

今後とも慢性的な疾患を対象として広く使用されている薬剤同士の配合剤が開発されてくると考えられる。しかし、配合される薬剤数の増加や、異種疾患を適応とした配合剤の可能性にも留意していく必要があると考えられた。

E. 結論

現在までに欧米で承認され市場に流通している配合剤と、国内製薬企業が開発予定の配合剤は、いずれも同じ適応の範囲内での配合剤であり、適応は高血圧症、高コレステロール血症、糖尿病、喘息または COPD、高眼圧症といった疾患領域が多く、同様であった。配合剤数は 2 剤が大半であるが、高血圧を適応とする配合剤では 3 剤のものもあった。また欧米で承認取り下げとなった品目の中には異種疾患を適応とした配合剤もあり、配合剤数の増加や異種疾患を適応とした配合剤の開発の可能性も留意していく必要がある。

F. 健康危険情報 なし

G. 研究発表 なし

H. 知的財産権の出願・登録状況 なし

(参考資料)

- 1) U.S. Food and Drug Administration, Drug Approval Reports
(<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu>)
- 2) European Medicines Agency, Human Medicines/European public assessment reports
(http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124)

3) 日本製薬工業協会 平成 26 年 3 月期決算の概要と平成 27 年 3 月期業績見込み 薬業各社業績

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4) ㈱メディサーチ 医薬品企業売上ランキング 2013 年度 国内市場売上上位 20 社

(http://www.medisearch.co.jp/doukou_kakukaihatuhi.html)

表2 FDAにより承認された配合剤

Drug Name	Active Ingredients	Company	Approval Date	Indication		prescription/OTC
TEKTURN HCT	ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE	NOVARTIS	01/18/2008	Hypertension	高血圧	prescription
SIMCOR	NIACIN; SIMVASTATIN	ABBVIE	02/15/2008	primary hypercholesterolemia and mixed dyslipidemia	高コレステロール血症、脂質異常症	prescription
TREXIMET	NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE	SMITHKLINE BEECHAM	04/15/2008	Acute treatment of Migraine	片頭痛の急性治療	prescription
PRANDIMET	METFORMIN HYDROCHLORIDE; REPAGLINIDE	NOVO NORDISK INC	06/23/2008	type 2 diabetes mellitus	Ⅱ型糖尿病	prescription
EPIDUO	ADAPALENE; BENZOYL PEROXIDE	GALDERMA LABS LP	12/08/2008	Treatment of acne vulgaris	尋常性座瘡	prescription
EXFORGE HCT	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN	NOVARTIS	04/30/2009	treatment of hypertension	高血圧	prescription
XERESE	ACYCLOVIR; HYDROCORTISONE	VALEANT BERMUDA	07/31/2009	for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and children (6 years of age and older)	口唇ヘルペス	prescription
EMBEDA	MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE	ALPHARMA PHARMS	08/13/2009	the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time	持続する疼痛	prescription
TWYNSTA	AMLODIPINE BESYLATE; TELMISARTAN	BOEHRINGER INGELHEIM	10/16/2009	for the treatment of hypertension alone or with other antihypertensive agents	高血圧	prescription
ORABLOC	ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	PIERREL	02/26/2010	for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures	歯科治療の際の麻酔	prescription
VIMOVO	ESOMEPRAZOLE MAGNESIUM; NAPROXEN	HORIZON PHARMA	04/30/2010	Treatment of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in patients at risk for developing NSAID-associated	変形性関節炎、関節リウマチ、硬直性 脊椎炎	prescription
JALYN	DUTASTERIDE; TAMSULOSIN HYDROCHLORIDE	GLAXOSMITHKLINE	06/14/2010	Treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate	良性前立腺過形成	prescription
DULERA	FORMOTEROL FUMARATE; MOMETASONE FUROATE	MERCK SHARP DOHME	06/22/2010	Asthma	喘息	prescription
TRIBENZOR	AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL	DAIICHI SANKYO	07/23/2010	for the treatment of hypertension	高血圧	prescription
SUPREP BOWEL PREP KIT	MAGNESIUM SULFATE ANHYDROUS; POTASSIUM SULFATE; SODIUM SULFATE	BRAINTREE LABS	08/05/2010	osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults	大腸内視鏡検査のための緩下剤	prescription
SUBOXONE	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	RECKITT BENCKISER	08/30/2010	for maintenance treatment of opioid dependence	オピオイド依存の維持療法	prescription
TEKAMLO	ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE	NOVARTIS	08/26/2010	for the treatment of hypertension	高血圧	prescription
BEYAZ	DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM	BAYER HLTHCARE	09/24/2010	1. prevent pregnancy 2. treat symptoms of premenstrual dysphoric disorder (PMDD) 3. treat	1. 避妊 2. 月経前不快気分障害 3. に きび 4. 葉酸補充	prescription
NUEDEXTA	DEXTROMETHORPHAN HYDROBROMIDE; QUINIDINE	AVANIR PHARMS	10/29/2010	for the treatment of pseudobulbar affect (PBA)	仮性球情動	prescription
KOMBIGLYZE XR	METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE	ASTRAZENECA AB	11/05/2010	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate	Ⅱ型糖尿病	prescription
AMTURNIDE	ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE;	NOVARTIS	12/21/2010	for the treatment of hypertension	高血圧	prescription
DUEXIS	FAMOTIDINE; IBUPROFEN	HORIZON PHARMA	04/23/2011	for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers	関節リウマチ、変形性関節炎の症状緩和、胃潰瘍予防	prescription
ZUTRIPRO	CHLORPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE	CYPRESS PHARM	06/08/2011	1. Relief of cough and nasal congestion associated with common cold 2. Relief of symptoms including nasal congestion associated with upper respiratory allergies	1. 風邪による鼻づまり、咳の緩和 アレルギーによる鼻づまりの緩和	prescription

