

## OUR ASKS FOR THE FUTURE UK-EU RELATIONSHIP

### Introduction

The Specialised Healthcare Alliance (SHCA) is a coalition of more than 100 charities representing the interests of people living with rare and less common conditions.

People with rare and less common conditions, and those who care for them, rely on close cooperation with partner organisations and institutions in EU member states to maximise the impact of research efforts, ensure high quality care is delivered, and help achieve the best possible quality of life for patients.

Now that the UK has left the EU, the SHCA has produced this short briefing setting out our hopes for a future UK-EU relationship which will support the continuation of this close cooperation. This briefing is intended for all those with an interest in the issue, including ministers, officials and parliamentarians – and may be of particular help to parliamentarians contributing to debates on the Medicines and Medical Devices Bill.

This briefing has been informed by the views of our membership, and we are particularly grateful to those members – listed at the end of this briefing – who gave up their time to share their insights with us in depth.

The briefing contains 10 ‘asks’ of the Government, in its work to negotiate a future relationship with the EU, which will:

- Support research efforts, and patients’ access to new and innovative treatments
- Ensure the delivery of high quality care
- Help people living with rare and less common conditions enjoy the best possible quality of life

### Our asks on research and innovation

The current UK-EU relationship supports close collaboration on research, and allows our participation in EU-wide clinical trials and medicines authorisation arrangements which offer patients with rare diseases access to cutting-edge treatments.

We want a future relationship which:

#### 1. Allows the UK to continue to participate in EU-wide clinical trials

- Clinical trials of promising therapies for rare and less common conditions necessarily require a large population of potential patients
- If UK centres are not able to participate in EU-wide clinical trials, patients in the UK will miss out on the latest treatments
- For many rare and less common conditions, there are a number of trials of promising therapies planned over the coming years – and it is possible many UK patients will be unable to access them

## 2. Permits the UK's continued participation in Europe-wide research initiatives

- Many of our members rely on or support EU-funded research, including through the 'Horizon' programme which patient advocates participate in
- EU-wide research initiatives such as Horizon help forge links between UK researchers and researchers in other member states – underpinning the UK's global status and influence
- There are precedents for third country participation in EU research initiatives, and so the UK Government should prioritise early confirmation that this will continue

## 3. Supports the sharing of data for research

- A significant amount of research into rare and less common conditions relies on the use of international databases
- If the UK chose to diverge from EU rules on data-sharing, this may lead to friction in the sharing of data between the UK and other EU countries, creating barriers to research efforts
- Although the UK could choose to share data with other countries under new trade deals with them (such as with the US), the EU offers a relatively benign research environment in which intellectual property rights over data do not result in significant impediments to research

## 4. Facilitates the free flow of scientists and researchers between the UK and EU

- Expertise in rare conditions is often spread across many different countries, and research efforts are therefore facilitated by the free flow of those with this expertise between the UK and EU countries
- Any barriers to travel or migration as a result of our departure from the EU may therefore damage research which the UK is leading or supporting
- The UK should ensure mechanisms are put in place to mitigate these risks to the free flow of scientists and researchers

## 5. Delivers access to treatments no slower than existing arrangements

- In respect of many rare diseases, there will be many more patients in the larger EU-wide population than in the smaller UK population – meaning that new therapies may be launched in the EU before the UK if the UK chooses to have its own, separate licensing arrangements
- Any such delays in the launch of new rare disease therapies in the UK will only exacerbate the delays that patients already experience, compared to other countries in Europe, as a result of NHS reimbursement processes
- Any new UK-specific licensing regime for treatments should deliver access to rare disease treatments no slower than now – and the UK Government should grasp any opportunities to deliver faster access through conditional licensing arrangements and reforms to NHS reimbursement procedures

## Our asks on patient care

The current UK-EU relationship supports a high degree of collaboration on patient care, both through cross-border working between clinicians directly involved in the management of individual patients, and through the free flow of goods and other supplies required for patient care across the UK-EU border.

