Regulatory news

Pre-market assessment

Accelerated access pathways in Europe

European Union – The EMA has sought public comments on its revised guidelines on the implementation of accelerated assessment and conditional marketing authorization (1). The revised guidelines provide more details on how to justify fulfillment of a major public health interest and on the importance of planning and early dialogue. More recently, EMA has also launched a public consultation on its new proposed PRIME scheme to optimize development of priority medicines and facilitate patients’ access (2).

In their public input to the former consultation process (3), Health Action International (HAI), the International Society of Drug Bulletins (ISDB) and the Medicines in Europe Forum (MiEF) have emphasized the importance of concrete evidence demonstrating a new drug’s safety and therapeutic advance, of enforcing compliance with post-market obligations, and of ensuring transparency of accelerated decision-making by making assessment reports and expert statements publicly available. The three organizations have further published a joint briefing paper, in which they caution against adaptive pathways becoming the rule even when no genuine public health need exists (4).

(2) EMA News, 26 October 2015.
(3) HAI, ISDB, MiEF. Joint response to EMA public consultation. 30 September 2015.

Regulatory systems

New Zealand working on new regulatory regime

New Zealand – The New Zealand Government is working on a new and comprehensive national regulatory regime to regulate therapeutic products, i.e. the wide range products intended to be used in or on human beings for a therapeutic purpose including medical devices and cell and tissue therapies, which are currently not fully regulated in New Zealand. This follows the cessation of the Australia New Zealand Therapeutic Products Agency (ANZTPA) project. The intention is for a Bill to be introduced to Parliament in 2016.


Post-marketing control

EMA initiative to improve patient registries

European Union – The EMA has launched an initiative aimed at making better use of patient registries as a source of high-quality post-authorization data on medicines in clinical use.

Registries collect information over time on patients who are diagnosed with a particular disease or who receive particular treatments. Some registries are kept by pharmaceutical companies as a
regulatory requirement, while others are operated at national or international levels for example by physicians’ associations or national agencies. Existing registries are not sufficiently coordinated or harmonized, leading to inefficiencies.

The initiative is managed by a cross-committee task force and includes two components: a collaborative strategy and a pilot phase. The strategy aims to facilitate the interactions between coordinators of registries, regulators and pharmaceutical companies, and to identify methodological components for newly established registries to ensure that high quality and relevant data are collected. The pilot phase aims to test whether the strategy meets stakeholders’ needs on the basis of real-life examples. It is anticipated to last for two years. Participation will be determined on a case-by-case basis by the cross-committee task force.

► EMA News, 12 October 2015.

**Collaboration and harmonization**

**ICH announces organizational changes**

Geneva – The International Council for Harmonisation (ICH), formerly known as the International Conference on Harmonisation, has announced organizational reforms to equip it better to face the challenges of global pharmaceutical development and regulation.

The reforms aim to expand ICH beyond the current membership to make it a truly global initiative. Regulators around the world will be invited to join counterparts from Europe, Japan, USA, Canada and Switzerland as ICH regulatory members. This is matched by the possibility of wider inclusion of global industry sectors affected by ICH harmonization. ICH aims to be the leading platform for global pharmaceutical regulatory harmonisation, bringing together in a transparent manner all key regulatory authorities and industry stakeholders. The ICH operating structure will be an association under Swiss law, which establishes the new Assembly as the overarching governing body.

► ICH Press release, 26 October 2015.

**China and WHO collaborate on medicines quality**

Geneva – The long-standing collaboration between China and WHO to promote access to good quality pharmaceuticals was formalized in September 2015 when the Chinese Food and Drug Authority (CFDA) and WHO signed a ‘cooperation plan’ at WHO headquarters. The plan sets out a comprehensive package of measures that China will undertake with WHO’s technical assistance, specifically to improve the quality of generic medicines, create a more science based and efficient review and approval system, reduce drug submission backlogs and promote transparency of operations.