表2 FDAにより承認された配合剤

Drug Name	Active Ingredients	Company	Approval Date	Indication		prescription/OTC
REZIRA	HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE	CYPRESS PHARM	06/08/2011	Relief of cough and nasal congestion associated with common cold	風邪による咳、鼻づまりの緩和	prescription
COMPLERA	EMTRICITABINE; RILPIVIRINE HYDROCHLORIDE; TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	08/10/2011	A complete regimen for the treatment of HIV-1 infection in treatment-naïve adult patients	HIV-1感染	prescription
EDARBYCLOR	AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE	ARBOR PHARMS IRELAND	12/20/2011	for the treatment of hypertension, to lower blood pressure	高血圧	prescription
JENTADUETO	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	BOEHRINGER INGELHEIM	01/30/2012	To improve glycemic control in adults patients with type2 diabetes mellitus	Ⅱ型糖尿病	prescription
DYMISTA	AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE	MEDA PHARMS	05/01/2012	for the relief of symptoms of seasonal allergic rhinitis in patients	季節性アレルギー性鼻炎	prescription
QSYMIA	PHENTERMINE HYDROCHLORIDE; TOPIRAMATE	VIVUS	07/17/2012	Chronic Weight Management	長期体重管理	prescription
LUPANETA PACK	LEUPROLIDE ACETATE; NORETHINDRONE ACETATE	ABBVIE ENDOCRINE	12/14/2012	1. Initial management of the painful symptoms of endometriosis 2. Management of recurrence of symptoms	1. 子宮内膜症の初期疼痛管理 2. 再発管理	prescription
SUCLEAR	MAGNESIUM SULFATE; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; POTASSIUM SULFATE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM	BRAINTREE LABS	01/18/2013	for cleansing of the colon in preparation for colonoscopy in adults	大腸内視鏡検査のための緩下剤	prescription
OSENI	ALOGLIPTIN BENZOATE; PIOGLITAZONE HYDROCHLORIDE	TAKEDA PHARMS USA	01/25/2013	an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Ⅱ型糖尿病	prescription
KAZANO	ALOGLIPTIN BENZOATE; METFORMIN HYDROCHLORIDE	TAKEDA PHARMS USA	01/25/2013	an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Ⅱ型糖尿病	prescription
SIMBRINZA	BRIMONIDINE TARTRATE; BRINZOLAMIDE	ALCON RES LTD	04/19/2013	for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	開放隅角緑内障、高眼圧症の眼圧低下	prescription
LIPTRUZET	ATORVASTATIN CALCIUM; EZETIMIBE	MERCK SHARP DOHME	05/03/2013	treatment of primary hypercholesterolemia and homozygous familial hypercholesterolemia	高コレステロール血症	prescription
OMIDRIA	KETOROLAC TROMETHAMINE; PHENYLEPHRINE HYDROCHLORIDE	OMEROS	05/30/2014	1. Maintaining pupil size by preventing intraoperative miosis 2. Reducing postoperative	1. 手術中の縮瞳を防ぐための瞳孔サイズ維持 2. 術後の疼痛緩和	prescription
TARGINIQ	NALOXONE HYDROCHLORIDE; OXYCODONE HYDROCHLORIDE	PURDUE PHARMA LP	07/23/2014	1. the management of pain severe enough to require daily, around-the-clock, long-term opioin treatment and for which alternative treatment options are inadequate	疼痛管理	prescription
TRIUMEQ	ABACAVIR SULFATE; DOLUTEGRAVIR SODIUM;	VIIV HLTHCARE	08/22/2014	HIV-1 injection	HIV-1感染	prescription
CONTRACE	BUPROPION HYDROCHLORIDE; NALTREXONE HYDROCHLORIDE	TAKEDA PHARMS USA	09/10/2014	an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management	体重管理	prescription
XIGDUO XR	DAPAGLIFLOZIN;METFORMIN HYDROCHLORIDE	ASTRAZENECA AB	10/29/2014	an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Ⅱ型糖尿病	prescription
OBREDON	HYDROCOZONE BITARTRATE; GUAIFENESIN	SOVEREIGN PHARMA LLC	11/14/2014	symptomatic relief of cough and to loosen mucus associated with the common cold	風邪の諸症状	prescription

