

New Active Substances (NASs) approved by six major authorities in 2016

Prepared by:

Magdalena Bujar, MSc, Research Analyst

Neil McAuslane, PhD, Scientific Director

Lawrence Liberti, MSc, RPh, RAC, Executive Director

Centre for Innovation in Regulatory Science (CIRS)
The Johnson Building, 77 Hatton Garden
London
EC1N 8JS
UK

Email: cirs@cirsci.org
Website: www.cirsci.org

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EMA NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval
Episalvan	betulae cortex dry extract (5-10 : 1); extraction solvent: n-heptane 95% (w/w)	Birken AG	14/01/2016				
Briviact	brivaracetam	UCB Pharma SA	14/01/2016				
Tagrisso	osimertinib mesylate	AstraZeneca AB	02/02/2016				
Portrazza	necitumumab	Eli Lilly Nederland B.V.	15/02/2016				
Zurampic	lesinurad	Grünenthal GmbH	18/02/2016				
Wakix	pitolisant	Bioprojet Pharma	31/03/2016				
Taltz	ixekizumab	Eli Lilly Nederland B.V.	25/04/2016				
Lonsurf	trifluridine / tipiracil hydrochloride	Les Laboratoires Servier	25/04/2016				
Idelvion	albutrepenonacog alfa	CSL Behring GmbH	11/05/2016				
Empliciti	elotuzumab	Bristol-Myers Squibb	11/05/2016				
Alprolix	eftrenonacog alfa	Swedish Orphan Biovitrum AB (publ)	12/05/2016				
Uptravi	selexipag	Actelion Registration Ltd	12/05/2016				
Darzalex	daratumumab	Janssen-Cilag International N.V.	20/05/2016				
Strimvelis	autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ADA) cDNA sequence from human haematopoietic stem/progenitor (CD34+) cells	GlaxoSmithKline Trading Services Limited	26/05/2016				

*Expedited review refers to EMA Accelerated Assessment

EMA NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Exceptional Circumstances	Conditional Approval
Galafold	migalastat hydrochloride	Amicus Therapeutics UK Ltd	26/05/2016	**			
Zavicefta	ceftazidime / avibactam	AstraZeneca AB	24/06/2016				
Ongentys	opicapone	Bial - Portela & C ^o , S.A.	24/06/2016				
Epclusa	sofosbuvir / velpatasvir	Gilead Sciences International Ltd	06/07/2016				
Zepatier	elbasvir / grazoprevir	Merck Sharp & Dohme Limited	22/07/2016	**			
Cinqaero	reslizumab	Teva Pharmaceuticals Limited	16/08/2016				
Zalmoxis	Allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (LNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)	MolMed SpA	18/08/2016				
Truberzi	eluxadolone	Allergan	19/09/2016				
Lartruvo	olaratumab	Eli Lilly Nederland B.V.	09/11/2016				
Ibrance	palbociclib	Pfizer Limited	09/11/2016				
Parsabiv	etelcalcetide hydrochloride	Amgen Europe B.V.	11/11/2016				
Ninlaro	ixazomib citrate	Takeda Pharma A/S	21/11/2016	**			
Venclyxto	venetoclax	AbbVie Ltd	05/12/2016				
Ocaliva	obeticholic acid	Intercept Pharma Ltd	12/12/2016				

