Conversion of Community Marketing Authorisations to UK Marketing Authorisations — letters to industry

Documents

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Details

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The legislation that will come into force in a no-deal Brexit will, subject to being approved by Parliament, automatically convert Community Marketing Authorisations (CMAs) into UK Marketing Authorisations (MAs) on 31 October 2019 (so-called 'grandfathering').

To facilitate the grandfathering process. The MHRA has sent a letter to MAHs that sets out the actions that companies are requested to take concerning authorised Community Marketing Authorisations (CMAs) or inflight CAPS.

We have allocated a PL number based on each presentation within the product range rather than a separate number for each pack size. This means that there will usually be fewer UK authorisation numbers issued compared with those issued by the European Medicines Agency.

If your company holds one or more CMA and has not received this second letter, please email capconversion@mhra.gov.uk so we can verify the appropriate contact details.

For more information see our guidance on <u>Converting Centrally Authorised</u>
<u>Products (CAPs) to UK Marketing Authorisations (MAs), 'grandfathering' and managing lifecycle changes.</u>

Published 21 January 2019 Last updated 9 October 2019 <u>+ show all updates</u>

- 1. 9 October 2019 Change of text within Stay up to date box.
- 2. 26 September 2019 Published three new letters sent to industry regarding conversion of Community Marketing Authorisations to UK Marketing Authorisations
- 3. 21 January 2019 First published.

UN Human Rights Council 42 - General Comment: The Human Rights Situation in Yemen

The UK supports this resolution, L.16, and the renewal of the mandate of the Group of Eminent Experts for a further year.

The most recent report produced by this group set out in stark terms the impact of the conflict on the lives of civilians, and the obligation on all parties to the conflict to adhere to their international legal obligations.

We believe the group has done this in a fair and balanced manner, though we would encourage them to also examine the conduct of those who back the protagonists. Iran's role in the violation of human rights in this conflict, through their support for the Houthi rebels, is something that should not be ignored.

It is regrettable that the work of this group is not universally supported, and that the experts have not had the necessary access to the conflict zone, or been able to visit many of the countries that are engaged in the conflict. We encourage engagement with the Group as a means of ensuring that their conclusions are as well informed as possible, and that they reflect the views of all.

It is also regrettable that there will again be two resolutions on Yemen. The impact of this Council is greater when it speaks with one voice on issues of such clear human rights concern. We commend the efforts made to explore possible common ground, and encourage them to continue to engage over the coming year.

In our view this resolution should be adopted by consensus. If a vote is called on it, the UK will vote in favour, and encourages others to also vote yes.

British High Commissioner to Sierra Leone presents his credentials to H.E

President Julius Maada Bio

The new British High Commissioner to Sierra Leone, Mr. Simon Mustard, presented his letters of credence to His Excellency President Dr. Julius Maada Bio on Wednesday 18th September 2019, at State House in Freetown.

On accepting the Letters of Credence, President Dr. Julius Maada Bio said:

"My government is very focused on human capital development, in both health and education terms, and keen to build greater capacity in key institutions to help foster and sustain economic growth. I hope the UK will continue to be active partners in these areas, alongside our continuing partnership in security."

In presenting his Credentials, Mr Simon Mustard said:

"I have already seen first-hand the deep partnership and friendship that exists between our countries, in areas ranging from security, to development, education, business growth and people to people links. I want to strengthen those links over the next few years, including pursuing greater innovation and city to city connections."

Before arriving in Freetown, Simon served in a variety of roles in the Diplomatic Service, including in Central America, Washington, the Middle East, London, as well as the UK's Special Envoy to Africa's Great Lakes Region and High Commissioner to Malawi. He comes from the City of Hull, birthplace of William Wilberforce. He is keen to see the existing links between Freetown and Hull develop further.

Thomas Cook update

Thank you, Mr Speaker with your permission I would like to make a statement on the steps the government has been taking to support those affected by the collapse of Thomas Cook, in particular for the 150,000 passengers left abroad without a flight back and also the 9,000 people here who have lost their jobs in the UK.

Mr Speaker, this is a very sad situation. All parties considered options to avoid how this company could be not put into administration. Ultimately, however, it was Thomas Cook and its directors took the decision themselves to place this company into insolvency proceedings and it ceased trading at 2.00am on Monday 23 September.

And I recognise that this is a very distressing situation for all those involved, and I would like to assure members of the House that the government

is committed to supporting those affected, including by <u>providing</u> repatriation flights free of charge for all of those people.

We'vee been contingency planning for some time to prepare for this scenario, under Operation Matterhorn. The government and the Civil Aviation Authority (CAA) have run similar operations in the past and have been working hard to minimise the disruption for passengers and to try to assist Thomas Cook's staff.

Even with our preparations and previous experience with Monarch, the task before us represents the largest peacetime repatriation ever undertaken in the UK.

Some disruption and delay is therefore inevitable and we ask for understanding, particularly for Thomas Cook staff, many of whom are still working alongside the government, to help ensure the safe return of their customers.