► WHO Essential medicines and health products, China – growing potential to supply affordable quality medicines [web page].

**Meeting of World Pharmacopoeias held in China**

China – The 6th International Meeting of World Pharmacopoeias was co-hosted by the Chinese Pharmacopoeia (ChP) and WHO in Suzhou, China, on 21–22 September 2015. Achieving global standards to expand access to quality medicines globally was key to the discussions of the meeting, which was...
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held in connection with the 2015 ChP Annual Scientific Symposium. Twelve pharmacopoeias from all around the globe attended, including the European Pharmacopoeia on behalf of its 38 signatories.

An important output of this international meeting was the finalization of the first-ever guideline on Good Pharmacopoeial practices, based on feedback received during wide global consultation, for presentation to the WHO Expert Committee on Specifications for Pharmaceutical Preparations. The Committee’s adoption of this guideline at its 50th meeting in October 2015 (see also page 481) marks a significant step forward in setting globally unified principles for creating quality standards for medicines.

WHO Essential medicines and health products. Meeting of World Pharmacopoeias in China benefits the world’s [web page].

Regulators of United Kingdom and India sign agreement

New Delhi – The Medicines and Healthcare products Regulatory Agency (MHRA) and the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare of the Republic of India have signed a Memorandum of Understanding (MOU). The agreement aims to facilitate regulatory information exchange and technical cooperation of mutual benefit, helping to protect the health and public safety in the two countries.

In 2014, MHRA carried out 125 inspections in non-EU countries, 49 of which were in India. Approximately 25% of the medicines sold in the United Kingdom are made in India. The agreement is part of a concerted effort to promote good manufacturing practices throughout the pharmaceutical industry, benefitting the global public. Similar agreements are already in place between MHRA and counterpart bodies in China and America.

WHO Press release, 5 October 2015.

EMA and WHO share non-public information

European Union – The European Commission, EMA and WHO have concluded a working arrangement that allows timely sharing of non-public information on the safety, quality and efficacy of medicines already authorized or under review in the European Union (EU), or prequalified or under review by WHO. This cooperation started on 1st September 2015.

The arrangement will make it easier and quicker to communicate and take action to protect public health. Examples of information that may be shared include:

• pharmacovigilance data, particularly urgent information on EU-originating or non-EU originating adverse reactions;
• information on applications for scientific advice, orphan medicine designation, marketing authorization, post-authorization activities of significant public health interest, and applications for agreement of paediatric investigation plans; and
• data and reports related to inspections, manufacturing facilities and clinical research activities.

Approved

**Insulin degludec & insulin aspart for diabetes mellitus**

**Product name:** Ryzodeg 70/30®

**Dosage form:** Injection

**Class:** Combination of a long-acting insulin analog (insulin degludec) and a rapid-acting human insulin analog (insulin aspart): **ATC code:** A10AD06

**Approval:** FDA

**Use:** Improvement of glycaemic control in adults with type 1 and 2 diabetes mellitus

**Benefits:** Additional treatment option for diabetes; ability to reduce HbA1c equivalent to reductions achieved with FDA-approved long-acting or pre-mixed insulin products.

**Safety information:** The product should not be used in patients with diabetic ketoacidosis. Like other insulins, it may cause severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock, as well as hypoglycaemia which can be life-threatening.

**Notes:** The FDA has also approved insulin degludec (Tresiba®) which was approved by EMA in 2013.

> **FDA News release, 25 September 2015.**

**Efmosoctocog alfa for haemophilia A**

**Product name:** Elocta®

**Dosage form:** Powder and solvent for solution for injection

**Class:** Antihaeimorrhagic (**ATC code:** B02)

**Approval:** EMA (orphan designation)

**Use:** Treatment and prophylaxis of bleeding in patients with haemophilia A

**Benefits:** provide adequate prophylaxis in terms of annualised bleeding

**Benefits:** Ability to provide adequate prophylaxis in terms of annualised bleeding rate, to control bleeding on demand and to provide haemostatic efficacy for surgical procedures.