*Expedited review refers to EMA Accelerated Assessment

**Originally expedited but reverted to standard during review

FDA NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval
ZEPATIER NDA #208261	ELBASVIR; GRAZOPREVIR	MERCK SHARP DOHME	28/01/2016					
BRIVIACT NDA #205836	BRIVARACETAM	UCB INC	18/02/2016					
IDELVION	Coagulation Factor IX (Recombinant), Albumin Fusion Protein	CSL Behring Recombinant Facility AG	04/03/2016					
ANTHIM BLA #125509	OBILTOXAXIMA B	ELUSYS THERAPEUTICS INC	18/03/2016					
TALTZ BLA #125521	IXEKIZUMAB	ELI LILLY AND CO	22/03/2016					
CINQAIR BLA #761033	RESLIZUMAB	TEVA RESPIRATORY LLC	23/03/2016					
DEFITELIO NDA #208114	DEFIBROTIDE SODIUM	JAZZ PHARMS INC	30/03/2016					
VENCLEXTA NDA #208573	VENETOCLAX	ABBVIE INC	11/04/2016					
NUPLAZID NDA #207318	PIMAVANSERIN TARTRATE	ACADIA PHARMS INC	29/04/2016					
TECENTRIQ BLA #761034	ATEZOLIZUMAB	GENENTECH INC	18/05/2016					
AFSTYLA	Antihemophilic Factor (Recombinant), Single Chain	CSL Behring Recombinant Facility AG	25/05/2016					
AXUMIN NDA #208054	FLUCICLOVINE F-18	BLUE EARTH	27/05/2016					
OCALIVA NDA #207999	OBETICHOLIC ACID	INTERCEPT PHARMS INC	27/05/2016					
NETSPOT NDA #208547	GALLIUM DOTATATE GA- 68	AAA USA INC	01/06/2016					
EPCLUSA NDA #208341	SOFOSBUVIR; VELPATASVIR	GILEAD SCIENCES INC	28/06/2016					

* Expedited review refers to FDA Priority Review

FDA NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Fast Track	Break-through	Accelerated Approval
XIIDRA NDA #208073	LIFITEGRAST	SHIRE DEV LLC	11/07/2016					
ADLYXIN NDA #208471	LIXISENATIDE	SANOFI- AVENTIS US	27/07/2016					
EXONDYS 51 NDA #206488	ETEPLIRSEN	SAREPTA THERAPS INC	19/09/2016					
LARTRUV O BLA #761038	OLARATUMAB	ELI LILLY AND CO	19/10/2016					
ZINPLAVA BLA #761046	BEZLOTOXUMAB	MERCK SHARP DOHME	21/10/2016					
EUCRISA NDA #207695	CRISABOROLE	ANACOR PHARMS INC	14/12/2016					
RUBRACA NDA #209115	RUCAPARIB CAMSYLATE	CLOVIS ONCOLOGY INC	19/12/2016					
SPINRAZA NDA #209531	NUSINERSEN SODIUM	BIOGEN IDEC	23/12/2016					

* Expedited review refers to FDA Priority Review

PMDA NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Sakigake
Repatha	Evolocumab	Amgen Astellas BioPharma K.K	22/01/2016			
Provocholine /Kenbran	Methacholine chloride	Sanwa Kagaku Kenkyusho/Santen Pharmaceutical	22/01/2016			
Targretin	Bexarotene	Minophagen	22/01/2016			
Sabril	Vigabatrin	Sanofi	28/03/2016			
Sycrest	Asenapine maleate	Meiji Seika Pharma	28/03/2016			
Fycompa	Perampanel hydrate	Eisai	28/03/2016			
Nucala	Mepolizumab	GlaxoSmithKline	28/03/2016			
Kanuma	Sebelipase alfa	Alexion	28/03/2016			
Tafinlar	Dabrafenib mesilate	Novartis	28/03/2016			
Mekinist	Trametinib dimethyl sulfoxide	Novartis	28/03/2016			
Xofigo	Radium (223Ra) dichloride	Bayer	28/03/2016			
Zykadia	Ceritinib	Novartis	28/03/2016			
Tagrisso	Osimertinib mesilate	AstraZeneca	28/03/2016			
Imbruvica	Ibrutinib	Janssen	28/03/2016			
Adynovate	Rurioctocog alfa pegol	Baxter Limited	28/03/2016			
Primaquine	Primaquine phosphate	Sanofi	28/03/2016			
Kovaltry	Octocog beta	Bayer	28/03/2016			
Genvoya	elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide	Japan Tobacco	17/06/2016			
Okinobel	Oxcarbazepine	Nobel Pharma	04/07/2016			
Kyprolis	Carfilzomib	ONO	04/07/2016			
Vimpat	Iacosamide	UCB	04/07/2016			
Praluent	alirocumab	Sanofi Aventis	04/07/2016			
Taltz	Ixekizumab	Eli Lilly	04/07/2016			
Lumicef	brodalumab	Kyowa Hakko Kirin	04/07/2016			

