R&D BER and Section 3 of the HGL on research and development agreements provided sufficient legal certainty on R&D agreements companies can conclude without the risk of infringing competition law?

- (●) Yes
- ( ) No
- ( ) Do not know

* 4.4 Please explain your reply

Text of 1 to 1500 characters will be accepted

There is value - in terms of legal certainty and the promotion of competition - in having a BER for R&D agreements but the current BER is overly complex. Legal certainty would be improved materially by, along with increasing market share thresholds:
(1) clearly restating that the notion of potential competition is predicated on likely and foreseeable market entry in a relatively short period of time, e.g. ruling out the mere targeting of a therapeutic indication or innovation space in the pharmaceutical sector. Only at a later stage, close to production, can potential overlaps in innovation poles be determined as targets or applications may change or may, at the outset, be undefined. Identifying the mere ability and/or interest in conducting research in the same “space” should not be sufficient to categorise parties as (potential) competitors.
(2) Simplifying "joint exploitation": under the current rules, agreeing on price or output is not allowed except if parties sell through a joint sales organisation ("JSO"). The pharmaceutical industry is witnessing more collaborative innovation that is helping to develop and bring to market new medicines faster. Where parties have made significant investments in co-developing a new product, there should be grounds for them to share profits and determine pricing where there is no JSO.

* 4.5 In your view, does the R&D BER increase legal certainty compared with a situation where the R&D BER would not exist but only the HGL applied?

- (●) Yes
- ( ) No
- ( ) Do not know

* 4.6 Please explain your reply

Text of 1 to 1500 characters will be accepted

In principle, the application of the R&D BER increases legal certainty for market operators subject to the caveats at 4.2 and 4.4 above.

* 4.7 In your view, have the Specialisation BER and Section 4 of the HGL on production agreements provided sufficient legal certainty on production /specialisation agreements companies can conclude without the risk of infringing competition law?

- (●) Yes
- ( ) No
- ( ) Do not know

* 4.8 Please explain your reply

Text of 1 to 1500 characters will be accepted

Yes, but raising the safe harbour threshold from 20 to 25% would be consistent with the threshold applied to joint R&D and would provide greater legal certainty.

* 4.9 In your view, does the Specialisation BER increase legal certainty compared with a situation where the Specialisation BER would not exist but only the HGL applied?
  - (●) Yes
  - ( ) No
  - ( ) Do not know

* 4.10 Please explain your reply

Text of 1 to 1500 characters will be accepted

We consider that the Specialisation BER provides a clearly structured approach for assessing specialisation agreements.

In this section we would like to have your opinion on the extent to which the HGL have provided sufficient legal certainty on horizontal cooperation agreements companies can undertake without the risk of infringing competition law. Please specify your answer according to the different types of horizontal agreements.

* 4.11 In your view, have the HGL provided sufficient legal certainty on agreements involving **information exchange** in the sense of Section 2 of the HGL?
  - (●) Yes
  - ( ) No
  - ( ) Do not know

* 4.12 Please explain your reply

Text of 1 to 1500 characters will be accepted

At an EU level, the HGL provide helpful legal certainty in relation to information exchange. But novel concepts/issues have arisen since the entry into force of the HGL, notably in relation to sustainability (see further, our response to question 4.20) and in the digital sphere (e.g. big data & algorithms).

The use of "big data" is increasingly important in the pharmaceutical sector. Real world evidence gathered from patient data sources helps develop effective medicines and treatments.

The European Commission should provide a light-touch, principles-based guidance on information exchange, so as to allow flexibility given the fast pace of change in the economy. The revised rules should codify existing case law and avoid being too granular or overly stringent, especially as regards data-related pooling practices which are generally pro-competitive and subject to constant innovation and change. This is also explicitly recognised by the Bundeskartellamt in its paper "Big Data und Wettbewerb" (October 2017).

* 4.13 In your view, have the HGL provided sufficient legal certainty on **purchasing agreements** in the sense of Section 5 of the HGL?

- (●) Yes
- ( ) No
- ( ) Do not know

* 4.14 Please explain your reply

Text of 1 to 1500 characters will be accepted

We consider the provisions in the HGL on purchasing agreements to be sufficiently clear.