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**Safety information:** Hypersensitivity reactions have been reported rarely.

> **EMA/CHMP Summary of opinion, 24 September 2015.**

**Modified antihaeimophilic factor (recombinant)**

**Product name:** Adynovate®

**Dosage form:** Lyophilized powder for solution for intravenous injection.

**Class:** Blood coagulation factor

**Approval:** FDA

**Use:** On-demand treatment and control of bleeding episodes for prophylaxis in patients with haemophilia A.

**Benefits:** This PEGylated product potentially requires less frequent injections than unmodified antihaeimophilic factor.

> **FDA News release, 13 November 2015.**

**Coagulation Factor X (human) for hereditary Factor X deficiency**

**Product name:** Coagadex®

**Class:** Blood coagulation factor; **ATC code:** B02BD13

**Approval:** FDA (orphan designation)

**Use:** Treatment of individuals aged 12 and older with hereditary Factor X deficiency for on-demand treatment and control of bleeding episodes, and for perioperative management of bleeding in patients with mild hereditary Factor X deficiency.

**Benefits:** The availability of a purified Factor X concentrate increases treatment options for patients with this rare hereditary condition.

> **FDA News release, 20 October 2015.**

**Patiromer for hyperkalaemia**

**Product name:** Veltassa®

**Dosage form:** Powder for oral suspension

**Class:** Potassium binder; polymer

**Approval:** FDA

**Use:** Treatment of hyperkalaemia. Not appropriate for rapid correction of severe
hyperkalaemia as lowering of serum potassium may take hours to days.

**Benefits**: In clinical trials, patiromer was effective in lowering potassium levels in hyperkalaemic participants with chronic kidney disease taking one or more renin-angiotensin-aldosterone system inhibitors.

**Safety information**: Patiromer binds many other orally administered drugs, which could decrease their absorption and reduce their effects. It should be taken at least six hours before or after any other orally administered medication.

► FDA News release, 21 October 2015.

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**Elvitegravir & cobicistat & emtricitabine & tenofovir alafenamide for HIV infection**

**Product name**: Genvoya®

**Dosage form**: Film-coated tablet

**Class**: Antiretroviral, fixed-dose combination; 

**ATC code**: J05AR18

**Approval**: EMA

**Use**: Treatment of adults and adolescents infected with human immunodeficiency virus 1 without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

**Benefits**: Potent antiretroviral response in a once daily, single pill regimen; lower impact on renal safety and bone mineral density than tenofovir disoproxil.

► EMA/CHMP Summary of opinion, 24 September 2015.

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**Uridine triacetate for a rare hereditary metabolic disorder**

**Product name**: Xuriden®

**Dosage form**: Oral granules

**Class**: Nucleoside

**Approval**: FDA (orphan drug designation)

**Use**: Treatment of hereditary orotic aciduria, a very rare metabolic disorder that prevents the body from synthesizing uridine, a necessary component of ribonucleic acid (RNA). This causes blood count disorders and urinary tract obstruction due to the formation of orotic acid crystals, resulting in failure to thrive and developmental delays.

**Benefits**: Uridine replacement; stabilisation of the haematologic parameters.

► FDA News release, 21 October 2015.

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**Trifluridine & tipiracil for advanced colorectal cancer**

**Product name**: Lonsurf®

**Dosage form**: Tablet

**Class**: combination of a nucleoside metabolic inhibitor (trifluridine) and a thymidine phosphorylase inhibitor (tipiracil); 

**ATC code**: L01BC59

**Approval**: FDA

**Use**: Treatment of patients with advanced (metastatic) colorectal cancer who have been previously treated with chemotherapy and biological therapy.