表3 EMAにより承認された配合剤

Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication	
Brimica Genuair	aclidinium / formoterol fumarate dihydrate	Almirall S.A	19/11/2014	Brimica Genuair is indicated as a maintenance bronchodilator treatment for airflow obstruction and relief of symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	慢性閉塞性肺疾患 (COPD)
Budesonide/Formoterol Teva	budesonide / formoterol fumarate dihydrate	Teva Pharma B.V.	19/11/2014	Budesonide/Formoterol Teva is indicated in adults 18 years of age and older only. AsthmaBudesonide/Formoterol Teva is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting 2 adrenoceptor agonist) is appropriate: in patients not adequately controlled with inhaled corticosteroids and as needed inhaled short-acting 2 adrenoceptor agonists.or in patients already adequately controlled on both inhaled corticosteroids and long-acting 2 adrenoceptor agonists. COPDSymptomatic treatment of patients with severe COPD (FEV1 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	慢性閉塞性肺疾患 (COPD)
Budesonide/Formoterol Teva Pharma B.V.	budesonide / formoterol	Teva Pharma B.V.	19/11/2014	Budesonide/Formoterol Teva Pharma B.V. is indicated in adults 18 years of age and older only. AsthmaBudesonide/Formoterol Teva Pharma B.V. is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting 2 adrenoceptor agonist) is appropriate: in patients not adequately controlled with inhaled corticosteroids and as needed inhaled short-acting 2 adrenoceptor agonists. or in patients already adequately controlled on both inhaled corticosteroids and long-acting 2 adrenoceptor agonists.	喘息
Duaklir Genuair	aclidinium bromide / formoterol fumarate dihydrate	Almirall S.A	19/11/2014	Duaklir Genuair is indicated as a maintenance bronchodilator treatment for airflow obstruction and relief of symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	慢性閉塞性肺疾患 (COPD)
Rezolsta	darunavir / cobicistat	Janssen-Cilag International N.V.	19/11/2014	Rezolsta, is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus 1 (HIV 1) infection in adults aged 18 years or older. Genotypic testing should guide the use of Rezolsta	HIV1
Vylaer Spiromax	budesonide / formoterol fumarate dihydrate	Teva Pharma B.V.	19/11/2014	Vylaer Spiromax is indicated in adults 18 years of age and older only. AsthmaVylaer Spiromax is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting 2 adrenoceptor agonist) is appropriate: in patients not adequately controlled with inhaled corticosteroids and as needed inhaled short-acting 2 adrenoceptor agonists.or in patients already adequately controlled on both inhaled corticosteroids and long-acting 2 adrenoceptor agonists. COPDSymptomatic treatment of patients with severe COPD (FEV1 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	喘息
Harvoni	sofosbuvir / ledipasvir	Gilead Sciences International Ltd	17/11/2014	Harvoni is indicated for the treatment of chronic hepatitis C (CHC) in adults.	慢性C型肝炎
Xultophy	insulin degludec / liraglutide	Novo Nordisk A/S	18/09/2014	Xultophy is indicated for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with basal insulin do not provide adequate glycaemic control.	II型糖尿病