* 4.15 In your view, have the HGL provided sufficient legal certainty on **commercialisation agreements** in the sense of Section 6 of the HGL

- (●) Yes
- ( ) No
- ( ) Do not know

* 4.16 Please explain your reply

Text of 1 to 1500 characters will be accepted

The scope of the HGL on commercialisation agreements is overly broad, catching a wide range of cooperation agreements, as evidenced by recital 225 of the HGL. The HGL should focus on where problems are likely to occur rather than casting the net so widely.

In our view, there should be a stronger presumption that the centre of gravity is at R&D level, even if the agreement involves pairing of/combining existing technologies / developed products. Collaboration agreements are increasingly complex and typically involve a combination of various forms of collaborations. As long as there is meaningful R&D at the centre of joint R&D efforts, the R&D BER and HGL should apply. Innovation is not a straightforward process, fully defined at the outset. Innovation mostly takes place in small incremental steps, not in giant leaps. Being one step closer to joint production does not mean that the centre of gravity shifts to joint production or commercialisation. E.g., A collaboration between two companies in the pharmaceutical industry that both have potential drugs at Phase III trials, should not be categorised as joint production. The guidance provided in para. 137-139 of the HGL (when R&D which may have restrictive effects) suffices in practice.

* 4.17 In your view, have the HGL provided sufficient legal certainty on **standardisation agreements** in the sense of Section 7 of the HGL

- (●) Yes
- ( ) No
- ( ) Do not know

* 4.18 Please explain your reply

Text of 1 to 1500 characters will be accepted

We consider the provisions in the HGL on standardisation, whilst not of particular relevance to the pharmaceutical industry, to be sufficiently clear.

* 4.19 In your view, have the HGL provided sufficient legal certainty on **other types of horizontal cooperation agreements** that are currently not specifically addressed in the HGL (for example sustainability agreements)

- ○ Yes
- ◉ No
- ○ Do not know

* 4.20 Please explain your reply

Text of 1 to 1500 characters will be accepted

Industry collaboration in relation to sustainability will be critical and guidance is currently lacking. Specifically, there is a lack of recognition under the HGL / Article 101(3) TFEU Guidelines of benefits which arise over the longer term or which are not easy to quantify or which benefit consumers outside the market in which the price increase (which may result from the collaboration) arises.

Given that sustainability projects may already fit within some of the existing categories in the HGL, it would be appropriate to improve the sections of the HGL dealing with "efficiencies". Consideration should also be given to the implications of the Wouters judgment (public policy goals which take an arrangement outside of Article 101 (1) TFEU), which could be reflected in the revised HGL.

There are other issues specific to the pharmaceutical sector. Combinations of competing products are an increasing phenomenon. Bringing combinations of products from multiple manufacturers to the market (more quickly) gives rise to substantial efficiencies, such as earlier access and better patient outcomes/care, and greater budgetary certainty/sustainability for healthcare systems. But the pathway to patient access may be unduly hindered by competition law sensitivities that may not be well understood by healthcare authorities.

* 4.21 In your view, are there other types of horizontal cooperation agreements outside those identified in the current HGL that should have been specifically addressed in order to increase legal certainty?

- ◉ Yes
- ○ No
- ○ Do not know

* 4.22 If Yes, please list those types of agreements and explain your reasons

Text of 1 to 3000 characters will be accepted

See response to question 4.20.

Identification of pro-competitive horizontal agreements

The R&D BER and the Specialisation BER set out a number of conditions that R&D and specialisation agreements need to meet in order to benefit from the block exemption. The HGL provide additional guidance on how to interpret these conditions. These conditions have been defined with the purpose to give exemption only to those agreements for which it can be assumed with sufficient certainty that they generate efficiencies that outweigh, in line with Article 101(3) of the Treaty, the harm caused by the restriction of competition.

Based on your experience, have the following provisions in the **R&D BER** allowed to correctly identify the horizontal cooperation agreements that are compliant with Article 101 of the Treaty?