**Benefits**: Additional treatment option for metastatic colorectal cancer.

**Safety information**: Risk of severe myelosuppression. Complete blood counts should be obtained before starting each treatment cycle, and patients should be monitored throughout treatment.

Women should be advised of potential risks to developing foetuses. Women on treatment with this product should not breastfeed.

► FDA News release, 22 September 2015.

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**Blinatumomab for certain acute lymphoblastic leukaemias**

**Product name**: Blincyto®

**Dosage form**: Powder in a vial for preparing a concentrate for solution for infusion, and stabilising solution

**Class**: Bispecific T-cell engager antibody; 

**ATC code**: L01XC19

**Approval**: EMA (conditional marketing authorization; orphan designation)

**Use**: Treatment of adults with Philadelphia chromosome-negative relapsed or
refractory B-precursor acute lymphoblastic leukaemia.

**Benefits:** Ability to increase the proportion of patients who have complete remission and molecular remission within the first two treatment cycles.

► EMA CHMP Summary of opinion, 24 September 2015.

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**Nectumumab for advanced squamous non-small cell lung cancer**

**Product name:** Portrazza®

**Dosage form:**

**Class:** monoclonal antibody, EGFR-blocker: 

**ATC code:** L01XC22

**Approval:** FDA

**Use:** Treatment of patients with advanced (metastatic) squamous non-small cell lung cancer who have not previously received medication specifically for this cancer.

**Benefits:** New treatment option for certain patients with squamous cell lung cancer, ability to extend survival.

**Safety information:** The product carries a boxed warning to alert health care providers about serious risks of cardiac arrest and sudden death, as well as hypomagnesaemia with potentially fatal outcomes.

► FDA News release, 24 November 2015.

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**Cobimetinib for metastatic melanoma**

**Product name:** Cotellic®

**Dosage form:** Film-coated tablets

**Class:** Antineoplastic agent; mitogen-activated protein kinase (MAPK) pathway inhibitor: 

**ATC code:** L01XE

**Approval:** EMA, FDA (priority review; orphan drug designation)

**Use:** In combination with vemurafenib, treatment of unresectable or metastatic melanoma in patients with a BRAF V600 mutation

**Benefits:** Longer progression-free survival in melanoma patients with a BRAFV600 mutation, compared with vemurafenib monotherapy.

**Safety information:** May cause severe side effects including cardiomyopathy, rhabdomyolysis, new skin tumours, retinal detachment, liver damage, bleeding and severe skin rash due to photosensitivity. Women taking cobimetinib should use effective contraception.

**Notes:** The product was first approved by Swissmedic in August 2015.

► EMA CHMP Summary of opinion, 24 September 2015.

FDA News release, 10 November 2015.

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**Irinotecan liposome injection for advanced pancreatic cancer**

**Product name:** Onivyde®

**Dosage form:** Liposome injection

**Class:** Antineoplastic agent; 

**ATC code:** L01XX19

**Approval:** FDA (orphan designation; priority review)

**Use:** In combination with fluorouracil and leucovorin, to treat patients with advanced (metastatic) pancreatic cancer who have been previously treated with gemcitabine-based chemotherapy.

**Benefits:** Longer survival period, compared to patients treated with fluorouracil and leucovorin only.

**Safety information:** The medicine carries a Boxed Warning about the risks of severe neutropenia and diarrhoea. Death due to sepsis following neutropenia has been reported in patients treated with irinotecan. The medicine is not FDA-approved for use as a single agent.

► FDA Press announcement, 22 October 2015.

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**Carfilzomib for a rare type of blood cancer**

**Product name:** Kyprolis®

**Dosage form:** Powder for solution for injection
Class: Irreversible proteasome inhibitor;  
ATC code: L01XX45

Approval: EMA (accelerated assessment, orphan designation)

Use: In combination with lenalidomide and dexamethasone, treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Benefits: More sustained inhibition of targeted proteasome with minimal inhibition of other non-targeted enzymes; longer progression-free interval.

