

Explanatory Memorandum to the Regulated Advocacy Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019

This Explanatory Memorandum has been prepared by the Health and Social Services Department and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Regulated Advocacy Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019.

I am satisfied that the benefits justify the likely costs.

Huw Irranca-Davies
Minister for Children, Older People and Social Care

10 December 2018

PART 1

1. Description

In 2011 the Welsh Government published the white paper *Sustainable Social Services: A Framework for Action*. This set out an ambitious plan to create a new integrated and person-centred approach to social services provision in Wales. To achieve this new approach, in the last Assembly term, the Welsh Government made two pieces of primary legislation: the Social Services and Well-being (Wales) Act 2014 (“The 2014 Act”) and the Regulation and Inspection of Social Care (Wales) Act 2016 (“The 2016 Act”).

The 2016 Act was passed by the National Assembly for Wales on 24 November 2015 and received Royal Assent on 18 January 2016. It reforms the regulation and inspection regime for specified services. These services are listed in Section 2, and include ‘an advocacy service’ to be specified in regulations to be made by the Welsh Ministers. The 2016 Act provides the statutory framework for the regulation and inspection of social care services and the social care workforce. It enables the Welsh Ministers to put in place a number of items of subordinate legislation through the making of regulations, the publication of statutory guidance and the issuing of codes of practice.

This Explanatory Memorandum relates to Regulations that will come into force on 29 April 2019. They are about the specification of advocacy services to be regulated and the standards against which they will be regulated.

Statutory guidance to accompany the Regulations (under section 29 of the 2016 Act), published for consultation at the same time, has been revised and is published in draft on the Welsh Government website, to aid scrutiny of the Regulations. The statutory guidance will be finalised and published in spring 2019.

<https://gov.wales/topics/health/socialcare/regulation/?skip=1&lang=en>

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

No specific matters have been identified.

3. Legislative background

The powers enabling these Regulations to be made are contained in Sections 27 and 28, and Schedule 1 of the 2016 Act.

These Regulations are being laid before the National Assembly under the affirmative procedure.

Regulations about advocacy services, registered service providers and responsible individuals

Section 2 of the 2016 Act lists the types of service to be regulated under the Act. Subsection 2 refers to Schedule 1 which makes further provision about the meaning of the terms used and allows the Welsh Ministers to specify an 'advocacy service' for the purposes of Section 2.

Section 27 of the 2016 Act allows the Welsh Ministers to make regulations setting out the requirements imposed upon a registered service provider in relation to a regulated service. Section 28 of the 2016 Act allows the Welsh Ministers to make regulations setting out the specific responsibilities of the responsible individual for the service in respect of the service for which they are registered.

4. Purpose & intended effect of the legislation

These Regulations:

- Define advocacy services for the purposes of the 2016 Act which fall within the regulation and inspection regime it establishes. This will be limited to those services which must statutorily be provided by local authorities under the 2014 Act for looked after children, care leavers and children in need of care and support.
- Set the standards against which advocacy services will be regulated and inspected under the 2016 Act. These are drafted to be applicable to all people in receipt of advocacy services so as to support extension of regulation to all services when market stability allows.

5. Consultation

A 12- week consultation on these regulations ran between 23 May and 16 August 2018. Further details on the consultation process are set out in the Regulatory Impact Assessment below.

Section 27(4) of the 2016 Act provides that "Before making regulations under this section the Welsh Ministers must – (a) consult any persons they think appropriate, and (b) publish a statement about the consultation." To discharge this requirement, a summary of the responses, together with the Welsh Government's analysis and conclusions is being laid with this Explanatory Memorandum and can be found at:

<https://beta.gov.wales/advocacy-services-regulations>

Section 27(5) of the 2016 Act provides that "The Welsh Ministers must lay a copy of a statement published under subsection (4)(b) before the National Assembly for Wales". Therefore a copy of the summary of responses can also be found at:

<http://www.assembly.wales/en/bus-home/Pages/Plenary.aspx?assembly=5&category=Laid%20Document>

PART 2 - REGULATORY IMPACT ASSESSMENT

Advocacy

The 2016 Act creates a new system of regulation and inspection for advocacy services in Wales. This is supported by a requirement for service providers to register with Care Inspectorate Wales (CIW). The Act also sets out the high level information required when submitting an application to register a service. Additionally, the Act states that a person must specify the regulated service the person wants to provide, the places at, from or in relation to which the service is to be provided and the person designated as responsible individual. If a provider wishes to vary their registration, the application to do so must contain details of the variation sought by the provider.

