欧米の医療機器規制の見直し

欧米においても、医療機器規制の見直しが議論されている。

■米国

- 2009年１月、米国版会計検査院(GAO：General Accounting Office)がFDAの 510k制度（同等性調査）の改善を勧告。リスクの高い医療機器は、より厳格な市販前審査プロセスにより承認されるべきであると指摘。現在、FDAにおいて、510k制度の見直し作業が進められている。

- 510kで上市された医療機器の不具合等が議会でも指摘され、FDAは現在、改善検討中との情報。

■欧州

- EU委員会が公表している医療機器指令の改定に向けた道筋によれば、EU委員会は医療機器指令を改正し、医療機器の安全性と性能に関する評価に係る責任を第三者機関から規制当局に移管し、CEマークに変えて製造販売許可制度に移行することを視野に入れて検討中。

- 2012年１月21日号Lancet誌によれば、英国規制当局の医療機器安全委員会委員が、欧州の第三者認証制度であるCEマーク制度は医療機器の安全性を保証していない、英国の医療機器規制システムには深刻な脆弱性と欠陥があると指摘。

- 2011年５月米国医療機器業界誌Gray Sheet誌によれば、欧州心臓病学会が、欧州医薬品庁（EMA）による中央審査方式の導入を提言。また、British Medical Journal誌は欧州の医療機器規制は目的に叶っていないと指摘。

各国の医療機器規制(1)

＊GHTF:医療機器規制国際整合化会合Global Harmonization Task Force。日米欧豪加の規制当局・産業界代表によりなる医療機器の規制の国際整合化を進める会議。クラス分類、規制レベル、国際基準の活用、表示事項、市販後不具合報告、品質管理等について整合文書を作成.

国名	医療機器法が単独で存在	医薬品と機器が同じ法律		法律名	分類と規制 (GHTF＊クラス分類(4クラス)を参考にしているが、若干の幅がある。)	参考
		章分け	一緒に			
日本			○	薬事法	医療機器を4クラスに分類 ・クラスⅠ　届出 ・クラスⅡ　第三者認証 ・クラスⅢ/Ⅳ 承認	・GHTFルールに準じ、医療機器ごとに国がクラスを決定 ・国際基準を活用
米国		△ (章分けは×だが、)「承認」等について別の規定。	△ 不正医薬品の流通部分　等	食品・医薬品・化粧品法 (Federal Food, Drug & Cosmetic Act(version of the United States Code, 2006 Edition, Supplement 3 current through January 5, 2010.)) ※連邦規則(Code of Federal Regulation)として法典化	医療機器を3クラスに分類 ・クラスⅠ　届出(製品リスト提出) ・クラスⅡ/Ⅲ　市販前届※/承認(PMA) ※前例品と実質的同等であることを市販前に510(k)届出で確認	・医療機器ごとに国がクラスを決定 ・クラスⅡの一部は、FDAが認定した第三者機関の510(k)確認審査を受けた後にFDAの最終判断を受けることが可能。 ・国際基準を活用 ※510kで上市された医療機器の不具合回収等が議会でも指摘され、FDAは改善に取り組んでいる。
欧州		欧州指令で加盟国に法制化指示 ※国内法制の形式は加盟国が決定		・能動埋込式医療機器指令 90/385/EEC(active implantable medical devices:埋込式能動医療機器) ・医療機器指令 93/42/EEC(2007/47/EEC改正)(medical devices：医療機器) ・体外診断用医療機器指令 98/79/EC(In vitro diagnostics：体外診断用医療機器)	医療機器を4クラスに分類 ・クラスⅠ　自己認証(滅菌品、測定機能を有する機器を除く) ・クラスⅡa/Ⅱb/Ⅲ 第三者認証 Ⅱa/Ⅱb　品質システム監査が基本 Ⅲ　－品質システム監査に加え、Design Dossierによる第三者認証機関の審査)	・医療機器ごとのクラス指定ではなく、GHTFルールによるクラスの考え方を公布。申請者がこのクラス規則に従い選定 ・国際基準を活用 ・欧州域内で流通する医療機器にはCEマークが必要(欧州指令) ※CEマークは、製品が欧州の法令に適合することを企業が自己責任のもと宣言するもの。医療機器は、第三者認証機関の適合性確認の結果をもとに自己宣言する機器と、自らの責任で自己宣言できる機器が存在。 ※埋め込み型医療機器及びクラスⅢ機器:既存の臨床データで十分と判断出来る場合を除き、治験が必要。(MDD　NNEX X) ※人体埋め込み医療機器の不具合等(例:人工乳房)から、事前の臨床試験を求める範囲が拡大する傾向。 現行欧州指令も欧州規則に改定し、国の関与を強化することを検討中。
	仏		○		公衆衛生法典 (Code de la sante publique) ※法律のカテゴリーごとに章典化	同上 (クラスは、欧州指令を引用)
	独	○			医療機器法 (Medizinproduktegesetz)	同上 (クラスは、欧州指令を引用)

各国の医療機器規制(2)

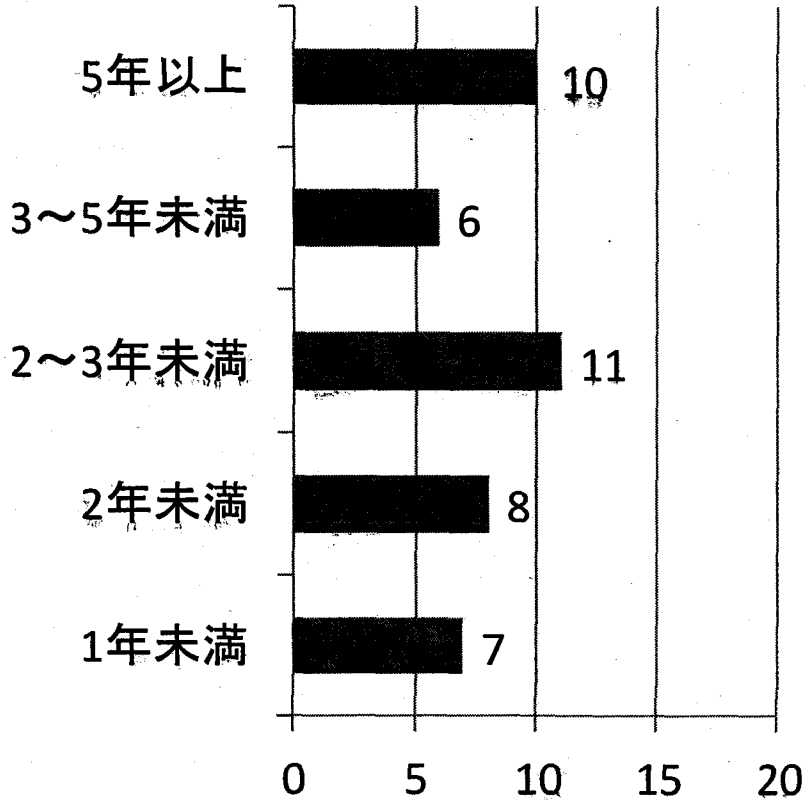
国　名	医療機器法が単独で存在	医薬品と機器が同じ法律		法　律　名	規制の分類 (GHTFクラス分類(4クラス)を参考にしているが、若干の幅がある。)	参　考
		章分け	一緒に			
韓　国	○			医療機器法 [一部改定2008.12.26　第9185号]　施行日2009.6.27 (Medical Device Act)	医療機器を4クラスに分類 ・クラスⅠ　　届出 ・クラスⅡ～Ⅳ　国が承認	・「製造業」、「輸入業」で規制 ・クラスⅡを第三者認証制度に移行途中
中　国	○			医療機器監督管理条例 (国務院令第276号、2000年4月施行) (Regulations for the Supervision and Administration of Medical Devices)	(国産の場合) 医療機器を3クラスに分類 ・クラスⅠ　市町村による登録 ・クラスⅡ　省・自治区による登録 ・クラスⅢ　国による登録 (輸入の場合) 国による登録	・「国産医療機器」と「輸入医療機器」で規制が別:輸入医療機器はクラスにかかわらず全てSFDAに登録 ・現在、安全対策の強化に向け改正検討中 ・製品によっては安全認証(CCC認証)が必要

(備考)GHTF(Global Harmonization Task Force)　医療機器規制国際整合化会議
日本の医療機器のクラスⅠ, Ⅱ, Ⅲ, Ⅳは, GHTF文書「医療機器のクラス分類」のクラスA, B, C, Dに対応する。