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Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication	
Clopidogrel/Acetylsalicylic acid Teva	clopidogrel / acetylsalicylic acid	Teva Pharma B.V.	01/09/2014	Clopidogrel/Acetylsalicylic acid Teva is indicated for the prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). Clopidogrel/Acetylsalicylic acid Teva is a fixeddose combination medicinal product for continuation of therapy in: NonST segment elevation acute coronary syndrome (unstable angina or nonQwave myocardial infarction) including patients undergoing a stent placement following percutaneous coronary intervention ST segment elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy	アテローム血栓症
Triumeq	abacavir sulfate / dolutegravir sodium / lamivudine	ViiV Healthcare UK Limited	01/09/2014	Triumeq is indicated for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg. Before initiating treatment with abacavir-containing products, screening for carriage of the HLA-B*5701 allele should be performed in any HIV-infected patient, irrespective of racial origin (see section 4.4). Abacavir should not be used in patients known to carry the HLA-B*5701 allele.	HIV
Simbrinza	brinzolamide / brimonidine tartrate	Alcon Laboratories (UK) Ltd	18/07/2014	Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.	開放隅角緑内障、高眼圧症
Anoro	umeclidinium bromide / vilanterol trifenate	Glaxo Group Ltd	08/05/2014	Anoro is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	慢性閉塞性肺疾患 (COPD)
Laventair	umeclidinium bromide / vilanterol	Glaxo Group Ltd	08/05/2014	Laventair is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	慢性閉塞性肺疾患 (COPD)
Revinty Ellipta	fluticasone furoate / vilanterol trifenate	Glaxo Group Ltd	02/05/2014	Asthma IndicationRevinty Ellipta is indicated in the regular treatment of asthma in adults and adolescents aged 12 years and older, where use of a combination product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: patients not adequately controlled with inhaled corticosteroids and as needed inhaled short acting beta2-agonists. COPD IndicationRevinty Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV1 70% predicted normal (post-bronchodilator) in patients with an exacerbation history despite bronchodilator therapy.	喘息
BiResp Spiromax	budesonide / formoterol fumarate dihydrate	Teva Pharma B.V.	28/04/2014	BiResp Spiromax is indicated in adults 18 years of age and older only. Asthma BiResp Spiromax is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting 2 adrenoceptor agonist) is appropriate:-in patients not adequately controlled with inhaled corticosteroids and as needed inhaled short-acting 2 adrenoceptor agonists.or-in patients already adequately controlled on both inhaled corticosteroids and long-acting 2 adrenoceptor agonists. Chronic obstructive pulmonary disease Symptomatic treatment of patients with severe chronic obstructive pulmonary disease - COPD (FEV1 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	喘息

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Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication	
DuoResp Spiromax	budesonide / formoterol fumarate dihydrate	Teva Pharma B.V.	28/04/2014	DuoResp Spiromax is indicated in adults 18 years of age and older only. Asthma DuoResp Spiromax is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting 2 adrenoceptor agonist) is appropriate:-in patients not adequately controlled with inhaled corticosteroids and as needed inhaled short-acting 2 adrenoceptor agonists.or-in patients already adequately controlled on both inhaled corticosteroids and long-acting 2 adrenoceptor agonists. Chronic obstructive pulmonary disease Symptomatic treatment of patients with severe chronic obstructive pulmonary disease - COPD (FEV1 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	喘息
Ultrair Breezhaler	glycopyrronium bromide / indacaterol maleate	Novartis Europharm Ltd	23/04/2014	Ultrair Breezhaler is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	慢性閉塞性肺疾患 (COPD)
Vokanamet	canagliflozin / metformin hydrochloride	Janssen-Cilag International N.V.	23/04/2014	Vokanamet is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: - in patients not adequately controlled on their maximally tolerated doses of metformin alone - in patients on their maximally tolerated doses of metformin along with other glucose lowering medicinal products including insulin, when these do not provide adequate glycaemic control (see sections 4.4, 4.5, and 5.1 for available data on different add on therapies) - in patients already being treated with the combination of canagliflozin and metformin as separate tablets	Ⅱ型糖尿病
Xigduo	metformin hydrochloride / dapagliflozin propanediol monohydrate	Bristol-Myers Squibb/AstraZeneca EEIG	16/01/2014	Xigduo is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: in patients inadequately controlled on their maximally tolerated dose of metformin alone in combination with other glucose lowering medicinal products, including insulin, in patients inadequately controlled with metformin and these medicinal products/li in patients already being treated with the combination of dapagliflozin and metformin as separate tablets.	Ⅱ型糖尿病
Fortacin	lidocaine / prilocaine	Plethora Solutions Limited	15/11/2013	Treatment of primary premature ejaculation in adult men.	早漏
Relvar Ellipta	fluticasone furoate / vilanterol	Glaxo Group Ltd	13/11/2013	Asthma Indication: Relvar Ellipta is indicated in the regular treatment of asthma in adults and adolescents aged 12 years and older, where use of a combination product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: patients not adequately controlled with inhaled corticosteroids and as needed inhaled short acting beta2-agonists. COPD Indication: Relvar Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV1 70% predicted normal (post-bronchodilator) in patients with an exacerbation history despite bronchodilator therapy.	喘息／慢性閉塞性肺疾患 (COPD)

