UK-CAB 74: Meeting report
Meeting with MSD
Friday 16 October 2020

Zoom virtual meeting

Present from MSD:

James Read:	Director, Policy & External Affairs (UK) Communications External Affairs (UK)
Rima Lahoulou:	Principal Scientist, Research Science EU Clinical Development
Harriet Middleton:	Associate director, Policy & Communications

The meeting was largely run by James Read, with Rima Lahoulou occasionally adding a few comments.

Contents

UK-CAB participants (listed at end of report)

Background and Summary

MSD had sent the Steering Group an email immediately before the meeting stating that: *"...we are not able to discuss specific details of individual medicines – either medicines already available or those in development."*

In practice this meant that they were unable to discuss anything specific about medication, even if that information was already in the public domain, as would be the case for topics covered at the HIV Conference in Glasgow. The meeting was therefore largely dominated by very general information about the company and a repetition of Government advice about COVID. UK-CAB members politely expressed their concern about this and asked why policy had been changed, as this has not been the case at other meetings with MSD. This will be followed up – see below Point 5.

MSD's pipeline for HIV ART is looking at long-acting options and fewer side-effects (maybe dual rather than triple therapy?).

They are looking at longer-acting PrEP.

With a history of developing vaccines since the 50s, the company is now working (with others) on a COVID vaccine, but NOT currently an HIV vaccine.

PrEP community feedback
They wanted to hear from us: "…*For what kind of people is oral PrEP not satisfactory - where could we do better? Are there communities who are not being effectively reached by PrEP, who remain at risk?"* In the event, as the meeting was over-running, we chose to continue with the planned programme rather than to provide feedback.

HIV Research Approaches
Historically levels of women participating in their ART trials has been poor (15%) but they were now aiming for 33%. They are developing more support for women, with transport, childcare support and women-specific recruitment information.

Brexit and COVID impact on supplies of medication
Plans have been made to ensure that there is no negative impact on availability of their drugs in the UK in 2021, as a result of either Brexit or COVID.

Further background to the meeting
The evening before the meeting, UK-CAB received an email from MSD saying:
"I need also to update you that our medical and regulatory review of our presentation for this year has meant that we are not able to discuss specific details of individual medicines – either medicines already available or those in development."

UK-CAB replied, stressing that we valued and wanted technical information that was in the public domain (for example, presented at Glasgow) to be discussed. Minutes before the meeting started a reply was received saying:
"Let's see how the discussion goes and we would absolutely welcome UKCAB feedback on the nature of the meeting with MSD today."

The UK-CAB Steering Group will review comments from the meeting, and in the feedback survey in order to prepare a suitable reply to MSD.

Meeting Content

James outlined the topics to be covered, responding to the UK-CAB questions sent to MSD.

1. **Pipeline**
2. **COVID-19**
3. **Vaccine Research**
4. **HIV**
5. **PrEP**
6. **HIV Research Approaches**
7. **Brexit**

1. Pipeline

A rather general question had been sent, primarily to allow MSD the freedom to talk about their ongoing and future trials. However, the general question was answered with a superficial and very general reply. Their pipeline is geared to:

- Getting everyone to undetectable
- Reducing side-effects (short- and long-term)
- Making treatment easier
- U=U
- PrEP
- Best QoL for PLWH
-

So from this, as we already said at the pre-meeting, MSD is looking at long-acting ARVs, both for ART and PrEP. They had a slide that said no more than moving from daily to perhaps weekly to perhaps longer-term dosing. They may also move to dual rather than triple therapy for ART, to reduce side-effects.

But they put absolutely no meat on these bones…no mention of HOW they were going to do this, with what products, or what studies they were doing to get to these laudable endpoints. This led to some discussion. UK-CAB members said that they really wanted more detail than this. We value the opportunity to be able to discuss (for example) trial results presented at conferences in more detail. Not everyone can afford to go to conferences. And reading the papers can be difficult. Much better is the opportunity to discuss things in more detail at a meeting with the company, which allows for a 2-way information exchange.

Those present from MSD were apologetic, but said that they not able to do this on this occasion. On pressing, they said they were bound by regulations. Further questioning revealed that the approach was unique to the UK since they said that these restrictions would not apply to ECAB or EATG meetings. It also emerged that the interpretation of regulations was unique to each individual company.