医療機器審査員の審査経験年数

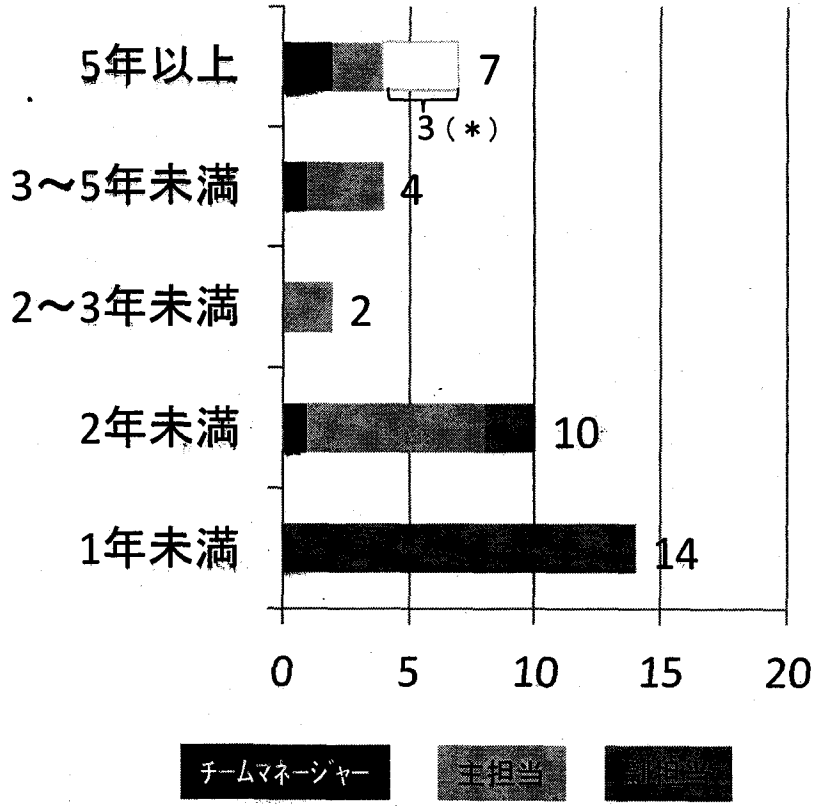
H24.2.1現在

新・改良（一、二部）



＊新・改良医療機器の審査体制については、次頁のとおり、審査員が双方に渡り審査することがあるため一括して示している。

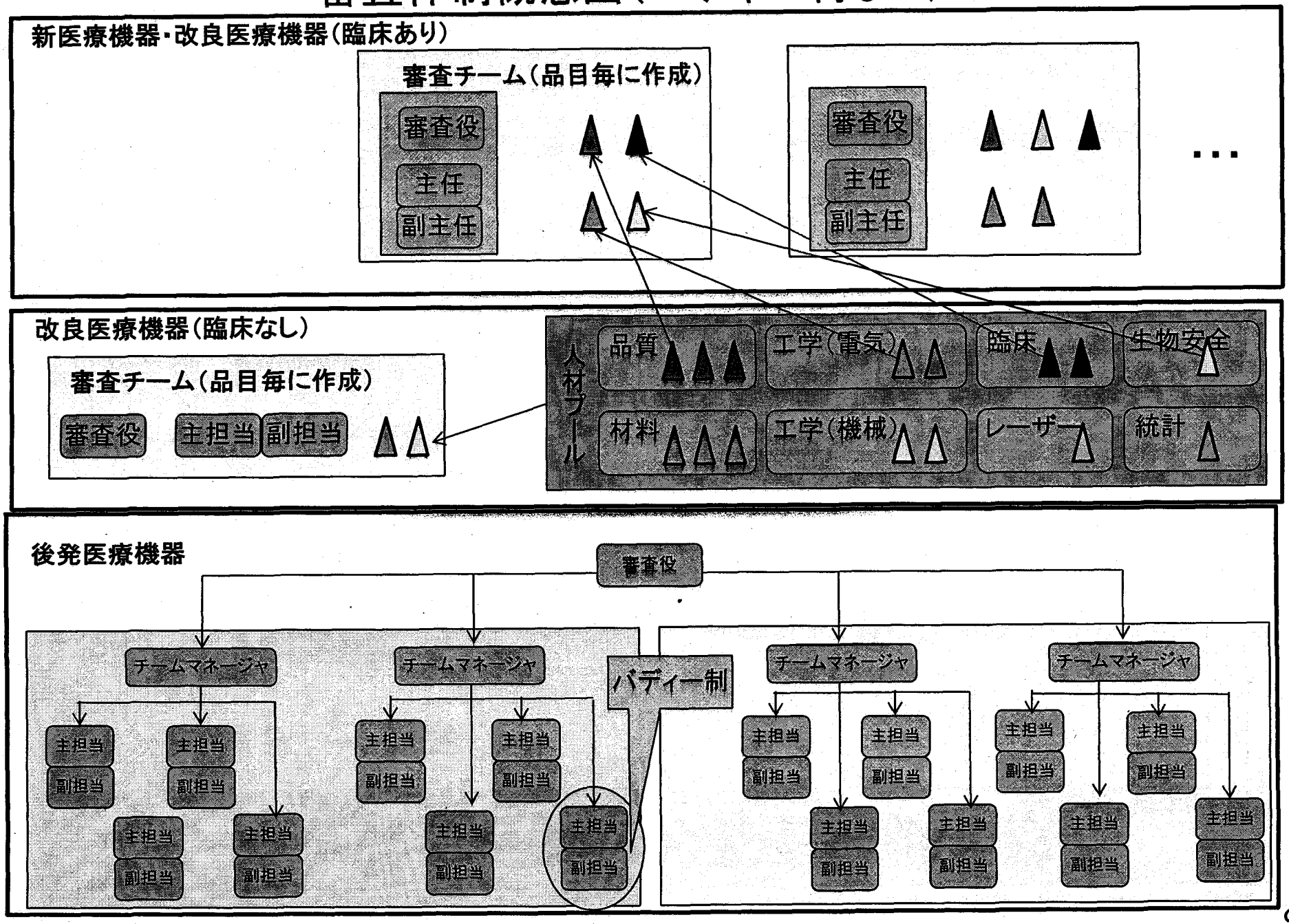
後発（三部）



＊チームマネージャーの医療機器審査部経験年数2年未満の1名は医療機器安全対策関係業務と合計し、5年以上の経験を有する。

（＊）上記表にある人数の他、医療機器審査第三部には、部長1名、審査役1名、主査1名が在籍。

審査体制概念図（バディー制など）



ＰＭＤＡとＦＤＡの新・改良医療機器手数料比較

（単位: 円）　（2012年ベース）

区　分	FDA		PMDA	
	審査手数料	製造所登録料（5年分）	審査手数料	製造業許可手数料（5年毎）
新医療機器（基準なし、臨床あり）ｸﾗｽⅣ	17,604,000	1,248,640	10,745,100	239,750
新医療機器（基準なし、臨床あり）ｸﾗｽⅢ、Ⅱ	17,604,000	1,248,640	8,252,600	239,750
改良医療機器（基準なし、臨床あり）ｸﾗｽⅣ	13,203,040	1,248,640	8,252,600	239,750
改良医療機器（基準なし、臨床あり）ｸﾗｽⅢ、Ⅱ	13,203,040	1,248,640	5,227,300	239,750
改良医療機器（基準なし、臨床なし）ｸﾗｽⅣ	2,640,640	1,248,640	3,090,000	239,750
改良医療機器（基準なし、臨床なし）ｸﾗｽⅢ、Ⅱ	2,640,640	1,248,640	1,679,700	239,750

＊1　PMDAの区分とFDAの区分は必ずしも合致しないため、主として対応する区分を比較した。
＊2　PMDAの手数料には、GCP等信頼性調査、QMS適合調査の手数料を含む。（相談手数料は任意であるので含まない。）
＊3　FDAの手数料は、1ドル80円換算した標準額を記載したが、小規模企業向けには、特別に低額の手数料が設定されている。

【製造業の手数料について】
○　FDA: 毎年、製造所毎に登録料が必要で、2012年の登録料162，320円が2013年は220，560円、2014年は256，000円、2015年は300，000円、2016年は309，760円に上がる予定である。（毎年金額が異なり2012年～2016年の5年間で1，248，640円要する。）
○日本: 各都道府県ごとに定められており（東京: 新規239,750円）、製造所ごとに業許可手数料が必要。また、5年ごとに更新手数料（東京153,450円がある。

ＰＭＤＡとＦＤＡの後発医療機器手数料比較

（単位：円）　（2012年ベース）

区　分	FDA		PMDA、都道府県	
	審査手数料	製造所登録料（5年分）	審査手数料	製造業許可手数料（5年毎）
後発医療機器（基準なし、臨床なし）ｸﾗｽⅣ	323,920(510k)～1,232,320(PMA Supplement)	1,248,640	2,502,300	239,750
後発医療機器（基準なし、臨床なし）ｸﾗｽⅢ、Ⅱ	323,920(510k)～1,232,320(PMA Supplement)	1,248,640	1,679,700	239,750
後発医療機器（基準あり、臨床なし）ｸﾗｽⅣ	323,920(510k)～1,232,320(PMA Supplement)	1,248,640	1,163,800	239,750
後発医療機器（基準あり、臨床なし）ｸﾗｽⅢ、Ⅱ	323,920(510k)～1,232,320(PMA Supplement)	1,248,640	613,900	239,750

＊1　PMDAの区分とFDAの区分は必ずしも合致しないため、主として対応する区分を比較した。
＊2　PMDAの手数料には、QMS適合調査の手数料を含む。（相談手数料は任意であるので含まない。）
＊3　FDAの手数料は、1ドル80円換算した標準額を記載したが、小規模企業向けには、特別に低額の手数料が設定されている。また、FDAにおいていわゆる日本の後発品審査にあたるものとしては、主としてクラスⅡ対象の510kによるもの（約32万円）と主としてクラスⅡ・Ⅲ対象のPMAのReal time supplement（約123万円）がある。

【製造業の手数料について】
○　FDA：毎年、製造所毎に登録料が必要で、2012年の登録料162，320円が2013年は220，560円、2014年は256，000円、2015年は300，000円、2016年は309，760円に上がる予定である。（毎年金額が異なり2012年～2016年の5年間で1，248，640円要する。）
○日本：各都道府県ごとに定められており（東京：新規239,750円）、製造所ごとに業許可手数料が必要。また、5年ごとに更新手数料（東京153,450円がある。