* Expedited review refers to PMDA Priority Review

PMDA NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Sakigake
Signifor	Pasireotide	Novartis	28/09/2016			
Brilinta	Ticagrelor	AstraZeneca	28/09/2016			
Ovidrel	choriogonadotropin alfa	Merck Serono	28/09/2016			
Deselex	desloratadine	MSD	28/09/2016			
Bilanoa	Bilastine	Taiho Pharmaceutical	28/09/2016			
Idelvion	Albutrepenonacog alfa	CSL	28/09/2016			
Keytruda	Pembrolizumab	MSD	28/09/2016			**
Emplicity	ELOTUZUMAB	BRISTOL MYERS SQUIBB	28/09/2016			
Xifaxan	Rifaximin	Asuka Pharmaceutical	28/09/2016			
Uptravi	selexipag	Nippon Shinyaku	28/09/2016			
Juxtapid	Lomitapide	AEGERION PHARMACEUTICALS	28/09/2016			
Iclusig	ponatinib hydrochloride	Otsuka Pharmaceutical	28/09/2016			
Carbaglu	Carglumic acid	Pola Pharma	28/09/2016			
PRAXBIND	Idarucizumab	Japan Boehringer Ingelheim	28/09/2016			
Grazyna	grazoprevir	MSD	28/09/2016			
Erelsa	elbasavir	MSD	28/09/2016			
Ximency	Daclatasvir, asunaprevir, beclabuvir hydrochloride	Bristol-Myers Squibb	19/12/2016			
Parsabiv	Etelcalcetide hydrochloride	Ono pharmaceutical	19/12/2016			
Mozobil	Plerixafor	Sanofi	19/12/2016			
Amyvid	Florbetapir F-18	Fujifilm RI Pharma	19/12/2016			
Linzess	Linaclotide	Astellas Pharma	19/12/2016			
Riamet	Artemether, lumefantrine mixt	Novartis Pharma	19/12/2016			
Otezla	Apremilast	Celgene	19/12/2016			
Tecfidera	Dimethyl fumarate	Biogen	19/12/2016			

* Expedited review refers to PMDA Priority Review

** Keytruda received Sakigake designation, but for a follow-on indication of advanced/recurrent unresectable gastric cancer, whereas the NAS listed is for unresectable melanoma

Health Canada NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan**	Notice of Compliance with conditions (NOC/c)
KYPROLIS	CARFILZOMIB	AMGEN CANADA INC	15/01/2016			
ZEPATIER	GRAZOPREVIR, ELBASVIR	MERCK CANADA INC	19/01/2016			
UPTRAVI	SELEXIPAG	ACTELION PHARMACEUTICALS LTD	20/01/2016			
IDELVION	ALBUTREPENONACOG ALFA	CSL BEHRING CANADA INC	26/01/2016			
ORKAMBI	IVACAFTOR, LUMACAFTOR	VERTEX PHARMACEUTICALS (CANADA) INCORPORATED	26/01/2016			
BRIDION	SUGAMMADEX	MERCK CANADA INC	05/02/2016			
COTELLIC	COBIMETINIB FUMARATE	HOFFMANN LA ROCHE LIMITED	22/02/2016			
SUNVEPRA	ASUNAPREVIR	BRISTOL-MYERS SQUIBB CANADA	09/03/2016			
BRIVLERA	BRIVARACETAM	UCB CANADA INC	09/03/2016			
XTORO	FINAFOXACIN	ALCON CANADA INC	11/03/2016			
IBRANCE	PALBOCICLIB	PFIZER CANADA INC	16/03/2016			
RAVICTI	GLYCEROL PHENYL BUTYRATE	HORIZON PHARMA IRELAND LTD	18/03/2016			
PRALUENT (PFP), PRALUENT (PFS)	ALIROCUMAB	SANOFI-AVENTIS CANADA INC	11/04/2016			
BLEXTEN	BILASTINE	ARALEZ PHARMACEUTICALS TRADING DAC	21/04/2016			
PRAXBIND	IDARUCIZUMAB	BOEHRINGER INGELHEIM (CANADA) LTD LTEE	29/04/2016			
LYNPARZA	OLAPARIB	ASTRAZENECA CANADA INC	29/04/2016			
ZONTIVITY	VORAPAXAR SULFATE	MERCK CANADA INC	13/05/2016			
TALTZ	IXEKIZUMAB	ELI LILLY CANADA INC	25/05/2016			
EMPLICITI	ELOTUZUMAB	BRISTOL-MYERS SQUIBB CANADA	21/06/2016			