Safety information: Serious side effects include blood abnormalities and cardiac events. A follow-up plan was approved to monitor the safety and efficacy of carfilzomib.


Ixazomib for multiple myeloma
Product name: Ninlaro®
Dosage form: Capsule

Class: Antineoplastic – first oral proteasome inhibitor; ATC code: L01XX50

Approval: FDA (orphan drug designation; priority review)

Use: In combination lenalidomide and dexamethasone, to treat patients with multiple myeloma who have received at least one prior therapy.

Benefits: New oral treatment with ability to slow disease progression when other therapy has failed.


Talimogene laherparepvec for advanced melanoma
Product name: Imlygic®
Dosage form: Solution for injection

Class: Oncolytic virus derived from HSV-1 (a first-in-class advanced therapy medicinal product)

Approval: EMA, FDA

Use: Treatment of adults with unresectable melanoma. The product is directly injected into lesions in the skin or lymph nodes.

Benefits: Increased durable response rate – defined as disappearance of the tumours or at least 50% reduction of tumours lasting at least six months – compared to treatment with the immune stimulatory protein human GM-CSF. The product has not been shown to improve overall survival or to have an effect on melanoma that has spread to the brain, bone, liver, lungs, or other internal organs.

Safety information: This product is a modified live oncolytic herpes virus therapy, therefore herpes virus infection can occur. Given this, the product should not be used in patients who are immunocompromised, or in pregnant women.

► EMA Press release, 23 October 2015.
FDA News release, 27 October 2015.

Mepolizumab for asthma
Product name: Nucala®
Dosage form: Powder for solution for injection

Class: Humanised monoclonal antibody targeting human interleukin-5; ATC code: L04AC06

Approval: EMA, FDA

Use: Treatment of patients 12 years and older with severe refractory eosinophilic asthma.

Benefits: Can reduce the number of asthma exacerbations in patients who either remain uncontrolled on their previous standard of care or who are dependent on systemic corticosteroids.

Safety information: Hypersensitivity reactions can occur within hours or days of treatment.

► EMA/CHMP Summary of opinion, 24 September 2015.
FDA News release, 4 November 2015.

Osimertinib for certain non-small cell lung cancers
Product name: Tagrisso®
Dosage form: Tablet
Class: Third-generation tyrosine kinase inhibitor

Approval: FDA (breakthrough therapy designation, priority review and orphan drug designation; accelerated approval. Continued approval for this indication may be contingent upon further confirmatory studies.)

Use: Treatment of patients with advanced non-small cell lung cancer whose tumours have the T790M epidermal growth factor receptor (EGFR) mutation and have progressed on or after treatment with other EGFR-blocking therapy.

Benefits: Reduction of tumour size was observed in more than half of the patients treated in two clinical trials.

Safety information: May cause serious side effects, including inflammation of the lungs and injury to the heart. May cause harm to a developing foetus.

Notes: The FDA also approved a companion diagnostic test (cobas EGFR Mutation Test v2) to detect the T790M mutation.

Daratumumab for multiple myeloma

Product name: Darzalex®

Dosage form: Injection for intravenous use

Class: Antineoplastic; human CD38-directed monoclonal antibody

Approval: FDA (breakthrough therapy designation, priority review and orphan drug designation; accelerated approval)

Use: Treatment of treat patients with multiple myeloma who have received at least three prior treatments.

Benefits: Ability to achieve complete or partial reduction in tumour burden.

Safety information: Daratumumab may cause serious infusion reactions. Daratumumab may interfere with certain tests that are done by blood banks (such as antibody screening) for patients who need a blood transfusion.

Cariprazine for schizophrenia and bipolar disorder

Product name: Vraylar®

Dosage form: Capsules

Class: Antipsychotic, ATC code: N05AX15

Approval: FDA

Use: Treatment of schizophrenia and bipolar disorder in adults.