PMDAにおける手数料単価の算出方法

- 各手数料単価は、各業務に要する人件費、物件費等の実費の積み上げにより算出

手数料単価＝人件費（業務1件の所要時間×人件費組織単価）
＋物件費（業務1件の所要時間×物件費組織単価）
＋各種経費（通信運搬費、システム経費、事務所借料、管理経費等）

- 各費用の内容については、以下のとおり

人件費・・・・・申請又は相談の申込から審査・調査終了又は相談実施までの一連の業務、書類の保管・管理に係る人件費

物件費・・・・・申請又は相談の申込から審査・調査終了又は相談実施までの一連の業務、書類の保管・管理に係る物件費

各種経費・・・各手数料区分に係る経費を見込件数で除して算出
※ 各手数料区分に係る経費は、相談等に係る総支出に業務比率（各手数料区分ごとの総所要時間を全体の手数料に係る総所要時間で除した数）を乗じて算出
※ 通信運搬費については、相談1件あたりの費用とする。

単体ソフトウェアの各国規制の比較　○は規制対象、×は規制対象としていない

考え方	分類	定義	製品例	日本	欧州	米国	豪州	加	GHTF
診断・治療の目的を意図したもの	医療機器の構成品であるソフトウェア	【医療機器標準搭載ソフトウェア】 医療機器に標準搭載されたソフトウェア。本体の医療機器と一緒に市場流通する。	CT等の組み込みソフトウェア等	○※	○	○	○	○	○
		【医療機器オプションソフトウェア】 医療機器のオプション製品。本体の医療機器と別に市場流通するが、本体の構成品であるので必ず特定の本体にインストールされる。	CTのモダリティーコンソール用オプションソフト等	○※	○	○	○	○	○
	単独の医療用アプリケーションソフトウェア	【医療用アプリケーションソフトウエア①】 ソフトウェア単独で医療上の有用性があり、診療用途を意図したソフトウェア。単独製品として流通し、かつPC等の汎用ハードウェアにインストールすることを意図したソフトウェア。	診断機能を持った医療用アプリケーション	×	○	○	○	○	○
		【医療用アプリケーションソフトウェア②】 医療機器で取得した患者の生体情報や画像情報などの臨床データのさらなる処理は行わずに診療のために保管、転送、又は表示等することを意図したソフトウェア。拡大・縮小・回転などを含む。単独製品として流通し、かつPC等の汎用ハードウェアにインストールすることを意図したソフトウェア。	生体検査システムソフトウェア	×	○	○	○	○	○
直接診断・治療目的を意図していないか、又は診断・治療に役に立つ機能・性能を備えていない	医療情報システムソフトウェア	【医療情報システムソフトウェア①】 医療機器で取得した患者の生体情報や画像情報などの臨床データを取り扱うが、診療のために提供することを意図しない。	教育用・学習用電子カルテソフトウェア	×	×	×	×	詳細不明	詳細不明
		【医療情報システムソフトウェア②】 患者の病歴や検査日程など非臨床データを取り扱うことを目的としたソフトウェア	電子情報システムソフトウェア、電子カルテソフトウェア	×	×	×	×	詳細不明	詳細不明

医療機器の国際的動向を踏まえた品質、有効性及び安全性の評価に関する研究（平成21年度厚生労働科学研究）報告書を参考に改変

※ソフトウェアをインストールした医療機器本体として規制している　中国、韓国も単独医療用ソフトウェアを規制

コンビネーション製品の取扱いについて

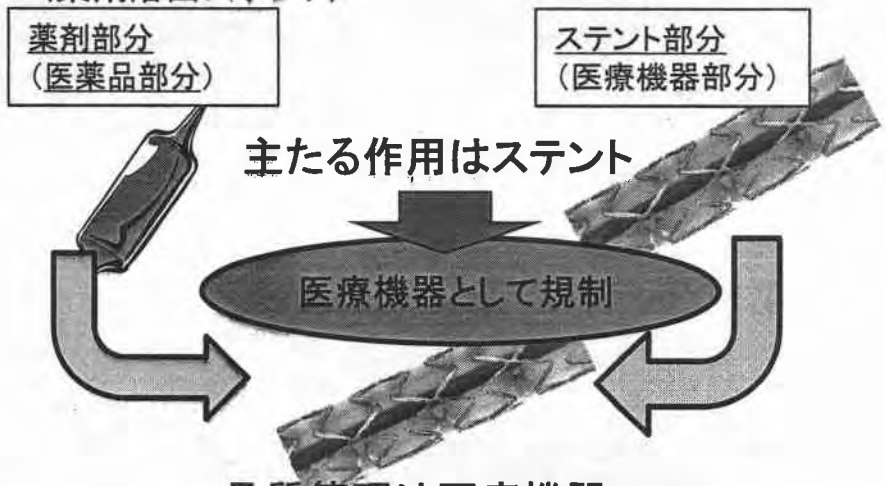
コンビネーション製品とは

2つ又はそれ以上の医薬品及び医療機器で構成される製品。物理的、化学的又はその他の方法で組み合わされ、混合され、又は単一体とし製品化されるもの。
主たる作用に応じて、医薬品又は医療機器どちらかとして規制を受ける。

＜医薬品たるコンビネーション製品＞
（自己注射用ペン型インスリン注入器）

品質管理は医薬品GMP
健康被害は副作用報告
（その他の例）プレフィルドシリンジ製剤

＜医療機器たるコンビネーション製品＞
（薬剤溶出ステント）

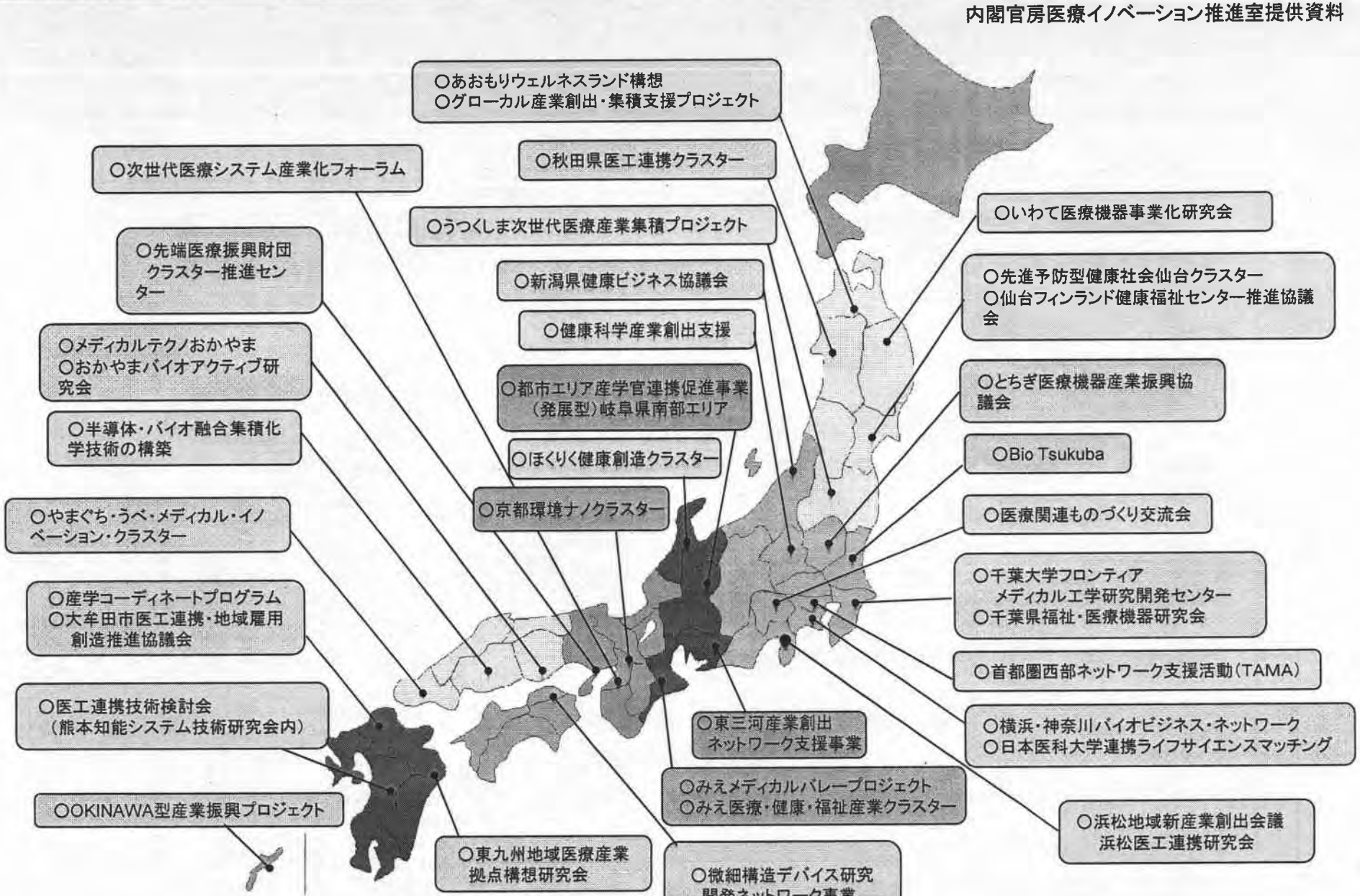


品質管理は医療機器QMS
健康被害は不具合報告
（その他の例） ヘパリンコーティングカテーテル

＜検討課題＞
- ■医薬品又は医療機器のどちらに該当するかについての基準が不明確
- ■医薬品の医療機器部分又は医療機器の医薬品部分に対する製造時の品質管理や副作用・不具合報告の取扱いが不明確
  （自己注射用ペン型インスリン注入器のペン型注入器部分による事故は、副作用か不具合のどちらで報告するか。）