* 4.23 The list of definitions that apply for R&D agreements that can benefit from exemption in Article 1 of the R&D BER
  - ○ Yes
  - ◉ No
  - ○ Do not know

* 4.24 If No, please explain what aspect of this provision fails to correctly identify R&D agreements that are compliant with Article 101 of the Treaty

Text of 1 to 1500 characters will be accepted

Paid-for R&D agreements, as defined under Art. 1(a)(vi) R&D BER, should fall outside the scope of BER R&D. The BER R&D is primarily aimed at collaborations taking place between partners on an equal footing. In contrast, paid-for R&D arrangements are vertical relationships whereby one party "outsources" its development activities to a third party, similar to the situations described in the Commission's Subcontracting Notice. Many concepts under the R&D BER, such as the "access rights" under Art. 3 of the R&D BER introduce unnecessary complexity and are not in keeping with the reality of vertical relationships or the dynamism of research today. Paid-for R&D arrangements should be assessed under the TTBER or the Subcontracting Notice or the R&D rules should be simplified in this respect.

* 4.25 The conditions for exemption listed in Article 3 of the R&D BER, regarding, for instance, access to the final results of the R&D, access to pre-existing know-how and joint exploitation.
  - ○ Yes
  - ◉ No
  - ○ Do not know

* 4.26 If No, please explain what aspect of these conditions fails to correctly identify R&D agreements that are compliant with Article 101 of the Treaty

Text of 1 to 1500 characters will be accepted

No, the conditions for exemption are overly complex and do not always incentivise innovation. There needs to be a fuller assessment of how confidentiality can be protected, especially in today's increasingly high-tech environment where the economic consequences of having an R&D partner breach confidentiality may be immediate and drastic. Without the possibility of ensuring proper protection against such confidentiality breaches, companies may be dissuaded from collaborating altogether.

In addition, taking into account the guidance provided in recital 138 of the HGL (relating to R&D directed at an entirely new product/ technology), legal certainty would be increased if the following R&D agreements are exempted more generally:
(1) R&D agreements relating to basic research;

(2) R&D directed at entirely new products at the development stage (and where any prospect of commercialisation is years away), where no determination of R&D poles is possible (e.g. R&D agreements relating to a product without, and prior to, targeting a specific disease indication). These types of agreements foster innovation and do not have restrictive effects on competition.

These arrangements are particularly relevant for industries with long development cycles for new products.

* 4.27 The absence of a market share threshold for non-competing undertakings, the market share threshold of 25% for competing undertakings and the application thereof provided for in Articles 4 and 7 of the R&D BER
  - ○ Yes
  - ○ No
  - ◉ Do not know

* 4.29 The limits regarding the duration of the exemption provided for in Article 4
  - ○ Yes
  - ◉ No
  - ○ Do not know

* 4.30 If No, please explain what aspect of these conditions fails to correctly identify R&D agreements that are compliant with Article 101 of the Treaty

Text of 1 to 1500 characters will be accepted

The seven year limit on the exemption is unnecessarily complicated.

* 4.31 The list identified in Article 5 of the R&D BER which make the exemption not available for agreements that have as their object certain restrictions or limitations ('hardcore restrictions')
  - ○ Yes
  - ◉ No
  - ○ Do not know

* 4.32 If No, please explain what aspect of these conditions fails to correctly identify R&D agreements that are compliant with Article 101 of the Treaty

Text of 1 to 1500 characters will be accepted

The list is too broad. It needs to be reconsidered in line with economic reality. There should be no R&D-related hard core restrictions. Prohibiting agreement on price/output unless distribution by a JSO is too restrictive given vast investments in joint development. In absence of a single market for pharmaceuticals, companies should be able to agree not to sell a jointly developed product in a territory if that entails significant knock-on effects due to international reference pricing (IRP).
The previous R&D BER provided an exemption for fixing prices to immediate customers also in the event of specialization in distribution between parties. Parties in global R&D and commercialization agreements often allocate distribution rights to different parties across the world. Due to IRP between geographies (eg Canada to EU countries), parties that have invested significantly in R&D and taken considerable commercial risks in

jointly developing a product, should be able to agree on the pricing globally, regardless of who distributes in the EU. If EEA-distribution rights are allocated to one party, there is no price competition between parties within the EEA. By excluding reference to Art.1(1)(m)(iii) in Art.5(c), the R&D BER raises concerns for global R&D and commercialization agreements. Reverting to the system in the previous BER or HGL to provide additional guidance would be desired. Finally, Art. 5(a) does not give due weight to the need for parties to protect confidentiality.