Benefits: Reduction of symptoms of schizophrenia and bipolar disorder.

Safety information: As all other FDA-approved products for treatment of schizophrenia and bipolar disorder, the product has a Boxed Warning about an increased risk of death associated with the use of these drugs in older people with dementia-related psychosis. Neither cariprazine nor any other drug in this class is approved to treat such patients.

Daratumumab for multiple myeloma

Product name: Darzalex®

Dosage form: Injection for intravenous use

Class: Antineoplastic; human CD38-directed monoclonal antibody

Approval: FDA (breakthrough therapy designation, priority review and orphan drug designation; accelerated approval)

Use: Treatment of treat patients with multiple myeloma who have received at least three prior treatments.

Benefits: Ability to achieve complete or partial reduction in tumour burden.

Safety information: Daratumumab may cause serious infusion reactions. Daratumumab may interfere with certain tests that are done by blood banks (such as antibody screening) for patients who need a blood transfusion.

Naloxone nasal spray for opioid overdose

Product name: Narcan®

Dosage form: Nasal spray

Class: Antidote; ATC code: V03AB15
Idarucizumab for reversal of dabigatran anticoagulant effect

Product name: Praxbind®
Dosage form: Solution for injection/infusion
Class: Humanised monoclonal antibody fragment; ATC code: V03AB
Approval: EMA
Use: Indicated in adult patients treated with dabigatran etexilate (Pradaxa®) when rapid reversal of the latter’s anticoagulant effects is required: (1) for emergency surgery/urgent procedures or (2) In life-threatening or uncontrolled bleeding. For hospital use only.
Benefits: Ability to reverse the anticoagulant effect of dabigatran within 5 minutes of administration, enabling clinical emergency management of patients if needed. Does not interfere with routine treatment in case of bleeding or urgent surgery.

Patiromer for hyperkalaemia

Product name: Veltassa®
Dosage form: Powder for oral suspension
Class: Potassium binder; polymer
Approval: FDA
Use: Treatment of hyperkalaemia. Not appropriate for rapid correction of severe hyperkalaemia because lowering of serum potassium may take hours to days.
Benefits: In clinical trials, patiromer was effective in lowering potassium levels in hyperkalaemic participants with chronic kidney disease taking one or more renin-angiotensin-aldosterone system inhibitors.
Safety information: Patiromer binds many other orally administered drugs, which could decrease their absorption and reduce their effects. It should be taken at least six hours before or after any other orally administered medication.
► FDA News release, 21 October 2015.

Pyronaridine-artesunate – paediatric antimalarial formulation

Product name: Pyramax®
Additional dosage form: Granules for oral suspension
Class: Antimalarial, artemisinin combination therapy
Approval: EMA positive opinion under Article 58. This programme allows the EMA to assess and give a scientific opinion in cooperation with the World Health Organization (WHO) for medicines intended exclusively for markets outside the European Union (EU). Through this mechanism, regulators outside the EU can use the CHMP assessment as part of their national authorisation process.
Newly approved use: Treatment of malaria caused by P. falciparum and P. vivax in children and infants weighing 5 kg to less than 20 kg under 20 kg. Restrictions were also removed on repeated courses of treatment in patients and on its use only in areas of low malaria transmission with evidence of artemisinin resistance.
Note: This artemisinin combination therapy was first evaluated as film-coated tablets in 2012 and received a positive opinion under EMA's Article 58 programme. (1)
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Approved

This paediatric antimalarial formulation as well as the film-coated tablet formulation for adults and children weighing >20kg were developed by the product development partnership Medicines for Malaria Venture (MMV) and Shin Poong Pharmaceutical Co. Ltd., Republic of Korea. (2)

► (1) EMA/CHMP Summary of opinion, 19 November 2015.

(2) MMV Press release, 20 November 2015.