各地域での医工連携取り組み例

内閣官房医療イノベーション推進室提供資料



ライフ・イノベーションの一体的な推進

平成24年度予算案 ：127億円

目的：日本発の革新的な医薬品・医療機器等の創出により、健康長寿社会を実現するとともに、国際競争力強化による経済成長に貢献する。

課題

① 創薬・治療法の開発を促進

国民のニーズの高い疾患に対する創薬・治療法の開発（再生医療含む。）に特化した研究費の配分が十分でなく、選択と集中が必要である。

② 臨床研究を促進

日本の豊富な基礎研究の成果から革新的な医薬品等を創出するためには、国際水準で臨床研究を行い、質の高いデータをもとに薬事承認につなげるための基盤構築が必要である。

③ 承認審査を促進

再生医療など革新的な医療技術の開発や承認審査には、有効性・安全性・品質の評価手法を予め確立しておくことが必要である。

④ 新技術を適正に評価

新たな医療技術等の保険収載に際し、さらなるイノベーションの評価や、開発のインセンティブを確保しつつ、費用対効果も勘案した評価が必要である。

施策の推進

① 個別重点分野の研究開発・実用化支援 （71億円）

- がん（小児がん、難治がん等）、B型肝炎、うつ病、難治性・希少性疾患等
- 再生医療（研究開発の基盤構築と免疫拒絶、がん化への対応）
- iPS細胞等ヒト幹細胞を用いた創薬基盤技術の開発
- 個別化医療を推進するためのバイオバンクの整備等

② 臨床研究中核病院等の整備及び機能強化 （34億円）

- 臨床研究中核病院を新たに5か所選定し、研究を支援する人材などの体制を重点的に整備する。
- 国立高度専門医療研究センターの体制整備を行い、臨床研究等を支援する。

③ 技術の進歩に対応する薬事承認審査・安全対策の向上 （21億円）

- 新たな技術に対応する審査の迅速化と安全対策の充実・強化のため、開発途上の最先端の技術の安全性と有効性を評価できる人材の育成や、人材の交流による研究成果を開発側と規制側で共有する。
- 新技術の未知のリスクに対応する安全対策の強化と医薬品・医療機器等の生産・流通のグローバル化への対応を進める。

④ 費用対効果を勘案した医療技術等の評価に関する研究・調査 （0．8億円）

- 諸外国で行われている評価体系で医療経済評価を試行的に実施した場合の、実行可能性等を検証する。研究報告等も踏まえ、社会的影響やガイドラインの策定等の検討・調査を行う。

① 個別重点分野の研究開発・実用化支援

予算案：71億円

○国民のニーズの高い疾患等に対する医薬品・医療機器等の開発に特化した研究に集中的に配分

1. がん診断・治療研究の推進

【背景】（１６億円）
・世界トップレベルの基礎研究が国内での実用化に至っておらず、医薬品の逆輸入が急増している。
【取組の概要】
・難治性がん、小児がん等の希少がんを中心に、革新的診断法・治療薬の実用化のための前臨床試験や質の高い臨床試験を強力に推進。

2. B型肝炎の創薬実用化研究等の推進

【背景】（２８億円）
・B型肝炎はC型肝炎と比較して治療成績が低く、画期的な新規治療薬の開発が望まれている。
【取組の概要】
・B型肝炎の画期的な新規治療薬の開発等を目指し、基盤技術の開発を含む創薬研究や、治療薬としての実用化に向けた臨床研究等を総合的に推進。

3. 気分障害の診断・治療研究の推進

【背景】（０．５億円）
・うつ病を含む気分障害患者は急増し、100万人を超えているが、客観的な診断指標が乏しく、効果的な治療法が確立されていない。
【取組の概要】
・脳機能画像等を用いた客観的な診断法や病態メカニズムに応じた効果的な治療法の開発により、臨床場面での応用を目指す。

4. 希少疾病用医薬品・医療機器の開発支援

【背景】（２億円）
・既存の助成額・助成内容では、希少疾病用医薬品・医療機器の十分な開発が実施されていない。
【取組の概要】
・極めて患者数が少ない希少疾病（1,000人未満）に対する助成率を引き上げるとともに、支援対象を非臨床試験に広げ、開発支援。

5. 再生医療、iPS細胞研究等の推進

【背景】（１２億円）
・革新的医療技術である再生医療の実用化には、安全性・品質の確保が重要な課題である。
・再生医療の実用化に向け、研究の促進とともに、国民に正確な情報を提供する必要がある。
【取組の概要】
・iPS細胞等ヒト幹細胞を用いた再生医療技術の研究開発の基盤を構築するとともに、移植時の課題である拒絶反応及びがん化に関する研究、並びに移植後の診断検査技術の開発を推進する。
・ヒト幹細胞データベースを構築し、ヒト幹細胞に係る情報を広く研究者等に提供することによりヒト幹細胞研究を促進するとともに、患者（国民）への情報提供を行う。
・iPS細胞から作られた細胞を用いて医薬品の安全性等を評価するための技術の開発及びヒト幹細胞を用いた新たな創薬技術の確立を図る。

6. 個別化医療の推進

【背景】（１３億円）
・個人のゲノム情報に基づく副作用の少ない効率的な個別化医療の推進に当たり、そのための基盤整備等が必要。
【取組の概要】
・国立高度専門医療研究センターが連携してバイオバンクを整備し、収集した生体試料を活用した研究等を実施。

② 臨床研究中核病院等の整備及び機能強化

予算案：34億円

課題１　質の高い臨床研究を行うための十分なインフラ（臨床研究コーディネーター及びその他の必要な人材）がないため、臨床研究の質が薬事承認申請データとして利用可能な水準を満たさず、臨床研究で得られた成果を有効活用できない。

課題２　小児疾患や難病など、患者数が少ないために企業が開発し難い分野の治験を実施できていない。

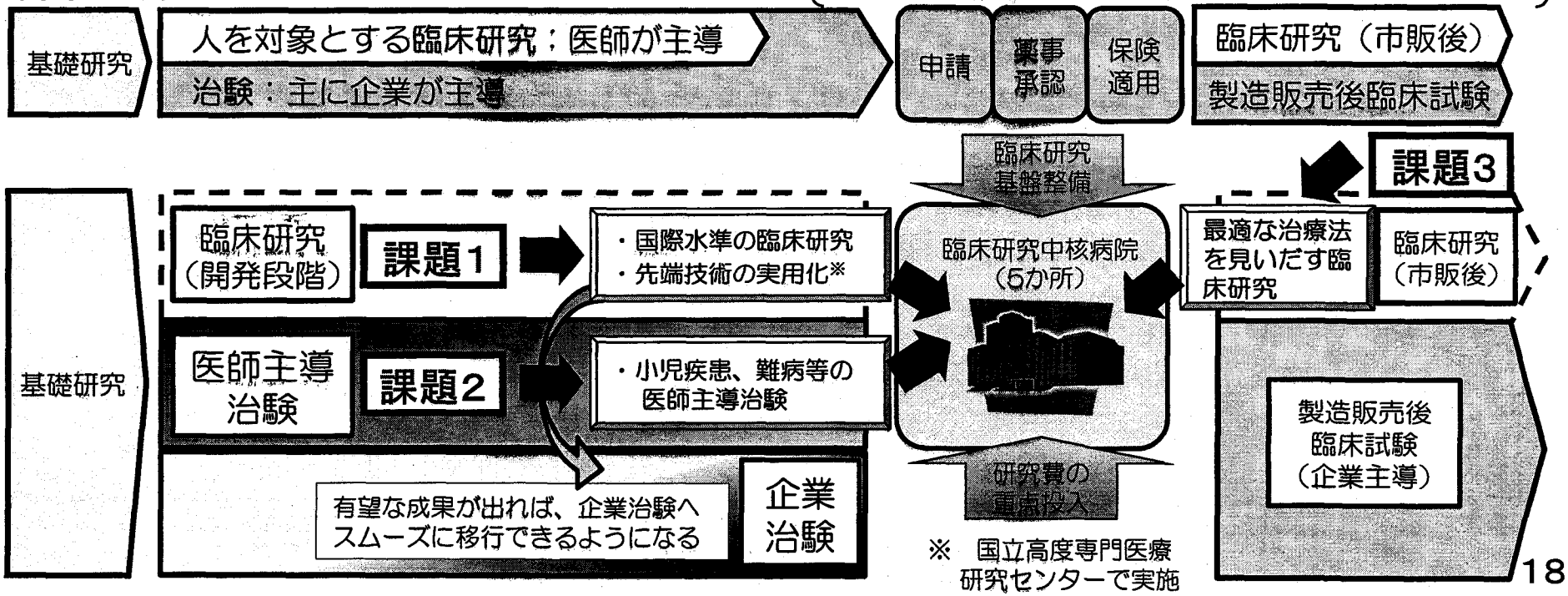
課題３　既存薬の組み合わせなどにより最適な治療法を見いだす臨床研究は、薬事法に基づく適応範囲の拡大につながらず使用患者が増大しないため、企業の取り組むインセンティブが少ない。