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Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication	
Corbilita (previously Levodopa/Carbidopa/Entacapone Sandoz)	levodopa / carbidopa / entacapone	Orion Corporation	11/11/2013	Corbilita is indicated for the treatment of adult patients with Parkinsons disease and end-of-dose motor fluctuations not stabilised on levodopa/dopa decarboxylase (DDC) inhibitor treatment.	パーキンソン病
Evarrest	human fibrinogen / human thrombin	Omrrix Biopharmaceuticals N. V.	25/09/2013	Evarrest is indicated in adults for supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis.	手術時の止血
Incresync	alogliptin / pioglitazone / metformin hydrochloride	Takeda Pharma A/S	19/09/2013	Incresync is indicated as a second- or third-line treatment in adult patients aged 18years and older with type-2 diabetes mellitus: as an adjunct to diet and exercise to improve glycaemic control in adult patients (particularly overweight patients) inadequately controlled on pioglitazone alone, and for whom metformin is inappropriate due to contraindications or intolerance; in combination with metformin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients (particularly overweight patients) inadequately controlled on their maximal tolerated dose of metformin and pioglitazone. In addition, Incresync can be used to replace separate tablets of alogliptin and pioglitazone in those adult patients aged 18years and older with type-2 diabetes mellitus already being treated with this combination. After initiation of therapy with Incresync, patients should be reviewed after three to six months to assess adequacy of response to treatment (e.g. reduction in HbA1c). In patients who fail to show an adequate response, Incresync should be discontinued. In light of potential risks with prolonged pioglitazone therapy, prescribers should confirm at subsequent routine reviews that the benefit of Incresync is maintained (see section 4.4).	Ⅱ型糖尿病
Ultibro Breezhaler	glycopyrronium bromide	Novartis Europharm Ltd	19/09/2013	Ultibro Breezhaler is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	慢性閉塞性肺疾患 (COPD)
Vipdomet	alogliptin benzoate / metformin hydrochloride	Takeda Pharma A/S	19/09/2013	Vipdomet is indicated in the treatment of adult patients aged 18 years and older with type-2 diabetes mellitus: as an adjunct to diet and exercise to improve glycaemic control in adult patients, inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin; in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and pioglitazone; in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.	Ⅱ型糖尿病
Xoterna Breezhaler	indacaterol / glycopyrronium bromide	Novartis Europharm Ltd	19/09/2013	Xoterna Breezhaler is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	慢性閉塞性肺疾患 (COPD)
Cholib	fenofibrate / simvastatin	Abbott Healthcare Products Ltd.	26/08/2013	Cholib is indicated as adjunctive therapy to diet and exercise in high cardiovascular risk adult patients with mixed dyslipidaemia to reduce triglycerides and increase HDL C levels when LDL C levels are adequately controlled with the corresponding dose of simvastatin monotherapy.	脂質代謝異常症

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Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication	
Voncento	human coagulation factor VIII / von Willebrand factor	CSL Behring GmbH	12/08/2013	Von Willebrand disease (VWD) Treatment of haemorrhage or prevention and treatment of surgical bleeding in patients with VWD, when desmopressin (DDAVP) treatment alone is ineffective or contraindicated. Haemophilia A (congenital factor-VIII deficiency) Prophylaxis and treatment of bleeding in patients with haemophilia A.	フォン・ウィルブラント病
Nuedexta	dextromethorphan / quinidine	Jenson Pharmaceutical Services Limited	24/06/2013	Nuedexta is indicated for the symptomatic treatment of pseudobulbar affect (PBA) in adults (see section 4.4). Efficacy has only been studied in patients with underlying amyotrophic lateral sclerosis or multiple sclerosis.	仮性球情動
Stribild	cobicistat / emtricitabine / tenofovir disoproxil fumarate	Gilead Sciences International Limited	24/05/2013	Treatment of human immunodeficiency virus 1 (HIV 1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV 1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild.	HIV
Actelsar HCT	telmisartan / hydrochlorothiazide	Actavis Group hf	13/03/2013	Treatment of essential hypertension. Actelsar HCT fixed-dose combination (40 mg telmisartan / 12.5 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on telmisartan alone. Actelsar HCT fixed-dose combination (80 mg telmisartan / 12.5 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on telmisartan alone. Actelsar HCT fixed-dose combination (80 mg telmisartan / 25 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on Actelsar HCT 80 mg / 12.5 mg (80 mg telmisartan / 12.5 mg hydrochlorothiazide) or adults who have been previously stabilised on telmisartan and hydrochlorothiazide given separately.	本態性高血圧
Tolucombi	telmisartan / hydrochlorothiazide	Krka, d.d., Novo mesto	13/03/2013	Tolucombi fixed-dose combination (80 mg telmisartan/25 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on Tolucombi 80 mg/12.5 mg (80 mg telmisartan/12.5 mg hydrochlorothiazide) or adults who have been previously stabilised on telmisartan and hydrochlorothiazide given separately.	高血圧
Ryzodeg	insulin degludec / insulin aspart	Novo Nordisk A/S	21/01/2013	Treatment of diabetes mellitus in adults	糖尿病
Jentadueto	linagliptin / metformin	Boehringer Ingelheim International GmbH	20/07/2012	Treatment of adult patients with type-2 diabetes mellitus: Jentadueto is indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin. Jentadueto is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.	Ⅱ型糖尿病