*Expedited review refers to Health Canada Priority Review

**Health Canada does not have an orphan policy

Health Canada NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan**	Notice of Compliance with conditions (NOC/c)
DARZALEX	DARATUMUMAB	JANSSEN INC	29/06/2016			
TAGRISSO	OSIMERTINIB, OSIMERTINIB MESYLATE	ASTRAZENECA CANADA INC	05/07/2016			
EPCLUSA	SOFOSBUVIR, VELPATASVIR	GILEAD SCIENCES CANADA INC	11/07/2016			
CINQAIR	RESLIZUMAB	TEVA CANADA LIMITED	20/07/2016			
RUPATADINE	RUPATADINE FUMARATE	PEDIAPHARM INC	20/07/2016			
BEPREVE	BEPOTASTINE BESILATE	BAUSCH & LOMB INC	27/07/2016			
NINLARO	IXAZOMIB CITRATE	TAKEDA CANADA INC	04/08/2016			
MDK-NITISINONE	NITISINONE	MENDELIKABS INC	20/09/2016			
ALECENSARO	ALECTINIB HYDROCHLORIDE	HOFFMANN LA ROCHE LIMITED	29/09/2016			
VENCLEXTA	VENETOCLAX	ABBVIE CORPORATION	30/09/2016			
LIXIANA	EDOXYBAN	DAIICHI SANKYO INC	04/11/2016			
ADYNOVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED	BAXALTA CANADA CORPORATION	17/11/2016			
AFSTYLA	LONOCTOCOG ALFA	CSL BEHRING CANADA INC	12/12/2016			
LANCORA	IVABRADINE HYDROCHLORIDE	SERVIER CANADA INC	23/12/2016			

*Expedited review refers to Health Canada Priority Review

**Health Canada does not have an orphan policy

Swissmedic NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)
Sivextro	tedizolidi phosphas	MSD Merck Sharp & Dohme AG	05/01/2016			
Lynparza	olaparibum	AstraZeneca AG	14/01/2016			
Vimizim	elosulfasum alfa	DRAC AG	19/01/2016			
Spedra	avanafilum	A. Menarini AG	22/01/2016			
Repatha	evolocumabum	Amgen Switzerland AG	05/02/2016			
Mekinist	trametinibum dimethylis sulfoxidum	Novartis Pharma Schweiz AG	22/02/2016			
Blincyto	blinatumomabum	Amgen Switzerland AG	25/02/2016			
Zerbaxa	ceftozani sulfas tazobactamum natricum	MSD Merck Sharp & Dohme AG	03/03/2016			
Zepatier	elbasvirum grazoprevirum monohydricum	MSD Merck Sharp & Dohme AG	01/04/2016			
Nucala	mepolizumabum	GlaxoSmithKline AG	07/04/2016			
Jinarc	tolvaptanum	Otsuka Pharmaceutical	21/04/2016			
Praluent	alirocumabum	Sanofi-Aventis (Suisse) SA	22/04/2016			
Nuwiq	simoctocogum alfa	Octapharma AG	26/05/2016			
Empliciti	elotuzumabum	Bristol-Myers Squibb SA	06/06/2016			
Urorec	silodosinum	Pierre Fabre Pharma SA	09/06/2016			
Brintellix	vortioxetini hydrobromidum	Lundbeck (Schweiz) AG	09/06/2016			
Elocta	efmorococogum alfa	Swedish Orphan Biovitrum AG	23/06/2016			
Obizur	susococogum alfa	Baxalta Schweiz AG	23/06/2016			
Tagrisso	osimertinibi mesilas	AstraZeneca AG	11/07/2016			
Imlygic	talimogenum laherparepvecum	Amgen Switzerland AG	13/07/2016			