国際水準（ICH-GCP準拠）の臨床研究中核病院を５か所整備し、研究費を重点投入するとともに、国立高度専門医療研究センターの体制整備を行い臨床研究等を支援する。

★　社会保障・税一体改革成案において、臨床研究中核病院を平成23年度から３年間で15か所程度創設することを明記。

臨床研究中核病院：（整備5.1億円＋研究1億円）×5か所＝31億円
国立高度専門医療研究センター：　開発・臨床応用研究等＝3億円

＜創薬の流れ＞



※　国立高度専門医療研究センターで実施

③ 技術の進歩に対応する薬事承認審査・安全対策の向上　予算案：21億円

【背景】　社会保障・税一体改革成案で、医療イノベーション、ライフイノベーションの推進、ドラッグ・ラグ、デバイス・ラグの早期解消などの諸改革が求められている。
また、第4期科学技術基本計画（平成23年8月19日閣議決定）においても、これらの諸改革の実現のために、レギュラトリーサイエンス※の充実・強化による審査指針・基準の策定や人材の養成・確保等が求められている。

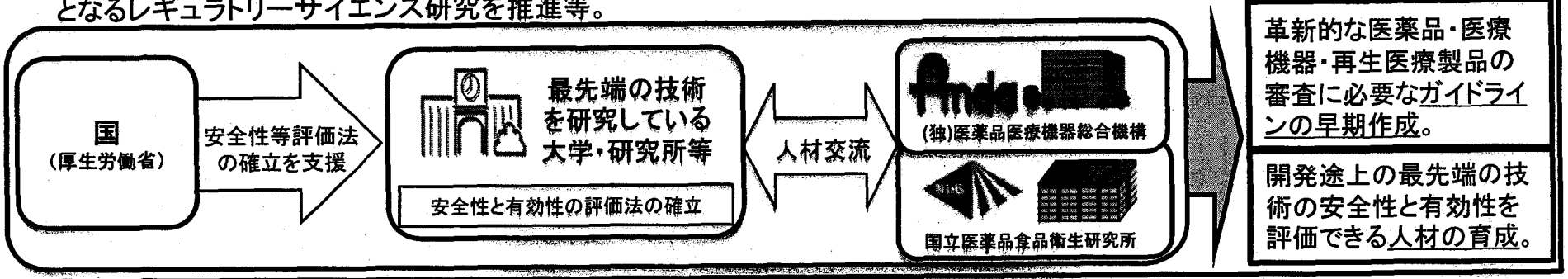
※レギュラトリーサイエンス：　科学技術の成果を人と社会に役立てることを目的に、根拠に基づく的確な予測、評価、判断を行い、科学技術の成果を人と社会との調和の上で最も望ましい姿に調整するための科学（平成23年8月19日閣議決定「科学技術基本計画」より）

（1）革新的医薬品・医療機器・再生医療製品の安全性と有効性の評価法の確立、人材の育成【11.9億円】

○ 最先端の技術を研究している大学等におけるレギュラトリーサイエンスを基盤とした安全性と有効性の評価法の確立を支援。
○ 併せて、大学等、国立医薬品食品衛生研究所（NIHS）、独立行政法人医薬品医療機器総合機構（PMDA）等の間で人材交流を行い、人材を育成。

（2）革新的医薬品・医療機器・再生医療製品の承認審査の迅速化に必要なガイドラインの作成に向けた研究の推進等　【3.7億円】

最先端の技術を研究している大学等における成果も活用し、NIHS・PMDAにおいて審査に必要なガイドライン作成の基盤となるレギュラトリーサイエンス研究を推進等。



（3）新技術の未知のリスクに対応する安全対策の強化【3.5億円】

○ PMDAにおいて大規模医療情報データベースを安全対策に活用するための分析手法を開発。
○ 独立行政法人国立成育医療研究センターに「小児と薬情報センター」を設置し、小児への医薬品使用情報を収集。

（4）医薬品・医療機器・再生医療製品の生産・流通のグローバル化への対応【1.8億円】

○ PMDAにおいて海外主要国における医薬品・医療機器・再生医療製品の承認情報を収集・整理し、データベースを構築。
○ 個人輸入される偽造医薬品等による健康被害や医薬品等の不正輸入に関する情報を収集するホットラインの設置と、消費者に偽造医薬品等に関する注意啓発を実施。

④費用対効果を勘案した医療技術等の評価に関する研究・調査　予算案：0.8億円

課題

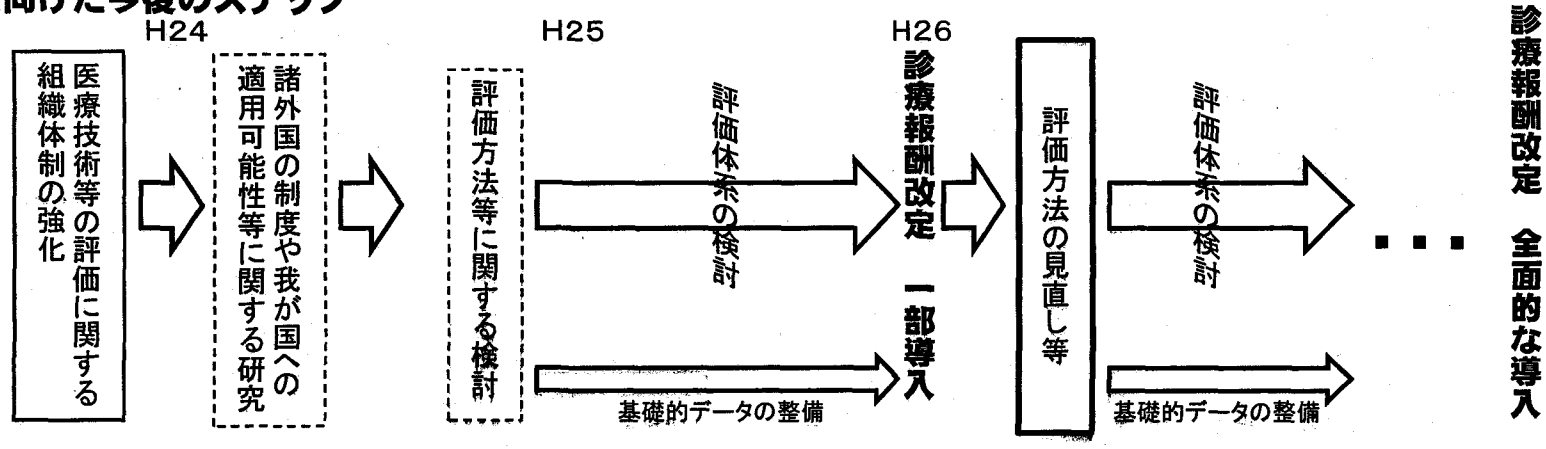
○ 革新的な医療技術、日本発の医薬品、医療機器の開発について、そのイノベーションを医療保険上適切に評価し、開発のインセンティブを確保する必要がある。

○ 持続可能な医療保険制度の維持に向けて、限りある資源を効率的に配分する必要がある。

（医薬品の例）

医療技術、医薬品、医療機器の保険適用の際の、保険点数、薬価、医療材料価格の設定におけるさらなるイノベーションの評価及び、費用対効果を勘案した評価の導入に向けた取組を実施

導入に向けた今後のステップ



参考）社会保障・税一体改革成案　工程表

○　医療イノベーション（抜粋）　保険償還価格の設定における医療経済的な観点を踏まえたイノベーションの評価等のさらなる検討

費用対効果を勘案した医療技術等の評価に関する研究

（予算案　0.3億円）

医療技術等の保険価格等における評価において、さらなるイノベーションの評価や、開発のインセンティブを確保しつつ、費用対効果も勘案した評価を行うため、実際に諸外国で行われている評価体系で医療経済評価を実施した場合における、各評価方法の実務上の利点・欠点を明らかにし、実行可能性、政策応用可能性等を検証する。

医療技術等の評価に関する調査・検討

（予算案　0.5億円）

医療技術等の保険価格等における評価を日本に導入するにあたり、研究報告等も踏まえつつ、日本への導入方法や国内における医療経済評価ガイドライン等に係る検討会の開催及び日本で評価する際に参考とするために海外の評価実績事例集の集積事業等を実施する。

医療機器に関する課題について

運用改善において、迅速に対応すべき課題

○ 製造所での組立が困難な大型の医療機器の製造所以外の場所での組立
○ 一部変更承認申請を不要とする範囲の明確化
○ 信頼性調査が必要な範囲の明確化
○ 海外市場実績のある医療機器の非臨床試験や臨床試験データの取扱い　等

医療機器業界からの要請や実情把握

＋

「医療機器規制制度タスクフォース」（※）において議論。
（※）行政の担当者と医療機器業界の実務者が医療機器の規制・制度やその運用の見直しについて、迅速かつ的確に検討を行う場を設け、平成24年2月から議論を開始。
（第1回：2/9、第2回：2/22、第3回：3/7、第4回：3/29）

法律改正において、検討すべき課題

○ 薬事法のQMS調査について、国際的な整合性を踏まえ、特にリスクの高い医療機器等を除き、例えば製品群ごとなど、調査対象をまとめることができるように規定を改正するべきではないか。

○ 薬事法に、品質の確保を前提に、ソフトウェアなどの取扱いについて、新たに規定を追加するべきではないか。

○ 薬事法に、医療機器に医薬品を組合せた製品（いわゆるコンビネーション製品）の副作用・不具合報告、品質管理上等の取扱いについて、新たに規定を追加するべきではないか。

○ 医療機器の特性を踏まえて、医療機器に関する法体系の在り方を広く見直す必要があるのではないか。
医療機器に関する法律を新たに制定することや、医療機器を章立てにすること等について、様々な留意点を十分踏まえつつ、医療機器に関する望ましい法体系について検討を進めるべきではないか。