表3 EMAにより承認された配合剤

Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication
Eviplera	emtricitabine / rilpivirine hydrochloride /tenofovir disoproxil fumarate	Gilead Sciences International Ltd.	28/11/2011	Eviplera is indicated for the treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with a viral load 100,000 HIV-1 RNA copies/mL (see sections 4.2, 4.4 and 5.1). As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera (see sections 4.4 and 5.1).
Komboglyze	metformin hydrochloride /saxagliptin hydrochloride	AstraZeneca AB	24/11/2011	Komboglyze is indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type-2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets. Komboglyze is also indicated in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type-2 diabetes mellitus when insulin and metformin alone do not provide adequate glycaemic control.
Eurartesim	piperaquine tetraphosphate / dihydroartemisinin	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A	27/10/2011	Eurartesim is indicated for the treatment of uncomplicated Plasmodium falciparum malaria in adults, children and infants 6 months and over and weighing 5 kg or more. Consideration should be given to official guidance on the appropriate use of antimalarial agents.
Levodopa/Carbidopa/Entacapone Orion	levodopa / carbidopa / entacapone	Orion Corporation	24/08/2011	Levodopa/Carbidopa/Entacapone Orion is indicated for the treatment of adult patients with Parkinson's disease and end-of-dose motor fluctuations not stabilised on levodopa / dopa-decarboxylase (DDC)-inhibitor treatment.
Zoely	norgestrel acetate / estradiol	Teva B.V.	27/07/2011	Oral contraception
Pravafenix	fenofibrate / pravastatin	Laboratoires SMB S.A.	14/04/2011	Pravafenix is indicated for the treatment of high-coronary-heart-disease (CHD)-risk adult patients with mixed dyslipidaemia characterised by high triglycerides and low HDL-cholesterol (C)levels whose LDL-C levels are adequately controlled while on a treatment with pravastatin-40-mg monotherapy.
Rasilamlo	aliskiren / amlodipine	Novartis Europharm Ltd.	14/04/2011	Rasilamlo is indicated for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone.
Teysuno	tegafur / gimeracil / oteracil	Nordic Group BV	14/03/2011	Teysuno is indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin.
Ifirmacombi	irbesartan / hydrochlorothiazide	Krka, d.d., Novo mesto	04/03/2011	Treatment of essential hypertension. This fixed dose combination is indicated in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.
Lamivudine/Zidovudine Teva	lamivudine / zidovudine	Teva Pharma B.V.	28/02/2011	Lamivudine/Zidovudine Teva is indicated in antiretroviral combination therapy for the treatment of human-immunodeficiency-virus (HIV) infection.

表3 EMAにより承認された配合剤

Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication	
Twynsta	telmisartan / amlodipine	Boehringer Ingelheim International GmbH	07/10/2010	Treatment of essential hypertension in adults: Add-on therapy Twynsta is indicated in adults whose blood pressure is not adequately controlled on amlodipine. Replacement therapy Adult patients receiving telmisartan and amlodipine from separate tablets can instead receive tablets of Twynsta containing the same component doses.	本態性高血圧
DuoCover	clopidogrel / acetylsalicylic acid	Sanofi-aventis groupe	15/03/2010	DuoCover is indicated for the prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). DuoCover is a fixed-dose combination medicinal product for continuation of therapy in: non-ST-segment-elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) including patients undergoing a stent placement following percutaneous coronary intervention; ST-segment-elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy.	アテローム血栓症
DuoPlavin	clopidogrel / acetylsalicylic acid	Sanofi Pharma Bristol-Myers Squibb SNC	15/03/2010	DuoPlavin is indicated for the prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). DuoPlavin is a fixed-dose combination medicinal product for continuation of therapy in: non-ST-segment-elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) including patients undergoing a stent placement following percutaneous coronary intervention; ST-segment-elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy.	アテローム血栓症
Ristfor	sitagliptin / metformin hydrochloride	Merck Sharp & Dohme Ltd.	15/03/2010	For patients with type-2 diabetes mellitus: Ristfor is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin. Ristfor is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. Ristfor is indicated as triple combination therapy with a peroxisome proliferator-activated-receptor-gamma (PPAR) agonist (i.e. a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPAR agonist. Ristfor is also indicated as add-on to insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dose of insulin and metformin alone do not provide adequate glycaemic control.	Ⅱ型糖尿病
Irbesartan/Hydrochlorothiazide Teva	irbesartan / hydrochlorothiazide	Teva Pharma B.V.	26/11/2009	Treatment of essential hypertension. This fixed-dose combination is indicated in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.	本態性高血圧
Copalia HCT	amlodipine / valsartan / hydrochlorothiazide	Novartis Europharm Ltd.	04/11/2009	Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation.	本態性高血圧