* 4.33 The list of obligations included in agreements to which the exemption does not apply ('excluded restrictions'), identified in Article 6 of the R&D BER
  - (•) Yes
  - ( ) No
  - ( ) Do not know

Based on your experience, have the following provisions in the **Specialisation BER** allowed to correctly identify the horizontal cooperation agreements that are compliant with Article 101 of the Treaty?

* 4.35 The definitions that apply for the purposes of the Specialisation BER, in Article 1
  - (•) Yes
  - ( ) No
  - ( ) Do not know

* 4.37 The explanations on the type of specialisation agreements to which the exemption applies, provided by Article 2 of the Specialisation BER
  - (•) Yes
  - ( ) No
  - ( ) Do not know

* 4.39 The market share threshold of 20% and its application, provided for in Articles 3 and 5 of the Specialisation BER
  - ( ) Yes
  - (•) No
  - ( ) Do not know

* 4.40 If No, please explain what aspect of these provisions fails to correctly identify Specialisation agreements that are compliant with Article 101 of the Treaty

Text of 1 to 1500 characters will be accepted

Greater legal certainty would be provided by increasing the safe harbour threshold to 25% in line with the threshold applied to joint R&D.

* 4.41 The list identified in Article 4 of the Specialisation BER which make the exemption not available for agreements that have as their object price fixing, certain limitations of output or sales or market or customer allocation ('hardcore restrictions')
  - (•)

Yes
- No
- Do not know

4.43 Based on your experience, are there other elements, besides those listed in the previous questions that should have been clarified, added, or removed to improve the guidance given by the BERs?

Text of 1 to 3000 characters will be accepted

No.

* 4.44 Based on your experience, are there other types of horizontal cooperation agreements outside those identified in the R&D and Specialisation BERs which would satisfy the conditions of Article 101(3) of the Treaty?
- Yes
- (•) No
- Do not know

* 4.46 Based on your experience, have the BERs and the HGL had any impacts that were not expected or not intended?
- Yes
- (•) No
- Do not know

5 Efficiency (were the costs involved proportionate to the benefits?)

In this section, we would like to have your view concerning the efficiency of the HBERs and the HGL. In your view, do you consider that the costs (for example, legal fees, delays in implementation) of analysing the conditions and applying these instruments is proportionate to the benefits (for example, faster self assessment) of having the rules in place?

Costs

* 5.1 Please describe the different types of costs of applying the current R&D and Specialisation BERs; and the HGL

Text of 1 to 1500 characters will be accepted

Due to the complexity of the current rules, it is costly to get to legal certainty since many agreements fall outside the BER safe harbours, requiring individual assessment.

5.2 Please explain whether you can express the above costs in money terms

Text of 1 to 1000 characters will be accepted

N/A

5.3 Please provide an estimate of your quantifiable costs both in terms of value (in EUR) and as a percentage of your annual turnover (or, in the case of a business association, of the annual turnover of the members you are representing)

Text of 1 to 500 characters will be accepted

N/A

5.4 Please explain how you calculate these costs

Text of 1 to 1500 characters will be accepted

N/A

* 5.5 In your view, how have the costs generated by the application of the R&D or the Specialisation BER or the HGL evolved **compared with the previous legislative framework** (Reg. 2659/2000 on R&D, Reg. 2658/2000 on Specialisation agreements and the accompanying horizontal guidelines)?

- (●) Costs increased
- ( ) Costs decreased
- ( ) Do not know

* 5.6 Please explain your reply

Text of 1 to 1500 characters will be accepted

The current Specialisation BER does not materially differ from the previous Specialisation BER. We recognise that although the current R&D BER exempts more agreements and contains more exceptions to the hardcore restrictions, costs of compliance are still material due to the fact the current rules are overly complex and lack sufficient flexibility.