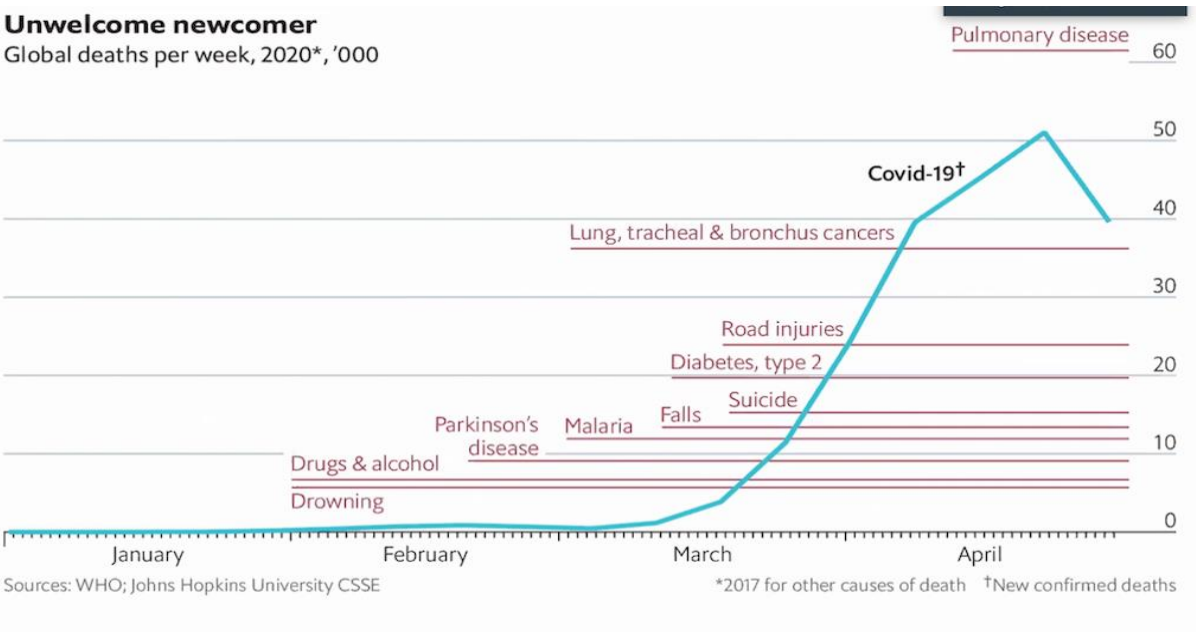
UK-CAB needs to understand what has changed - this was not the case last time MSD came. Nor is it clear why the UK is different to Europe. UK-CAB needs to understand the ABPI regulations, and why MSD are interpreting them in such a prohibitive way now and is writing to the company for further clarification.

2. COVID-19

MSD spent a lot of time unnecessarily going into great detail on the general advice for COVID-19 as provided by the Government:

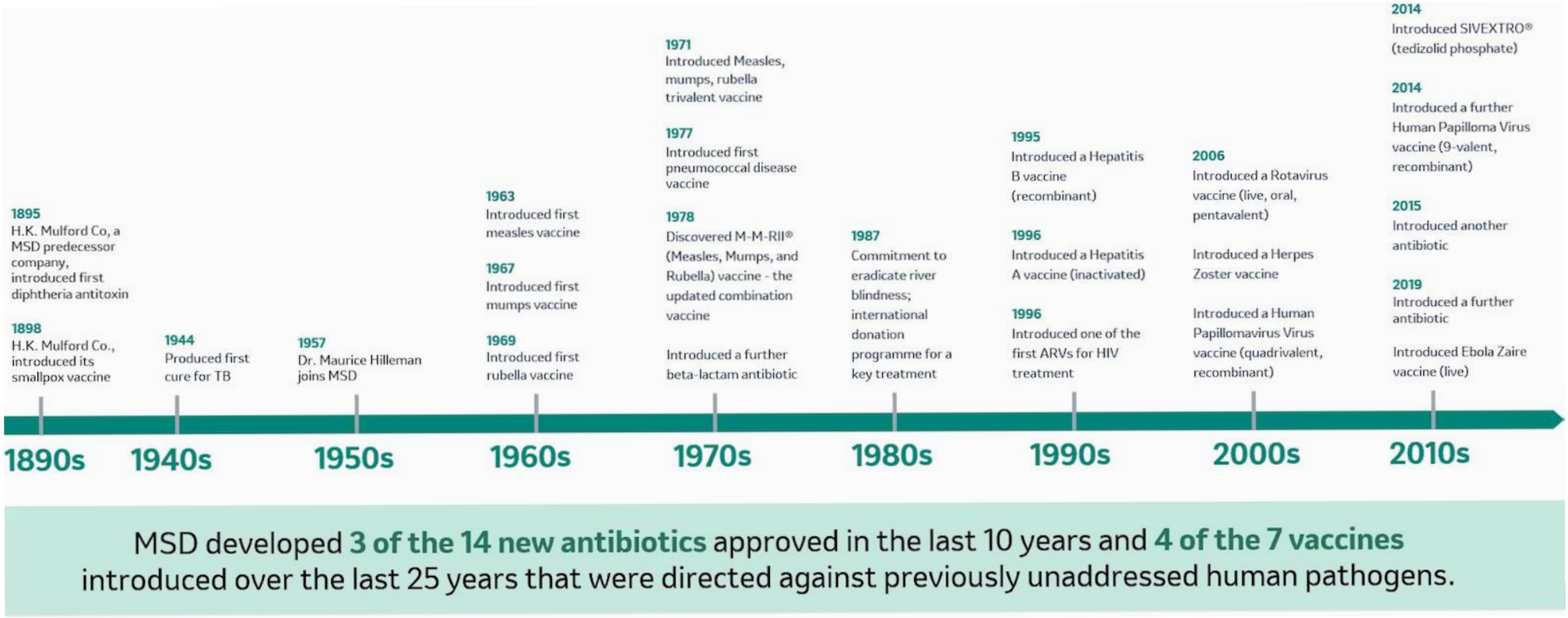
- Hand washing
- Distancing
- Avoid crowds
- Masks
- Avoid touching eyes, mouth, nose
- Cover when coughing/sneezing
- Self-isolate if ill
- Get medical help if needed
- Stay up-to-date