For example, the situation reported in Cuba overnight being reported on the media. The aircraft left this morning (25 September 2019), and all the passengers from Cuba scheduled to come home today are on that flight.

Mr Speaker, normally, the CAA's responsibility for bringing back passengers back would extend only to customers covered by the ATOL scheme. However, there would have simply been insufficient capacity worldwide in the aviation market to book tickets independently and bring themselves home for those non-ATOL related.

Some passengers would have had to wait for a week, or more, and others would have suffered personal hardship, financial hardship as they waited for another flight.

This would have created, in my view, further economic problems, with people unable to return to work, and unable to be reunited with their families.

With tens of thousands of passengers abroad and with no easy means of returning to the UK, I instructed the CAA to ensure all those currently abroad were able to return ATOL or non-ATOL.

Due to the size, complexity and geographical scope of the Thomas Cook business, it has not been possible to replicate their exact airline and schedule. In the case of Monarch's collapse in 2017, the CAA was able to resource enough aircraft of the right size and the right types to closely match the airline's own aircraft.

But with Thomas Cook, a much bigger airline as well as providing a global network of package holidays, as a result, this operation has been a lot more challenging, and some of the passengers will be travelling home on commercial flights where others have available seats.

And I know the whole House will want to thank all the airlines and ground staff who have offered assistance to Thomas Cook passengers in this difficult situation.

I'd like to update the House with the latest information and give Hon Members a sense of the scale of the operation that has been going on:

- we have put arrangements in place to bring back 150,000 people, across 50 different locations
- this requires over 1000 flights by CAA chartered aircraft over a 2 week period. Passengers will be able to complete their full holidays so they shouldn't be leaving early and should return on the day they were intended to
- so far in the first 2 days of this operation, we have brought home nearly 30,000 of the 150,000 passengers on over 130 dedicated CAA flights, with a further 16,500 passengers that we hope to repatriate today on something like 70 flights. I checked before I came into the house and it is proceeding according to these amended schedules
- so far, 95% of people have been repatriated on their original date of departure and again we haven't been able to bring everyone back from the airport they went to because of the different sizes and shapes of the aircraft available
- in the first 2 days, we have therefore, provided onward travel for 2,300 passengers, and arranged an additional fight from Gatwick to Glasgow to relocate passengers who have flown back to the wrong airport because of the scheduling issue
- the CAA has reached out to over 3,000 hotels issuing letters of guarantee to ensure British holidaymakers can remain in their hotels. That has been followed up with calls and contact from FCO officials
- there are over 50 overseas airports involved around the Mediterranean,
 North Africa and in North America and 11 UK airports engaged in this programme
- there've been over 100,000 calls to our customer service centres
- and over 2 million unique visitors to the CAA's dedicated website (thomascook.caa.co.uk), that was in the first day alone, with over 7,000,000 page views
- in total, there have been 10 government departments and agencies involved, including the in London, and our extensive diplomatic and consular network in the affected countries worldwide

I have been hugely impressed as the programme has been rolling out the last couple of days and the response from everyone involved including Thomas Cook passengers has generally been positive — with many praising the CAA, local staff and government officials. Even though there has been considerable disruption. For example, people haven't been able to advance check in, as people are used to doing, instead having to queue and therefore causing queues as seen on television screens. It has though been generally well organised and extremely professional by all those involved.

Mr Speaker, despite these robust plans and their success so far, this is an incredibly distressing situation for all concerned. One of my top priorities remains helping those passengers abroad get back to the UK and do so safely.

Employees

But in addition to supporting passengers, we have also been working across government to ensure the 9,000 former Thomas Cook employees in the UK and those overseas receive the support that they need as well.

The decision by the Thomas Cook Group's board has been deeply upsetting for employees who are losing their jobs.

DWP's Jobcentre Plus <u>Rapid Response Service</u> is in place, helping workers get back into employment. The Jobcentre Plus Rapid Response Managers across the UK are ready to engage with the liquidators to start that vital work.

There are special arrangements for UK employees who are owed redundancy pay and notice pay by their insolvent employer: the <u>Redundancy Payments Service</u> in the <u>Insolvency Service</u> can pay statutory amounts owed to the former employees from the National Insurance Fund.

My Rt Hon Friend, the Secretary of State for Business Energy and Industrial Strategy is establishing a cross-government Task Force to address the impact on employees and local communities. This will help to overcome barriers to attending training, securing a job or self-employment, such as providing child care costs, tools, work clothes, travel costs.

My Colleagues and I have also been in contact with those members whose constituencies will have been hardest hit by these job losses, and given assurances that we will work with the industry to offer what support we can and in fact all Rt Hon Friends constituencies have been affected in some way even from working in a shop location.

My colleague, the Secretary of State for Business Energy and Industrial Strategy has also written to the Financial Reporting Council to ensure they prioritise, as a matter of urgency, an investigation into both the causes of the company's failure and the conduct of its directors and of its auditors.