The transformative pace of scientific and technological advancement in the pharmaceutical sector is the result of R&D collaborations taking place across an entire ecosystem including universities, small biotech and tech companies. The European Commission should adopt a more holistic approach to:
(1) avoid the application of rigid rules that are not always aligned with commercial reality,
(2) ensure the EU remains globally competitive by encouraging investments and innovation across high tech industries in the EU that require a highly skilled work force.

5.7 Please provide an estimate of the possible change in costs and explain your estimation

Text of 1 to 1500 characters will be accepted

N/A

In your view, would the costs of ensuring compliance of your horizontal cooperation agreements (or the agreements of your members) with Article 101 of the Treaty would be different **if the current HBERs were not in place but only the HGL applied**?

* 5.8 Were the **R&D BER** not in place, the cost of ensuring compliance
  - (•) Would increase
  - ( ) Would decrease
  - ( ) Do not know

* 5.9 Please explain your reply

Text of 1 to 1500 characters will be accepted

Costs would likely increase even if it is uncertain how many procompetitive agreements today actually fall strictly within or outside the BERs.

5.10 Please provide an estimate of the possible change in costs and explain your estimation

Text of 1 to 1500 characters will be accepted

N/A

5.11 Were the **Specialisation BER** not in place, the cost of ensuring compliance
  - (•) Would increase
  - ( ) Would decrease
  - ( ) Do not know

* 5.12 Please explain your reply

Text of 1 to 1500 characters will be accepted

See above.

5.13 Please provide an estimate of the possible change in costs and explain your estimation

Text of 1 to 1500 characters will be accepted

N/A

Benefits

* 5.14 Please describe the benefits, if any, of having the R&D and Specialisation BERs; and the HGL

Text of 1 to 1500 characters will be accepted

The R&D and Specialisation BERs provide a certain level of legal certainty by virtue of the safe harbour. The HGL help market operators self-assess many common forms of cooperation agreements. We refer to our responses to questions under section 4 outlining areas for improvement.

Benefits vs. costs

In your view, does the application of the R&D and Specialisation BERs and the HGL generate costs that are proportionate to the benefits they bring (or, in the case of a business association, the benefits for the members you are representing)?

* 5.15 Regarding the **R&D BER**
  - ○ Costs are proportionate to benefits
  - ○ Costs are not proportionate to benefits
  - ◉ Do not know

* 5.17 Regarding the **Specialisation BER**
  - ○ Costs are proportionate to benefits
  - ○ Costs are not proportionate to benefits
  - ◉ Do not know

* 5.19 Regarding the **HGL**
  - ○ Costs are proportionate to benefits
  - ○ Costs are not proportionate to benefits
  - ◉ Do not know

6 Relevance (do the objectives still match the needs or problems?)

In this section, we would like to understand if the objectives of the HBERs and the HGL are still up-to-date considering the developments that have taken place since their publication.

6.1 Please identify major trends and developments (for example legal, economic, political) that, based on your experience, have affected the application of the BERs and HGL. Please provide a short explanation with concrete examples in case you consider that (parts of) the HBERs or HGL do not sufficiently allow to address them

1000 characters max. for each row

	Major trends/changes	Articles of the HBERs and/or recitals of the HGL	Short explanation/concrete examples
1	Pharmaceutical R&D	R&D BER, Section 3 HGL	• Innovation in pharmaceutical R&D is taking place at breakneck speed and is of huge societal importance. It requires substantial investments and necessitates partnerships across multiple private and public players. Expensive clinical trials and the strict regulatory environment in practice also necessitate cooperation to get new medicines to the market quickly. It is therefore imperative that companies have legal certainty to incentivise collaboration in a broad sense. • Bringing combinations of products from multiple manufacturers to the market (more quickly) brings substantial efficiencies, such as earlier access and better patient outcomes, and greater budgetary certainty/sustainability for healthcare systems.
2	Digitalisation (data pooling & algorithms)	Section 2 HGL	The use of "big data" is increasingly important in the pharmaceutical sector and often entails cooperating with novel types of partners. Real world evidence gathered from patient data sources helps develop effective medicines and treatments faster. The revised rules should codify existing case law and avoid being too granular or overly stringent since data-related pooling practices are generally pro-competitive and subject to constant innovation and change.