They did show an interesting graph, though, from The Economist:



3. Vaccine research

MSD outlined their long history in vaccines (see figure below), but did not tell us about what they were doing now.


1895
H.K. Mulford Co, a MSD predecessor company, introduced first diphtheria antitoxin
1898
H.K. Mulford Co., introduced its smallpox vaccine
1890s
1944
Produced first cure for TB
1940s
1957
Dr. Maurice Hilleman joins MSD
1950s
1963
Introduced first measles vaccine
1967
Introduced first mumps vaccine
1969
Introduced first rubella vaccine
1960s
1971
Introduced Measles, mumps, rubella trivalent vaccine
1977
Introduced first pneumococcal disease vaccine
1978
Discovered M-M-RII® (Measles, Mumps, and Rubella) vaccine - the updated combination vaccine
Introduced a further beta-lactam antibiotic
1970s
1987
Commitment to eradicate river blindness; international donation programme for a key treatment
1980s
1995
Introduced a Hepatitis B vaccine (recombinant)
1996
Introduced a Hepatitis A vaccine (inactivated)
1996
Introduced one of the first ARVs for HIV treatment
1990s
2006
Introduced a Rotavirus vaccine (live, oral, pentavalent)
Introduced a Herpes Zoster vaccine
Introduced a Human Papillomavirus Virus vaccine (quadrivalent, recombinant)
2000s
2014
Introduced SIVEXTRO® (tedizolid phosphate)
2014
Introduced a further Human Papilloma Virus vaccine (9-valent, recombinant)
2015
Introduced another antibiotic
2019
Introduced a further antibiotic
Introduced Ebola Zaire vaccine (live)
2010s
MSD developed 3 of the 14 new antibiotics approved in the last 10 years and 4 of the 7 vaccines introduced over the last 25 years that were directed against previously unaddressed human pathogens.

MSD said that there were lots of COVID-19 research going on globally, and that MSD was focusing its efforts as follows:

- Protecting employees
- Ensuring existing meds and vaccines reach customers
- Develop COVID meds and vaccine
- Support for healthcare providers and communities

They did not respond to questions other than to state that:

"Our company is leveraging our strong legacy and expertise in vaccines and anti-invectives to thoughtfully select and develop SARS-CoV-2 candidates."

They also said that they were collaborating with others:

- NIH-ACTIV
- Institute for Systems Biology
- Gates Foundation CEO Roundtable on COVID
- ACT-Accelerator

And they told us about the Vaccine Makers Pledge:

"…ongoing commitment to developing and testing potential vaccines for COVID in accordance with high ethical standards and sound scientific principles."

And:

"We are fully committed to affordable and equitable global access for our meds and vaccines across geographies and socioeconomic status."