These Regulations set out:

- the meaning of an advocacy service for the purposes of the Act.
- requirements upon a service provider in relation to a registered advocacy service;
- requirements on a responsible individual in relation to an advocacy service in respect of which the individual is designated.

In drafting the Regulations our approach has been, as far as is appropriate, to achieve consistency with the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017, and to reflect the views of the Technical Group on Advocacy which was established to consider the development of standards for Independent Advocacy providers; the development of Regulations and statutory guidance under the 2016 Act; and the National Standards and Outcomes Framework and the Code on Advocacy under Part 10 of the Social Services and Well-being (Wales) Act 2014.

Definition

Currently advocacy services are not regulated. Advocacy services are varied; provided on the basis of a combination of statutory entitlements and services offered on a paid or voluntary basis; and without a clear and consistent understanding of the market place in which advocacy is offered and provided. It is not possible, therefore, to establish certainty as to what effect a broad definition of 'advocacy service', for the purposes of the 2016 Act would have on the provision and availability of advocacy in Wales.

The approach taken therefore, would allow eventually for the extension of the regulatory framework to providers of advocacy for adults and those children who do not fall within the scope of section 178 of the 2014 Act at the point where there is clearer evidence of the impact the 2016 Act will impose on service providers. Any such extension would require amendment of these Regulations and would be subject to resolution of the National Assembly for Wales in accordance with Section 187 of the Regulation and Inspection of Social Care (Wales) Act 2016.

A Technical Group of advocacy providers and stakeholders was established with the aim, amongst other things, of advising on the development of regulations and statutory

guidance under the 2016 Act. The Group agreed that the opportunity for transitional arrangements should be explored as part of implementation. It was agreed that providers of children's statutory advocacy, because of their historic experience of delivering with local government, were more likely to be in a strong position to respond to the registration and inspection requirements. There are currently two service providers in Wales who will be affected in the short term. Longer term timelines can be considered for other advocacy service providers subject to there being a clear expectation that providers be working towards registration. The Group reflected the importance of ensuring that the drive for greater access to good quality advocacy services should reflect realistic expectations and not undermine and unsettle stability.

This Regulatory Impact Assessment does not present a 'do nothing' option as the National Assembly for Wales has determined, by passing the 2016 Act, that an advocacy service, as defined by Regulations to be made under Schedule 1 of the 2016 Act, should be subject to a regulation and inspection regime. These Regulations are intended to give effect to that intention.

i) Options

Option one – Replicate the provisions of the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017

Under the 2016 Act the following are listed in Section 2 as regulated services:

- A care home service;
- A secure accommodation service;
- A residential family centre service;
- An adoption service;
- A fostering service;
- An adult placement service;
- An advocacy service;
- A domiciliary support service.

Under this option the provisions of the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 would apply to regulated advocacy services in the same way that they do to other regulated services¹ without modification.

Option two – Modify the provisions of the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017

Advocacy services, however defined, are of a clearly different nature to services which provide accommodation or domiciliary support and so it is necessary to consider which of the provisions should apply, which should not, and what modifications may be appropriate so that advocacy services may become a regulated service.

An exercise was undertaken, with the assistance of the Technical Group on Advocacy, to identify appropriate adaptations and modifications. The provisions of the Regulated

¹ Those services regulated under phase 2: Care Home Services, Secure Accommodation Services, Residential Family Care Services and Domiciliary Support Services.

Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 that are applicable to regulated advocacy services are listed below with some commentary.

General requirements on service providers – the bulk of this would be applicable to regulated advocacy services with the proviso that a regulated advocacy service must have in place a policy dealing with confidentiality issues. This reflects the particular circumstances in which information may be shared between an advocate and a service user and the fact that such sharing will often prefigure the provision of other services offering care and support. There is a need to protect both the confidentiality of the service user and the professionalism of the provider with a clear explanation of what the limits of confidentiality are in the interests of both.

Requirements on service providers as to the steps to be taken before agreeing to provide care and support – the requirements in Part 4 of the 2017 Regulations will apply to advocacy services, with the deletion of ‘admission’ in Regulation 14 (2). It is not our intention that an advocacy service provider should undertake its own assessment of an individual’s care and support needs. We do, however, require that an advocacy provider should make an initial assessment of its ability to meet the individual’s needs for advocacy.

Requirements on service providers as to the steps to be taken on commencement of the provision of care and support – provisions in respect of advocacy plans and reviews of advocacy plans are less extensive than those relating to personal plans in the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 reflecting the distinction whereby day to day care and support is not supplied by an advocacy service.

Requirements on service providers as to the information to be provided to individuals on commencement of the provision of care and support – this replicates Part 6 with modifications reflecting the application of this provision to regulated advocacy services.

Requirements on service providers as to the standard of care and support to be provided – these provisions are effectively replicated with modifications reflecting their application to advocacy services. Less focus is placed on continuity of care and greater focus on confidentiality as a result of this consideration.

Requirements on service providers – safeguarding – these provisions apply to regulated advocacy service providers other than those provisions more suitable to regulated social care service providers who provide accommodation, such as those requiring a service provider to have a policy supporting individuals to manage their money or to prohibit the use of corporal punishment. The overarching requirement and the requirement to have policies and procedures in place for the prevention of abuse, neglect and improper treatment remain.

Requirements on service providers as to premises - will only be applicable in respect of the overarching requirement and the secure storage of records. This reflects consultation feedback on the nature and use of premises used by advocacy service providers.

Other requirements on service providers – provisions relating to notifications and records which apply explicitly to care homes do not apply. Notifications with respect to children admitted into, or discharged from, a place at which accommodation is provided to children are not required in respect of advocacy. Notification with respect to the death of a child accommodated in a secure children's home do not apply. Provisions regarding conflicts of interest are modified to remove reference to financial interests and care homes. Notifications in respect of child exploitation are replicated and have been expanded to ensure that criminal exploitation is treated in the same way as sexual exploitation. Requirements relating to a complaints policy and procedures and whistleblowing provisions are retained.

Requirements on responsible individuals for monitoring, reviewing and improving the quality of the regulated service – these are modified to reflect the applicability of provisions to advocacy services.

Offences - we intend that the regulations specify that the failure by service providers or responsible individuals to meet certain requirements is an offence, as in Part 21 of the 2017 Regulations. Where failures relate to the same or similar requirements under these regulations similar offences are created.

Requirements on responsible individuals for ensuring effective oversight of the service; Requirements on responsible individuals for ensuring compliance of the service; and Regulations under Section 21(5) of the Act – these provisions are all replicated for advocacy services.

Preferred Option: For the reasons set out under 'Benefits/Risks' below, option two is the preferred option.

ii) Costs

Options one and two

Costs to CIW

The cost to CIW of providing a regulation and inspection regime under the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 is addressed in the Regulatory Impact Assessment² which accompanied those Regulations. The marginal cost to CIW of extending this regime to advocacy services is estimated as likely to be small under either option.

Costs to service providers

Provisions under the following Parts of the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 apply to advocacy services. Under option one they are applied unmodified; modifications relevant to option two are noted in the text where appropriate.

² <http://www.assembly.wales/laid%20documents/sub-ld11277-em/sub-ld11277-em-e.pdf>

There is clearly an interaction between the definition of an advocacy service for the purposes of these Regulations and the extent to which service providers meet, or are in a position to meet, the standards that are set out in the Regulations, even though the sector is currently unregulated. For this reason, the costs identified below are presented in a cost per provider format.