*Expedited review refers to Swissmedic Priority Review

Swissmedic NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan	Procedure with prior notification (VmVA)
Praxbind	idarucizumabum	Boehringer Ingelheim (Schweiz) GmbH	20/07/2016			
Kanuma	sebelipasum alfa	Alexion Pharma GmbH	21/07/2016			
Adenuric	febuxostatum	A. Menarini AG	11/08/2016			
Uptravi	selexipagum	Actelion Pharmaceuticals Ltd	15/08/2016			
Strensiq	asfotasum alfa	Alexion Pharma GmbH	16/08/2016			
Idelvion	albutrepenonacogum alpha	CSL Behring AG	30/08/2016			
Revestive	teduglutidum	DRAC AG	01/09/2016			
Genvoya	cobicistatum elvitegravirum emtricitabinum tenofovirum alafenamidum hemifumaras	Gilead Sciences Switzerland Sàrl	01/09/2016			
Orkambi	lvacaftorum; lumacaftorum	Vertex Pharmaceuticals (CH) GmbH	02/09/2016			
Adynovi	rurioctocogum alfa pegolum	Baxalta Schweiz AG	06/09/2016			
Zontivity	vorapaxarum sulfatum	MSD Merck Sharp & Dohme AG	19/09/2016			
Dopaview	fluorodopum(18-F)	ADVANCED ACCELERATOR	21/09/2016			
Epclusa	sofosbuvirum velpatasvirum	Gilead Sciences Switzerland Sàrl	22/09/2016			
Briviact	brivaracetamum	UCB-Pharma SA	06/10/2016			
Alprolix	eftrenonacogum alpha	Swedish Orphan Biovitrum AG	25/10/2016			
Galafold	migalastati hydrochloridum	SFL Pharma GmbH	28/10/2016			
Darzalex	daratumumabum	Janssen-Cilag AG	06/12/2016			
Taltz	ixekizumabum	Eli Lilly (Suisse) SA	12/12/2016			
Adasuve	loxapinum	OrPha Swiss GmbH	13/12/2016			
Soolantra	ivermectinum	Galderma Schweiz AG	20/12/2016			

*Expedited review refers to Swissmedic Priority Review

TGA NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan
MOVANTIK	naloxegol (as oxalate)	AstraZeneca Pty Ltd	05/01/2016		
OPDIVO	nivolumab	Bristol-Myers Squibb Australia Pty Ltd	07/01/2016		
GENVOYA	tenofovir alafenamide (as fumarate) / elvitegravir / cobicistat / emtricitabine	Gilead Sciences Pty Ltd	12/01/2016		
STRENSIQ	asfotase alfa (rch)	Alexion Pharmaceuticals Australasia Pty Ltd	13/01/2016		
ENTRESTO	sacubitril / valsartan (combined as a sodium salt hydrate complex)	Novartis Pharmaceuticals Australia Pty Limited	15/01/2016		
LENVIMA	lenvatinib	Eisai Australia Pty Ltd	21/01/2016		
NUCALA	mepolizumab	GlaxoSmithKline Australia Pty Ltd	25/01/2016		
ESBRIET	pirfenidone	Roche Products Pty Ltd	25/02/2016		
ORKAMBI	lumacaftor/ivacaftor	Vertex Pharmaceuticals Australia Pty Ltd	02/03/2016		
UPTRAVI	selexipag	Actelion Pharmaceuticals Australia Pty Ltd	18/03/2016		
FARYDAK	panobinostat (as lactate)	Novartis Pharmaceuticals Australia Pty Ltd	23/03/2016		
ZYKADIA	ceritinib	Novartis Pharmaceuticals Australia Pty Ltd	24/03/2016		
COTELLIC	cobimetinib (as fumarate)	Roche Products Pty Ltd	01/04/2016		
OBIZUR	susoctocog alfa (bhk)	Baxalta Australia Pty Ltd	26/04/2016		
PRAXBIND	idarucizumab (rch)	Boehringer Ingelheim Pty Ltd	10/05/2016		
PRALUENT	alirocumab (rch)	Sanofi-Aventis Australia Pty Ltd	13/05/2016		
ZURAMPIC	lesinurad	AstraZeneca Pty Ltd	16/05/2016		
BELKYRA	deoxycholic acid	Allergan Australia Pty Ltd	19/07/2016		
TAGRISO	osimertinib mesilate	AstraZeneca Pty Ltd	29/07/2016		
BRIVIACT	brivaracetam	UCB Australia Pty Ltd T/A UCB Pharma Division of UCB Australia	02/08/2016		

*TGA has introduced an expedited (priority) review programme in 2017.