医薬品と異なる特性を有する医療機器については、医療機器の安全性を担保しつつ迅速な承認等をするために、 まずは、「医療機器規制制度TF」において、医療機器業界からの要望を把握した上で、迅速に医療機器を取り巻く承認等の制度の合理化のための運用改善を図る。
また、同時に、薬事法改正において対応すべき事項についても検討を進め、特に、医療機器の特性を踏まえた、医療機器に関する法体系の在り方について、着実に検討を進める。

諸外国における医薬品・医療機器規制の条文一覧（主なもの）

資料2－2

※実際の条文は、国別に後ろに添付。中国については一覧に掲載せず条文のみ添付。

国	医療機器法が存在	医薬品	医療機器
米	×	•新薬の上市には、承認が必要であり、医薬品に特有の申請書類の提出が必要（Sec 505）。 •承認しない場合の要件として、医薬品の特有の承認拒否事由が記載（Sec 505(d)）	•510k制度（市販前届出：医療機器の実質同等性で判断）があり、上市の90日前に提出 （Sec 510k） •リスクⅢの医療機器は、市販前承認が必要であり、機器に特有の申請書類の提出が必要（Sec 515）。 •承認しない場合の要件として、機器特有の承認拒否事由が記載(Sec 515(d))
独	○	•最終の医薬品は、本法律の範囲内で上市されなければならない。（Section 21 ） •医薬品の製造販売は、規制当局による書面での発給を受けなければならない（Section 25(1)） ［製造販売を認めることを拒否できる場合を規定］（Section 25(2)）］	•医療機器の基本要件への適合を要求 （Section 7） •特定の医療機器に関し、その医療機器が調和された標準等に適合する際は、現法の規定に適合するものとみなされる（Section 8） •CEマークは、各欧州指令に従って医療機器に使われなければならない（Section 9）
仏	×	•人に使われる医薬品に関する許可・監督のプロセスを定め、 AFSSAPSが上市に際する人への用途の医薬品の許可を行う。 •許可は適切な条件のもとで行われる。 •許可は5年の期間で与えられ、更新することができる	•患者・使用者・第三者の安全及び健康に関し、事前に医療機器の性能とともに、基本要件の適合性を証明できない限り、医療機器を輸入、市場に導入、使うことはできない。 •適合性の証明は、医療機器が持つクラスに従って、製造者自身、あるいはAFSSAPSによって指名される機関、又は他のEU加盟国の規制当局、又は欧州経済地域協定国当事者によって行われる。
韓	○	•医薬品製造を行おうとする者は、KFDA長官から免許（ライセンス）を得なければならない。 •医薬品製造者が製造された医薬品の販売を行おうとする場合には、製造販売の承認をKFDA長官から得るか、省令に従い製造販売製品報告書を提出しなければならない。（Article 31）	•医療機器製造を行おうとする者は、KFDA長官から製造業の許可を得なければならない（Article 6） •人体へのリスクが無視できるため医療機器の不具合等が発生した場合でも生命・健康に与える影響がほとんどない場合には、許可は品目類型ごとに与えられる。それ以外の場合には、製造許可は品目ごとに与えられる（Article 6） •医療機器について、適用の範囲、形態・構造、試験特性、表示を、医療機器に関する標準を定めることができる（Article 19）

諸外国における医薬品・医療機器規制に特徴的な条文

米国

	医薬品	医療機器
出　典	食品・医薬品・化粧品法 Federal Food, Drug & Cosmetic Act	
ポイント	○新薬の上市には、承認が必要であり、医薬品に特有の申請書類の提出が必要（Sec 505） ○承認しない場合の要件として、 ・医薬品が安全かどうかを示すための全ての方法で、適切な試験が含まれていない ・同一性・強度・品質・純度が製造プロセス等で十分に確保されない ・医薬品の安全性を決めるにあたり申請者が不十分な情報しか有しない 等の承認拒否事由が記載（Sec 505(d)）	○510k 制度（市販前届出；医療機器の実質同等性で判断）があり、上市の９０日前に提出（Sec 510） ○リスクⅢの医療機器は、市販前承認が必要、機器に特有の申請書類の提出が必要（Sec 515） ○承認しない場合の要件として、 ・機器が安全であることを示す合理的保証に欠ける ・機器に効果があることを示す合理的保証に欠ける ・有効な性能基準を満たさない 等の承認拒否事由が記載(Sec 515(e)) ○医療機器の性能基準の設定と活用を促進（Sec 514）
原　文	**Sec 505 (New Drug)** **(a) Necessity of effective approval of application** No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug. **(b) Filing application; contents** (1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application	**Sec 510 (Registration of producers of drugs or devices)** **(a)～(j)　略** **(k) Report preceding introduction of devices into interstate commerce** Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 523(a) of this title (in such form and manner as the Secretary

	(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 505B of this title. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.	shall by regulation prescribe)— (1) the class in which the device is classified under section 513 of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and (2) action taken by such person to comply with requirements under section 514 or 515 of this title which are applicable to the device. A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in 42 USC section 282(j)(1) shall be accompanied by the certification required under 42 USC section 282(j)(5)(B). Such certification shall not be considered an element of such notification. **Sec 515 (Premarket approval)** **(a) General requirement** A class III device— (1) which is subject to a regulation promulgated under subsection (b) of this section; or (2) which is a class III device because of section 513(f) of this title, is required to have, unless exempt under section 520(g) of

	The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A). (2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include— (A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section— (i) that such patent information has not been filed, (ii) that such patent has expired, (iii) of the date on which such patent will expire, or	this title, an approval under this section of an application for premarket approval or, as applicable, an approval under subsection (c)(2) of this section of a report seeking premarket approval. **(b) Regulation to require premarket approval** (1) In the case of a class III device which— (A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or (B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type, the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval. (2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain— (i) the proposed regulation; (ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device; (iii) opportunity for the submission of comments on

	(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and (B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use. (3) Notice of opinion that patent is invalid or will not be infringed.— (A) Agreement to give notice.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph. (B) Timing of notice.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph— (i) if the certification is in the application, not	the proposed regulation and the proposed findings; and (iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device. (B) If, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 513 of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 513(e) of this title. (3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2)(A)(ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516 of this title) initiate a proceeding under section 513(e) of this title to reclassify the

	later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or (ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application. (C) Recipients of notice.—An applicant required under this paragraph to give notice shall give notice to— (i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and (ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).	device subject to the proceeding terminated by such notice. (4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked. **(C) Application for premarket approval** (1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain— (A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective; (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device; (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; (D) an identifying reference to any performance standard under section 514 of this title which would be

	(D) Contents of notice.—A notice required under this paragraph shall— (i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and (ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed. (4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary. (B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) of this section prohibits an applicant from amending or supplementing the application to seek approval of a different strength. (5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under	applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard; (E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing; (F) specimens of the labeling proposed to be used for such device; (G) the certification required under 42 USC section 282(j)(5)(B) (which shall not be considered an element of such application); and (H) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require. (2)(A) Any person may file with the Secretary a report seeking premarket approval for a class III device referred to in subsection (a) of this section that is a reprocessed single-use

	paragraph (1) or under 42 USC section 262, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications. (B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or 42 USC section 262 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim or, with respect to an applicant for approval of a biological product under 42 USC section 262(k), any necessary clinical study or studies. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request. (C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins,	device. Such a report shall contain the following: (i) The device name, including both the trade or proprietary name and the common or usual name. (ii) The establishment registration number of the owner or operator submitting the report. (iii) Actions taken to comply with performance standards under section 514 of this title. (iv) Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use. (v) Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective. (vi) A description of the device's components, ingredients, and properties. (vii) A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device. (viii) Such samples of the device that the Secretary may reasonably require. (ix) A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations. (x) A statement that the applicant believes to the

	except— (i) with the written agreement of the sponsor or applicant; or (ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun. (D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved. (E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified. (F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the	best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report. (xi) Any additional data and information, including information of the type required in paragraph (1) for an application under such paragraph, that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device. (xii) Validation data described in section 510(*o*)(1)(A) of this title that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting such report. (B) In the case of a class III device referred to in subsection (a) of this section that is a reprocessed single-use device: (i) Subparagraph (A) of this paragraph applies in lieu of paragraph (1). (ii) Subject to clause (i), the provisions of this section apply to a report under subparagraph (A) to the same extent and in the same manner as such provisions apply to an application under paragraph (1).

	marketing of a safe and effective drug. (G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or 42 USC section 262 (including all scientific and medical matters, chemistry, manufacturing, and controls). (6) An application submitted under this subsection shall be accompanied by the certification required under 42 USC section 282(j)(5)(B). Such certification shall not be considered an element of such application. **(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order** (1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either— (A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the	(iii) Each reference in other sections of this chapter to an application under this section, other than such a reference in section 737 or 738 of this title, shall be considered to be a reference to a report under subparagraph (A). (iv) Each reference in other sections of this chapter to a device for which an application under this section has been approved, or has been denied, suspended, or withdrawn, other than such a reference in section 737 or 738 of this title, shall be considered to be a reference to a device for which a report under subparagraph (A) has been approved, or has been denied, suspended, or withdrawn, respectively. (3) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary— (A) may on the Secretary's own initiative, or (B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513 of this title, refer such application to the appropriate panel under section 513 of this title for study and for submission (within such period as he may establish) of a report and recommendation

	applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs. (2)～(4) 略 **(d) Grounds for refusing application; approval of application; "substantial evidence" defined** If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use	respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts. (4)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept and review such portion, during any period in which, under section 738(g) of this title, the Secretary does not have the authority to collect fees under section 738(a) of this title. (B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless a significant issue of safety or effectiveness provides the Secretary reason to review such accepted portion. (C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall, in writing, provide to the applicant a description of any deficiencies in such portion and identify the information that is required to correct these deficiencies, unless the applicant is no longer pursuing the application.