General requirements on service providers

Requirements on service providers as to the steps to be taken before agreeing to provide care and support – Provisions requiring a statement of purpose and the production of a series of policies and procedures would incur a small cost to service providers depending on the provider and the current policies and procedures they have in place. The Regulatory Impact Assessment for the Regulation and Inspection of Social Care (Wales) Bill estimated that it would take providers 4 working days (assuming the working week is 37 hours) to complete the annual report (now entitled “annual return” so as to distinguish this from the local authorities’ annual reports). The annual return, a requirement under Section 10 of the 2016 Act, contains a similar level of information in relation to a service as a SOP. It is therefore estimated that a statement of purpose will take a similar amount of time to complete.

The cost of producing a statement of purpose for each place at, from, or in relation to which a service is to be provided, as required in the Regulations under this option is £392. However, this figure will vary depending on the salary of the person producing the statement of purpose. As this figure is an estimate for a small service provider, it may also vary for a larger provider.

In relation to the series of policies and procedures required, the providers of existing advocacy services which we propose to include in these Regulations already have many of these in place as a matter of good practice. We expect additional costs, therefore, to be minimal.

Requirements on service providers as to the steps to be taken on commencement of the provision of care and support

Engagement with the sector has indicated that the providers of existing advocacy services which we propose to include in the scope of these Regulations already plan, review (if necessary) and record the services they are contracted to provide to an individual. As a result, additional costs arising for service providers under this option are expected to be minimal.

Requirements on service providers as to the information to be provided to individuals on commencement of the provision of care and support

Provisions requiring providers to prepare a written guide to the service and a service agreement which must be shared with each individual would incur a cost to service providers. The Regulatory Impact Assessment for the Regulation and Inspection of Social Care (Wales) Bill estimated that it would take providers 4 working days (assuming the working week is 37 hours) to complete the annual return. The annual return, a requirement under Section 10 of the 2016 Act, contains a similar level of

information in relation to a service as a written guide. It is therefore estimated that the written guide to the service will take a similar amount of time to complete.

The approximate cost of £392³ for each setting can also be applied to the cost of producing a standard service agreement, as required in the Regulations under option 1. However, this figure will vary depending on the salary of the person producing a service agreement. As this figure is an estimate for a small service provider, it may also vary for a larger provider. It will also vary according to the provider and the documentation they currently have in place.

A service agreement is not required under option 2 as it is not considered appropriate to the nature of advocacy interventions and the level of service which the individual can expect is addressed in the proposal to produce an advocacy plan.

Requirements on service providers as to the standard of care and support to be provided

The requirement to provide information in an appropriate language, style, presentation and format having regard to the individual's needs would incur a cost to service providers. The degree to which there will be a cost will be dependent on the requirements of the individual, the provider and the documentation they have in place.

Requirements on service providers – safeguarding

The requirement to have policies and procedures in place for the prevention of abuse, neglect and improper treatment and for responding to any allegation or evidence would incur a small cost to service providers. The Regulatory Impact Assessment for the Regulation and Inspection of Social Care (Wales) Bill estimated that it would take providers 4 working days (assuming the working week is 37 hours) to complete the annual return. The annual return, a requirement under Section 10 of the 2016 Act, contains a similar level of information as might be expected in these policies and procedures. It is therefore estimated that the requirement in Part 7 to have safeguarding policies and procedures in place will entail a similar cost of £392⁴ for each setting. However, this figure will vary depending on the salary of the person producing the policy. As this figure is an estimate for a small service provider, it may also vary for a larger provider. The actual additional cost for an individual provider will depend on the provider and the policies and procedures they currently have in place. The providers which we propose to register in the short term have indicated that they have such policies in place currently.

Requirements on service providers as to staffing

The requirement to undertake Disclosure and Barring Service (DBS) checks would incur a cost in staff time for service providers. The degree to which there will be a cost will be dependent on the provider and the arrangements they currently have in place.