表3 EMAにより承認された配合剤

Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication
Dafiro HCT	amlodipine besylate / valsartan / hydrochlorothiazide	Novartis Europharm Ltd.	04/11/2009	Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation. 本態性高血圧
Exforge HCT	amlodipine besylate / valsartan / hydrochlorothiazide	Novartis Europharm Limited	16/10/2009	Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation. 本態性高血圧
Vantavo (previously Alendronate sodium and colecalciferol, MSD)	alendronic acid / colecalciferol	Merck Sharp & Dohme Ltd.	16/10/2009	Treatment of postmenopausal osteoporosis in patients at risk of vitamin-D insufficiency. Vantavo reduces the risk of vertebral and hip fractures. Treatment of postmenopausal osteoporosis in patients who are not receiving vitamin-D supplementation and are at risk of vitamin-D insufficiency. Vantavo reduces the risk of vertebral and hip fractures. 閉経後骨粗しょう症
Rasilez HCT	aliskiren / hydrochlorothiazide	Novartis Europharm Ltd.	16/01/2009	Treatment of essential hypertension in adults. Rasilez HCT is indicated in patients whose blood pressure is not adequately controlled on aliskiren or hydrochlorothiazide used alone. Rasilez HCT is indicated as substitution therapy in patients adequately controlled with aliskiren and hydrochlorothiazide, given concurrently, at the same dose level as in the combination. Icandra is indicated in the treatment of type-2 diabetes mellitus: 本態性高血圧
Icandra (previously Vildagliptin / metformin hydrochloride Novartis)	vildagliptin / metformin hydrochloride	Novartis Europharm Ltd.	01/12/2008	Icandra is indicated in the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets. Icandra is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea. Icandra is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. II 型糖尿病
Zomarist	vildagliptin / metformin hydrochloride	Novartis Europharm Ltd.	01/12/2008	Zomarist is indicated in the treatment of type-2 diabetes mellitus: Zomarist is indicated in the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets. Zomarist is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea. Zomarist is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. II 型糖尿病
Azarga	brinzolamide / timolol	Alcon Laboratories (UK) Ltd	25/11/2008	Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction. 開放隅角緑内障、高眼圧症

表3 EMAにより承認された配合剤

Medicine Name	Active Substance	Marketing Authorisation Holder	Authorisation date	Indication
Evicel	human fibrinogen / human thrombin	Omrrix Biopharmaceuticals S.A.	06/10/2008	Evicel is used as supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis. Evicel is also indicated as suture support for haemostasis in vascular surgery.
Efficib	sitagliptin / metformin hydrochloride	Merck Sharp & Dohme Ltd.	16/07/2008	For patients with type-2 diabetes mellitus: Efficib is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin. Efficib is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. Efficib is indicated as triple combination therapy with a PPAR agonist (i.e. a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPAR agonist. Efficib is also indicated as add on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dosage of insulin and metformin alone do not provide adequate glycaemic control.
Janumet	sitagliptin / metformin hydrochloride	Merck Sharp & Dohme Ltd.	16/07/2008	For patients with type-2 diabetes mellitus: Janumet is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin. Janumet is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. Janumet is indicated as triple combination therapy with a PPAR agonist (i.e. a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPAR agonist. Janumet is also indicated as add on to insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dosage of insulin and metformin alone do not provide adequate glycaemic control.
Velmetia	sitagliptin / metformin hydrochloride	Merck Sharp & Dohme Ltd.	16/07/2008	For patients with type-2 diabetes mellitus: Velmetia is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin. Velmetia is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. Velmetia is indicated as triple combination therapy with a PPAR agonist (i.e. a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPAR agonist. Velmetia is also indicated as add on to insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dosage of insulin and metformin alone do not provide adequate glycaemic control.