	under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical	**(d)Action on application for premarket approval** (1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) of this section (except as provided in section 520(*l*)(3)(D)(ii) of this title or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall— (i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or (ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply. In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material

	investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. **(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health** The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after	facts pertinent to the proposed labeling. (B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) of this section unless he finds that the continued availability of the device is necessary for the public health. (ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e) of this title. (iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) of this title to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if— (I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c) of this section) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would

	such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be	invalidate the data or information; or (II) the data or information relates to a device approved under this section, is available for use under this chapter, and is relevant to the design and intended use of the device for which the application is pending. (2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that— (A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; (B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; (C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 520(f) of this title; (D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any

	delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) of this section or to comply with the notice requirements of section 510(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in	particular; or (E) such device <u>is not shown to conform in all respects to a performance standard in effect</u> under section 514 of this title compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard. Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary). (3)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c) of this section, to discuss the review status of the application. (ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies. (iii) The Secretary shall notify the applicant promptly of—

	any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505(g)(2)(D) of this title.	(I) any additional deficiency identified in the application, or (II) any additional information required to achieve completion of the review and final action on the application, that was not described as a deficiency in the written description provided by the Secretary under clause (ii). (B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph. (4) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section, and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g) of this section, of an order of the Secretary approving an application. (5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices— (A) representing breakthrough technologies, (B) for which no approved alternatives exist, (C) which offer significant advantages over existing

		approved alternatives, or (D) the availability of which is in the best interest of the patients. (6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f) of this title. (ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets

		appropriate content requirements for premarket approval supplements. (B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if— (I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and (II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device. (ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness. **(e) Withdrawal and temporary suspension of approval of application** (1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513 of this title, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds— (A) that such device is unsafe or ineffective under

		the conditions of use prescribed, recommended, or suggested in the labeling thereof; (B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof; (C) that the application contained or was accompanied by an untrue statement of a material fact; (D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a) of this title, (ii) has refused to permit access to, or copying or verification of, such records as required by section 704 of this title, or (iii) has not complied with the requirements of section 510 of this title; (E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing,

		packing, or installation of such device do not conform with the requirements of section 520(f) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity; (F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or (G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 514 of this title compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard. (2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain

		review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section. (3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application. **(f)~(g) 略** **Sec 514 (Performance Standards)** **(a) Reasonable assurance of safe and effective performance; periodic evaluation** (1) The special controls required by section 513(a)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under subsection (b) of this section if the device has been reclassified as a class II device under a regulation under section 513(e) of this title but such regulation

		provides that the reclassification is not to take effect until the effective date of such a standard for the device. (2) A performance standard established under subsection (b) of this section for a device— (A) shall include provisions to provide reasonable assurance of its safe and effective performance; (B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include— (i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems, (ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary, (iii) provisions for the measurement of the performance characteristics of the device, (iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were

		required, and (v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e) of this title; and (C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device. (3) The Secretary shall provide for periodic evaluation of performance standards established under subsection (b) of this section to determine if such standards should be changed to reflect new medical, scientific, or other technological data. (4) In carrying out his duties under this subsection and subsection (b) of this section, the Secretary shall, to the maximum extent practicable— (A) use personnel, facilities, and other technical support available in other Federal agencies, (B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and (C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

		(b) Establishment of a standard (1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device. (B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall— (i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device, (ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate, (iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 513(e) of this title based on new information relevant to the classification, and (iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary. (C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting

		justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device. (D) The Secretary shall provide for a comment period of not less than 60 days. (2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 513 of this title, either deny the request or give notice of an intent to initiate such change under section 513(e) of this title. (3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516 of this title) initiate a proceeding under section 513(e) of this title to reclassify the device subject to the proceeding terminated by

		such notice. (B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade. (4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard. (B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for

		introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment. (5)(A) The Secretary— (i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or (ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation, to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information

		and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary. (B) The Secretary shall establish advisory committees (which may not be panels under section 513 of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of

		title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A). **(c) Recognition of standard** (1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this chapter to which such standard is applicable. (B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this chapter. (2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register

		if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this chapter. (3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds— (i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or (ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review. (B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1). (C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.

諸外国の医薬品・医療機器規制に特徴的な条文

ドイツ

	医薬品	医療機器
出　典	Medicinal Products Act （Arzneimittelgesetz の独政府英訳版より）	Medical Devices Act （Medizinproduktegesetz の独政府英訳版より）
ポイント	・最終の医薬品は、本法律の範囲内で上市されなければならない（Section 21 ） ・医薬品の製造販売は、規制当局による書面での発給を受けなければならない（Section 25(1)） ・製造販売を拒否できる場合として、申請書類が不完全、十分に試験が行われていない、品質が確保されていない等が規定（Section 25(2)）	・医療機器に、有効な版の欧州指令に含まれる基本要件への適合性を要求（Section 7） ・特定の医療機器に関し、その医療機器が調和された標準等に適合する際は、現法の規定に適合するものとみなされる（Section 8） ・CE マークは、各欧州指令に従って医療機器に使われなければならない（Section 9）
原　文	**Section 21 (Obligation to obtain a marketing authorization)** (1) Finished medicinal products which are medicinal products as defined in Section 2 sub-section 1 or sub-section 2 number 1, may only be placed on the market within the purview of the present Act, if they have been authorised by the competent higher federal authority or if the Commission of the European Communities or the Council of the European Union has granted an authorisation for them to be placed on the market pursuant to Article 3 paragraph 1 or 2 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31st March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ EC No. L 136, p. 1), also in conjunction with Regulation (EC) No.	**Section 7 (Essential requirements)** (1) The essential requirements for active implantable medical devices, are the requirements contained in Annex 1 to Council Directive 90/385/EEC of 20th June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L189 of 20.7.1990, p. 17), last amended by Article 1 of Directive 2007/47/EC (OJ L 247 of 21.9.2007, p. 21), for *in vitro* diagnostic medical devices the requirements contained in Annex I to Directive 98/79/EC and, for other medical devices, the requirements contained in Annex I to Council Directive 93/42/EEC of 14th June 1993 on medical devices (OJ L 169 of 12.7.1993, p. 1), last amended by Article 2 of Directive 2007/47/EC (OJ L 247 of 21.9.2007, p. 21), in the valid version in each case. （以下、略）

	1901/2006 of the European Parliament and of the Council of 12th December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004 (OJ L 378 of 27th December 2006, p.1) or Regulation (EC) No. 1394/2007. The same shall apply to medicinal products which are not finished medicinal products and which are intended for administration to animals, provided they are not intended for distribution to pharmaceutical entrepreneurs holding an authorisation for the manufacture of medicinal products. （以下、略） **Section 25 (Decision on marketing authorization)** (1) The marketing authorisation, together with a marketing authorisation number, shall be issued in writing by the competent higher federal authority. The marketing authorisation shall only be applicable to the medicinal product specified in the marketing authorisation notice and, in the case of medicinal products manufactured according to homeopathic manufacturing procedures, it shall also apply to the degree of dilution mentioned in results published pursuant to Section 25 sub-section 7 sentence 1 of the version in force prior to 17th August 1994 and specified in the marketing authorisation notice. (2) The competent higher federal authority may only refuse to	**Section 8 (Harmonised standards, common technical specifications)** (1) If medical devices conform to harmonised standards or equivalent European Pharmacopoeia monographs or common technical specifications relating to the specific medical device, it shall be presumed in this respect that they conform to the provisions contained in the present Act. （以下、略） **Section 9 (The CE marking)** (1) The CE marking shall be used for active implantable medical devices according to the stipulations contained in Annex 9 to Directive 90/385/EEC, for *in vitro* diagnostic medical devices according to Annex X to Directive 98/79/EC, and for the other medical devices according to Annex XII to Directive 93/42/EEC. Marks and inscriptions which are likely to mislead third parties with regard to the meaning or graphic design of the CE marking may not be used. All other marks may be affixed to the medical device, the packaging or the instructions for use provided that the visibility, legibility and significance of the CE marking are not reduced as a result.

	grant the marketing authorisation if: 1. the documents submitted, including such documents as are to be submitted pursuant to a regulation of the European Community, are incomplete, 2. the medicinal product has not been sufficiently tested in accordance with the confirmed state of scientific knowledge or the other scientific information material referred to in Section 22 sub-section 3 does not correspond to the confirmed state of scientific knowledge, 3. the medicinal product does not show appropriate quality in accordance with recognized pharmaceutical rules, 4. the therapeutic efficacy attributed to the medicinal product by the applicant is lacking or is insufficiently substantiated by the applicant in accordance with the confirmed state of scientific knowledge, 5. the benefit/risk profile is unfavourable, 5a. in the case of a medicinal product containing more than one active substance, insufficient grounds are provided to demonstrate that each active substance contributes towards a positive assessment of the medicinal product, whereby the special features of the particular medicinal product should be considered in a risk evaluation, 6. the stated withdrawal period is not long enough, 6a. in the case of medicated pre-mixes, the test methods used for the qualitative and quantitative detection of the active	

	substances in the medicated feedstuffs cannot be routinely conducted, 6b. the medicinal product is intended for use in food-producing animals and contains a pharmacologically active constituent not listed in Annex I, II or III of Regulation (EEC) No.2377/90, 7. the marketing of the medicinal product or its administration to animals would violate legal regulations or a regulation or directive issued or a decision adopted by the Council or the Commission of the European Communities, 8. (deleted) The marketing authorisation may not be refused pursuant to sentence 1 number 4, because therapeutic results have been achieved in only a limited number of cases. Therapeutic efficacy is lacking if the applicant fails to prove, according to the confirmed state of scientific knowledge at the time, that a therapeutic effect can be produced with the medicinal product. Medical experience in the particular therapeutic field shall be considered. Pursuant to sentence 1 number 6b, the marketing authorisation may be refused if the medicinal product is intended for the treatment of individual equidae to which the conditions referred to in Article 6 paragraph 3 of Directive 2001/82/EC apply and if it fulfils the other conditions in Article 6 paragraph 3 of Directive 2001/82/EC. （以下、略）	