Extensions of indications

Anthrax vaccine adsorbed for post-exposure protection

Product name: BioThrax®

Dosage form: Suspension for intramuscular or subcutaneous injection

Class: Anthrax vaccine; ATC code: J07AC

Approval: FDA

Newly approved use: Together with antibiotic treatment, to prevent disease after confirmed or suspected exposure to anthrax spores.

► FDA News release, 23 November 2015.

Ipilimumab to prevent melanoma recurrence

Product name: Yervoy®

Dosage form: Injection for intravenous infusion

Class: Antineoplastic, monoclonal antibody that blocks CTLA-4; ATC code: L01XC11

Approval: FDA

Newly approved use: Adjuvant therapy for patients with stage III melanoma, to lower the risk that the melanoma will return following surgery.

Safety information: The product carries a Boxed Warning about potential fatal immune-mediated adverse reactions and unusual severe side effects.

► FDA News release, 28 October 2015.

Nivolumab for renal cell cancer

Product name: Opdivo®

Dosage form: Concentrate for solution for infusion

Class: Antineoplastic agent, monoclonal antibody, PD-1 receptor blocker; ATC code: L01XC17

Approval: FDA (breakthrough therapy designation, fast track designation, priority review)

Newly approved use: Treatment of patients with advanced (metastatic) renal cell carcinoma who have received prior anti-angiogenic therapy.

► FDA News release, 23 November 2015.

Pembrolizumab for advanced non-small cell lung cancer

Product name: Keytruda®

Dosage form: For injection: lyophilized powder in single-use vial for reconstitution

Class: Antineoplastic; PD-1 pathway blocker; ATC code: L01XC18

Approval: FDA (breakthrough therapy designation, accelerated approval).

Approved for use with a companion diagnostic, the PD-L1 IHC 22C3 pharmDx test, the first test designed to detect PD-L1 expression in non-small cell lung tumours.

Newly approved use: Treatment patients with advanced (metastatic) non-small cell lung cancer (NSCLC) whose disease has progressed after other treatments and whose tumours express the PD-L1 protein.

Notes: Pembrolizumab was previously approved for advanced melanoma by FDA and EMA.

► FDA News release, 2 October 2015.

WHO endorsements

Global Ebola virus and antibody reference standards

The WHO Expert Committee on Biological Standardization has endorsed two types of Ebola reference reagents as the global
standards for use in laboratory tests. The reference reagents were developed within a short time by the National Institute for Biological Standards and Control (NIBSC) and are made available to laboratories around the world through the NIBSC website (www.nibsc.org/products/brm_product_catalogue.aspx). The first standard is used for testing alongside patient samples to detect Ebola infection. The second measures Ebola antibody levels following infection, or following immunization with candidate vaccines.

The two standards will enable accurate measurement of Ebola virus and antibody, making it possible to compare results from different tests and different laboratories. By minimizing fragmentation and duplication of research efforts these global standards will help accelerate the development of new Ebola vaccines.

► MHRA Press release, 5 November 2015.

Malaria vaccine to be delivered in pilot projects
The World Health Organization’s Strategic Advisory Group of Experts on Immunization (SAGE) and the Malaria Policy Advisory Committee (MPAC) jointly recommended the implementation of 3–5 large pilot projects to understand how best to deliver a vaccine that protects against malaria in young children. The vaccine must be given in three doses one month apart, followed by a fourth dose 18 months later. The main question is how to ensure that each child receives all four doses.

The vaccine, known as RTS,S or Mosquirix®, was approved in July 2015 by EMA under its Article 58 procedure for medicines used outside the EU, subject to WHO recommendations on its use. It acts against P. falciparum, the most deadly malaria parasite globally and the most prevalent in Africa. It offers no protection against P. vivax malaria, which predominates in many countries outside Africa. The vaccine is a complementary tool that could be added to – but not replace – the core package of proven measures to prevent, diagnose and treat malaria.

► WHO News release, 23 October 2015.