3	Sustainability	Provisions relating to "efficiencies" in the Horizontal Rules	Industry collaboration in relation to sustainability has the potential to give rise to benefits which arise over the longer term or which benefit society beyond consumers in a given market and should be reflected in the sections of the HGL dealing with "efficiencies". Consideration should also be given to the implications of the Wouters judgment (public policy goals which take an arrangement outside of Article 101 (1) TFEU), which could be reflected in the revised HGL.
4			
5			
6			
7			

Do you think that it is still relevant to have the current HBERs and HGL in light of major trends or developments listed above?

* 6.2 The R&D BER and Section 3 of the HGL are
  - (●) Still relevant
  - ( ) No longer relevant
  - ( ) Do not know

* 6.3 Please explain your reply

Text of 1 to 1500 characters will be accepted

The R&D BER and Section 3 of the HGL remain relevant, especially for the pharmaceutical industry, where R&D is key and R&D collaborations frequent. However, as outlined in detail in our responses to section 4, the R&D BER, in its current format, provides limited assistance for the pharmaceutical industry specifically.

* 6.4 The Specialisation BER and Section 4 of the HGL are
  - (●) Still relevant
  - ( ) No longer relevant
  - ( ) Do not know

* 6.5 Please explain your reply

Text of 1 to 1500 characters will be accepted

The Specialisation BER and Section 4 of the HGL remain relevant.

* 6.6 Section 2 of the HGL on agreements involving information exchange is
  - (●) Still relevant
  - ( ) No longer relevant
  - ( ) Do not know

* 6.7 Please explain your reply

Text of 1 to 1500 characters will be accepted

Section 2 of the HGL remains relevant but should be updated in light of novel concepts/issues that have arisen since the adoption of the current HGL, such as sustainability and digitalisation (more specifically, big data & algorithms), and should leave room for flexibility in relation to these areas.

* 6.8 Section 5 of the HGL on purchasing agreements is
  - (●) Still relevant
  - ( ) No longer relevant

- Do not know

* 6.9 Please explain your reply

Text of 1 to 1500 characters will be accepted

N/A

* 6.10 Section 6 of the HGL on commercialisation agreements is
  - Still relevant
  - No longer relevant
  - Do not know

* 6.11 Please explain your reply

Text of 1 to 1500 characters will be accepted

Section 6 of the HGL on commercialisation agreements remains relevant but, as explained in our responses under section 4, the scope is overly broad.

* 6.12 Section 7 of the HGL on standardisation agreements is
  - Still relevant
  - No longer relevant
  - Do not know

* 6.13 Please explain your reply

Text of 1 to 1500 characters will be accepted

This is of lesser relevance to the pharmaceutical industry.

7 Coherence (Does the policy complement other actions or are there contradictions?)

* 7.1 In your view, are the HBERs and the HGL coherent with other instruments and /or case law that provide(s) guidance on the interpretation of Article 101 of the Treaty (e.g., other Block Exemption Regulations, the Vertical Guidelines and the Article 101(3) Guidelines)?
  - Yes
  - No

- Do not know

* 7.2 Please explain

Text of 1 to 3000 characters will be accepted

There is no major incoherence between the Horizontal Rules and other instruments that provide guidance on the interpretation of Article 101(1) TFEU but there are some small inconsistencies between various instruments.

For example, the Guidelines on Vertical Restraints considers one year a "short period of time" in relation to potential market entry (for purposes of assessing potential competition), whereas the R&D BER applies a three-year period. The vertical rules on price and output restraints should not necessarily be carried over to the R&D rules given the materiality of investments in joint R&D and the need to monetise those regardless of whether the end product is commercialised jointly.