They were asked some specific questions on vaccines, which they seemed largely unable to answer and said that they would come back to us on:

1. What HPV vaccine is used in the UK - is it quadrivalent or 9-valent?
2. What % of population would need to be vaccinated for COVID to ensure herd immunity
3. Are they doing any studies into Long-COVID? *No*
4. If somebody had Long-COVID symptoms, would a vaccine have any impact?
5. If someone has COVID, it appears that their immune response declines quite quickly. What are they looking for/expecting for the vaccine?
6. What is a realistic timeline to get COVID vaccine? *Depends how well trials go.*
7. Are MSD considering challenge trials for COVID?
8. *Not at this stage.*
9. How will MSD ensure global equitable access to their vaccine candidate? Will MSD hold an exclusive license if it is found effective? Will they be sharing data etc. in the WHO's COVID-19 Technology Access Pool? Unclear but expressed a willingness to share vaccine globally.
10. Are they doing HIV specific vaccine work? No

They went on to say that people with well-controlled HIV were NOT excluded from vaccine trials. And they intend these larger trials to look at diverse communities and risk categories, to evaluate safety and efficacy.

4. HIV

They had one slide on HIV ART. It was a reply to a very specific question:

How effective is 1200mg raltegravir once a day versus 400mg twice a day?

The reply was:

We would be pleased to address this question outside the meeting…

However, study data on this was presented at AIDS 2016:
https://www.aidsmap.com/news/jul-2016/once-daily-raltegravir-works-well-twice-daily-initial-hiv-treatment

And were reported in The Lancet in 2017:
https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(17)30128-5/fulltext

5. PrEP

They had nothing to tell us, despite the huge interest from the community in long-acting PrEP, and excitement over the initial results of MSD PrEP studies using Islatravir and MK-8507. The potential seems to be there for potentially once-a-year PrEP…which would be welcomed.

But they wanted to hear from us:
"For what kind of people is oral PrEP not satisfactory - where could we do better? Are there communities who are not being effectively reached by PrEP, who remain at risk?"

Time prevented discussion on this.

6. HIV Research Approaches

Their reply to our questions on women in trials:

They said that they had 15% women in DRIVE; and they were aiming for 33% for future trials. But they wouldn't tell us what trials (other than the names…P016, P017, P018, P019)

It was pointed out that 15% is very low; and 33% not very challenging, given that 57% of people living with HIV globally are women.

They talked about supporting women, by helping with childcare, travel costs, and female-specific recruitment material.

When asked about teratogenicity, they said this was important, but didn't elaborate on how it impacted trial recruitment. It was pointed out that there is a growing cohort of older women now past child-bearing age who would perhaps be suitable for trials.

They also said that their HIV studies now allow for people to identify as transgender and non-binary, and that they are planning further studies - a Phase 3 trial in cis men and trans women who have sex with men; and a PK and safety trial in trans men and trans women, including evaluation of drug-drug interactions with gender-affirming hormones…though without more specifics about which drugs and in what scenarios these trials were taking place.

7. Brexit

They are working to ensure a 6-week level of additional stock, and they do not anticipate a negative impact, either due to Brexit, or COVID.

They used a lot of warm words to say that they think they have it covered! They are working to ensure a 6-week additional stock, and they do not anticipate a negative impact, either due to Brexit, or COVID-19.

UK-CAB Participants

	NAME	Organisation	Destination
1	Andy Hilton	HiVitality, Positive Steps NW	St Annes
2	Ant Babajee	Positively UK	London
3	Ben Cromarty	Yorkshire Mesmac	Northallerton
4	Chris Sandford	Personal capacity	London
5	Damian Kelly	P.A.A.	Manchester
6	Harriet Mason	Youth Stop AIDS	London
7	Husseina Hamza	4MNet	London
8	James Dunworth	HIV i-Base	London
9	Jo Josh	UK-CAB SG Co-Chair Sophia Forum	Redhill, Surrey
10	Jose Mejia	METRO Charity	London
11	Memory Sachikonye	UK-CAB	London
12	Meriel Rattue	Positively Mindful CIC	Watford
13	Mr David King	Positively UK	London
14	Par Gustafsson	Body Positive Dorset	Bournemouth
15	Paul Clift	Personal capacity	London
16	Samantha Dawson	Body Positive Dorset	Bournemouth
17	Roy Trevelion	i-Base	London
18	Shiellah Mushunje	Dhiverse	Cambridge
19	Simon Horvat-Marvovic	Positively UK (Peer Mentor) THT Positive Voices	London
20	Simon Collins	HIV i-Base	London
22	Steve Atkinson	The Brunswick Centre	Huddersfield
22	Suzanne Thompson	HIV i-Base	London