We want a future relationship which:

### 6. Helps clinicians in the UK continue to work closely with clinicians in the EU

- Clinical teams caring for patients with rare and less common conditions sometimes have very close links with clinicians in EU countries – particularly for the rarest conditions. UK clinicians find these links valuable to help inform and guide the care they deliver
- These relationships are sometimes informal, and sometimes formal. An example of the latter are the ‘European Reference Networks’ of specialised healthcare providers across Europe, in which UK hospitals and centres – as well as patient advocates – participate. Another example are ‘cross-border healthcare’ arrangements, which allow patients in the UK to receive healthcare in the EU and vice versa – and thus facilitate the transfer of patients from UK specialist centres to centres in the EU without having to meet the costs themselves
- This close cooperation relies both on goodwill and a supportive legal framework, and neither should be undermined in negotiations on a future UK-EU relationship

### 7. Maintains an undisrupted supply of medicines and medical supplies

- People with rare and less common conditions rely on a large number of medicines and medical supplies which are imported to the UK from the EU. These include not only life-saving medicines, but also medical consumables, blood products and organs for transplant
- The Government’s plans for the potential disruption of ‘no deal’ in 2019 helped reassure patients that supplies would be maintained, even in the event of an unplanned departure from the EU
- We are anxious to ensure that the Government is able to provide similar reassurance now, in the run-up to the end of the transition period in December 2020. Without such reassurance, there is a risk that uncoordinated and counterproductive stockpiling by patients and their families will occur

### 8. Safeguards the ability of patients to participate in EU compassionate use programmes

- For many patients with rare diseases, and their families, the only hope of a better outcome is through accessing treatments provided through clinical trials. However, in some cases, narrow clinical trial protocols mean that patients are ineligible to participate – even though the treatment is felt by their clinicians to be of potential benefit
- In these instances, pharmaceutical companies often provide the treatment free-of-charge through compassionate use programmes outside of the clinical trial protocol. However, in these circumstances, and although the treatment is free, the rest of the healthcare must be paid for
- If the treatment is only available through a compassionate use programme in another EU country, the UK Government has historically paid for such healthcare costs under ‘reciprocal healthcare’

arrangements, through which the healthcare costs of UK patients in EU countries are met by the UK Government and vice versa. However, if these arrangements are not replicated, patients and their families will instead need to raise their own funds to pay for such treatment in EU countries

## 9. Facilitates the recruitment and retention of health and care workers

- Many people with rare and less common conditions rely on NHS and social care teams staffed by health and care professionals from EU countries. These professionals include doctors who are sometimes the leading specialists in their field, nurses who ensure patients experience high quality care, and care workers who take care of patients' day-to-day needs
- Unless immigration arrangements in the future help ensure an adequate flow of health and care professionals into the UK, patient care may be damaged
- The UK Government should take steps both to implement supportive immigration arrangements, and to reassure EU health and care professionals already in the UK that their presence here is welcome and valued. In respect of some conditions, the return of just a small number of specialist clinicians to their home EU countries might have a very large impact on the quality of care that can be delivered in the UK

## **Our asks on quality of life**

The current UK-EU relationship allows UK patients to benefit – through the reciprocal healthcare arrangements noted above – from care from EU health systems when they are in EU countries.

We want a future relationship which:

## 10. Retains arrangements for 'reciprocal healthcare'

- Many people with rare and less common conditions are unable to access holiday travel insurance on account of their healthcare needs, and reciprocal healthcare allows them and their families to enjoy holidays in EU countries and to lead as close to normal lives as possible
- The UK Government should ensure that any future UK-EU relationship maintains patients' freedom to travel to EU states and to receive healthcare there
- If a pan-EU reciprocal healthcare agreement cannot be reached, bilateral country-by-country arrangements should be sought – but care must be taken to avoid administrative complexity for patients and their families

## **About the SHCA and this briefing**

We are grateful to the following SHCA members who shared their detailed insights with us to help inform this briefing: the ArchAngel MLD Trust; the Cystic Fibrosis Trust; Fanconi Hope; HAE UK; Kidney Care UK; Muscular Dystrophy UK; the National Kidney Federation; Niemann-Pick UK; and the Tuberous Sclerosis Association.

The SHCA's work is generously funded by eight corporate supporters: Actelion; Amicus Therapeutics; BioMarin; CSL Behring; Gilead; Novartis; Sobi; and Takeda.

For any further information, please contact [team@shca.info](mailto:team@shca.info).

**SHCA, February 2020**