諸外国における医薬品・医療機器規制に特徴的な条文

フランス

	医薬品	医療機器
出　典	Code de la santé publique	
ポイント	・人に使われる医薬品に関する許可・監督のプロセスを定め、AFSSAPS が上市に際する人への用途の医薬品の許可を行う ・許可は適切な条件のもとで行われる ・許可は５年の期間で与えられ、更新することができる	・患者・使用者・第三者の安全及び健康に関し、事前に医療機器の性能とともに、基本要件の適合性を証明できない限り、医療機器を輸入、市場に導入、使うことはできない。 ・適合性の証明は、医療機器が持つクラスに従って、製造者自身、あるいは AFSSAPS によって指名される機関、又は他の EU 加盟国の規制当局、又は欧州経済地域協定国当事者によって行われる。
原　文	Article L5121-8 Toute spécialité pharmaceutique ou tout autre médicament fabriqué industriellement ou selon une méthode dans laquelle intervient un processus industriel ainsi que tout générateur, trousse ou précurseur qui ne fait pas l'objet d'une autorisation de mise sur le marché délivrée par l'Union européenne en application du règlement (CE) n° 726 / 2004 du Parlement européen et du Conseil, du 31 mars 2004, établissant des procédures communautaires pour l'autorisation et la surveillance en ce qui concerne les médicaments à usage humain et à usage vétérinaire, et instituant une Agence européenne des médicaments doit faire l'objet, avant sa mise sur le marché ou sa distribution à titre gratuit, d'une autorisation de mise sur le marché délivrée par l'Agence française de sécurité sanitaire des produits de santé.L'autorisation peut être assortie de conditions appropriées.	Article L5211-3 Les dispositifs médicaux ne peuvent être importés, mis sur le marché, mis en service ou utilisés, s'ils n'ont reçu, au préalable, un certificat attestant leurs performances ainsi que leur conformité à des exigences essentielles concernant la sécurité et la santé des patients, des utilisateurs et des tiers. La certification de conformité est établie, selon la classe dont relève le dispositif, soit par le fabricant lui-même, soit par un organisme désigné à cet effet par l'Agence française de sécurité sanitaire des produits de santé ou par l'autorité compétente d'un autre Etat membre de l'Union européenne ou partie à l'accord sur l'Espace économique européen. （以下、略）

	…… Une autorisation de mise sur le marché ne peut être délivrée qu'à un demandeur établi dans un Etat membre de l'Union européenne ou partie à l'accord sur l'Espace économique européen. L'autorisation est delivree pour une duree de cinq ans et peut ensuite etre renouvelee, les cas echeant, ….（以下、略）	

諸外国における医薬品・医療機器規制に特徴的な条文

韓国

	医薬品	医療機器
出　典	薬事法 〔Pharmaceutical Affairs Act （韓国政府英訳版より）〕	医療機器法 〔Medical Devices Act （韓国政府英訳版より）〕
ポイント	・医薬品製造を行おうとする者は、KFDA 長官から免許（ライセンス）を得なければならない。 医薬品製造者が製造された医薬品の販売を行おうとする場合には、製造販売承認を KFDA 長官から得るか、省令に従い製造販売製品報告書を提出しなければならない。 （Article　31）	・医療機器製造を行おうとする者は、KFDA 長官から製造業の許可を得なければならない（Article 6） ・人体へのリスクが無視できるため医療機器の不具合等が発生した場合でも生命・健康に与える影響がほとんどない場合には、許可は品目類型ごとに与えられる それ以外の場合には、製造許可は品目ごとに与えられる（Article 6） ・医療機器について、適用の範囲、形態・構造、試験特性、表示を、医療機器に関する標準を定めることができる（Article 19）
原　文	Article 31 (1) A person who intends to engage in business of manufacturing drugs shall obtain a license from the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare, after being equipped with necessary facilities pursuant to the standards for facilities prescribed by Presidential Decree. (2) In cases where a manufacturer under paragraph (1) intends to sell drugs manufactured (including cases of entrusting another manufacturer with manufacture), he/she shall obtain product approval of manufacture and sale (hereinafter referred to as "product approval") from the Commissioner of the Korea Food and	Article 6 (1) A person who intends to run a business manufacturing medical devices shall obtain a permit for the manufacturing business from the Commissioner of the Korea Food and Drug Administration for each factory: (以下、略) (2) A person who has manufacturing business permit obtained under the main sentence of paragraph (1) (hereinafter referred to as "manufacturer") shall obtain a manufacturing permit or file a manufacturing report in accordance with the following to classifications with respect to the medical devices that he/she intends to manufacture: 1. For medical devices specified and publicly notified by the Commissioner of the Korea Food and Drug Administration as those

	Drug Administration or submit a product report of manufacture and sale (hereinafter referred to as "product report"), as prescribed by Ordinance of the Ministry of Health and Welfare. （以下、略）	that are almost unlikely to pose any risk to life or health even by a failure or malfunction because they pose negligible risks to human bodies: To obtain a permit for manufacturing or file a report on manufacturing item category by item category 2. For any medical devices, other than those under subparagraph 1: To obtain a manufacturing permit or file a report on manufacturing item by item. （以下、略） Article 19 (Standard Specifications) As for a Medical device for which the Commissioner of the Korea Food and Drug Administration deems it necessary to establish standards for the quality of the medical device, he/she may establish standard specifications for such a medical devices, including the scope of application, the shape or structure, testing specifications, and labelling

諸外国における医薬品・医療機器規制に特徴的な条文

中　国

	医薬品	医療機器
出　典	医薬品管理法 〔Drug Administration Law of the People's Republic of China（中国政府英訳版）〕	医療機器監督管理条例 〔Regulations for the Supervision and Administration of Medical Devices（中国政府英訳版）〕
ポイント	・国務院の医薬品規制部門は全国の医薬品管理に責任 省・自治区・中央政府直轄の市の医薬品規制部門はその行政管理内の医薬品管理に責任（Article 5） ・医薬品製造施設は省・自治区・中央政府直轄の市の医薬品規制部門に承認を受け、医薬品製造証を受けなければならない。（Article 7） ・新薬又は国家医薬品規格で認められている医薬品の生産は国務院の医薬品規制部門の承認を受けなければならない（Article 31）	・国は医療機器を分類し、監督しなければならない（※3クラス）(Article 5) ・国は医療機器の製造につき製品の登録を行う （※クラスにより登録を受ける部門が異なる） （Article 8） ・製造される医療機器は国家標準または専門標準を満たさなければならない。国家標準は、標準当局と SFDA の共同で、専門標準は SFDA で策定（Article 15）
原　文	Article 5 The drug regulatory department under the State Council shall be responsible for drug administration nationwide. The relevant departments under the State Council shall be responsible for the related administrative work within the limits of their duties. The drug regulatory departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government shall be responsible for drug regulation in their administrative areas. The relevant departments of the said people's governments shall be responsible for the related regulatory work within the limits of their duties.	Article 5 The State shall classify medical devices and administer them based on this classification Class I Medical Devices are those for which safety and effectiveness can be ensured through routine administration; Class II Medical Devices are those for which further control is required to ensure their safety and effectiveness Class III Medical Devices are those which are implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus most be strictly controlled in respect to safety and effectiveness.

	The drug regulatory department under the State Council shall cooperate with the competent departments for comprehensive economic administration under the State Council in implementing pharmaceutical development programs and policies formulated by the State for the pharmaceutical industry. Article 7 The establishment of a drug manufacturer shall be subject to approval by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government and be granted the Drug Manufacturing Certificate, and, with the certificate, the manufacturer shall be registered with the administrative department for industry and commerce. No one may manufacturer drugs without the certificate. （以下、略） Article 31 Production of a new drug or drug admitted by national drug standards shall be subject to approval by the drug regulatory department under the State Council, and a drug approval number shall be issued for it, which the exception of the Chinese crude drugs and the prepared slices of Chinese crude drugs which where no control by approval number is exercised. The list of the Chinese crude drugs and the prepared slices of the Chinese crude	Article 8 The State shall implement a product registration system for the manufacturing of medical devices. Class I medical devices shall be inspected, approved and granted with a registration certificate by the drug regulatory authority of government of the municipalities consisting of districts. Class II medical devices shall be inspected, approved and granted with registration certificates by the drug regulatory authorities of provinces, autonomous regions and municipalitires directly under the central government. Class III medical devices shall be inspected, approved and granted with registration certificates by the drug regulatory authority directly under the State Council. Article 15 Medical devices manufactured shall meet the national standard, or professional standards when there are no relevant national standards available. National Standards of medical devices shall be formulated jointly by the standardization authority and the drug regulatory authority under the State Council. Professional standards of medical devices shall be formulated by the drug regulatory authority under the State Council.

	drugs to be controlled by the approval number shall be complied by the drug regulatory department under the State Council, in conjunction with the administrative department for traditional Chinese medicines under the State Council. A drug manufacturer may produce the drug only after an approval number is granted to it.	