Taxpayer

Mr Speaker, I am also aware of the duty this government has to the taxpayer, and while affected passengers have been told they will not have to pay to be flown back to the UK, we have entered into discussions with third parties with a view to recovering some of the costs of this large operation.

Around 60% of passengers have ATOL protection, and the CAA's Air Travel Trust Fund will contribute proportionately to the costs of repatriation, as well as refunding ATOL future bookings.

We will also look to recoup some of the costs from the relevant credit and debit card providers and travel insurers and we will look to recover costs from other travel providers through which passengers may have booked as their Thomas Cook holiday. We are also I should say in discussion with the Official Receiver to understand what costs can be recouped through the company's assets.

The final cost of repatriation for the Monarch situation back in 2017 was about £50 million including ATOL contributions. The repatriation effort for Thomas Cook is now known to be about twice the size and is more complicated for reasons I have explained.

It have also seen it suggested in the press that the government should have avoided the collapse with a bailout of up to £250 million for the company and its shareholders.

Given the perilous state of the business, including the companies £1.5 billion half year loss reported in May, followed by a further profit warning in November, this was simply not the case, with no guarantee that such an injection would have secured the future of the company.

And in effect Mr Speaker our concern is we would have put in £250 million and it would have risked being thrown away good money after bad. And then we'd still have had to pay for the cost of this repatriation.

It is quite clear that in the last several years the company ran into a number of different problems trying to expand itself out through investing more in the high street rather than less while the entire market was moving in the opposite direction.

The loss, nonetheless of an iconic British brand, with 178 year history, one of the oldest travel companies in the world, is an extremely sad moment.

However, this should not be seen as a reflection on the general health of the UK aviation industry, which continues to thrive. Passenger numbers are actually up, people are travelling more. The truth is the way people have booked their holidays has changed an enormous amount over the years but it didn't change as much with the company.

None of this should detract from the distress experienced by those businesses reliant on Thomas Cook, passengers and Thomas Cook employees who — as I've said — have worked above and beyond particularly in recent days during this distressing situation.

We have never had the collapse of an airline or holiday company on this scale before. We have responded swiftly and decisively. Right now our efforts are rightly focused on getting those passengers home and looking after those employees who have lost their jobs.

But we also need to understand whether any individuals have failed in their duties of stewardship within the company.

Then our efforts will turn to working through the reforms necessary to ensure passengers do not find themselves in this ridiculous situation again. We need to look at the options, not just ATOL, but also whether it is possible for airlines to be able to wind down in an orderly manner, they need to be able to look after their customers and we need to be able to ensure their planes can keep flying in order that we do not need end up having to set up a shadow airline for no matter what period of time.

This is where we will focus our efforts in the weeks and months ahead. But In order to do this we will require primary legislation, and dare I say it, a new session of this parliament.

Mr Speaker, in what has been a challenging time, may I put on record my appreciation for the work of all of those involved in this effort, and in particular Richard Moriarty, CEO of the CAA, who along with his team and my officials in the DfT have done an extraordinary job so far.

I am also grateful for the support of others, including the Mayor of Manchester, who has acknowledged the government's repatriation efforts and its work with all of the agencies involved to get people home.

This has been an unprecedented response to an unprecedented situation, and I am grateful to all parties who have stepped in to support these efforts.

Mr Speaker, I commend this statement to the House.

<u>Highways England statement following</u> <u>publication of DfT's Reported road</u> <u>casualties in Great Britain: 2018</u> <u>report</u>



Highways England's Head of Road Safety Richard Leonard said:

Our aim is to provide a network where no one is killed or injured while travelling on our roads — today's report indicates there is still much more that needs to be done. The numbers are very concerning and while over the last 15 years safety has improved and our roads are amongst the safest in the world, each incident is a tragedy for the individuals and the families involved.

Improving road safety needs safe roads, safe vehicles and safe

drivers. Safety is our top priority and we're working hard to improve England's motorway and A roads and we need your help. We all have a role to play to make sure we all get home, safe and well and we're asking all drivers to make their own safety, and that of other people, the most important thing to think about when they travel. Remember to check your vehicle, obey all signs and think about other drivers.

- The Strategic Road Network continues to be one of the safest in the world. Our network carries a third of all traffic and two-thirds of road freight equating to 95 billion road miles travelled per year.
- Our own assessment shows the number of people harmed on our network continues to reduce with the number of collisions (8,846, 4.3% lower than 2017) and casualties (13,380, 5.9% lower than 2017).
- Of concern indicated within our analysis is the number of those Killed or Seriously Injured (KSI's) on our network which in 2018 increased: with 250 reported road deaths, an increase of 5.9% compared with 2017; and 1737 people seriously injured, an increase of 7.4% compared with 2017.
- Increases in the number of KSIs have been reported on all road types on the network.
- Separate analysis of smart motorway all-lane running schemes continues to indicate that they are as safe as our wider motorway network.

General enquiries

Members of the public should contact the Highways England customer contact centre on 0300 123 5000.

Media enquiries

Journalists should contact the Highways England press office on 0844 693 1448 and use the menu to speak to the most appropriate press officer.

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