³[http://www.assembly.wales/laid%20documents/pri-ld10106-em%20-%20regulation%20and%20inspection%20of%20social%20care%20\(wales\)%20bill/pri-ld10106-em-e.pdf](http://www.assembly.wales/laid%20documents/pri-ld10106-em%20-%20regulation%20and%20inspection%20of%20social%20care%20(wales)%20bill/pri-ld10106-em-e.pdf)

⁴[http://www.assembly.wales/laid%20documents/pri-ld10106-em%20-%20regulation%20and%20inspection%20of%20social%20care%20\(wales\)%20bill/pri-ld10106-em-e.pdf](http://www.assembly.wales/laid%20documents/pri-ld10106-em%20-%20regulation%20and%20inspection%20of%20social%20care%20(wales)%20bill/pri-ld10106-em-e.pdf)

Requirements on service providers as to premises, facilities and equipment

The bulk of provisions within this Part of the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 are not applicable to advocacy services and we have removed those relating to facilities and equipment and some of those relating to premises. It is expected that the need for providers to have adequate facilities for the secure storage of records is likely to incur a small cost to service providers. The degree to which there will be an additional cost will be dependent on the provider and the arrangements they currently have in place

Other requirements on service providers

The requirement to keep and maintain specified records and make the required notifications will incur a cost to service providers. The degree to which there will be a cost will be dependent on the provider and the arrangements they currently have in place, including those required under contractual arrangements with service commissioners.

Requirements on responsible individuals

The requirements on Responsible Individuals (RIs) relate to the oversight of the service, ensuring the management is supervised, making reports on the quality of the service, adequacy of resources and other matters. The Responsible Individual must also make visits to the service in person and ensure the service is complying with other requirements, such as making notifications, recording incidents and complaints.

Although the Responsible Individual is not a paid employee, unless they are also the manager under s37 of the regulations, some additional costs may be incurred by providers. Using the ONS data from the Annual Survey of Hours and Earnings, which states that the gross hourly earnings for managers and directors in Social Services in 2017 was £19.29⁵, it is estimated that, assuming RIs spend most of their working day (8 hours) at a service during their visit, this would give a total cost, including on-costs, of £201 per visit. For quarterly visits, this gives an annual cost of approximately £800.

The regulations will also incur costs for service providers in terms of the requirement for Responsible Individuals to undertake quality of service reviews every six months. The Regulatory Impact Assessment for the Regulation and Inspection of Social Care (Wales) Bill estimated that it would take providers 4 working days (assuming the working week is 37 hours) to complete an annual return. The annual return, a requirement under Section 10 of the 2016 Act, contains a similar level of information to the quality of service review but as the quality of service review draws from existing monitoring information this should not take as long to complete. A reasonable estimation for this would be more like 2 working days, therefore incurring a cost of around £196 for each setting, every six months (£392 annually). However, this figure will vary depending on the salary of the person undertaking the review and may vary according to the size of the provider.

⁵ This figure is then uprated by 30% to include on-costs.

Combining the costs identified above gives an estimated annual cost of approximately £2,370 per provider. However, as explained, the cost per provider will depend upon the arrangements that are currently in place and the size of the provider.

iii) Benefits/Risks

Option one

The benefits of option one are that providers of advocacy services would be registered by CIW and regulated in accordance with standards which would apply, as far as appropriate, to all providers of regulated services. This would provide for clarity and consistency in the way services providing care and support are regulated but the risk is that this would not recognise the specific context in which advocacy services are provided and the related challenges.

Option two

The benefits of option two are that providers of advocacy services would be registered by CIW and regulated in accordance with standards which would apply, as far as appropriate, to all providers of regulated services *with relevant modifications to reflect the specific circumstances of advocacy services*. This would provide for clarity and consistency in the way services providing care and support are regulated while also recognising the specific context in which advocacy services are provided and the related challenges.