There are also some minor discrepancies between the R&D BER and the TTBER, for example, differences in the definition of:
(1) "technology markets" - The TTBER defines 'relevant technology market' as "the market for the licensed technology rights and their substitutes, that is to say all those technology rights which are regarded as interchangeable or substitutable by the licensee, by reason of the technology rights' characteristics, the royalties payable in respect of those rights and their intended use". The R&D BER defines 'relevant technology market' more broadly as "the relevant market for the technologies or processes capable of being improved, substituted or replaced by the contract technologies".
(2) "potential competitor'" - The R&D BER defines 'potential competitor' as an undertaking likely to enter the market "within not more than 3 years". The TTBER does not refer to any specific period of time in which market entry must be likely, but merely refers to "a short period of time".

Finally, in its Horizontal Merger Guidelines, the Commission's applies a (maximum) two year period in relation to determining whether a market operator is to be considered a 'potential competitor' , explicitly recognising that "[w]hat constitutes an appropriate time period depends on the characteristics and dynamics of the market, as well as on the specific capabilities of potential entrants." Thus, again, demonstrating the difference in approach to 'potential competition' in the various instruments.

* 7.3 In your view, are the HBERs and the HGL coherent with other existing or upcoming legislation or policies at EU or national level?

- (●) Yes
- ( ) No
- ( ) Do not know

* 7.4 Please explain

Text of 1 to 3000 characters will be accepted

Yes, but the Horizontal Rules need to be updated to reflect novel concepts/issues that have arisen since their entry into force. In line with the European Commission's Communication in relation to the renewed EU industrial policy strategy (2017), and the priorities of the new Commission, the revised rules should be sufficiently flexible to encourage more innovation collaboration across a broad ecosystem, the protection of confidential data, the ability to share the return from joint high risk investments to ensure that Europe remains an attractive hub for highly skilled knowledge based sectors such as the pharmaceutical industry.

8 EU added value (Did EU action provide clear added value?)

In this section, we would like to understand if the HBERs and the HGL have had added value. In the absence of the HBERs and the HGL, undertakings would have had to self-assess their horizontal cooperation agreement with the help of the remaining legal framework. This would include for instance the case law of the EU and national courts, the Article 101(3) Guidelines, the enforcement practice of the Commission and national competition authorities, as well as other guidance at EU and national level.

Please indicate whether, in your view, the HBERs and the HGL have had added value in the assessment of the compatibility of horizontal cooperation agreements with Article 101 of the Treaty

* 8.1 Has the R&D BER had added value in the assessment of the compatibility of horizontal cooperation agreements with Article 101 of the Treaty?
  - (●) Yes
  - ( ) No
  - ( ) Do not know

* 8.2 Please explain your reply

Text of 1 to 1500 characters will be accepted

Yes, we consider that the R&D BER provides a certain level of legal certainty but as explained in more detail in our responses to section 4, we consider that the R&D BER can be improved.

We refer to our responses to questions under section 4 outlining areas of improvement.

* 8.3 Has the Specialisation BER had added value in the assessment of the compatibility of horizontal cooperation agreements with Article 101 of the Treaty?
  - (●) Yes
  - ( ) No
  - ( ) Do not know

* 8.4 Please explain your reply

Text of 1 to 1500 characters will be accepted

Yes, we consider that the Specialisation BER provides a clearly structured approach for assessing specialisation agreements but, for the reasons explained in our responses to section 4, should be further improved upon.

* 8.5 Have the HGL had added value in the assessment of the compatibility of horizontal cooperation agreements with Article 101 of the Treaty?
  - (●) Yes
  - ( ) No
  - ( ) Do not know

* 8.6 Please explain your reply

Text of 1 to 1500 characters will be accepted

Yes, we consider that the HGL provide for a comprehensive framework aiding market operators in self-assessing their cooperation agreements. That said, we refer to our responses to questions under section 4 outlining areas of improvement.

9 Specific questions

Final comments and document upload

9.1 Is there anything else with regard to the R&D and Specialisation BERs and the HGL that you would like to add?

Text of 1 to 3000 characters will be accepted

No.

9.2 You may upload a file that further explains your position in more detail or further details the answers you have given

The maximum file size is 1 MB
Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

* 9.3 Please indicate whether the Commission services may contact you for further details on the information submitted, if required

- (●) Yes
- ( ) No

Contact

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