TGA NAS approvals in 2016



Brand Name	Generic Name	Marketing Authorisation Holder	Approval Date	Expedited Review*	Orphan
HEXVIX	hexaminolevulinate (as hydrochloride)	Juno Pharmaceuticals Pty Ltd	04/08/2016		
ZEPATIER	elbasvir / grazoprevir	Merck Sharp & Dohme (Australia) Pty Ltd	25/08/2016		
TALTZ	ixekizumab	Eli Lilly Australia Pty Ltd	01/09/2016		
EMPLICITI	elotuzumab	Bristol-Myers Squibb Australia Pty Ltd	12/09/2016		
IDELVION	albutrepenonacog alfa	CSL Behring Australia Pty Ltd	14/09/2016		
PROLASTIN C	alpha-1-proteinase inhibitor (human, Alpha1-PI)	Grifols Australia Pty Ltd	14/10/2016		
NINLARO	ixazomib (as citrate)	Takeda Pharmaceuticals Australia Pty Ltd	10/11/2016		
BELSOMRA	suvorexant	Merck Sharp & Dohme Australia Pty Ltd	11/11/2016		
ANTIZOL	fomepizole	AFT Pharmaceuticals Pty Limited	25/11/2016		
DUAVIVE	conjugated estrogens / bazedoxifene	Pfizer Australia Pty Ltd	12/12/2016		
EPCLUSA	sofosbuvir / velpatasvir	Gilead Sciences Pty Ltd	13/12/2016		
KYPROLIS	carfilzomib	Amgen Australia Pty Ltd	16/12/2016		

*TGA has introduced an expedited (priority) review programme in 2017.

Definitions

Approval time

Time calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.

New Active Substances (NAS)

A chemical, biological, biotechnology or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and is destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in humans. The term NAS also includes:

- An isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously available as a medicinal product but differing in properties with regard to safety and efficacy from that substance previously available
- A biological or biotech substance previously available as a medicinal product, but differing in molecular structure, nature of source material or manufacturing process and which will require clinical investigation.
- A radiopharmaceutical substance that is a radionuclide or a ligand not previously available as a medicinal product. Alternatively, the coupling mechanism linking the molecule and the radionuclide has not been previously available.

Applications that are excluded from the study

- Vaccines
- Any other application, where new clinical data were submitted.
- Generic applications.
- Those applications where a completely new dossier was submitted from a new company for the same indications as already approved for another company.
- Applications for a new or additional name, or a change of name, for an existing compound (i.e. a 'cloned' application).

Report prepared by

Magdalena Bujar, MSc, Research Analyst

Neil McAuslane, PhD, Scientific Director

Lawrence Liberti, PhD, MSc, RPh, RAC, Executive Director

Report date: 24/10/2017

Please cite this report as:

Bujar M, McAuslane N, Liberti L. 2017. *R&D Briefing 65: New drug approvals in six major authorities 2007 – 2016: Focus on the internationalisation of medicines*. Centre for Innovation in Regulatory Science. London, UK.

Acknowledgements

We are most grateful to Professor Mamoru Narukawa (Kitasato University Graduate School of Pharmaceutical Sciences, Japan), Helen MacLellan (Health Canada, Canada), the Therapeutic Goods Administration, Australia, and Petra Doerr (Swissmedic, Switzerland) for validating the approval data for PMDA, Health Canada, TGA and Swissmedic respectively that we have used in order to generate the analysis.

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Centre for Innovation in Regulatory Science (CIRS)

Friars House
160 Blackfriars Road
London
SE1 8EZ
UK

Email: cirs@cirsci.org

Website: www.cirsci.org

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