表4 国内製薬企業が開発中の配合剤

開発企業名	開発コード	又は製品名	成分名	効能又は効果	開発段階*	剤型
アステラス製薬(株)	EB178	ソリフェナシン、ミラベグロン		過活動膀胱における尿意切迫感、頻尿及び切迫性尿失禁	PⅢ	経口
大塚ホールディングス(株)	ASC-01	アリピプラゾール、セルトラリン		大うつ病	PⅢ	経口
	S-1 ティーエスワン	テガフル、ギメラシル、オテラシル		子宮頸がん	PⅢ	経口
	TAS-102 ロンサーフ	トリフルリジン、チピラシル		結腸・直腸がん	PⅢ	経口
	TAS-118	テガフル、ギメラシル、オテラシル、ホリナート		膵がん	PⅢ	経口
	YP-18 ゾジン	タゾバクタム、ピペラシリン		発熱性好中球減少症／抗生物質	申請中	注射剤
	OPC-1085EL	カルテオロール、ラタノプロスト		緑内障	PⅢ	点眼剤
田辺三菱製薬(株)	MT-2412	テネリグリブチン、カナグリフロジン		Ⅱ型糖尿病	PⅢ	
塩野義製薬(株)		ドルテグラビルナトリウム、アバカビル硫酸塩、ラミブジン		HIV感染症	米国・欧州	経口
参天製薬(株)	DE-111	タフルプロスト、チモロールマレイン酸塩		緑内障、高眼圧症	承認	点眼剤
小野薬品(株)	ONO-2160/CD	レボドパブロドラッグ、カルビドパ		パーキンソン病	PⅠ	経口
キョーリン製薬ホールディングス(株)	KRP-AB1102F	アクリジニウム、ホルモテロール		慢性閉塞性肺疾患	PⅢ	吸入
	フルティフォーム	フルチカゾン、ホルモテロール		気管支喘息	承認	吸入
ノバルティスファーマ(株)	LMF237	ビルダグリブチン、メトホルミン		Ⅱ型糖尿病	PⅢ	経口
グラクソスミスクライン(株)		ウメクリジニウム臭化物、ビランテロールトリフェニル酢酸塩		慢性閉塞性肺疾患	申請中	DS
		クリンダマイシン、過酸化ベンゾイル		尋常性ざ瘡	申請中	ゲル化剤
		クラブラン酸カリウム、アモキシシリン		急性副鼻腔炎	申請中	DS
		アトバコン、プログアニル塩酸塩		マラリア(小児)	申請準備中	経口
		フルチカゾンカルボン酸エステル、ビランテロールトリフェニル酢酸塩		慢性閉塞性肺疾患	PⅢ	DP
		フルチカゾンカルボン酸エステル、ビランテロールトリフェニル酢酸塩		気管支喘息(小児)	PⅡ	DP
アストラゼネカ(株)	CAZ-AVI	βラクタマーゼ阻害薬、セファロスポリン系抗生物		複雑性膀胱炎	PⅢ	
	CAZ-AVI	βラクタマーゼ阻害薬、セファロスポリン系抗生物		肺炎	PⅢ	
	AZD9291 + MEDI4736	チロシンキナーゼ阻害剤、抗PD-L1抗体 or MEK阻害剤		EGFR遺伝子変異陽性進行非細胞肺癌	PⅠ／Ⅱ	
	PT010	吸入ステロイド剤、長時間作用性β2刺激剤、長時間作用性ムスカリン受容体拮抗剤		慢性閉塞性肺疾患	PⅠ／Ⅱ	
	PT003	長時間作用性β2刺激剤、長時間作用性ムスカリン受容体拮抗剤		慢性閉塞性肺疾患	PⅠ／Ⅱ	
日本ベーリンガーインゲルハイム		チオトロピウム、オロダテロール		慢性閉塞性肺疾患	PⅢ	吸入
バイエル薬品(株)		アナストロゾール、レボノルゲストレル		子宮内膜症	PⅡ	

*:開発段階は、各出典資料による。

様式第 19

学 会 等 発 表 実 績

委託業務題目「医療用配合剤の評価のあり方に関する研究」

機関名 学校法人北里研究所

1. 学会等における口頭・ポスター発表 該当なし

発表した成果（発表題目、口頭・ポスター発表の別）	発表者氏名	発表した場所（学会等名）	発表した時期	国内・外の別

2. 学会誌・雑誌等における論文掲載 該当なし

掲載した論文（発表題目）	発表者氏名	発表した場所（学会誌・雑誌等名）	発表した時期	国内・外の別