Option two would ensure that the information and documentation provided will give CIW the ability to make a full and informed decision as to whether an applicant is fit to manage a service. This enhances CIWs ability to ensure poor providers are not registered and as such protects people using the services. This option has been developed with the Technical Group on Advocacy and as a result of responses to consultation on Phase 1 and Phase 3 of the implementation of the 2016 Act which indicated concern amongst stakeholders that requiring advocacy services to register will deter market entry and result in additional costs.

This provides for a more graduated approach which sets high standards for the delivery of advocacy services and respects the phase 1 Act implementation consultation response which indicated that a phased implementation would limit the risk of unknown consequences. It recognises the long history of the children's sector in delivering advocacy support for looked after and other specified children and that they are well placed to lead by example.

iv) Consultation

The consultation, which ran from 24 May to 16 August 2018, sought views on the draft Regulated Advocacy Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019, which in summary:

- define ‘advocacy services’, for the purpose of the 2016 Act, which fall within the regulation and inspection regime it establishes.
- place requirements on service providers and responsible individuals of regulated advocacy services under the 2016 Act

It also invited views on:

- draft statutory guidance for service providers and responsible individuals of regulated advocacy services on meeting service standards
- the potential inclusion of providers of other types of advocacy – including those for adults - within the registration and inspection regime, when evidence of its effect on market stability suggests that the market is sufficiently stable to accommodate this.

19 responses were received to the consultation.

Three consultation sessions across 2 national events were held as part of the consultation process. The first event was held on 16 July in Glyndwr University, Wrexham and the second was held on 19 July in the SWALEC Stadium, Cardiff.

The sessions aimed to encourage stakeholders to respond and to enable those attending to:

- gain an overview of the draft legislative framework and key changes it will effect;
- check their understanding of the proposals and seek clarity, if needed;
- consider potential implications for their role and organisation

Overall the uptake of places for the events was positive, with approximately 90 attendees in total in Cardiff and 40 delegates in Wrexham. A range of public, private, voluntary and third sector organisations were represented, including a number of service providers.

The majority of consultation responses received were positive and no significant concerns were raised over additional burdens arising from the new regulations.

The following minor changes were made to the legislation as a result of further consideration of engagement and consultation responses:

- References to ‘personal plan’ have been amended to ‘advocacy plan’ which clarifies the purposes of the plan referred to.
- Reference to ‘outcomes’ the individual wishes to achieve when considering the suitability of the service have been removed as this recognises that part of the purpose of the service is to assist the individual to determine desired outcomes.
- We have made clear that the duty of candour required of service providers does not override the confidentiality of the individual.

- Transitional arrangements have been introduced in recognition that, as a newly regulated service, the establishment and achievement of the relevant professional qualifications will take some time.
- The requirement for any premises which are used for the provision of the service to have adequate facilities for the supervision of staff has been removed.
- Criminal Exploitation has been added to the list of events which must be notified to the service regulator

v) Competition Assessment

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	Yes
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	Yes
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector categorised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

The filter test shows that it is not likely that the regulation will have any detrimental effect on competition; therefore a detailed assessment has not been conducted. We do not consider it necessary to undertake a competition assessment for these Regulations since they will not affect the business sector in any significant way.

vi) Post implementation review

As set out in the RIA for the Act the Welsh Government has two clear aims for the regulation and inspection of social care, the Act and as such these regulations. They are:

- To secure the well-being of citizens; and
- To improve the quality of social care.

The Act makes provision for a number of key reporting mechanisms which will offer a set of clear evidence to inform the post implementation review and establish how successful the Act has been in achieving both of these aims. The reporting mechanisms include:

- Annual returns from service providers.
- Annual reports from local authorities and the review of those reports as undertaken in the Annual Review of Performance and Evaluation of Performance by the service regulator.
- The annual report from the Welsh Ministers in their role as the service regulator.
- The annual report of the workforce regulator.

CIW will monitor the implementation of these Regulations following their coming-into-force date of 29 April 2019.